DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Medical Device User Fee Rates for Fiscal Year 2008

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing the fee rates and payment procedures for medical device user fees for fiscal year (FY) 2008. The Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), the Medical Device User Fee Stabilization Act of 2005 (MDUFSA), and the Medical Device User Fee Amendments of 2007 (Title II of the Food and Drug Administration Amendments Act of 2007 (FDAAA)), authorizes FDA to collect user fees for certain medical device submissions, and annual fees both for certain periodic reports and for certain establishments subject to registration. The FY 2008 fee rates are provided in this notice. These fees apply from October 1, 2007, through September 30, 2008. To avoid delay in the review of your application, you should pay the fee before or at the time you submit your application to FDA. The fee you must pay is the fee that is in effect on the later of the date that your application is received by FDA or the date your fee payment is received. If you want to pay a reduced small business fee, you must qualify as a small business before you make your submission to FDA; if you do not qualify as a small business before you make your submission to FDA, you will have to pay the higher standard fee. This notice provides information on how the fees for FY 2008 were determined, the payment procedures you should follow, and how you may qualify for reduced small business fees.

FOR FURTHER INFORMATION CONTACT:

For further information on MDUFMA: Visit FDA's Web site, *http://www.fda.gov/cdrh/mdufma*.

For questions relating to this notice: Yanming Chae, Office of Financial Management (HFA–120), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5042.

SUPPLEMENTARY INFORMATION:

I. Background

Section 738 of the act (21 U.S.C. 379j) establishes fees for certain medical device applications, submissions, supplements, and notices (for simplicity, this notice refers to these collectively as ''submissions''); for periodic reporting on class III devices; and for the registration of certain establishments. Under statutorily defined conditions, a qualified applicant may receive a fee waiver or may pay a lower small business fee (see 21 U.S.C. 379j(d) and (e)).

Under the act, the fee rate for each type of submission is set at a specified percentage of the standard fee for a premarket application (a premarket application is a premarket approval application (PMA), a product development protocol (PDP), or a biologics licensing application (BLA)). The act specifies the standard fee for a premarket application for each year from FY 2008 through FY 2012; the standard fee for a premarket application received by FDA during FY 2008 is $185,000. From this starting point, this notice establishes FY 2008 fee rates for other types of submissions, and for periodic reporting, by applying criteria specified in the act.

The act specifies the annual fee for establishment registration for each year from FY 2008 through FY 2012; the registration fee for FY 2008 is $1,706. There is no reduction in the registration fee for small businesses. An establishment must pay the annual registration fee if it is any of the following types of establishments:

- *Manufacturer.* An establishment that makes by any means any article that is a device, including an establishment that sterilizes or otherwise makes such article for or on behalf of a specification developer or any other person.
- *Single-use device reprocessor.* An establishment that performs manufacturing operations on a single-use device that has previously been used on a patient.
- *Specification developer.* An establishment that develops specifications for a device that is distributed under the establishment's name but which performs no manufacturing, including an establishment that, in addition to developing specifications, also arranges for the manufacturing of devices labeled with another establishment's name by a contract manufacturer.

The fees for FY 2008 go into effect on October 1, 2007, and will remain in effect through September 30, 2008.

II. Fees for FY 2008

Under the act, all submission fees and the periodic reporting fee are set as a percent of the standard (full) fee for a premarket application (see 21 U.S.C. 379j(a)(2)(A)), and the act sets the standard fee for a premarket application at $185,000 for FY 2008 (see 21 U.S.C. 379j(b); this is referred to as the ''base fee''). The fees set by reference to the base (see 21 U.S.C. 379j(a)(2)(A)) fee are—

- For a panel-track supplement, 75 percent of the base fee;
- For a 180-day supplement, 15 percent of the base fee;
- For a real-time supplement, 7 percent of the base fee;
- For a 30-day notice, 1.6 percent of the base fee;
- For a 510(k) premarket notification, 1.84 percent of the base fee;
- For a 513(g) request for classification information, 1.35 percent of the base fee; and
- For an annual fee for periodic reporting concerning a class III device, 3.5 percent of the base fee.

