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Display Date 7-31-08
Publication Date 8-1-08
Certifier SLPR

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0420]

Medical Device User Fee Rates for Fiscal Year 2009

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) 2009. 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 2009 fee rates are provided in this notice. These fees apply from October 1, 2008, through September 30, 2009. 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

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information on how the fees for FY 2009 were determined, the payment procedures you should follow, and how you may qualify for reduced small business fees.

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

For questions relating to this notice: David Miller, Office of Financial Management (HFA–100), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3917.

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 2009 is $200,725. From this starting point, this notice establishes FY 2009 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 2009 is $1,851. There is no reduction in the registration fee for small businesses. An establishment must pay the 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 2009 go into effect on October 1, 2008, and will remain in effect through September 30, 2009.

II. Fees for FY 2009

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, including a biologic licensing application (BLA) and a premarket report, at $200,725 for FY 2009 (see 21 U.S.C. 379j(b); this is referred to as the "base fee"). The fees set by reference to the base 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)). There is no small business rate for the annual establishment registration fee; all establishments pay the same fee. Table 1 of this document sets out the FY 2009 rates for all medical device fees.

TABLE 1.—MEDICAL DEVICE FEES FOR FY 2009

Application Fee Type	Standard Fee, as a Percent of the Standard Fee for a Premarket Application	FY 2009 Standard Fee	FY 2009 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	$200,725	$50,181
Premarket report (submitted under section 515(c)(2) of the act)	100%	$200,725	$50,181
Efficacy supplement (to an approved BLA under section 351 of the PHS Act)	100%	$200,725	$50,181
Panel-track supplement	75%	$150,544	$37,636
180-day supplement	15%	$30,109	$7,527
Real-time supplement	7%	$14,051	$3,513
510(k) premarket notification submission	1.84%	$3,693	$1,847
30-day notice	1.6%	$3,212	$1,606
513(g) request for classification information	1.35%	$2,710	$1,355
Annual Fee Type			
Annual fee for periodic reporting on a class III device	3.5%	$7,025	$1,756
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	$1,851	$1,851

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 2008, your status as a small business will expire at the close of business on September 30, 2008. You must re-qualify for FY 2009 in order to pay small business fees during FY 2009.

If you are a domestic (U.S.) business, and wish to qualify as a small business for FY 2009, you must submit the following to FDA:

(1) A completed FY 2009 MDUFMA Small Business Qualification Certification (Form FDA 3602). This form is provided in FDA's guidance document, "FY 2009 Medical Device User Fee Small Business Qualification and Certification," available on FDA's Internet 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. The most recent tax year will be 2008, except—

- If you submit your FY 2009 MDUFMA Small Business Qualification before April 15, 2009, and you have not yet filed your return for 2008, you may use tax year 2007.
- If you submit your FY 2009 MDUFMA Small Business Qualification on or after April 15, 2008, and have not yet filed your 2008 return because you obtained an extension, you may submit your most-recent return filed prior to the extension.

(3) For each of your affiliates, either—

- 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
- 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.

If you are a foreign business, and wish to qualify as a small business for FY 2009, you must submit the following:

(1) A completed FY 2009 MDUFMA Foreign Small Business Qualification Certification (Form FDA 3602A). This form is provided in FDA's guidance document, "FY 2009 Medical Device User Fee Small Business Qualification and Certification," available on FDA's Internet 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—

- 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 (2007 or later), or

- 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 for 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, 2008 through September 30, 2009, you must pay the fee in effect for FY 2009. 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 U.S. Bank determines whether the fee rates for FY 2008 or FY 2009 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 below 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 (PIN) and Medical Device User Fee Cover Sheet From FDA Before Submitting Either the Application or the Payment (Note: Both the FY 2008 and FY 2009 fee rates will be available on the Cover Sheet Web Site beginning on the date of publication of this notice, and the FY 2008 rates will no longer appear after September 30, 2008.)

