

not signify FDA endorsement or concurrence with any of the conclusions or recommendations contained within the report. FDA may, in the future, take additional measures to solicit public input in the report and specific recommendations contained therein. FDA will not adopt any of the recommendations contained in the report before the close of this comment period.

**DATES:** Submit either electronic or written comments on the report by September 30, 2011.

**ADDRESSES:** See the **SUPPLEMENTARY INFORMATION** section for electronic access to the document. Submit electronic comments on the preliminary report to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Philip Desjardins, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5452, Silver Spring, MD 20993-0002, 301-796-5678.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

In September 2009, CDRH convened an internal 510(k) Working Group as part of a two-pronged, comprehensive assessment of the 510(k) process. The first prong of this evaluation consisted of an internal evaluation of the 510(k) process, resulting in the publication of the CDRH preliminary internal evaluation entitled: "510(k) Working Group Preliminary Report and Recommendations" (<http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDRH/CDRHReports/UCM220784.pdf>). This preliminary report was intended to communicate preliminary findings and recommendations regarding the 510(k) program and actions CDRH might take to address identified areas of concern. The report was issued on August 5, 2010 (75 FR 47307). After reviewing public comment, CDRH issued a plan of action for implementation of the previously announced recommendations on January 19, 2011 (<http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDRH/CDRHReports/UCM239450.pdf>).

The second prong of the comprehensive assessment of the 510(k) process was an independent study by the IOM. At the request of FDA, IOM

process and made recommendations aimed at protecting the health of the public and making available a mechanism to achieve timely access of medical devices to the market. On July 29, 2011, IOM released the report "Medical Devices and the Public's Health, The FDA 510(k) Clearance Process at 35 Years." While FDA has not yet had the opportunity to fully evaluate this report, the agency does recognize the strong public interest in the comprehensive assessment of the 510(k) process and the IOM report. For this reason, FDA is opening a public docket and requesting public comment on the report. The establishment of this public docket does not signify agency endorsement or concurrence with any of the conclusions or recommendations contained within the report. FDA may, in the future, take additional measures to solicit public input in the report and specific recommendations contained therein. FDA will not adopt any of the recommendations contained in the report before the close of this comment period.

##### **II. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

##### **III. Electronic Access**

The IOM report entitled: "Medical Devices and the Public's Health, The FDA 510(k) Clearance Process at 35 Years" can be obtained from the IOM Web site at <http://www.iom.edu/Activities/PublicHealth/510KProcess.aspx>.

Dated: July 26, 2011.

**Nancy K. Stade,**

*Deputy Director for Policy, Center for Devices and Radiological Health.*

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**BILLING CODE 4160-01-P**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

[Docket No. FDA-2011-N-0542]

#### **Medical Device User Fee Rates for Fiscal Year 2012**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the fee rates and payment procedures for medical device user fees for fiscal year (FY) 2012. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by 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 for certain periodic reports and for certain establishments subject to registration. The FY 2012 fee rates are provided in this document. These fees apply from October 1, 2011, through September 30, 2012. 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. In order 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 be required to pay the higher standard fee. This document provides information on how the fees for FY 2012 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 the Medical Device User Fee and Modernization Act (MDUFMA): visit FDA's Web site, <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm>.

For questions relating to this notice: Contact David Miller, Office of Financial Management (HFA-100), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301-796-7103.

**SUPPLEMENTARY INFORMATION:**

## I. Background

Section 738 of the FD&C Act (21 U.S.C. 379j) establishes fees for certain medical device applications, submissions, supplements, and notices (for simplicity, this document 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 FD&C 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 license application (BLA)). The FD&C Act specifies the standard fee for a premarket application for each year from FY 2008 through FY 2012; however, the standard fee for a premarket application received by FDA during FY 2012, which is set in the statute (\$256,384), is adjusted in accordance with the offset provisions of the FD&C Act. Using this adjusted fee rate for FY 2012 as a starting point, this

document establishes FY 2012 fee rates for other types of submissions, and for periodic reporting, by applying criteria specified in the FD&C Act.

The FD&C Act specifies the annual fee for establishment registration for each year from FY 2008 through FY 2012; the registration fee for FY 2012 is \$2,364, which is also adjusted in accordance with the offset provisions of the FD&C Act. 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 establishment:

- **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 additional processing and 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.

