Dated: July 21, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0007]

Medical Device User Fee Rates for Fiscal Year 2017

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) 2017. 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 2017, which apply from October 1, 2016, through September 30, 2017. 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 2017, you should not submit a FY 2017 Small Business Qualification and Certification request. This document provides information on how the fees for FY 2017 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/ForIndustry/UserFees/MedicalDeviceUserFee/ucm20081521.htm.*

For questions relating to this notice: Maurille Beheton, Office of Financial Management, Food and Drug Administration, 8455 Colesville Rd. (COLE–14202C), Silver Spring, MD 20993–0002, 301–796–4689.

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 2017 is $268,443. From this starting point, this document establishes FY 2017 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 2017 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 2017

The total revenue amount for FY 2017 is $130,184,348, as set forth in the statute prior to the inflation adjustment and offset of excess collections (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 2017 are described in this document.

A. Inflation Adjustment

MDUFA specifies that the $130,184,348 is to be adjusted for inflation increases for FY 2017 using two separate adjustments—one for payroll costs and one for non-pay cost (see 21 U.S.C. 379j(c)(2)). The base inflation adjustment for FY 2017 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 2017. The 3-year average is 1.8759 percent (rounded).

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

Fiscal Year	2013	2014	2015	3-Year average
Total PC&B	$1,927,703,000	$2,054,937,000	$2,232,304,000	.....
Total FTE	13,974	14,555	15,484	.....
PC&B per FTE	$137,949	$141,184	$144,168	.....
Percent change from previous year	1.1690%	2.3451%	2.1136%	1.8759%

The payroll adjustment is 1.8759 percent multiplied by 60 percent, or 1.1255 percent.

The statute specifies that the component of the inflation adjustment for non-payroll costs for FY 2017 is the average annual percent change that occurred in the Consumer Price Index (CPI) for urban consumers (Washington-Baltimore, DC–MD–VA–WV; not seasonally adjusted; all items; annual index) for the first 3 of the preceding 4 years of available data multiplied by 0.40, or 40 percent (see 21 U.S.C. 379j(c)(2)(C)).

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

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

Fiscal year	2013	2014	2015	3-Year average
Annual CPI	152.500	154.847	155.353	.....
Annual Percent Change	1.5232%	1.5390%	0.3268%	.....
3-Year Avg. Percent Change in CPI	.....	.....	.....	1.1297%

The non-pay adjustment is 1.1297 percent multiplied by 40 percent, or 0.4519 percent.

Next, the payroll adjustment (1.1255 percent or 0.011255) is added to the non-pay adjustment (0.4519 percent or 0.004519), for a total of 1.5774 percent (or 0.015774). To complete the inflation adjustment, 1 (100 percent or 1.0) is added for a total base inflation adjustment of 1.015774 for FY 2017.

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 2017 (1.015774) is compounded by multiplying it by the compounded applicable inflation adjustment for FY 2016 (1.064457), as published in the **Federal Register** of August 3, 2015 (80 FR 46033 to 46039), to reach the applicable inflation adjustment of 1.081248 (rounded) (1.015774 times 1.064457) for FY 2017. We then multiply the total revenue amount for FY 2017 ($130,184,348) by 1.081248, yielding an inflation adjusted total revenue amount of $140,762,000 (rounded to the nearest thousand dollars).

B. Offset for Excess Collections Through FY 2016

Under the offset provision of the FD&C Act (see section 738(i)(4) (21 U.S.C. 379j(i)(4))), if the cumulative amount of fees collected during FY 2013 through FY 2015, added to the amount estimated to be collected for FY 2016, exceeds the cumulative amount appropriated for these four FYs, the excess shall be credited to the appropriation account of the Food and Drug Administration and shall be subtracted from the amount of fees that would otherwise be authorized to be collected for FY 2017. Table 3 presents the amount of MDUFA fees collected during FY 2013 through FY 2015 (actuals), and the amount estimated to be collected for FY 2016, and compares those amounts with the fees specified to be appropriated in these four FYs.

TABLE 3—STATEMENT OF FEES APPROPRIATED, FEES COLLECTED, AND DIFFERENCES AS OF JUNE 30, 2016

Fiscal year	Fee appropriated	Fees collected	Difference
2013 Actual	$97,722,000	$103,991,182	$6,269,182
2014 Actual	114,833,000	124,297,628	9,464,628
2015 Actual	128,282,000	139,712,238	11,430,238
2016 Estimate	134,667,000	134,667,000	0
Total	478,504,000	505,668,048	27,164,048
Unearned Revenue Included in Above Amount	.....	.....	12,485,897
Excess Collections Less Unearned Revenue (Offset Amount)	.....	.....	14,678,151

The total amount FDA expects to have collected in excess of appropriations by the end of FY 2016 is $27,164,048. However, of that amount, a total of $12,485,897 represents unearned revenue—primarily fees paid for applications that have not yet been received. The unearned revenue is held in reserve either to refund, if no application is submitted, or to apply toward the future FY when the application is received. The net of these two figures, $14,678,151, is the amount that FDA has received in excess of appropriations that is available for obligation, and the amount by which fee revenue will be offset in FY 2017.