For all submissions other than a 510(k) premarket notification, a 30-day notice, and a 513(g) request for classification information, the small business fee is 25 percent of the standard (full) fee (see 21 U.S.C. 379j(d)(2)(C)). For a 510(k) premarket notification submission, a 30-day notice, and a 513(g) request for classification information, the small business fee is 50 percent of the standard (full) fee (see 21 U.S.C. 379j(e)(2)(C) and (d)(2)(C), respectively). There is no small business rate for annual establishment registration fee; all establishments pay the same fee. Table 1 of this document sets out the FY 2008 rates for all medical device fees.

TABLE 1.—MEDICAL DEVICE FEES FOR FY 2008

	Standard Fee, as a Percent of the Standard Fee for a Premarket Application	FY 2008 Standard Fee	FY 2008 Small Business Fee
Application Fee Type			

TABLE 1.—MEDICAL DEVICE FEES FOR FY 2008—Continued

	Standard Fee, as a Percent of the Standard Fee for a Premarket Application	FY 2008 Standard Fee	FY 2008 Small Business Fee
Premarket application (a PMA submitted under section 515(c)(1) of the act (21 U.S.C. 360e(c)(1)), a PDP submitted under section 515(f) of the act, or a BLA submitted under section 351 of the Public Health Service (PHS) Act (42 U.S.C. 262))	Set in statute	$185,000	$46,250
Premarket report (submitted under section 515(c)(2) of the act)	100%	$185,000	$46,250
Efficacy supplement (to an approved BLA under section 351 of the PHS act)	100%	$185,000	$46,250
Panel-track supplement	75%	$138,750	$34,688
180-day supplement	15%	$27,750	$6,938
Real-time supplement	7%	$12,950	$3,237
510(k) premarket notification submission	1.84%	$3,404	$1,702
30-day notice	1.6%	$2,960	$1,480
513(g) request for classification information	1.35%	$2,498	$1,249
Annual Fee Type			
Annual fee for periodic reporting on a class III device	3.5%	$6,475	$1,619
Annual establishment registration fee (to be paid by each establishment that is a manufacturer, a single-use device reprocessor, or a specification developer, as defined by 21 U.S.C. 379i(13))	Set in statute	$1,706	$1,706

III. How to Qualify as a Small Business for Purposes of Medical Device Fees

If your business has gross receipts or sales of no more than $100 million for the most-recent tax year, you may qualify for reduced small business fees. If your business has gross sales or receipts of no more than $30 million, you may also qualify for a waiver of the fee for your first premarket application (PMA, PDP, or BLA) or premarket report. You must include the gross receipts or sales of all of your affiliates along with your own gross receipts or sales when determining whether you meet the $100 million or $30 million threshold. If you want to pay the small business fee rate for a submission, or you want to receive a waiver of the fee for your first premarket application or premarket report, you should submit the materials showing you qualify as a small business 60 days before you send your submission to FDA. If you make a submission before FDA finds that you qualify as a small business, you must pay the standard fee for that submission.

If your business qualified as a small business for FY 2007, your status as a small business will expire at the close of business on September 30, 2007. You must re-qualify for FY 2008 in order to pay fees at the small business rate during FY 2008.

If you are a domestic (U.S.) business, and wish to qualify as a small business for FY 2008, you must submit the following to FDA:

(1) A completed FY 2008 MDUFMA Small Business Qualification Certification (Form FDA 3602). This form is provided in FDA's guidance document ''FY 2008 Medical Device User Fee Small Business Qualification and Certification,'' available on FDA's Web site at *http://www.fda.gov/cdrh/mdufma*. This form is not available separate from the guidance document.

(2) A certified copy of your Federal (U.S.) Income Tax Return for the most recent tax year (2006 or later).