## II. Offsetting Fee Amounts for Collections in Excess of Appropriations in FY 2008 through FY 2011

Under the offset provision of the FD&C Act (see section 739(h)(4) (21 U.S.C. 379j–11(h)(4))), if the cumulative amount of fees collected during FY 2008 through FY 2010, together with the estimated amount to be collected in FY 2011, exceeds the aggregate amounts specified to be appropriated in these four FYs in section 739(h)(3) of the FD&C Act, the aggregate amount in excess shall be credited to the appropriation account of FDA and subtracted from the amount of fees that would otherwise be collected in FY 2012. Table 1 of this document presents the amount of MDUFMA fees collected during FY 2008 through FY 2010 (actuals), and the amount estimated to be collected in FY 2011, and compares those amounts with the fees specified to be appropriated in these four FYs in section 739(h)(3) of the FD&C Act.

TABLE 1—STATEMENT OF FEES APPROPRIATED, FEES COLLECTED, AND DIFFERENCES AS OF SEPTEMBER 30, 2010

| Fiscal year                                                    | Fees appropriated | Fees collected | Difference |
|----------------------------------------------------------------|-------------------|----------------|------------|
| 2008 Actual .....                                              | \$48,431,000      | \$49,314,691   | \$883,691  |
| 2009 Actual .....                                              | 52,547,000        | 59,731,482     | 7,184,482  |
| 2010 Actual .....                                              | 57,014,000        | 66,949,587     | 9,935,587  |
| 2011 Estimate .....                                            | 61,860,000        | 61,860,000     | 0          |
| Cumulative Total .....                                         | .....             | .....          | 18,003,760 |
| Unearned Revenue Included in Above Amount .....                | .....             | .....          | 8,491,930  |
| Excess Collections Less Unearned Revenue (Offset Amount) ..... | .....             | .....          | 9,511,830  |

The total amount FDA expects to have collected in excess of appropriations by the end of FY 2011 is \$18,003,760. However, of that amount, a total of \$8,491,930 represents unearned revenue—primarily fees paid for applications that have not yet been received. The unearned revenue is held in reserve either to refund, if no application is submitted, or to apply toward the future FY when the application is received. The net of these two figures, \$9,511,830, is the amount that FDA has received in excess of appropriations that is available for obligation, and the amount by which fee revenue will be offset in FY 2012.

For FY 2012, the statute authorizes \$67,118,000 in user fees (see section 738(h)(3)(E)). In order to determine the

revised collection amount, we deduct the net excess collection amount of \$9,511,830 from \$67,118,000, and the revised revenue target for FY 2012 becomes \$57,606,170. Stated as a percent, this is 85.8281 percent of the original revenue target for FY 2012. Accordingly, if we multiply this percentage by the revenue amounts for the two fees set in statute, \$256,384 for a Premarket Application fee and \$2,364 for an Establishment Registration Fee (see 21 U.S.C. 379j(b)), the reduced fees for FY 2012 are \$220,050 for a premarket application fee and \$2,029 for the annual establishment registration fee.

It is important to note that the appropriation for FY 2012 still must be \$67,118,000 as specified in the statute,

so that the \$9,511,830 in user fees collected in prior years is appropriated and available for obligation.

## III. Fees for FY 2012

Under the FD&C 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 offset fee for the standard premarket application, including a BLA, a premarket report, and an efficacy supplement, for FY 2012. As calculated previously, the FY 2012 premarket application fee is \$220,050. This is referred to as the “base fee.” The fees set by reference to the base fee are as follows:

- 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) (21 U.S.C. 360(c)(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(d)(2)(C) and 379j(e)(2)(C).)

The annual fee for establishment registration, after reduction as calculated in the previous section, is \$2,029 in FY 2012. There is no small business rate for the annual establishment registration fee; all

establishments pay the same fee. The statute authorizes increases in the annual establishment fee for FY 2011 and subsequent years if the estimated number of establishments submitting fees for FY 2009 is fewer than 12,250. (See 21 U.S.C. 379j(c)(2)(A).) The number of establishments submitting fees in FY 2009 was in excess of 12,250, so no establishment fee increase is warranted under this provision of the statute.

Table 2 of this document sets out the FY 2012 rates for all medical device fees.