For FY 2017, the statute authorizes $140,762,000 in user fees. In order to determine the revised collection amount, we deduct the net excess collection amount of $14,678,151 from $140,762,000, and the revised revenue target for FY 2017 becomes $126,083,000 (rounded down to the nearest thousand dollars).

III. Fees for FY 2017

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 4 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 2017. Most of the fee paying submission counts are published in the MDUFA Financial Report to Congress each year.

TABLE 4—3-YEAR AVERAGE OF FEE PAYING SUBMISSIONS

Application type	FY 2013 actual	FY 2014 actual	FY 2015 actual	3-Year average
Full Fee Applications	23	25	42	30
Small Business	9	5	7	7
Panel-Track Supplement	19	12	22	18
Small Business	0	3	3	2
180-Day Supplements	128	122	143	131
Small Business	21	24	15	20
Real-Time Supplements	182	192	204	193
Small Business	23	19	28	23
510(k)s	3,149	3,034	2,768	2,984
Small Business	1,202	1,037	1,037	1,092
30-Day Notice	956	934	920	937
Small Business	69	91	71	77
513(g) (21 U.S.C. 360c(g)) Request for Classification Information	65	69	75	70
Small Business	38	31	33	34
Annual Fee for Periodic Reporting [1]	614	514	544	557
Small Business [1]	54	56	68	59
Establishment Registration [2]	23,477	24,026	25,363	24,289

[1] Includes collection of quarter 4 billing for FY 2015 during FY 2016.
[2] Establishment Registration total comes from the registration system and will vary from the financial report.

The information in table 4 is necessary to estimate the amount of revenue that will be collected based on the fee amounts. Table 5 displays both the estimated revenue using the FY 2017 base fees set in statute and the estimated revenue after the inflation adjustment and offset of excess collections to the FY 2017 base fees. Using the fees set in statute and the 3 year averages of fee paying submissions, the collections would total $144,335,998, which is $18,252,998 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 $126,083,000 as possible without exceeding the limit. This is done by calculating the percentage difference between the statutory revenue limit and the estimated resulting 2017 revenue collections, and then lowering the fees proportionally by that percentage (rounded to the nearest dollar). The fees in the second column from the right are those we are establishing in FY 2017, which are the standard fees.

TABLE 5—FEES NEEDED TO ACHIEVE NEW FY 2017 REVENUE TARGET

Application type	FY 2017 Statutory fees (base fees)	Estimated resulting 2017 revenue	Adjusted FY 2017 fees to meet revenue target (standard fees)	FY 2017 Revenue from adjusted fees
Full Fee Applications	$268,443	$8,053,290	$234,495	$7,034,850
Small Business	67,111	469,777	58,624	410,368
Panel-Track Supplement	201,332	3,623,976	175,871	3,165,678
Small Business	50,333	100,666	43,968	87,936
180-Day Supplements	40,266	5,274,846	35,174	4,607,794
Small Business	10,067	201,340	8,794	175,880
Real-Time Supplements	18,791	3,626,663	16,415	3,168,095
Small Business	4,698	108,054	4,104	94,392
510(k)s	5,369	16,021,096	4,690	13,994,960
Small Business	2,685	2,932,020	2,345	2,560,740
30-Day Notice	4,295	4,024,415	3,752	3,515,624
Small Business	2,148	165,396	1,876	144,452
513(g) Request for Classification Information	3,624	253,680	3,166	221,620
Small Business	1,812	61,608	1,583	53,822
Annual Fee for Periodic Reporting	9,396	5,233,572	8,207	4,571,299
Small Business	2,349	138,591	2,052	121,068
Establishment Registration	3,872	94,047,008	3,382	82,145,398
Total	.....	144,335,998	.....	126,073,976

The standard fee (adjusted base amount) for a premarket application, including a BLA, and for a premarket report and a BLA efficacy supplement, is $234,495 for FY 2017. The fees set by reference to the standard fee for a premarket application are:

- For a panel-track supplement, 75 percent of the standard fee;
- For a 180-day supplement, 15 percent of the standard fee;
- For a real-time supplement, 7 percent of the standard fee;
- For a 510(k) premarket notification, 2 percent of the standard fee;
- For a 30-day notice, 1.6 percent of the standard fee;

- For a 513(g) request for classification information, 1.35 percent of the standard fee; and
- For an annual fee for periodic reporting concerning a class III device, 3.5 percent of the standard fee.

