The guidance represents the Agency's current thinking on Center for Devices and Radiological Health's Appeals Processes: Questions and Answers About 517A. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the Internet. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm*. Guidance documents are also available at *http://www.regulations.gov*. Persons unable to download an electronic copy of ''Center for Devices and Radiological Health Appeals Processes: Questions and Answers About 517A,'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1821 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910–0120; the collections of information found in 21 CFR part 814 have been approved under OMB control number 0910–0231; and the collections of information in 21 CFR part 814, subpart H have been approved under OMB control number 0910–0332. The collections of information in the guidance document ''Center for Devices and Radiological Health Appeals Processes'' have been approved under OMB control number 0910–0738.

V. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of 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, and will be posted to the docket at *http://www.regulations.gov*.

Dated: July 24, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–17901 Filed 7–29–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0007]

Medical Device User Fee Rates for Fiscal Year 2015

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) 2015. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Medical Device User Fee Amendments of 2012 (MDUFA III), authorizes FDA to collect user fees for certain medical device submissions and annual fees both for certain periodic reports and for establishments subject to registration. This notice establishes the fee rates for FY 2015, which apply from October 1, 2014, through September 30, 2015. To avoid delay in the review of your application, you should pay the standard 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 recognized by the U.S. Treasury. If you want to pay a reduced small business fee, you must qualify as a small business before making your submission to FDA; if you do not qualify as a small business before making your submission to FDA, you will have to pay the higher standard fee. Please note that the establishment registration fee is not eligible for a reduced small business fee. As a result, if the establishment registration fee is the only medical device user fee that you will pay in FY 2015, you should not submit a FY 2015 Small Business Qualification and Certification request. This document provides information on how the fees for FY 2015 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 Medical Device User Fees:* Visit FDA's Web site at *http://www.fda.gov/mdufa*.

For questions relating to this notice: David Miller, Office of Financial Management, Food and Drug Administration, 8455 Colesville Rd. (COLE–14202E), Silver Spring, MD 20993–0002, 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'' or ''applications''); 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).) Additionally, the Secretary of Health and Human Services (the Secretary) may, at the Secretary's sole discretion, grant a fee waiver or reduction if the Secretary finds that such waiver or reduction is in the interest of public health. (See 21 U.S.C. 379j(f).)

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 base fee for a premarket application for each year from FY 2013 through FY 2017; the base fee for a premarket application received by FDA during FY 2015 is $258,019. From this starting point, this document establishes FY 2015 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 base fee for establishment registration for each year from FY 2013 through FY 2017; the base fee for an establishment registration in FY 2015 is $3,750. There is no reduction in the registration fee for small businesses. Each establishment that is registered (or is required to register) with the Secretary under section 510 of the FD&C Act (21 U.S.C. 360) because such establishment is engaged in the manufacture, preparation, propagation, compounding, or processing of a device is required to pay the annual fee for establishment registration.

II. Revenue Amount for FY 2015

The base revenue amount for FY 2015 is $125,767,107, as set forth in the statute prior to the inflation adjustment. (See 21 U.S.C. 379j(b)(3)(C).) MDUFA directs FDA to use the yearly revenue amount as a starting point to set the standard fee rates for each fee type. The fee calculations for FY 2015 are described in this document.

Inflation Adjustment

MDUFA specifies that the $125,767,107 is to be further adjusted for inflation increases for FY 2015 using two separate adjustments—one for payroll costs and one for non-pay cost (see 21 U.S.C. 379j(c)(2)).

The component of the inflation adjustment for payroll costs shall be the sum of one plus the average annual percent change in the cost of all personnel compensation and benefits (PC&B) paid per full-time equivalent position (FTE) at FDA for the first 3 of the 4 preceding FYs, multiplied by 0.60, or 60 percent (see 21 U.S.C. 379j(c)(2)(C)). The data on total PC&B paid and numbers of FTE paid, from which the average cost per FTE can be derived, are published in FDA's Justification of Estimates for Appropriations Committees.