(3) For each of your affiliates, either—

(A) If the affiliate is a domestic (U.S.) business, a certified copy of the affiliate's Federal (U.S.) Income Tax Return for the most recent tax year, or

(B) If the affiliate is a foreign business and cannot submit a Federal (U.S.) Income Tax Return, a National Taxing Authority Certification completed by, and bearing the official seal of, the National Taxing Authority of the country in which the affiliate is headquartered. This certification must show the amount of gross receipts or sales for the most recent tax year, in both U.S. dollars and the local currency of the country, the exchange rate used in converting the local currency to U.S. dollars, and the dates of the gross receipts or sales collected. The applicant should also submit a statement signed by the head of the applicant's firm or by its chief financial officer that the applicant has submitted certifications for all of its affiliates, identifying the name(s) of each affiliate(s), or that the applicant has no affiliates. The National Taxing Authority is the foreign equivalent of the U.S. Internal Revenue Service.

If you are a foreign business, and wish to qualify as a small business for FY 2008, you must submit the following:

(1) A completed FY 2008 MDUFMA Foreign Small Business Qualification Certification (Form FDA 3602A). This form is provided in FDA's guidance document ''FY 2008 Medical Device User Fee Small Business Qualification and Certification,'' available on FDA's Web site at *http://www.fda.gov/cdrh/mdufma*. This form is not available separate from the guidance document.

(2) A National Taxing Authority Certification, completed by, and bearing the official seal of, the National Taxing Authority of the country in which the firm is headquartered. This certification must show the amount of gross receipts or sales for the most recent tax year, in

both U.S. dollars and the local currency of the country, the exchange rate used in converting the local currency to U.S. dollars, and the dates of the gross receipts or sales collected.

(3) For each of your affiliates, either—

(A) If the affiliate is a domestic (U.S.) business, a certified copy of the affiliate's Federal (U.S.) Income Tax Return for the most recent tax year (2006 or later), or

(B) If the affiliate is a foreign business and cannot submit a Federal (U.S.) Income Tax Return, a National Taxing Authority Certification completed by, and bearing the official seal of, the National Taxing Authority of the country in which the firm is headquartered. This certification must show the amount of gross receipts or sales for the most recent tax year, in both U.S. dollars and the local currency of the country, the exchange rate used in converting the local currency to U.S. dollars, and the dates of the gross receipts or sales collected. The applicant should also submit a statement signed by the head of the applicant's firm or by its chief financial officer that the applicant has submitted certifications for all of its affiliates, identifying the name(s) of each affiliate(s), or that the applicant has no affiliates. The National Taxing Authority is the foreign equivalent of the U.S. Internal Revenue Service.

IV. Procedures for Paying Application and Annual Report Fees

If your application or submission is subject to a fee and is received by FDA from October 1, 2007, through September 30, 2008, you must pay the fee in effect for FY 2008. The later of the date that the application or annual report is received in the reviewing center's document room or the date that the check is received by US Bank determines whether the fee rates for FY 2007 or FY 2008 apply. FDA must receive the correct fee at the time that an application or annual report is submitted, or the application or annual report will not be accepted for filing or review.

FDA requests that you follow the steps in this section before submitting a medical device application or annual report subject to a fee. Please pay close attention to these procedures to ensure that FDA links the fee with the correct application. (Note: In no case should the check for the fee be submitted to FDA with the application.)

A. Step One—Secure a Payment Identification Number and Medical Device User Fee Cover Sheet From FDA Before Submitting Either the Application or the Payment. Note: FY 2008 fee rates will be available on the Cover Sheet Web site beginning on the date of publication of this notice

Log onto the MDUFMA Web site at *http://www.fda.gov/oc/mdufma* and, under the forms heading, click on the link ''User Fee Cover Sheet.'' Complete the Medical Device User Fee Cover Sheet. Be sure you choose the correct application submission date range. After completing data entry, print a copy of the Medical Device User Fee Cover Sheet and note the unique Payment Identification Number located in the upper right-hand corner of the printed cover sheet.

B. Step Two—Electronically Transmit a Copy of the Printed Cover Sheet with the Payment Identification Number to FDA's Office of Financial Management

Once you are satisfied that the data on the cover sheet is accurate, electronically transmit that data to FDA according to instructions on the screen. Because electronic transmission is possible, applicants are required to set up a user account and use passwords to assure data security in the creation and electronic submission of cover sheets.

C. Step Three—Mail Payment and a Copy of the Completed Medical Device User Fee Cover Sheet to the St. Louis Address Specified in This Section

- Make the payment in U.S. currency by check, bank draft, or U.S. Postal money order payable to the Food and Drug Administration. (FDA's tax identification number is 53–0196965, should your accounting department need this information.)
- Please write your application's unique Payment Identification Number, from the upper right-hand corner of your completed Medical Device User Fee Cover Sheet, on your check, bank draft, or U.S. Postal money order.
- Mail the payment and a copy of the completed Medical Device User Fee Cover Sheet to: Food and Drug Administration, P.O. Box 956733, St. Louis, MO 63195–6733. (Please note that this address is for payments of application and annual report fees only and is not to be used for payment of annual establishment registration fees.)

If you prefer to send a check by a courier (such as FEDEX, DHL, UPS, etc.), the courier may deliver the check to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314–418–4821 if you have any questions concerning courier delivery.)

It is helpful if the fee arrives at the bank at least 1 day before the application arrives at FDA. FDA records the official application receipt date as the later of the following:

- The date the application was received by FDA.
- The date US Bank receives the payment. US Bank is required to notify FDA within 1 working day, using the Payment Identification Number described previously.

D. Step Four—Submit Your Application to FDA with a Copy of the Completed Medical Device User Fee Cover Sheet

Please submit your application and a copy of the completed Medical Device User Fee Cover Sheet to one of the following addresses:

- Medical device applications should be submitted to: Food and Drug Administration, Center for Devices and Radiological Health, Document Mail Center (HFZ–401), 9200 Corporate Blvd., Rockville, MD 20850.
- Biologic applications should be sent to: Food and Drug Administration, Center for Biologics Evaluation and Research, Document Control Center (HFM–99), suite 200N, 1401 Rockville Pike, Rockville, MD 20852–1448.

V. Procedures for Paying Annual Establishment Fees

Procedures for paying annual establishment fees are different from the previously mentioned procedures for paying application, submission, and annual report fees. An establishment is not legally registered in FY 2008 until it has both completed the following steps to register and paid any fee that may be applicable (see 21 U.S.C. 379j(f)(2)).

A. Step One—Complete the Information Online to Update Your Establishment's Registration for FY 2008, or to Register a New Establishment for FY 2008

Log onto CDRH's Web site at *http://www.fda.gov/cdrh/reglistpage.html* and follow the link from that page to the FDA Unified Registration and Listing System (FURLS). If you already have a registered medical device establishment, FDA has sent you a letter that contains your account ID and password for logging into FURLS. If you are an owner or operator registering for the first time, you will need to create a FURLS account. There are tutorials available from the FURLS/FDA Industry Systems homepage that demonstrate how to create FURLS user accounts.

Once you obtain your account ID and password, you will enter them and log into FURLS. From the FURLS/FDA Industry Systems menu, there will be a button that you will click to go to the Device Registration and Listing Module (DRLM) of FURLS. New establishments will register their establishment and existing establishments will re-register their establishments using choices on the DRLM menu. Once you make your selection—either Register a Facility or Annual Re-registration—the system will prompt you through the entry of information about your establishment and your devices.

If you have any problems with this process you may call 240–276–0111 for assistance. (Note: This phone number is for assistance with establishment registration and establishment fee payment only, and not for any other aspects of medical device user fees.)

