Due to a clerical error, capital costs and operating and maintenance costs that appeared in a notice published in the **Federal Register** of October 20, 2009 (74 FR 53749) were incorrect. There are actually no capital and maintenance costs; additionally, the hours per response which were reported as 10 are actually 15. Table 1 of this document contains the correct hour burden.

Dated: January 12, 2010.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2010–794 Filed 1–15–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0486]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry, FDA, and Foreign Governments: Fiscal Year 2010 Medical Device User Fee Small Business Qualification and Certification

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 February 18, 2010.

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: 202–395–7285, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0508. Also include the FDA docket number found in brackets in the heading of the document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–5156, *Daniel.Gittleson@fda.hhs.gov*.

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.

Guidance for Industry, FDA, and Foreign Governments: Fiscal Year 2010 Medical Device User Fee Small Business Qualification and Certification—OMB Control Number 0910–0508—Extension

Section 101 of the Medical Device User Fee and Modernization Act (MDUFMA) amends the Federal Food, Drug, and Cosmetic Act (the act) to provide for user fees for certain medical device applications. FDA published a **Federal Register** notice on August 3, 2009 (74 FR 38444), announcing fees for fiscal year (FY) 2010. 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 (FDA Form 3602—For Domestic Small Business Applicants For FY 2010). 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 (product development protocol, biologics licensing application, 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 (FDA Form 3602A— For Foreign Small Business Applicants). The 2007 Amendments provide an alternative way for a foreign business to qualify as a small business eligible to pay a significantly lower fee when a medical device user fee must be paid. Before passage of the 2007 Amendments, the only way a business could qualify as a small business was to submit a Federal (U.S.) income tax return showing its gross receipts or sales that did not exceed a statutory threshold, currently, $100 million. If a business could not provide a Federal income tax return, it did not qualify as a small business and had to pay the standard (full) fee. Because many foreign businesses have not, and cannot, file a Federal (U.S.) income tax return, this requirement has effectively prevented those businesses from qualifying for the small business fee rates. Thus, foreign governments, including the European Union, have objected. In lieu of a Federal income tax return, the 2007 Amendments will allow a foreign business to qualify as a small business by submitting a certification from its national taxing authority, the foreign equivalent of our Internal Revenue Service. This certification, referred to as a "National Taxing Authority Certification," must: Be in English; be from the national taxing authority of the country in which the business is headquartered; provide the business' gross receipts or sales for the most recent year, in both the local currency and in U.S. dollars, and the exchange rate used in converting local currency to U.S. dollars; provide the dates during which the reported receipts or sales were collected; and bear the official seal of the national taxing authority. Both FDA Forms 3602 and 3602A are available in the guidance document, "Guidance for Industry, FDA and Foreign Governments: FY 2010 MDUFMA Small Business Qualification and Certification," available on the Internet at: *http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/UCM179257.pdf*.

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 2010.

The FDA Form 3602 burden is based on the number of applications received in the last 3 years. FDA believes most entities that submit FDA Form 3602A will not have any affiliates, and very few will have more than three or four affiliates. Based on our experience with FDA Form 3602A, FDA believes each business will require 1 hour to complete Sections I and II. FDA does not have any data on the time that will be required to complete Section III, the National Taxing Authority Certification, because there is a different tax verification process by each country's National Taxing Authority. The information collection for FDA Form 3602 is currently approved under OMB control

number 0910–0508. The information collection for FDA Form 3602A is currently approved under OMB control number 0910–0613. With this request for approval, FDA is requesting to consolidate OMB approvals 0910–0508 and 0910–0613 into one information collection using the OMB control number 0910–0508.

In the **Federal Register** of October 23, 2009 (74 FR 54826), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

FDA Form No.	No. of Respondents	Annual Frequency of Response	Total Annual Responses	Hours per Response	Total Hours
3602	3,000	1	3,000	1	3,000
3602A Sections I and II	340	1	340	1	340
3602A Section III	33	7	231	1	231
Totals					3,571

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

Dated: January 12, 2010.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2010–792 Filed 1–15–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0001]

Endocrinologic and Metabolic 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: Endocrinologic and Metabolic 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 February 24, 2010, from 8 a.m. to 5 p.m.

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

Contact Person: Paul Tran, RPh., 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: *paul.tran@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512536. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: The committee will discuss the safety and efficacy of new drug application (NDA) 22–505, for EGRIFTA (tesamorelin acetate) sterile lyophilized powder for injection, by Theratechnologies, Inc. EGRIFTA is an analogue (a chemical compound that resembles another compound in structure) of growth hormone releasing hormone (GHRH). The proposed indication (use) for EGRIFTA in this application is to induce and maintain a reduction of excess visceral abdominal fat in human immunodeficiency virus (HIV)-infected patients with lipodystrophy (a condition in which abnormal deposits of fat are seen partly as a result of using certain drugs to treat HIV disease).

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before February 17, 2010. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. 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 February 9, 2010. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by February 10, 2010.

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 Paul Tran at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisory*