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* (*Note:* Only full payments are accepted. No partial payments can be made online.) Once you search for your invoice, select ''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 less than $25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be made using U.S. bank accounts as well as U.S. credit cards.

FDA has partnered with the U.S. Department of the Treasury to utilize *Pay.gov*, a web-based payment application, for online electronic payment. The *Pay.gov* feature is available on the FDA Web site after completing the Generic Drug User Fee Cover Sheet and generating the user fee ID number.

Please include the user fee ID number on your check, bank draft, or postal money order and make payable to the order of the Food and Drug Administration. Your payment can be mailed to: Food and Drug Administration, P.O. Box 979108, St. Louis, MO 63197–9000. If checks are to be sent by a courier that requests a street address, the courier can deliver checks to: U.S. Bank, Attention: Government Lockbox 979108, 1005 Convention Plaza, St. Louis, MO 63101. (*Note:* This U.S. Bank address is for courier delivery only. If you have any questions concerning courier delivery, contact the U.S. Bank at 314–418–4013. This telephone number is only for questions about courier delivery). Please make sure that the FDA post office box number (P.O. Box 979108) is written on the check, bank draft, or postal money order.

If paying by wire transfer, please reference your unique user fee ID number when completing your transfer. Without your unique user fee ID number, the payment may not be applied. If the payment amount is not applied, the invoice amount would be referred to collections. The originating financial institution may charge a wire transfer fee. Please ask your financial institution about the wire transfer fee and include it with your payment to ensure that your fee is fully paid. Use the following account information when sending a payment by wire transfer: U.S. Department of Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, account number: 75060099, routing number: 021030004, SWIFT: FRNYUS33, Beneficiary: FDA, 8455 Colesville Rd., 14th Floor, Silver Spring, MD 20993–0002. If needed, FDA's tax identification number is 53–0196965.

Dated: August 24, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–18377 Filed 8–28–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–0007]

Medical Device User Fee Rates for Fiscal Year 2018

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) 2018. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Medical Device User Fee Amendments of 2017 (MDUFA IV), 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 2018, which apply from October 1, 2017, through September 30, 2018. 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 2018, you should not submit a FY 2018 Small Business Qualification and Certification request. This document provides information on how the fees for FY 2018 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 *https://www.fda.gov/ForIndustry/UserFees/MedicalDeviceUserFee/ucm20081521.htm.*

For questions relating to this notice: Robert Marcarelli, Office of Financial Management, Food and Drug Administration, 8455 Colesville Rd. (COLE–14202F), Silver Spring, MD 20993–0002, 301–796–7223.

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, notices, and requests (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)).

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 2018 through FY 2022; the base fee for a premarket application received by FDA during FY 2018 is $294,000. From this starting point, this document establishes FY 2018 fee rates for certain 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 2018 through FY 2022; the base fee for an establishment registration in FY 2018 is $4,375. There is no reduction in the registration fee for small businesses. Each establishment that is registered (or is required to register) with the Secretary of Health and Human Services 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 2018

The total revenue amount for FY 2018 is $183,280,756, as set forth in the

statute prior to the inflation adjustment (see 21 U.S.C. 379j(b)(3)). MDUFA 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 2018 are described in this document.

Inflation Adjustment

MDUFA specifies that the $183,280,756 is to be adjusted for inflation increases for FY 2018 using two separate adjustments—one for payroll costs and one for non-payroll costs (see 21 U.S.C. 379j(c)(2)). The base inflation adjustment for FY 2018 is the sum of one plus these two separate adjustments, and is compounded as specified in the statute (see 21 U.S.C. 379j(c)(2)(C) and 379j(c)(2)(B)).

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 three of the four 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 2018. The 3-year average is 2.2354 percent (rounded).

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

Fiscal year	2014	2015	2016	3-year average
Total PC&B	$2,054,937,000	$2,232,304,000	$2,414,728,159	.....
Total FTE	14,555	15,484	16,381	.....
PC&B per FTE	$141,184	$144,168	$147,408	.....
Percent change from previous year	2.3451%	2.1136%	2.2474%	2.2354%

The payroll adjustment is 2.2354 percent multiplied by 60 percent, or 1.3412 percent.

The statute specifies that the component of the inflation adjustment for non-payroll costs for FY 2018 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 *https://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 THREE-YEAR AVERAGE PERCENT CHANGE IN BALTIMORE-WASHINGTON AREA CPI

Fiscal year	2014	2015	2016	3-year average
Annual CPI	154.847	155.353	157.180	.....
Annual Percent Change	1.5390%	0.3268%	1.1760%	.....
3-Year Avg. Percent Change in CPI	.....	.....	.....	1.0139%

The non-pay adjustment is 1.0139 percent multiplied by 40 percent, or 0.4056 percent.

Next, the payroll adjustment (1.3412 percent or 0.013412) is added to the non-payroll adjustment (0.4056 percent or 0.004056), for a total of 1.7468 percent (or 0.017468). To complete the inflation adjustment, 1 (100 percent or 1.0) is added for a total base inflation adjustment of 1.017468 for FY 2018.

MDUFA IV provides for this inflation adjustment to be compounded for FY 2018 and each subsequent fiscal year (see 21 U.S.C. 379j(c)(2)(B)(ii)). The base inflation adjustment for FY 2018 (1.017468) is compounded by multiplying it by the compounded applicable inflation factors from FY 2016 and FY 2017 (1.020416 times 1.015774 or 1.036512). To complete the compounded inflation adjustment for FY 2018, the FY 2016 and FY 2017 compounded adjustment (1.036512) is multiplied by the FY 2018 base inflation adjustment (1.017468) to reach the applicable inflation adjustment of 1.054618 (rounded) for FY 2018. We then multiply the total revenue amount for FY 2018 ($183,280,756) by 1.054618, yielding an inflation adjusted total revenue amount of $193,291,000 (rounded to the nearest thousand dollars).

III. Fees for FY 2018

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)).

A. Inflation Adjustment

MDUFA specifies that the base fees of $294,000 (premarket application) and $4,375 (establishment registration) are to be adjusted for inflation for FY 2018 using the same methodology as that for the total revenue inflation adjustment in section II (see 21 U.S.C. 379j(c)(2)(D)(i)). Multiplying these base fees by the compounded inflation adjustment of 1.054618 yields inflation adjusted base fees of $310,058 (premarket application) and $4,614 (establishment registration).

B. Further Adjustments

After the applicable inflation adjustment to fees is done, FDA may increase, if necessary to achieve the inflation adjusted total revenue amount, the base fee amounts on a uniform proportionate basis (see 21 U.S.C. 379j(c)(2)(D)(ii)). If necessary after this adjustment, FDA may further increase the base establishment registration fees to generate the inflation adjusted total revenue amount (see 21 U.S.C. 379j(c)(3)).

C. Calculation of Fee Rates

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 2018. Most of the fee-paying submission

counts are published in the MDUFA Financial Report to Congress each year.

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

Application type	FY 2014 actual	FY 2015 actual	FY 2016 actual	3-year average
Full Fee Applications	25	42	41	36
Small Business	5	7	10	7
Panel-Track Supplement	12	22	18	17
Small Business	3	3	1	2
De Novo Classification Request [1]	.....	.....	.....	40
Small Business [1]	.....	.....	.....	10
180-Day Supplements	122	143	139	135
Small Business	24	15	18	19
Real-Time Supplements	192	204	202	199
Small Business	19	28	29	25
510(k)s	3,034	2,768	2,784	2,862
Small Business	1,037	1,037	1,046	1,040
30-Day Notice	934	920	1,029	961
Small Business	91	71	80	81
513(g) (21 U.S.C. 360c(g)) Request for Classification Information	69	75	69	71
Small Business	31	33	47	37
Annual Fee for Periodic Reporting [2]	668	554	576	599
Small Business [2]	74	73	74	74
Establishment Registration	24,626	25,363	26,222	25,404

[1] Three-year average for De Novo is based on estimate used during MDUFA IV negotiations.
[2] Includes collection of quarter four billing for FY 2016 during FY 2017.