Table 1 summarizes the actual cost and FTE data for the specified FYs, and provides the percent change from the previous FY and the average percent change over the first 3 of the 4 FYs preceding FY 2015. The 3-year average is 1.8829 percent.

TABLE 1—FDA PC&B'S EACH YEAR AND PERCENT CHANGE

Fiscal year	2011	2012	2013	3-Year average
Total PC&B	$1,761,655,000	$1,824,703,000	$1,927,703,000	
Total FTE	13,331	13,382	13,974	
PC&B per FTE	$132,147	$136,355	$137,949	
Percent change from previous year	1.2954%	3.1843%	1.1690%	1.8829%

The payroll adjustment is 1.8829 percent multiplied by 60 percent, or 1.1297 percent.

The statute specifies that the portion of the inflation adjustment for non-payroll costs for FY 2015 is the average annual percent change that occurred in the Consumer Price Index (CPI) for urban consumers (Washington-Baltimore, DC-MD-VA-WV; not seasonally adjusted; all items; annual index) for the first 3 of the preceding 4 years of available data multiplied by 0.40, or 40 percent (see 21 U.S.C. 379j(c)(2)(C)).

Table 2 provides the summary data and the 3-year average percent change in the specified CPI for the Baltimore-Washington area. This data is published by the Bureau of Labor Statistics and can be found on their Web site at *http://data.bls.gov/cgi-bin/surveymost?cu* by checking the box marked ''Washington-Baltimore All Items, November 1996=100—CUURA311SA0'' and then clicking on the ''Retrieve Data'' button.

TABLE 2—ANNUAL AND 3-YEAR AVERAGE PERCENT CHANGE IN BALTIMORE-WASHINGTON AREA CPI

Fiscal year	2011	2012	2013	3-Year average
Annual CPI	146.975	150.212	152.500	
Annual percent change	3.3449%	2.2024%	1.5232%	
3-Year average percent change in CPI				2.3568%

The non-pay adjustment is 2.3568 percent multiplied by 40 percent, or 0.9427 percent.

To complete the inflation adjustment, the payroll adjustment (1.1297 percent) is added to the non-pay adjustment (0.9427 percent), for a total of 2.0724 percent, and plus one equals to 1.020724.

MDUFA III provides for this inflation adjustment to be compounded beginning in FY 2015 (see 21 U.S.C. 379j(c)(2)(B)(ii)). The FY 2015 inflation rate is multiplied by the FY 2014 inflation rate of 1.02198 percent as published in the **Federal Register** of August 2, 2013 (78 FR 46970), to reach the compound rate of 1.04316. The base revenue amount for FY 2015 ($125,767,107) is then multiplied by the compound inflation rate of 1.04316, yielding an inflation adjusted amount of $131,195,000 (rounded to the nearest thousand dollars).

III. Fees for FY 2015

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)). For FY 2015, the base fee will be adjusted as specified in the FD&C Act for inflation (see 21 U.S.C. 379j(b) and (c)). Table 3 provides the last 3 years of fee paying submission counts and the 3-year average. These numbers are used to project the fee paying submission counts that FDA will receive in FY 2015. The fee paying submission counts are published in the MDUFA Financial Report to Congress each year.

TABLE 3—3-YEAR AVERAGE OF FEE PAYING SUBMISSIONS

Application type	FY 2011 actual	FY 2012 actual	FY 2013 actual	3-Year average
Full Fee Applications	24	25	23	24
Small Business	7	6	9	7
Panel-Track Supplement	7	12	19	13
Small Business	1	0	0	0
180-Day Supplements	92	145	128	122
Small Business	15	21	21	19

TABLE 3—3-YEAR AVERAGE OF FEE PAYING SUBMISSIONS—Continued

Application type	FY 2011 actual	FY 2012 actual	FY 2013 actual	3-Year average
Real-Time Supplements	145	196	182	174
Small Business	17	22	23	21
510(k)s	2,398	2,865	3,149	2,804
Small Business	938	1,086	1,202	1,075
30-Day Notice	755	801	956	837
Small Business	67	60	69	65
513(g) Request for Classification Information	40	46	65	50
Small Business	35	30	38	34
Annual Fee for Periodic Reporting	466	478	614	519
Small Business	*78*	39	54	57
Establishment Registration [1]	.....	.....	24,462	24,462

[1] Estimate for establishment registration based on FY 2013 actual numbers because the criteria for this fee changed beginning in FY 2013 and no comparable data for a 3-year average is available.

