side effects such as nausea and fatigue, and less common but serious adverse events such as blood clots, infection, seizures, and cancer.)

4. In certain HIV cure research studies, you would be asked to stop any other HIV medications that you are currently taking. How would this affect your decision whether to participate in an HIV cure research study?

5. The process of informed consent is an important way for the researchers to communicate the purpose of an HIV research study, as well as its expected benefits and potential risks, so that people can make an informed decision whether to participate in the study.

a. How should the informed consent clearly communicate to you the purpose of an HIV cure research study, particularly when a study is designed only to provide scientific information that could guide future research and development of treatments?

b. How should the informed consent clearly communicate to you the potential benefits of an HIV cure research study? In particular, how should the informed consent describe benefit when we do not think that participants in the study may gain any direct health benefits?

c. How should informed consent communicate clearly to you the potential risks of participating in an HIV cure research study? In particular, how should the informed consent describe a study if there is very limited understanding about how the medications or interventions may affect participants or what are the potential risks of those interventions or medications?

d. Is there any other information that you would find helpful when deciding whether to enter an HIV cure research study?

6. What else do you want FDA to know about HIV Cure Research from your perspective?

III. How To Submit 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 29, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–18630 Filed 8–1–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0007]

Medical Device User Fee Rates for Fiscal Year 2014

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) 2014. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Medical Device User Fee Amendments of 2012, which was signed by the President on July 9, 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. The FY 2014 fee rates are provided in this document. These fees apply from October 1, 2013, through September 30, 2014. 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 recognized by the U.S. Treasury. 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 document provides information on how the fees for FY 2014 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 (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'' 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 2014 is $252,960. From this starting point, this document establishes FY 2014 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 2014 is $3,200. 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 2014

The base revenue amount for FY 2014 is $112,580,497, as set forth in the statute prior to the inflation adjustment. MDUFA directs FDA to use the yearly revenue amount as a starting point to set the fee rates for each fee type. The fee calculations for FY 2014 are described in this document.

Inflation Adjustment

MDUFA specifies that the $112,580,497 is to be further adjusted for inflation increases for FY 2014 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 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 .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 that 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 2014. The 3-year average is 2.05 percent.

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

Fiscal year	2010	2011	2012	3-Year average
Total PC&B	$1,634,108,000	$1,761,655,000	$1,824,703,000	.....
Total FTE	12,526	13,331	13,382	.....
PC&B per FTE	$130,457	$132,147	$136,355	.....
Percent change from previous year	1.67%	1.30%	3.18%	2.05%

The payroll adjustment is 2.05 percent multiplied by 60 percent, or 1.23 percent.

The statute specifies that the portion of the inflation adjustment for non-payroll costs for FY 2014 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 .40, or 40 percent (see 21 U.S.C. 379j(c)(2)(C)).

Table 2 provides the summary data for the 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

Year	2010	2011	2012	3-Year average
Annual CPI	142.218	146.975	150.212	.....
Annual percent change	1.72%	3.34%	2.20%	2.42%

The non-pay adjustment is 2.42 percent times 40 percent, or .968 percent.

To complete the inflation adjustment, the payroll component (1.230 percent) is added to the non-pay component (0.968 percent), for a total inflation adjustment of 2.198 percent (rounded), and then one is added, making 1.02198. The base revenue amount for FY 2014 ($112,580,497) is then multiplied by 1.02198, yielding an inflation adjusted amount of $115,055,000 (rounded to the nearest thousand dollars).

III. Fees for FY 2014

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 2014, 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. These numbers are used to project the fee paying submission that FDA will receive in FY 2014. The fee paying submission counts are published in the Agency's MDUFA Financial Report to Congress each year.

TABLE 3—3-YEAR AVERAGE OF FEE PAYING SUBMISSIONS

Application type	FY 2010 actual	FY 2011 actual	FY 2012 actual	3-Year average
Full Fee Applications	32	24	25	27
Small Business	8	7	6	7
Panel Track Supplement	11	7	12	10
Small Business	2	1	0	1
180-Day Supplements	103	92	145	113
Small Business	20	15	21	19
Real-Time Supplements	146	145	196	162
Small Business	20	17	22	20
510(k)s	2,367	2,398	2,865	2,543
Small Business	1,032	938	1,086	1,019
30-Day Notice	669	755	801	742
Small Business	78	67	60	68
513(g) Request for Classification Information	56	40	46	47
Small Business	25	35	30	30
Annual Fee for Periodic Reporting	427	466	478	457
Small Business	78	*78*	39	65

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

Application type	FY 2010 actual	FY 2011 actual	FY 2012 actual	3-Year average
Establishment Registration [1] *	.....	.....	.....	22,500

[1] Estimate for establishment registration based on preliminary FY 2013 numbers because the criteria for this fee changed beginning in FY 2013.

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 2014 base fees set in statute and the estimated revenue adding the inflation adjustment to the FY 2014 base fees. The increases to the base fees are needed in order to collect the new revenue target of $115,055,000.