TABLE 2—MEDICAL DEVICE FEES FOR FY 2012

| Application fee type                                                                                                                                                                                                                                       | Standard Fee, as a Percent of the standard fee for a premarket application | FY 2012 standard fee | FY 2012 small business fee |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------|----------------------|----------------------------|
| Premarket application (a PMA submitted under section 515(c)(1) of the FD&C Act (21 U.S.C. 360e(c)(1)), a PDP submitted under section 515(f) of the FD&C Act, or a BLA submitted under section 351 of the Public Health Service (PHS) Act (42 U.S.C. 262)). | Set in statute at \$256,382, but offset by multiplying by 85.8281 percent. | \$220,050            | \$55,013                   |
| Premarket report (submitted under section 515(c)(2) of the FD&C Act) ..                                                                                                                                                                                    | 100% .....                                                                 | 220,050              | 55,013                     |
| Efficacy supplement (to an approved BLA under section 351 of the PHS Act).                                                                                                                                                                                 | 100% .....                                                                 | 220,050              | 55,013                     |
| Panel-track supplement .....                                                                                                                                                                                                                               | 75% .....                                                                  | 165,038              | 41,259                     |
| 180-day supplement .....                                                                                                                                                                                                                                   | 15% .....                                                                  | 33,008               | 8,252                      |
| Real-time supplement .....                                                                                                                                                                                                                                 | 7% .....                                                                   | 15,404               | 3,851                      |
| 510(k) premarket notification submission .....                                                                                                                                                                                                             | 1.84% .....                                                                | 4,049                | 2,024                      |
| 30-day notice .....                                                                                                                                                                                                                                        | 1.6% .....                                                                 | 3,521                | 1,760                      |
| 513(g) (21 U.S.C. 360c(g)) request for classification information .....                                                                                                                                                                                    | 1.35% .....                                                                | 2,971                | 1,485                      |
| Annual Fee Type                                                                                                                                                                                                                                            |                                                                            |                      |                            |
| Annual fee for periodic reporting on a class III device .....                                                                                                                                                                                              | 3.5% .....                                                                 | 7,702                | 1,925                      |
| 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 at \$2,364, but offset by multiplying by 85.8281 percent.   | 2,029                | 2,029                      |

#### IV. 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. In order to pay the small business fee rate for a submission, or 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 2011, your status as a small business will expire at the close of business on September 30, 2011. You must re-qualify for FY 2012 in order to pay small business fees during FY 2012.

If you are a domestic (U.S.) business, and wish to qualify as a small business for FY 2012, you must submit the following to FDA:

1. A completed FY 2012 MDUFMA Small Business Qualification Certification (Form FDA 3602). This form is provided in FDA's guidance document, "FY 2012 Medical Device User Fee Small Business Qualification and Certification," available on FDA's Web site at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm>. 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 2011, except:

- If you submit your FY 2012 MDUFMA Small Business Qualification before April 15, 2012, and you have not yet filed your return for 2011, you may use tax year 2010.

- If you submit your FY 2012 MDUFMA Small Business Qualification on or after April 15, 2012, and have not yet filed your 2011 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. The National Taxing Authority is the foreign equivalent of the U.S. Internal Revenue Service. 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 of each affiliate, or that the applicant has no affiliates.

If you are a foreign business, and wish to qualify as a small business for FY 2012, you must submit the following:

1. A completed FY 2012 MDUFMA Foreign Small Business Qualification Certification (Form FDA 3602A). This form is provided in FDA's guidance document, "FY 2012 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:
  - 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 (2010 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. The National Taxing Authority is the foreign equivalent of the U.S. Internal Revenue Service. 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 of each affiliate, or that the applicant has no affiliates.

#### V. Procedures for Paying Application Fees

If your application or submission is subject to a fee and your payment is received by FDA from October 1, 2011, through September 30, 2012, you must pay the fee in effect for FY 2012. The later of the date that the application 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 2011 or FY 2012 apply. FDA must receive the correct fee at the time that an application is submitted, or the application will not be accepted for filing or review.

FDA requests that you follow the steps in the paragraphs that follow when submitting a medical device application subject to a fee 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. Both the FY 2011 and FY 2012 Fee Rates Will Be Available on the User Fee Web Site Beginning on the Date of Publication of This Document, and Only the FY 2012 Rates Will Appear After September 30, 2011)*

Log on to the MDUFMA Web site at: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm> and under the MDUFMA Forms heading, click on the link "Create a 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, 2011. One choice is for applications that will be received on or before September 30, 2011, which are subject to FY 2011 fee rates. A second choice is for applications that will be received on or after October 1, 2011, which are subject to FY 2012 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. 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—Submit Payment for the Completed Medical Device User Fee Cover Sheet as Described in This Section, Depending on the Method You Will Use to Make Payment*

1. If paying with a paper check:

- All paper checks must be in U.S. currency from a U.S. bank and made 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.

- Mail the paper check and a copy of the completed 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 Federal Express (FEDEX), DHL, United Parcel Service (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.)