B. Step Two—Determine Whether an Annual Registration Fee is Required and Get Your Invoice if a Fee is Due

After you enter your establishment registration information into the system, you will be informed whether or not the payment of an annual registration fee is required to complete your registration (these fees are only required for device manufacturers, single-use re-processors, and specification developers as stated in section I of this document). If your establishment is subject to a fee, you will be given a summary sheet that: (1) Tells you what your payment options are and (2) leads you to a link for your specific invoice, which will be available on-line as a portable document format (PDF) file that you should print copies of; one to submit with your payment (if not submitted electronically) and the other to keep for your records.

C. Step Three—Pay Your Invoice, if Required

Make the payment, if required, in U.S. currency. The summary page will include payment information that may permit you the option of paying electronically. If that option is provided, you may follow the instructions provided to make payment electronically. If that option is not provided, or you choose not to make your payment electronically, you may pay by check.

Your check, made in U.S. dollars and drawn on a U.S. bank, can be mailed to: Food and Drug Administration, P.O. Box 70961, Charlotte, NC 28272–0961. (Please note that this is different than the address for payments of application and annual report fees and is to be used only for payment of annual establishment registration fees.)

If checks are to be sent by a courier that requests a street address, the courier can deliver the checks to: Wachovia Bank, Attn: Food and Drug Administration—Lockbox 70961, rm. NC0810, 1525 West WT Harris Blvd., Charlotte, NC 28262. (Note: This Wachovia Bank address is for courier delivery only; do not send mail to this address.)

Please make sure that the FDA post office box number (P.O. Box 70961) is written on the check, along with the invoice number printed on your invoice. A copy of your printed invoice should also be mailed in the same envelope with your check. FDA's tax identification number is 53–0196965.

Wire transfers may also be used to pay annual establishment fees. The routing and transit number is 021030004 and the account number is 75060099. The invoice number should also be included with any wire transfer information, to assure that the invoice is properly credited.

FDA is in the process of implementing alternate Web-based payment methods, and the option of electronic payment may not be immediately available for FY 2008 payments. For more information on these payment options and when they will be available, please visit FDA's Web site at *http://www.fda.gov*, select the appropriate user fee type, and click on ''User Fee Cover Sheet.''

Dated: October 4, 2007.

Randall W. Lutter,

Deputy Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

In Vitro Analysis of Cell/Scaffold Medical Products; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA), Center for Biologics Evaluation and Research and Center for Devices and Radiological Health, and the National Institute of Standards and Technology are announcing a public workshop entitled: In Vitro Analysis of Cell/Scaffold Medical Products. The purpose of the public workshop is to discuss issues that should be considered when evaluating cell/scaffold medical products and to determine which test methods are currently available and which new analytical procedures should be further researched for the evaluation of cell/scaffold medical products.

Date and Time: The public workshop will be held on December 6 and 7, 2007, from 8:30 a.m. to 4 p.m.

Location: The public workshop will be held at the National Transportation and Safety Board, 490 L'Enfant Plaza East, SW., Washington, DC 20594.

Contact Person: Bernadette Kawaley, Center for Biologics Evaluation and Research (HFM–43), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–2000, FAX: 301–827–3079, e-mail: *CBERTraining@fda.hhs.gov* (Subject line: Tissue Engineering Workshop).

Registration: Mail or fax your registration information (including name, title, firm name, address, telephone and fax numbers) to the contact person by November 15, 2007. There is no registration fee for the public workshop. Early registration is recommended because seating is limited. Registration on the day of the public workshop will be provided on a space available basis beginning at 8 a.m.

If you need special accommodations due to a disability, please contact Bernadette Kawaley (see *Contact Person*) at least 7 days in advance.

SUPPLEMENTARY INFORMATION: The public workshop will feature presentations by experts from the medical field and the government. The first day of the workshop will include discussions on in vitro assays of product performance. The second day of the workshop will include discussions on tools for quantifying the response of cells and tissues.

Transcripts: Transcripts of the public workshop may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857, approximately 15 working days after the public workshop at a cost of 10 cents per page. A transcript of the public workshop will be available on the Internet at*http://www.fda.gov/cber/minutes/workshop-min.htm*.

Dated: October 5, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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