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. (Two choices will be offered until October

1, 2008. One choice is for applications that will be received on or before September 30, 2008, which will be subject to FY 2008 fee rates. A second choice is for applications that will be received on or after October 1, 2008, which will be subject to FY 2009 fee rates.) After completing data entry, print a copy of the Medical Device User Fee Cover Sheet and note the unique PIN 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 PIN 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. Since 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 PIN, 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.

(Note: 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: U.S. Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101.

(Note: This address is for courier delivery only. Contact the U.S. 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 U.S. Bank receives the payment. U.S. Bank is required to notify FDA within 1 working day, using the PIN described previously in this document.

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

If you are required to pay an annual establishment registration fee, you must pay for each establishment prior to registration. Payment must be submitted by first creating a Device Facility Use Fee (DFUF) order through the User Fee Web site at *https://fdasfinapp8.fda.gov/OA_HTML/fdaCAcdLogin.jsp*. You will be issued a PIN once you place your order. After payment has been processed, you will be issued a payment confirmation number (PCN). You will not be able to register your establishment if you do not have a PIN and a PCN. An establishment required to pay an annual establishment registration fee is not legally registered in FY 2009 until it has completed the steps in this section to register and pay any applicable fee (see 21 U.S.C. 379j(f)(2)).

A. Step One—Submit a Device Facility User Fee Order With a PIN From FDA Before Registering or Submitting Payment

To submit a DFUF order, you must create or have previously created a user account and password for the User Fee Web site listed in this section. After creating a user name and password, log onto the Annual Facility User Fee 2009 store. Complete the DFUF order by entering the number of establishments you are registering. Once you are satisfied that the data on the order is accurate, electronically transmit that data to FDA according to instructions on the screen. Print a copy of the final DFUF order and note the unique PIN located in the upper right-hand corner of the printed order.

B. Step Two—Pay for Your DFUF Order

Unless paying by credit card, all payments must be in U. S. currency and drawn on a U.S. bank. The DFUF order will include payment information, including details on how you can pay online using a credit card or electronic checks. Follow the instructions provided to make an electronic payment. If

you prefer not to pay online, you may pay by a check, in U.S. dollars and drawn on a U.S. bank, mailed to: Food and Drug Administration, P.O. Box 70961, Charlotte, NC 28272–0961.

(Note: This address is different from the address for payments of application and annual report fees and is to be used only for payment of annual establishment registration fees.)

If a check is sent by a courier that requests a street address, the courier can deliver the check 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 both of the following numbers are written on your check: (1) The FDA post office box number (P.O. Box 70961), and (2) the PIN that is printed on your order. A copy of your printed order should also be mailed along with your check. FDA's tax identification number is 53–0196965.

Wire transfers may also be used to pay annual establishment fees. For wire transfer information, please contact the user fee helpdesk at 301–827–9539 or *userfees@fda.gov.*

C. Step Three—Complete the Information Online to Update Your Establishment's Annual Registration for FY 2009, or to Register a New Establishment for FY 2009

Go to CDRH's Web site at *http://www.fda.gov/cdrh/reglistpage.html* and click the "Electronic Registration and Listing System (FURLS)" link on the left of the page. This opens up a new page with important information about FURLS. After reading this information click on the link at the bottom of the

page. That takes you to an FDA Industry Systems page with tutorials that demonstrate how to create a new FURLS user account if your establishment did not create an account in FY 2008.

Enter your existing account ID and password to 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 need to register and existing establishments will update their annual registration using choices on the DRLM menu. Once you choose to register or update your annual 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, e-mail *reglist@cdrh.fda.gov* or call 240–276–0111 for assistance.

(Note: This e-mail address and phone number are for assistance with establishment registration only, and not for any other aspects of medical device user fees.)

D. Step Four—Enter Your DFUF Order PIN and PCN

After completing your annual or initial registration and device listing, you will be prompted to enter your DFUF order PIN and PCN, when applicable. Fees are only required for those establishments defined in section I of this document.

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Dated: 7/28/08

July 28, 2008.

Jeffrey Shuren,
Associate Commissioner for Policy and Planning.

[FR Doc. 08–????? Filed ??–??–08; 8:45 am]

BILLING CODE 4160–01–S

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