The information in Table 3 is necessary to estimate the amount of revenue that will be collected based on the fee amounts. Table 4 displays both the estimated revenue using the FY 2015 base fees set in statute and the estimated revenue adding the inflation adjustment to the FY 2015 base fees. Using the fees set in statute and the 3-year averages of fee paying submissions, the collections would total $134,915,821, which is $3,720,821 higher than the statutory revenue amount. Accordingly the PMA and establishment fee should be decreased by 2.761%, rounded to the nearest whole dollar, so that collections come as close to the statutory limit of $131,195,000 as possible without exceeding the limit. The fees in the second column from the right are those we are establishing in FY 2015, which are the standard fees.

TABLE 4—FEES NEEDED TO ACHIEVE NEW FY 2015 REVENUE TARGET

Application type	FY 2015 statutory fees	Resulting 2015 revenue	Adjusted FY 2015 fees to meet revenue target	FY 2015 revenue from adjusted fees
Full Fee Applications	$258,019	$6,192,456	$250,895	$6,021,480
Small Business	64,505	451,535	62,724	439,068
Panel-Track Supplement	193,514	2,515,682	188,171	2,446,223
Small Business	48,379	0	47,043	0
180-Day Supplements	38,703	4,721,766	37,634	4,591,348
Small Business	9,676	183,844	9,409	178,771
Real-Time Supplements	18,061	3,142,614	17,563	3,055,962
Small Business	4,515	94,815	4,391	92,211
510(k)s	5,160	14,468,640	5,018	14,070,472
Small Business	2,580	2,773, 500	2,509	2,697,175
30-Day Notice	4,128	3,455,136	4,014	3,359,718
Small Business	2,064	134,160	2,007	130,455
513(g) Request for Classification Information	3,483	174,150	3,387	169,350
Small Business	1,742	59,228	1,694	57,596
Annual Fee for Periodic Reporting	9,031	4,687,089	8,781	4,557,339
Small Business	2,258	128,706	2,195	130,455
Establishment Registration	3,750	91,732,500	3,646	89,188,452
Total	.....	134,915,821	.....	131,180,735

The standard fee (adjusted base amount) for a premarket application, including a BLA, and for a premarket report and a BLA efficacy supplement, is $250,895 for FY 2015. The fees set by reference to the standard fee for a premarket application are:

- For a panel-track supplement, 75 percent of the standard fee;
- For a 180-day supplement, 15 percent of the standard fee;
- For a real-time supplement, 7 percent of the standard fee;
- For a 510(k) premarket notification, 2 percent of the standard fee;
- For a 30-day notice, 1.6 percent of the standard fee;
- For a 513(g) request for classification information, 1.35 percent of the standard fee; and
- For an annual fee for periodic reporting concerning a class III device, 3.5 percent of the standard 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 for the submission. (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 for the submission. (See 21 U.S.C. 379j(d)(2)(C) and (e)(2)(C).)

The annual fee for establishment registration, after adjustment, is set at $3,646 for FY 2015. There is no small business rate for the annual establishment registration fee; all establishments pay the same fee.

Table 5 summarizes the FY 2015 rates for all medical device fees.