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 the FY 2018 base fees set in statute (column one) and the inflation adjusted base fees (per calculations in section III.A.) (column two). Using the inflation adjusted fees and the 3-year averages of fee paying submissions, the collections would total $192,850,757, which is $440,243 lower than the statutory revenue limit. Accordingly, the next step in the fee setting process is to increase the base fee amounts on a uniform proportionate basis to generate the inflation adjusted total revenue amounts (see 21 U.S.C. 379j(c)(2)(D)(ii) and table 4, column three). Applying these further adjusted fee rates to the 3-year average of fee paying submissions results in the establishment registration fee rate being increased by $10 to determine the new establishment registration fee rate of $4,624 (see 21 U.S.C. 379j(c)(3) and table 4, column three), leaving a total revenue shortfall of $12,278. The fees in the second column from the right are those we are establishing in FY 2018, which are the standard fees.

TABLE 4—FEES NEEDED TO ACHIEVE NEW FY 2018 REVENUE TARGET

Application type	FY 2018 statutory fees (base fees)	FY 2018 inflation adjusted statutory base fees	Adjusted FY 2018 fees to meet revenue target (standard fees)	FY 2018 revenue from adjusted fees
Full Fee Applications	$294,000	$310,058	$310,764	$11,187,504
Small Business	73,500	77,514	77,691	543,837
Panel-Track Supplement	220,500	232,543	233,073	3,962,241
Small Business	55,125	58,136	58,268	116,272
De Novo Classification Request	88,200	93,017	93,229	3,729,160
Small Business	22,050	23,254	23,307	233,070
180-Day Supplements	44,100	46,509	46,615	6,293,025
Small Business	11,025	11,627	11,654	221,426
Real-Time Supplements	20,580	21,704	21,753	4,328,847
Small Business	5,145	5,426	5,438	135,950
510(k)s	9,996	10,542	10,566	30,239,892
Small Business	2,499	2,635	2,642	2,747,680
30-Day Notice	4,704	4,961	4,972	4,778,092
Small Business	2,352	2,480	2,486	201,366
513(g) Request for Classification Information	3,969	4,186	4,195	297,845
Small Business	1,985	2,093	2,098	77,626
Annual Fee for Periodic Reporting	10,290	10,852	10,877	6,515,323
Small Business	2,573	2,713	2,719	201,206
Establishment Registration	4,375	4,614	4,624	117,468,096
Total	.....	.....	.....	193,278,722

The standard fee (adjusted base amount) for a premarket application, including a BLA, and for a premarket report and a BLA efficacy supplement, is $310,764 for FY 2018. 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 de novo classification request, 30 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 an annual fee for periodic reporting concerning a class III device, 3.5 percent of the standard fee;
- For a 510(k) premarket notification, 3.4 percent of the standard fee;
- For a 30-day notice, 1.6 percent of the standard fee; and
- For a 513(g) request for classification information, 1.35 percent of the standard fee.

For all submissions other than 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) and (e)(2)(C)). For 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)).

The annual fee for establishment registration, after adjustment, is set at $4,624 for FY 2018. There is no small business rate for the annual establishment registration fee; all establishments pay the same fee.

Table 5 summarizes the FY 2018 rates for all medical device fees.

TABLE 5—MEDICAL DEVICE FEES FOR FY 2018

Application fee type	Standard fee (as a percent of the standard fee for a premarket application)	FY 2018 standard fee	FY 2018 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 specified in statute.	$310,764	$77,691
Premarket report (submitted under section 515(c)(2) of the FD&C Act)	100	310,764	77,691
Efficacy supplement (to an approved BLA under section 351 of the PHS Act)	100	310,764	77,691
Panel-track supplement	75	233,073	58,268
De novo classification request	30	93,229	23,307
180-day supplement	15	46,615	11,654
Real-time supplement	7	21,753	5,438
510(k) premarket notification submission	3.40	10,566	2,642
30-day notice	1.60	4,972	2,486
513(g) request for classification information	1.35	4,195	2,098
Annual Fee Type			
Annual fee for periodic reporting on a class III device	3.50	10,877	2,719
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 specified in statute.	4,624	4,624

IV. How To Qualify as a Small Business for Purposes of Medical Device Fees

If your business, including your affiliates, 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, including your affiliates, 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 (*i.e.* PMA, PDP, or BLA) or premarket report. 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 at least 60 days before you send your submission to FDA. FDA will review your information and determine whether you qualify as a small business eligible for the reduced fee and/or fee waiver. 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 2017, your status as a small business will expire at the close of business on September 30, 2017. You must re-qualify for FY 2018 in order to pay small business fees during FY 2018.

If you are a domestic (U.S.) business, and wish to qualify as a small business for FY 2018, you must submit the following to FDA:

1. A completed FY 2018 MDUFA Small Business Qualification Certification (Form FDA 3602). This form is provided in FDA's guidance document, ''FY 2018 Medical Device User Fee Small Business Qualification and Certification,'' available on FDA's Web site at *https://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 2017, except:

If you submit your FY 2018 MDUFA Small Business Qualification before April 15, 2018, and you have not yet filed your return for 2017, you may use tax year 2016.

If you submit your FY 2018 MDUFA Small Business Qualification on or after April 15, 2018, and have not yet filed your 2017 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 2018, you must submit the following:

1. A completed FY 2018 MDUFA Foreign Small Business Qualification Certification (Form FDA 3602A). This form is provided in FDA's guidance document, ''FY 2018 Medical Device User Fee Small Business Qualification and Certification,'' available on FDA's Web site at *https://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 (2017 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, 2017, and September 30, 2018, you must pay the fee in effect for FY 2018. 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 2017 or FY 2018 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:* Do not send your user fee check 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, 2017. One choice is for applications and fees that will be received on or before September 30, 2017, which are subject to FY 2017 fee rates. A second choice is for applications and fees received on or after October 1, 2017, which are subject to FY 2018 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 is accurate, electronically transmit that 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. 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). 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. Secure electronic payments can be submitted using the User Fees Payment Portal at *https://userfees.fda.gov/pay. Note:* Only full payments are accepted. No partial payments can be made online. Once you search for your invoice, select ''Pay Now'' to be redirected to *Pay.gov*. Electronic payment options are based on the balance due. Payment by credit card is available for balances that are less than $25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be made using U.S bank accounts as well as 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 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 U.S. Bank address is for courier delivery only. If you have any questions concerning courier delivery contact U.S. Bank at 314–418–4013. This telephone number is only for 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. If the financial institution charges a wire transfer fee it is required that you add that amount to the payment to ensure that the invoice is paid in full.

Use the following account information when sending a wire transfer: 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 Road, 14th Floor, 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 an FDA Document Control Center 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 the address located at *https://www.fda.gov/cdrh submissionaddress.*

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 to the pending PMA or a supplement to the approved PMA.

1. The preferred payment method is online using electronic check (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* (*Note:* Only full payments are accepted. No partial payments can be made online). Once you search for your invoice, select ''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 are less than $25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be made using U.S. bank accounts as well as U.S. credit cards.

2. If paying with a paper check:

The check 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 the 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.)

To send a check by a courier, the courier must deliver the check and printed copy of the cover sheet to: U.S. Bank, Attn: Government Lockbox 979033, 1005 Convention Plaza, St. Louis, MO 63101. (*Note:* This U.S. Bank address is for courier delivery only. If you have any questions concerning courier delivery contact U.S. Bank at 314–418–4013. This telephone number is only for questions about courier delivery).

3. When paying by a wire transfer it is required that the invoice number is included, without the invoice number the payment may not be applied. If the payment amount is not applied the invoice amount would be referred to collections. The originating financial institution may charge a wire transfer fee. If the financial institution charges a wire transfer fee it is required that you add that amount to the payment to ensure that the invoice is paid in full.

Use the following account information when sending a wire transfer: 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., 14th Floor, Silver Spring, MD 20993–0002.

VII. Procedures for Paying Annual Establishment Registration Fees

To pay the annual establishment registration 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 2018 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 2018 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 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 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:* The check must be in U.S. currency and drawn on a U.S. bank, and 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. If you have any questions concerning courier delivery contact U.S. Bank at 314–418–4013. This telephone number is only for questions about courier delivery).

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 registration 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. If the financial institution charges a wire transfer fee it is required that you add that amount to the payment to ensure that the invoice is paid in full. Use the following account information when sending a wire transfer: 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., 14th Floor, 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 2018, or To Register a New Establishment for FY 2018

Go to the Center for Devices and Radiological Health's Web site at *https://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 2017. Manufacturers of licensed biologics should register in the BER system at *https://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 this 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 the BER system should be directed to *https://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: August 24, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–18378 Filed 8–28–17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–4119]

Food Safety Modernization Act Third-Party Certification Program User Fee Rate for Fiscal Year 2018

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the fiscal year (FY) 2018 annual fee rate for recognized accreditation bodies and accredited certification bodies, and the fee rate for accreditation bodies applying to be recognized in the third-party certification program that is authorized by the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the FDA Food Safety Modernization Act (FSMA).

FOR FURTHER INFORMATION CONTACT: Donald Prater, Office of Foods and Veterinary Medicine, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 3234, Silver Spring, MD 20993, 301–348–3007.

DATES: This fee is effective October 1, 2017.

SUPPLEMENTARY INFORMATION:

I. Background

Section 307 of FSMA, Accreditation of Third-Party Auditors, amended the FD&C Act to create a new provision, section 808, under the same name. Section 808 of the FD&C Act (21 U.S.C. 384d) directs FDA to establish a program for accreditation of third-party certification bodies [1] conducting food safety audits and issuing food and facility certifications to eligible foreign entities (including registered foreign food facilities) that meet our applicable requirements. Under this provision, we established a system for FDA to recognize accreditation bodies to accredit certification bodies, except for limited circumstances in which we may directly accredit certification bodies to participate in the third-party certification program.

Section 808(c)(8) of the FD&C Act directs FDA to establish a reimbursement (user fee) program by which we assess fees and require reimbursement for the work FDA performs to establish and administer the third-party certification program under section 808 of the FD&C Act. The user fee program for the third-party certification program was established by a final rule entitled ''Amendments to Accreditation of Third-Party Certification Bodies to Conduct Food Safety Audits and To Issue Certifications to Provide for the User Fee Program'' (81 FR 90186, December 14, 2016).

The FSMA FY 2018 third-party certification program user fee rate announced in this notice is effective on October 1, 2017, and will remain in effect through September 30, 2018.

II. Estimating the Average Cost of a Supported Direct FDA Work Hour for FY 2018

In each year, the costs of salary (or personnel compensation) and benefits for FDA employees account for between 50 and 60 percent of the funds available to, and used by, FDA. Almost all of the remaining funds (operating funds) available to FDA are used to support FDA employees for paying rent, travel, utility, information technology, and other operating costs.

A. Estimating the Full Cost per Direct Work Hour in FY 2018

Full-time Equivalent (FTE) reflects the total number of regular straight-time hours—not including overtime or holiday hours—worked by employees,

[1] For the reasons explained in the third-party certification final rule (80 FR 74570 at 74578–74579, November 27, 2015), and for consistency with the implementing regulations for the third-party certification program in 21 CFR parts 1, 11, and 16, this notice uses the term ''third-party certification body'' rather than the term ''third-party auditor'' used in section 808(a)(3) of the FD&C Act.