FDA records the official application receipt date as the later of the following: (1) The date the application was received by FDA or (2) the date U.S. Bank receives the payment. It is helpful if the fee arrives at the bank at least 1 day before the application arrives at FDA. U.S. Bank is required to notify FDA within 1 working day, using the PIN described previously in this document.

2. If paying with a credit card or electronic check (Automated Clearing House (ACH)):

FDA has partnered with the U.S. Department of the Treasury to utilize Pay.gov, a Web based payment system,

for online electronic payment. You may make a payment via electronic check or credit card after submitting your coversheet. To pay online, select the "Pay Now" button. Credit card transactions for cover sheets are limited to \$5,000.

3. If paying with a wire transfer:

- Please include your application's unique PIN, from the upper right-hand corner of your completed Medical Device User Fee cover sheet, in your wire transfer. Without the PIN, your payment may not be applied to your cover sheet and review of your application will be delayed.

- The originating financial institution may charge a wire transfer fee between \$15 and \$35. Please ask your financial institution about the fee and include it with your payment to ensure that your cover sheet is fully paid.

Use the following account information when sending a wire transfer: New York Federal Reserve Bank, U.S. Department of Treasury, TREAS NYC, 33 Liberty St, New York, NY 10045, Acct. No. 75060099, Routing No. 021030004, SWIFT: FRNYUS33, Beneficiary: FDA, 1350 Piccard Dr., Rockville, MD 20850.

*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:

1. Medical device applications should be submitted to: Food and Drug Administration, Center for Devices and Radiological Health, Document Mail Center—WO66, rm. 0609, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002.

2. 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.

**VI. Procedures for Paying the Annual Fee for Periodic Reporting**

As of FY 2011, you are no longer able to create a cover sheet and obtain a PIN to pay the MDUFMA Annual Fee for Periodic Reporting. Instead, you will be invoiced at the end of the quarter in which your PMA Periodic Report is due. Invoices will be sent based on the details included on your PMA file; you are responsible to ensure your billing information are kept up-to-date (you can update your contact for the PMA by submitting an amendment).

1. If paying with a paper check:

- All paper checks must be in U.S. currency from a U.S. bank and made 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 invoice number.
- Mail the paper check and a copy of invoice 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 Federal Express (FEDEX), DHL, United Parcel Service (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.)

2. If paying with a wire transfer:

- Please include your invoice number in your wire transfer. Without the invoice number, your payment may not be applied and you may be referred to collections.

- The originating financial institution may charge a wire transfer fee between \$15 and \$35. Please ask your financial institution about the fee and include it with your payment to ensure that your invoice is fully paid.

Use the following account information when sending a wire transfer: New York Federal Reserve Bank, U.S. Department of Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Acct. No. 75060099, Routing No. 021030004, SWIFT: FRNYUS33, Beneficiary: FDA, 1350 Piccard Dr., Rockville, MD 20850.

**VII. Procedures for Paying Annual Establishment Fees**

In order to pay the annual establishment fee, firms must access the Device Facility User Fee (DFUF) Web site at [https://userfees.fda.gov/OA\\_HTML/furls.jsp](https://userfees.fda.gov/OA_HTML/furls.jsp). (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**). The Web site includes a short interactive questionnaire to help you ascertain whether an annual registration payment is required for your type of facility. If you are required to pay an annual establishment registration fee, you must pay for each establishment prior to registration. You will create a DFUF order and 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 2012 until it has completed the steps in the paragraphs that follow to register and pay any applicable fee. (See 21 U.S.C. 379j(f)(2).)

Companies that do not manufacture any product other than a licensed biologic are required to register in the Blood Establishment Registration (BER) system. FDA's Center for Biologics Evaluation and Research (CBER) will send establishment registration fee invoices annually to these companies.

*A. Step One—Submit a Device Facility User Fee (DFUF) 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 through the User Fee Web site listed previously in this section. After creating a user name and password, log into the Establishment Registration User Fee 2012 store. Complete the DFUF order by entering the number of establishments you are registering that require payment. 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 Device Facility User Fee Order*

Unless paying by credit card, all payments must be in U. S. currency and drawn on a U.S. bank.

1. If paying with a credit card or electronic check (ACH):

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.

2. If paying with a paper check:

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: U.S. Bank, Attn: Government Lockbox 979108, St. Louis, MO 63197–9000. (**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: U.S. Bank, Attn: Government Lockbox 979108, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This U.S. Bank address is for courier delivery only; do not send mail to this address.)