For all submissions other than a 510(k) premarket notification, a 30-day notice, and a 513(g) request for classification information, the small business fee is 25 percent of the standard (full) fee for the submission (see 21 U.S.C. 379j(d)(2)(C)). For a 510(k) premarket notification submission, a 30-day notice, and a 513(g) request for classification information, the small business fee is 50 percent of the standard (full) fee for the submission (see 21 U.S.C. 379j(d)(2)(C) and (e)(2)(C)).

The annual fee for establishment registration, after adjustment, is set at $3,382 for FY 2017. There is no small business rate for the annual establishment registration fee; all establishments pay the same fee.

Table 6 summarizes the FY 2017 rates for all medical device fees.

TABLE 6—MEDICAL DEVICE FEES FOR FY 2017

Application fee type	Standard fee (as a percent of the standard fee for a premarket application)	FY 2017 Standard fee	FY 2017 Small business fee
Premarket application (a PMA submitted under section 515(c)(1) of the FD&C Act (21 U.S.C. 360e(c)(1)), a PDP submitted under section 515(f) of the FD&C Act, or a BLA submitted under section 351 of the Public Health Service Act (the PHS Act) (42 U.S.C. 262)).	Base fee specified in statute at $268,443, but multiplied by 87.3538 percent.	$234,495	$58,624
Premarket report (submitted under section 515(c)(2) of the FD&C Act) ..	100	234,495	58,624
Efficacy supplement (to an approved BLA under section 351 of the PHS Act).	100	234,495	58,624
Panel-track supplement	75	175,871	43,968
180-day supplement	15	35,174	8,794
Real-time supplement	7	16,415	4,104
510(k) premarket notification submission	2	4,690	2,345
30-day notice	1.60	3,752	1,876
513(g) request for classification information	1.35	3,166	1,583
Annual Fee Type:			
Annual fee for periodic reporting on a class III device	3.50	8,207	2,052
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 at $3,872, but multiplied by 87.3538 percent.	3,382	3,382

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. 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 2016, your status as a small business will expire at the close of business on September 30, 2016. You must re-qualify for FY 2017 in order to pay small business fees during FY 2017.

If you are a domestic (U.S.) business, and wish to qualify as a small business for FY 2017, you must submit the following to FDA:

1. A completed FY 2017 MDUFA Small Business Qualification Certification (Form FDA 3602). This form is provided in FDA's guidance document, ''FY 2017 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 2016, except:

If you submit your FY 2017 MDUFA Small Business Qualification before April 15, 2017, and you have not yet filed your return for 2016, you may use tax year 2015.

If you submit your FY 2017 MDUFA Small Business Qualification on or after April 15, 2017, and have not yet filed your 2016 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 2017, you must submit the following:

1. A completed FY 2017 MDUFA Foreign Small Business Qualification Certification (Form FDA 3602A). This form is provided in FDA's guidance document, ''FY 2017 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 (2016 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, 2016, and September 30, 2017, you must pay the fee in effect for FY 2017. 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 2016 or FY 2017 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, 2016. One choice is for applications and fees that will be received on or before September 30, 2016, which are subject to FY 2016 fee rates. A second choice is for applications and fees received on or after October 1, 2016, which are subject to FY 2017 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.* Once you search for 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 less than $25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be drawn on 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 the 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. 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: 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 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 Control Center, 10903 New Hampshire Ave., Building 66, Rm. 0609, Silver Spring, MD 20993–0002.

2. Biologics license applications and other medical device submissions reviewed by the Center for Biologics Evaluation and Research 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 to the PMA.

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.* Once you search for 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 less than $25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be drawn on 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 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 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).

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: 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 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 2017 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 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:

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. 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 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: 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 2017, or To Register a New Establishment for FY 2017

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 2016. 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 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 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 25, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–17903 Filed 7–28–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1039]

General Wellness: Policy for Low Risk Devices; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''General Wellness: Policy for Low Risk Devices.'' The guidance is intended to provide clarity to industry and FDA staff on Center for Devices and Radiological Health's (CDRH) compliance policy for low-risk products that promote a healthy lifestyle (general wellness products). By clarifying the policy on general wellness products, we hope to improve the predictability, consistency, and transparency on CDRH's regulation of these products. For purposes of the guidance, CDRH defines ''general wellness products'' as products which meet the following factors: They are intended for only general wellness use as defined in the guidance and present a low risk to the safety of users and other persons.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2014–N–1039 for ''General Wellness: Policy for Low Risk Devices.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper