FDA's estimate of the reporting burden is based on actual data obtained from industry over the past several years where there are approximately 90 firms subject to this requirement. It is estimated that each of these firms on the average prepares 20 written agreements per year. The recordkeeping requirements of 21 CFR 801.150(a)(2) consist of making copies and maintaining the actual reporting requests which are required under the reporting section of this collection.

Dated: November 9, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–19283 Filed 11–14–06; 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; Submission for Office of Management and Budget Review; 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 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 December 15, 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: Denver Presley, Jr., Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

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 Device User Fee and Modernization Act Small Business Qualification Certification (Form FDA 3602)—(OMB Control Number 0910–0508)—Extension

The Medical Device User Fee and Modernization Act (MDUFMA) small business qualification certification form (Form FDA 3602), 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 license 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 the guidance document entitled ''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.

In the **Federal Register** of August 29, 2006 (71 FR 51196), FDA published a 60-day notice soliciting comments on the information collection provisions. In response to that notice, no comments were received.

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					2,000

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

The burden is based on the number of applications received in the last 3 years.

Dated: November 9, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–19285 Filed 11–14–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Joint Meeting of the Anti-Infective Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committees: Anti-Infective Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee.

General Function of the Committees: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on December 14, 2006, from 8 a.m. to 6 p.m. and on December 15, 2006, from 8 a.m. to 5 p.m.

Location: Crowne Plaza/Silver Spring, The Ballrooms, 8777 Georgia Ave., Silver Spring, MD. The hotel telephone number is 301–589–0800.

Contact Person: Sohail Mosaddegh, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, FAX: 301–827–6776, e-mail: *sohail.mosaddegh@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington DC area), codes 3014512530 or 3014512535. Please call the Information Line for up-to-date information on this meeting.

Agenda: On both days, the committee will discuss the overall benefit to risk considerations for the approved product KETEK (telithromycin), new drug application (NDA) 21–144, with the current indications of: Acute bacterial exacerbations of chronic bronchitis, acute bacterial sinusitis, and community acquired pneumonia, manufactured by Sanofi-Aventis.

The background material will become available no later than the day before the meeting and will be posted on FDA's Web site at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm* under the headings Anti-Infective Drugs Advisory Committee or Drug Safety and Risk Management Advisory Committee. (Click on the year 2006 and scroll down to the above named committee meetings.)

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committees. Written submissions may be made to the contact person on or before November 30, 2006. Oral presentations from the public will be scheduled between approximately 10 a.m. to 11 a.m. on December 15, 2006. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before November 30, 2006.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Sohail Mosaddegh at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: November 8, 2006.

Randall W. Lutter,

Associate Commissioner for Policy and Planning.

[FR Doc. E6–19249 Filed 11–14–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0414]

Psychopharmacologic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Psychopharmacologic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on December 13, 2006, from 8 a.m. to 5 p.m.

Addresses: Electronic comments should be submitted to*http://www.fda.gov/dockets/ecomments*. Select ''2006N–0414 Suicidality data from Adult Antidepressant Trials'' and follow the prompts to submit your statement. Written comments should be submitted to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, by close of business on December 1, 2006. All comments received will be posted without change, including any personal information provided. Comments received on or before December 1, 2006, will be provided to the committee before the meeting.

Location: Hilton Washington DC/Silver Spring, The Maryland Ballroom, 8727 Colesville Rd., Silver Spring, MD. The hotel phone number is 301–589–5200.

Contact Person: Cicely Reese, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, FAX: 301–827–6776, e-mail: *Cicely.Reese@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512544. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss the results of the FDA ongoing meta-analysis of suicidality data from adult antidepressant trials. The background material will become available no later than the day before the meeting and will be posted on FDA's Web site at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*. Under the heading ''Psychopharmacologic Drugs Advisory Committee (PDAC).'' (Click on year 2006 and scroll down to PDAC meetings).

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written