Please make sure that both of the following are written on your check: (1) The FDA lockbox number (Lockbox 979108) 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.

3. If paying with a wire transfer:

Wire transfers may also be used to pay annual establishment fees. To send a wire transfer, please read and comply with the following information:

- Include your order's unique PIN, from the upper right-hand corner of your completed Medical Device User Fee order, in your wire transfer. Without the PIN your payment may not be applied to your facility and your registration will be delayed.

- The originating financial institution usually charges a wire transfer fee between \$15 and \$35. Please ask your financial institution about the fee and include it with your payment to ensure that your order is fully paid. Use the following account information when sending a wire transfer: New York Federal Reserve Bank, U.S. Dept of Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Acct. No. 75060099, Routing No. 021030004, SWIFT: FRNYUS33, Beneficiary: FDA, 5600 Fishers Lane, Rockville, MD 20857.

*C. Step Three—Complete the Information Online To Update Your Establishment's Annual Registration for FY 2012, or to Register a New Establishment for FY 2012*

Go to CDRH's Web site at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/default.htm> and click the "Access Electronic Registration" link on the left of the page. This opens up a new page with important information about the FDA Unified Registration and Listing System (FURLS). After reading this information, click on the link (Access Electronic Registration) at the bottom of the page. This link 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 2010 or FY 2011. Biologics manufacturers should register in the BER system at <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/>

*EstablishmentRegistration/BloodEstablishmentRegistration/default.htm.*

Enter your existing account ID and password to log into FURLS. From the FURLS/FDA Industry Systems menu, click on the Device Registration and Listing Module (DRLM) of FURLS button. New establishments will need to register and existing establishments will update their annual registration using selections 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@cdhrh.fda.gov](mailto:reglist@cdhrh.fda.gov) or call 301-796-7400 for assistance. (Note: this e-mail address and this telephone number are for assistance with establishment registration only, and not for any other aspects of medical device user fees.) Problems with BER should be directed to [bloodregis@fda.hhs.gov](mailto:bloodregis@fda.hhs.gov) or call 301-827-3546.

*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. This process does not apply to licensed biologic devices. CBER will send invoices for payment of the establishment registration fee to companies who only manufacture licensed biologics devices. Fees are only required for those establishments defined in section I of this document.

Dated: July 26, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2011-N-0559]

**Prescription Drug User Fee Rates for Fiscal Year 2012**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the rates for prescription drug user fees for fiscal year (FY) 2012. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Prescription Drug User Fee Amendments of 2007 (Title 1 of the Food and Drug Administration

Amendments Act of 2007 (FDAAA)) (PDUFA IV), authorizes FDA to collect user fees for certain applications for approval of drug and biological products, on establishments where the products are made, and on such products. Base revenue amounts to be generated from PDUFA fees were established by PDUFA IV, with provisions for certain adjustments. Fee revenue amounts for applications, establishments, and products are to be established each year by FDA so that one-third of the PDUFA fee revenues FDA collects each year will be generated from each of these categories. This document establishes fee rates for FY 2012 for application fees for an application requiring clinical data (\$1,841,500), for an application not requiring clinical data or a supplement requiring clinical data (\$920,750), for establishment fees (\$520,100), and for product fees (\$98,970). These fees are effective on October 1, 2011, and will remain in effect through September 30, 2012. For applications and supplements that are submitted on or after October 1, 2011, the new fee schedule must be used. Invoices for establishment and product fees for FY 2012 will be issued in August 2011, using the new fee schedule.

**FOR FURTHER INFORMATION CONTACT:**

David Miller, Office of Financial Management (HFA-100), Food and Drug Administration, 1350 Picard Dr., PI50, Rm. 210J, Rockville, MD 20850, 301-796-7103.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

Sections 735 and 736 of the FD&C Act (21 U.S.C. 379g and 379h, respectively), establish three different kinds of user fees. Fees are assessed on the following: (1) Certain types of applications and supplements for approval of drug and biological products, (2) certain establishments where such products are made, and (3) certain products (section 736(a) of the FD&C Act). When certain conditions are met, FDA may waive or reduce fees (section 736(d) of the FD&C Act).

For FY 2008 through FY 2012, the base revenue amounts for the total revenues from all PDUFA fees are established by PDUFA IV. The base revenue amount for FY 2008 is to be adjusted for workload, and that adjusted amount becomes the base amount for the remaining 4 FYs. That adjusted base revenue amount is increased for drug safety enhancements by \$10,000,000 in each of the subsequent 4 FYs, and the increased total is further adjusted each year for inflation and workload. Fees for