TABLE 5—MEDICAL DEVICE FEES FOR FY 2015

	Standard fee (as a percent of the standard fee for a premarket application)	FY 2015 standard fee	FY 2015 small business fee
Application fee type:			
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 (21 U.S.C. 360e(f)), or a BLA submitted under section 351 of the Public Health Service Act (the PHS Act) (42 U.S.C. 262)).	Base fee adjusted as specified in the statute.	$250,895	$62,724
Premarket report (submitted under section 515(c)(2) of the FD&C Act).	100%	$250,895	$62,724
Efficacy supplement (to an approved BLA under section 351 of the PHS Act).	100%	$250,895	$62,724
Panel-track supplement	75%	$188,171	$47,043
180-day supplement	15%	$37,634	$9,409
Real-time supplement	7%	$17,563	$4,391
510(k) premarket notification submission	2%	$5,018	$2,509
30-day notice	1.60%	$4,014	$2,007
513(g) (21 U.S.C. 360c(g)) request for classification information.	1.35%	$3,387	$1,694
Annual Fee Type:			
Annual fee for periodic reporting on a class III device	3.50%	$8,781	$2,195
Annual establishment registration fee (to be paid by the establishment engaged in the manufacture, preparation, propagation, compounding, or processing of a device, as defined by 21 U.S.C. 379i(13)).	Base fee adjusted as specified in the statute.	$3,646	$3,646

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. 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 (full) fee for that submission.

If your business qualified as a small business for FY 2014, your status as a small business will expire at the close of business on September 30, 2014. You must re-qualify for FY 2015 in order to pay small business fees during FY 2015.

If you are a domestic (U.S.) business, and wish to qualify as a small business for FY 2015, you must submit the following to FDA:

1. A completed FY 2015 MDUFA Small Business Qualification Certification (Form FDA 3602). This form is provided in FDA's guidance document, ''FY 2015 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 2014, except:

If you submit your FY 2015 MDUFA Small Business Qualification before April 15, 2015, and you have not yet filed your return for 2014, you may use tax year 2013.

If you submit your FY 2015 MDUFA Small Business Qualification on or after April 15, 2015, and have not yet filed your 2014 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 must 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 2015, you must submit the following:

1. A completed FY 2015 MDUFA Foreign Small Business Qualification Certification (Form FDA 3602A). This form is provided in FDA's guidance document, ''FY 2015 Medical Device User Fee Small Business Qualification and Certification,'' available on FDA's Internet site at *http://www.fda.gov/mdufa*. 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 (2014 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 must 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, 2014, through September 30, 2015, you must pay the fee in effect for FY 2015. The later of the date that the application is received in the reviewing center's document room or the date the U.S. Treasury recognizes the payment determines whether the fee rates for FY 2014 or FY 2015 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 below before 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. Secure a Payment Identification Number (PIN) and Medical Device User Fee Cover Sheet From FDA Before Submitting Either the Application or the Payment

Log on to the MDUFA Web site at: *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm* and click on ''MDUFA FORMS'' at the left side of the page, and then under the MDUFA Forms heading, click on the link ''Create MDUFA 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, 2014. One choice is for applications and fees that will be received on or before September 30, 2014, which are subject to FY 2014 fee rates. A second choice is for applications and fees received on or after October 1, 2014, which are subject to FY 2015 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. Electronically Transmit a Copy of the Printed Cover Sheet With the PIN

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 password to assure data security in the creation and electronic submission of cover sheets.

C. Submit Payment for the Completed Medical Device User Fee Cover Sheet

1. If paying with 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 cover sheet. To pay online, select the ''Pay Now'' button. Credit card transactions for cover sheets are limited to $49,999.99.

2. 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 979033, St. Louis, MO 63197–9000. (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, the courier may deliver the check to: U.S. Bank, Attn: Government Lockbox 979033, 1005 Convention Plaza, St. Louis, MO 63101. (**Note:** This address is for courier delivery only. Contact U.S. Bank at 314–418–4013 if you have any questions concerning courier delivery.)

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 may be delayed.

• The originating financial institution may charge a wire transfer fee. Please ask your financial institution about the fee and add it to 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, 8455 Colesville Rd., Silver Spring, MD 20993–0002.

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 the U.S. Treasury recognizes the payment. It is helpful if the fee arrives at the bank at least 1 day before the application arrives at FDA.

D. 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, 10903 New Hampshire Ave., Bldg. 66, Rm. 0609, Silver Spring, MD 20993–0002.

2. Biologics license applications should be sent to: Food and Drug Administration, Center for Biologics Evaluation and Research, Document Control Center, 10903 New Hampshire Ave, Bldg. 71, Rm. G112, Silver Spring, MD 20993–0002.