TABLE 4—FEES NEEDED TO ACHIEVE NEW FY 2014 REVENUE TARGET

Application type	FY 2014 base fees	Estimated revenue	Adjusted FY 2014 fees (standard fee)	Adjusted revenue
Full Fee Applications	$252,960	$6,829,920	$258,520	$6,980,040
Small Business	63,240	442,680	64,630	452,410
Panel-Track Supplement	189,720	1,897,200	193,890	1,938,900
Small Business	47,430	47,430	48,473	48,473
180-Day Supplements	37,944	4,287,672	38,778	4,381,914
Small Business	9,486	180,234	9,695	184,205
Real-Time Supplements	17,707	2,868,566	18,096	2,931,552
Small Business	4,427	88,536	4,524	90,480
510(k)s	5,059	12,865,546	5,170	13,147,310
Small Business	2,530	2,577,662	2,585	2,634,115
30-Day Notice	4,047	3,003,141	4,136	3,068,912
Small Business	2,024	137,610	2,068	140,624
513(g) Request for Classification Information	3,415	160,503	3,490	164,030
Small Business	1,707	51,224	1,745	52,350
Annual Fee for Periodic Reporting	8,854	4,046,095	9,048	4,134,936
Small Business	2,213	143,871	2,262	147,030
Establishment Registration	3,200	72,000,000	3,313	74,542,500
Total	.....	111,627,891	.....	115,039,781

The PMA and establishment registration fees were increased over the base by the inflation adjustment (2.198%) as determined earlier in this document. An additional $43 (rounded to the nearest whole dollar) was added to the establishment registration fee in order to collect the shortfall in revenue that resulted. This was done because the statute directs that, after the inflation adjustment is made, the base establishment registration fee amounts shall be further adjusted, as necessary, for total fee collections to achieve the total revenue amount specified after inflation adjustment (see 21 U.S.C. 379j(c)(3)). Without this additional adjustment to the establishment registration fee, the total collections would fall almost $1 million below the total specified revenue after adjustment for inflation.

The standard fee (adjusted base amount) for a premarket application, including a BLA, and for a premarket report and a BLA efficacy supplement, is $258,520 for FY 2014. 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 30-day notice, 1.6 percent of the standard fee;
- For a 510(k) premarket notification, 2 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 $3,313 for FY 2014. There is no small business rate for the annual establishment registration fee; all establishments pay the same fee.

Table 5 sets out the FY 2014 rates for all medical device fees.

TABLE 5—MEDICAL DEVICE FEES FOR FY 2014

	Standard fee (as a percent of the standard fee for a premarket application)	FY 2014 Standard fee	FY 2014 Small Business fee
Application Fee Type:			

TABLE 5—MEDICAL DEVICE FEES FOR FY 2014—Continued

	Standard fee (as a percent of the standard fee for a premarket application)	FY 2014 Standard fee	FY 2014 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 (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	$258,520	$64,630
Premarket report (submitted under section 515(c)(2) of the FD&C Act).	100%	258,520	64,630
Efficacy supplement (to an approved BLA under section 351 of the PHS Act).	100%	258,520	64,630
Panel-track supplement	75%	193,890	48,473
180-day supplement	15%	38,778	9,695
Real-time supplement	7%	18,096	4,524
510(k) premarket notification submission	2%	5,170	2,585
30-day notice	1.6%	4,136	2,068
513(g) (21 U.S.C. 360c(g)) request for classification information.	1.35%	3,490	1,745
Annual Fee Type:			
Annual fee for periodic reporting on a class III device.	3.5%	9,048	2,262
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	3,313	3,313

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 2013, your status as a small business will expire at the close of business on September 30, 2013. You must re-qualify for FY 2014 in order to pay small business fees during FY 2014.

If you are a domestic (U.S.) business, and wish to qualify as a small business for FY 2014, you must submit the following to FDA:

1. A completed FY 2014 MDUFA Small Business Qualification Certification (Form FDA 3602). This form is provided in FDA's guidance document, ''FY 2014 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 2013, except:

If you submit your FY 2014 MDUFA Small Business Qualification before April 15, 2014, and you have not yet filed your return for 2013, you may use tax year 2012.

If you submit your FY 2014 MDUFA Small Business Qualification on or after April 15, 2014, and have not yet filed your 2013 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 2014, you must submit the following:

1. A completed FY 2014 MDUFA Foreign Small Business Qualification Certification (Form FDA 3602A). This form is provided in FDA's guidance document, ''FY 2014 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 (2013 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, 2013, through September 30, 2014, you must pay the fee in effect for FY 2014. 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 2013 or FY 2014 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. 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

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, 2013. One choice is for applications and fees that will be received on or before September 30, 2013, which are subject to FY 2013 fee rates. A second choice is for applications and fees received on or after October 1, 2013, which are subject to FY 2014 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 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 314–418–4013 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 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.

2. 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.

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, 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, Bldg. 66, 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 MDUFA 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 is 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 on the check.
- 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 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 314–418–4013 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, 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://fdasfinapp8.fda.gov/OA_HTML/fdaCAcdLogin.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 2014 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. Step One—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 2014 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 are 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.

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:

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 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. 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 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, 1350 Piccard Dr., Rockville, MD 20850.

C. Step Three—Complete the Information Online To Update Your Establishment's Annual Registration for FY 2014, or To Register a New Establishment for FY 2014

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 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 2013. 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 *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 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 29, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–18623 Filed 8–1–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

Pulmonary-Allergy Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Pulmonary-Allergy Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on September 10, 2013, from 8 a.m. to 4:30 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993–0002. 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: Stephanie Begansky, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, email: PADAC@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 10, 2013, the committee will discuss the new molecular entity new drug application (NDA) 203975, for umeclidinium and vilanterol powder for inhalation (proposed trade name Anoro Ellipta), sponsored by Glaxo Group (d/b/a/GSK) for the long-term, once-daily, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease, including chronic bronchitis and emphysema.

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: 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 August 26, 2013. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 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 August 16, 2013. 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 August 19, 2013.

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 Stephanie Begansky at least 7 days in advance of the meeting.