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.*

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: July 29, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–18956 Filed 7–31–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0007]

Medical Device User Fee Rates for Fiscal Year 2016

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) 2016. 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 2016, which apply from October 1, 2015, through September 30, 2016. To avoid delay in the review of your application, you should pay the application 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 2016, you should not submit a FY 2016 Small Business Qualification and Certification request. This document provides information on how the fees for FY 2016 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 2016 is $263,180. From this starting point, this document establishes FY 2016 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 2016 is $3,872. 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 2016

The total revenue amount for FY 2016 is $129,339,949, as set forth in the statute prior to the inflation adjustment. (See 21 U.S.C. 379j(b)(3)(D)). MDUFA III (Pub. L. 112–144) directs FDA to use the yearly total revenue amount as a starting point to set the standard fee rates for each fee type. The fee calculations for FY 2016 are described in this document.

Inflation Adjustment

MDUFA III specifies that the $129,339,949 is to be adjusted for inflation increases for FY 2016 using two separate adjustments—one for payroll costs and one for non-pay costs (see 21 U.S.C. 379j(c)(2)). The base inflation adjustment for FY 2016 is the sum of one plus these two separate adjustments, and is compounded as specified (see 21 U.S.C. 379j(c)(2)(C)(1) and 379j(c)(2)(B)(ii)).

The component of the inflation adjustment for payroll costs is 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)).

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 2016. The 3-year average is 2.2328 percent (rounded).

TABLE 1—FDA PC&BS EACH YEAR AND PERCENT CHANGE

Fiscal year	2012	2013	2014	3-Year average
Total PC&B	$1,824,703,000	$1,927,703,000	$2,054,937,000	
Total FTE	13,382	13,974	14,555	

TABLE 1—FDA PC&BS EACH YEAR AND PERCENT CHANGE—Continued

Fiscal year	2012	2013	2014	3-Year average
PC&B per FTE	$136,355	$137,949	$141,184	
Percent change from previous year	3.1843%	1.1690%	2.3451%	2.2328%

The payroll adjustment is 2.2328 percent multiplied by 60 percent, or 1.3397 percent.

The statute specifies that the component of the inflation adjustment for non-payroll costs for FY 2016 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. These data are 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	2012	2013	2014	3-Year average
Annual CPI	150.212	152.500	154.847	
Annual Percent Change	2.2024%	1.5232%	1.5390%	
3-Yr Avg. Percent Change in CPI				1.7549%

The non-pay adjustment is 1.7549 percent multiplied by 40 percent, or 0.7019 percent.

Next, the payroll adjustment (1.3397 percent or 0.013397) is added to the non-pay adjustment (0.7019 percent or 0.007019), for a total of 2.0416 percent (or 0.020416). To complete the inflation adjustment, 1 (100 percent or 1.0) is added for a total base inflation adjustment of 1.020416 for FY 2016.

MDUFA III provides for this inflation adjustment to be compounded for FY 2015 and each subsequent fiscal year (see 21 U.S.C. 379j(c)(2)(B)(ii)). The base inflation adjustment for FY 2016 (1.020416) is compounded by multiplying it by the compounded applicable inflation adjustment for FY 2015 (1.04316), as published in the **Federal Register** of July 30, 2014 (79 FR 44178 to 44184), to reach the applicable inflation adjustment of 1.064457 (rounded) (1.020416 times 1.04316) for FY 2016. We then multiply the total revenue amount for FY 2016 ($129,339,949) by 1.064457, yielding an inflation adjusted total revenue amount of $137,677,000 (rounded to the nearest thousand dollars).

III. Fees for FY 2016

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)). 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 2016. 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 2012 actual	FY 2013 actual	FY 2014 actual	3-Year average
Full Fee Applications	25	23	25	24
Small Business	6	9	5	7
Panel-Track Supplement	12	19	12	14
Small Business	0	0	3	1
180-Day Supplements	145	128	122	132
Small Business	21	21	24	22
Real-Time Supplements	196	182	192	190
Small Business	22	23	19	21
510(k)s	2,865	3,149	3,034	3,016
Small Business	1,086	1,202	1,037	1,108
30-Day Notice	801	956	934	897
Small Business	60	69	91	73
513(g) Request for Classification Information	46	65	69	60
Small Business	30	38	31	33
Annual Fee for Periodic Reporting [1]	478	614	514	535
Small Business [1]	39	54	56	50
Establishment Registration [2]		23,477	24,026	23,752

[1] Includes collection of quarter 4 billing for FY 2014 during FY 2015.

[2] Establishment Registration total comes from the registration system and will vary from the financial report.

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 2016 base fees set in statute and the

estimated revenue after the inflation adjustment to the FY 2016 base fees. Using the fees set in statute and the 3-year averages of fee paying submissions, the collections would total $138,620,884, which is $943,884 higher than the statutory revenue limit. Accordingly the PMA and establishment fee need to be decreased so that collections come as close to the statutory revenue limit of $137,677,000 as possible without exceeding the limit. This is done by calculating the percentage difference between the statutory revenue limit and the estimated resulting 2016 revenue collections, and then lowering the fees proportionally by that percentage (rounded to the nearest dollar). After recalculating the fees, a further $1 negative adjustment is made to the establishment fee in order for the estimated revenue to not exceed the statutory limit. The fees in the second column from the right are those we are establishing in FY 2016, which are the standard fees.

TABLE 4—FEES NEEDED TO ACHIEVE NEW FY 2016 REVENUE TARGET

Application type	FY 2016 Statutory fees (base fees)	Estimated resulting 2016 revenue	Adjusted FY 2016 fees to meet revenue target (standard fees)	FY 2016 revenue from adjusted fees
Full Fee Applications	$263,180	$6,316,320	$261,388	$6,273,312
Small Business	65,795	460,565	65,347	457,429
Panel-Track Supplement	197,385	2,763,390	196,041	2,744,574
Small Business	49,346	49,346	49,010	49,010
180-Day Supplements	39,477	5,210,964	39,208	5,175,456
Small Business	9,869	217,118	9,802	215,644
Real-Time Supplements	18,423	3,500,370	18,297	3,476,340
Small Business	4,606	96,726	4,574	96,054
510(k)s	5,264	15,876,224	5,228	15,764,648
Small Business	2,632	2,916,256	2,614	2,896,312
30-Day Notice	$4,211	$3,777,267	$4,182	$3,751,254
Small Business	2,106	153,738	2,091	152,643
513(g) Request for Classification Information	3,553	213,180	3,529	211,740
Small Business	1,777	58,641	1,765	58,245
Annual Fee for Periodic Reporting	9,211	4,927,885	9,149	4,894,715
Small Business	2,303	115,150	2,287	114,350
Establishment Registration	3,872	91,967,744	3,845	91,326,440
Total		138,620,884		137,661,256

The standard fee (adjusted base amount) for a premarket application, including a BLA, and for a premarket report and a BLA efficacy supplement, is $261,388 for FY 2016. 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) (21 U.S.C. 360c(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 $3,845 for FY 2016. There is no small business rate for the annual establishment registration fee; all establishments pay the same fee.

Table 5 summarizes the FY 2016 rates for all medical device fees.

TABLE 5—MEDICAL DEVICE FEES FOR FY 2016

Application fee type	Standard fee (as a percent of the standard fee for a premarket application)	FY 2016 Standard fee	FY 2016 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.	$261,388	$65,347
Premarket report (submitted under section 515(c)(2) of the FD&C Act).	100	261,388	65,347
Efficacy supplement (to an approved BLA under section 351 of the PHS Act).	100	261,388	65,347
Panel-track supplement	75	196,041	49,010
180-day supplement	15	39,208	9,802
Real-time supplement	7	18,297	4,574
510(k) premarket notification submission	2	5,228	2,614

TABLE 5—MEDICAL DEVICE FEES FOR FY 2016—Continued

Application fee type	Standard fee (as a percent of the standard fee for a premarket application)	FY 2016 Standard fee	FY 2016 Small business fee
30-day notice	1.60	4,182	2,091
513(g) request for classification information	1.35	3,529	1,765
Annual Fee Type:			
Annual fee for periodic reporting on a class III device	3.50	9,149	2,287
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.	3,845	3,845

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 2015, your status as a small business will expire at the close of business on September 30, 2015. You must requalify for FY 2016 in order to pay small business fees during FY 2016.

A. Domestic (U.S.) Small Business

If you are a domestic (U.S.) business, and wish to qualify as a small business for FY 2016, you must submit the following to FDA:

1. A completed FY 2016 MDUFA Small Business Qualification Certification (Form FDA 3602). This form is provided in FDA's guidance document, ''FY 2016 Medical Device User Fee Small Business Qualification and Certification,'' available on FDA's Web site at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.*

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 2015, except:

If you submit your FY 2016 MDUFA Small Business Qualification before April 15, 2016, and you have not yet filed your return for 2015, you may use tax year 2014.

If you submit your FY 2016 MDUFA Small Business Qualification on or after April 15, 2016, and have not yet filed your 2015 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.

B. Foreign Small Business

If you are a foreign business, and wish to qualify as a small business for FY 2016, you must submit the following:

1. A completed FY 2016 MDUFA Foreign Small Business Qualification Certification (Form FDA 3602A). This form is provided in FDA's guidance document, ''FY 2016 Medical Device User Fee Small Business Qualification and Certification,'' available on FDA's Internet site at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.*

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 (2015 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 between October 1, 2015, and September 30, 2016, you must pay the fee in effect for FY 2016. 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 2015 or FY 2016 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 into the User Fee System at: *https://userfees.fda.gov/OA_HTML/mdufmaCAcdLogin.jsp.* 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, 2015. One choice is for applications and fees that will be received on or before September 30, 2015, which are subject to FY 2015 fee rates. A second choice is for applications and fees received on or after October 1, 2015, which are subject to FY 2016 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

When you are satisfied that the data on the cover sheet are accurate, electronically transmit the data to FDA according to instructions on the screen. 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) also known as eCheck):

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 cannot exceed $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. (If needed, FDA's tax identification number is 53–0196965.)
- 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 about 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. 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., Building 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, Building 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 for ensuring FDA has your current billing information, and you may update your contact information for the PMA by submitting an amendment.

1. The preferred payment method is online using electronic check (Automated Clearing House (ACH) also known as eCheck) or credit card (Discover, VISA, MasterCard, American Express). Secure electronic payments can be submitted using the User Fees Payment Portal at *https://userfees.fda.gov/pay.* After searching for and locating your invoice, click ''Pay Now'' to be redirected to Pay.gov. Note that electronic payment options are based on the balance due. Payment by credit card is available for balances that do not exceed $49,999.99. If the balance exceeds this amount, only the ACH option is available. Payments must be drawn on U.S bank accounts or made with U.S. credit cards.

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. (If needed, FDA's tax identification number is 53–0196965.)

- 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 about courier delivery.)

3. 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. 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

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 address after this document publishes in the **Federal Register**.) Create a DFUF order and you will be issued a PIN when 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 2016 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 2016 store. Complete the DFUF order by entering the number of establishments you are registering that require payment. When you are satisfied that the information in the order is accurate, electronically transmit the 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 or eCheck):

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. Include a copy of your printed order when you mail 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 (in 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 may be delayed.

The originating financial institution may charge a wire transfer fee. 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. (If needed, FDA's tax identification number is 53–0196965.)

C. Complete the Information Online To Update Your Establishment's Annual Registration for FY 2016, or To Register a New Establishment for FY 2016

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 2015. 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. When 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 telephone number are for assistance with establishment registration only; they are not to be used for questions related to 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 28, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–18907 Filed 7–31–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Heritable Disorders in Newborns and Children; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463, codified at 5 U.S.C. App.), notice is hereby given of the following meeting:

Name: Advisory Committee on Heritable Disorders in Newborns and Children

Dates and Times: August 27, 2015, 9 a.m. to 5 p.m.

August 28, 2015, 10 a.m. to 1 p.m.

Place: Webinar and In-Person, National Institutes of Health, 5635 Fishers Lane, Rockville, Maryland 20857

Status: The meeting will be open to the public with attendance limited to space availability. Participants also have the option of viewing the meeting via webinar. Whether attending in-person or via webinar, all participants must register for the meeting. Please register at *https://www.blsmeetings.net/ACHDNCAugust2015.* The registration deadline is Friday, August 14, 2015, 11:59 p.m. Eastern Time.

Purpose: The Advisory Committee on Heritable Disorders in Newborns and Children (Committee), as authorized by Public Health Service Act, Title XI, § 1111 (42 U.S.C. 300b-10), as amended by the Newborn Screening Saves Lives Reauthorization Act of 2014 (Pub. L. 113–240), was established to advise the Secretary of the Department of Health and Human Services about the development of newborn screening activities, technologies, policies, guidelines, and programs for effectively reducing morbidity and mortality in newborns and children having, or at risk for, heritable disorders. In addition, the Committee's recommendations regarding additional conditions/heritable disorders for screening that have been adopted by the Secretary are included in the Recommended Uniform Screening Panel (RUSP) and constitute part of the comprehensive guidelines supported by the Health Resources and Services Administration. Pursuant to section 2713 of the Public Health Service Act, codified at 42 U.S.C. 300gg–13, non-grandfathered health plans and group and individual health insurance issuers are required to cover evidence-informed care and screenings included in the HRSA-supported comprehensive guidelines without charging a co-payment, co-insurance, or deductible for plan years (in the individual market, policy years) beginning on or after the date that is one year from the Secretary's adoption of the condition for screening.

Agenda: The meeting will include: (1) A final evidence review report on the Adrenoleukodystrophy (ALD) condition nomination for inclusion in the RUSP; (2) a presentation by the Newborn Screening Technical Assistance and Evaluation Program (NewSTEPs) on their activities and the NewSTEPs data repository, a centralized and secure database designed for state newborn screening programs to explore data to meet program needs; (3) updates on the implementation of screening for Severe Combined Immunodeficiency, Critical Congenital Heart Disease, and Pompe Disease; and (4) updates from workgroups focused on cost analysis in newborn screening, newborn screening timeliness, and pilot studies for evidence-based reviews of conditions. Following the final evidence review report on ALD, the Committee also is expected to vote on whether or not to recommend to the Secretary the addition of ALD to the RUSP. Agenda items are subject to change as necessary or appropriate. The agenda, webinar information, Committee Roster, Charter, presentations, and other meeting materials will be located on the Advisory Committee's Web site at *http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders.*

Public Comments: Members of the public may present oral comments and/or submit written comments. Comments are part of the official Committee record. The public comment period is tentatively scheduled for both days of the meeting. Advance registration is required to present oral comments and/or submit written comments. Please register at *https://www.blsmeetings.net/ACHDNCAugust2015.* The registration deadline is Friday, August 14, 2015, 11:59 p.m. Eastern Time. Written comments must be received by the deadline in order to be included in the August meeting briefing book. Written comments should identify the individual's name, address, email, telephone number, professional or business affiliation, type of expertise (*i.e.,* parent, researcher, clinician, public health, etc.), and the topic/subject matter of comments. To ensure that all individuals who have registered to make oral comments can be accommodated, the allocated time may be limited. Individuals who are associated with groups or have similar interests may be requested to combine their comments and present them through a single representative. No audiovisual presentations are permitted. For additional information or questions on public comments, please contact Lisa Vasquez, Maternal and Child Health Bureau, Health Resources and Services Administration; email: *lvasquez@hrsa.gov.*

Contact Person: Anyone interested in obtaining other relevant information should contact Debi Sarkar, Maternal and Child Health Bureau, Health Resources and Services Administration, Room 18W68, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857; email: *dsarkar@hrsa.gov.*More information on the Advisory Committee is available at *http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders.*

Jackie Painter,

Director, Division of the Executive Secretariat.

[FR Doc. 2015–18953 Filed 7–31–15; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: HIV Molecular Biology.

Date: August 7, 2015.