VI. Procedures for Paying the Annual Fee for Periodic Reporting

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 is kept up-to-date, and you may update your contact information 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 on the check.
- Mail the paper check and a copy of invoice to: Food and Drug Administration, P.O. Box 979033, St. Louis, MO 63197–9000.

(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, the courier may deliver the check to: U.S. Bank, Attn: Government Lockbox 979033, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the U.S. Bank at 314–418–4013 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. Please ask your financial institution about the fee and add it to 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 the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Acct. No. 75060099, Routing No. 021030004, SWIFT: FRNYUS33, Beneficiary: FDA, 8455 Colesville Rd., Silver Spring, MD 20993–0002.

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*. (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**.) 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 2015 until it has completed the steps below to register and pay any applicable fee. (See 21 U.S.C. 379j(g)(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. Submit a 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 for the user fee Web site listed previously in this section. After creating a user name and password, log into the Establishment Registration User Fee FY 2015 store. Complete the DFUF order by entering the number of establishments you are registering that require payment. Once you are satisfied that the information in 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. 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.

1. If paying by 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 check. Follow the instructions provided to make an electronic payment.

2. If paying with a paper check:

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 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 post office box number (P.O. Box 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.

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 DFUF 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 may charge a wire transfer fee. Please ask your financial institution about the fee and add it to 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, 8455 Colesville Rd., Silver Spring, MD 20993–0002.

FDA's tax identification number is 53–0196965.

C. Complete the Information Online To Update Your Establishment's Annual Registration for FY 2015, or To Register a New Establishment for FY 2015

Go to the Center for Devices and Radiological Health's Web site at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/default.htm* and click the ''Access Electronic Registration'' link on the left side 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 ''Access Electronic Registration'' link in the middle 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 2014. Manufacturers of licensed biologics 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 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, email: *reglist@cdrh.fda.gov* or call 301–796–7400 for assistance. (**Note:** this email 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 BERS should be directed to *http://www.accessdata.fda.gov/scripts/email/cber/bldregcontact.cfm* or call 240–402–8360.

D. 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 establishments engaged only in the manufacture, preparation, propagation, compounding, or processing of licensed biologic devices. CBER will send invoices for payment of the establishment registration fee to such establishments.

Dated: July 23, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–17902 Filed 7–29–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

Cellular, Tissue and Gene Therapies 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). At least one portion of the meeting will be closed to the public.

Name of Committee: Cellular, Tissue and Gene Therapies 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 September 18, 2014, from 1 p.m. to 4 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, Rm. 1506–IR, Silver Spring, MD 20993–0002. The public is welcome to attend the meeting at the specified location where a speakerphone will be provided. Public participation in the meeting is limited to the use of the speakerphone in the conference room. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/default.htm;* under the heading ''Resources for You,'' click on ''Public Meetings at the FDA White Oak Campus.'' Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Gail Dapolito, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6124, Silver Spring, MD 20993–0002, 240–402–8046, *gail.dapolito@fda.hhs.gov;* or Rosanna Harvey, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6136, Silver Spring, MD 20993–0002, 240–402–8072, *rosanna.harvey@fda.hhs.gov;* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). 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 at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On September 18, 2014, the committee will meet by teleconference. In open session, the committee will hear updates of research programs in the Laboratory of Biochemistry, Division of Therapeutic Proteins, the Laboratory of Molecular Oncology and the Laboratory of Molecular and Developmental Immunology, Division of Monoclonal Antibodies, Office of Biotechnology Products, Office of Pharmaceutical Sciences, Center for Drug Evaluation and Research, FDA.

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 meeting link.

Procedure: On September 18, 2014, from 1 p.m. to 3:20 p.m., the meeting is open to the public. 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 September 11, 2014. Oral presentations from the public will be scheduled between approximately 2:20 p.m. and 3:20 p.m. Those individuals interested in making 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 September 3, 2014. 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 September 4, 2014.

Closed Committee Deliberations: On September 18, 2014, from approximately 3:20 p.m. to 4 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The committee will discuss reports of intramural research programs and make recommendations regarding personnel staffing decisions.

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 Gail Dapolito 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