Number: (202) 395–5806 *OR,* Email: *OIRA_submission@omb.eop.gov.*

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at website address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

1. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

2. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Reinstatement without change of a currently approved collection; *Title of Information Collection:* Hospice Survey and Deficiencies Report Form and Supporting Regulations; *Use:* We use the information collected as the basis for certification decisions for hospices that wish to obtain or retain participation in the Medicare and Medicaid programs. The information is used by CMS regional offices, which have the delegated authority to certify Medicare facilities for participation, and by State Medicaid agencies, which have comparable authority under Medicaid. The information on the Hospice Survey and Deficiencies Report Form is coded for entry into the OSCAR system. The data is analyzed by the CMS regional offices and by the CMS central office components for program evaluation and monitoring purposes. The information is also available to the public upon request. *Form Number:* CMS–643 (OMB control number: 0938–0379); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 4,801; *Total Annual Responses:* 1,600; *Total Annual Hours:* 1,600. (For policy questions regarding this collection contact Thomas Pryor at 410–786–1132.)

2. *Type of Information Collection Request:* Reinstatement with change of a previously approved collection; *Title of Information Collection:* Recognition of pass-through payment for additional (new) categories of devices under the Outpatient Prospective Payment System and Supporting Regulations; *Use:* Section 402 of the Benefits Improvement and Protection Act of 2000 (BIPA), enacted on December 21, 2000, made changes in the provision for transitional pass-through payment for devices under the hospital OPPS. Section 402 of BIPA amended section 1833(t)(6) of the Act to require that we abandon the item-specific approach in determining the eligibility of medical devices for transitional pass-through payments. This provision mandated that we adopt a category approach for making such payments. In accordance with this requirement, we would pay for any device that falls in categories we establish for this purpose. This provision required us to establish the initial set of categories, to include devices previously determined eligible for transitional pass-through payments, effective April 1, 2001.

The law made clear that application and approval processes are no longer required as the basis for determining an individual medical device's eligibility for transitional pass-through payments. However, we must assemble certain crucial information to be able to determine the appropriateness of establishing an additional (new) category. The information that we seek to collect is essential to determine whether additional categories of medical devices are appropriate for transitional pass-through payments. The intent of these provisions is to ensure that timely beneficiary access to new technologies is not jeopardized by inadequate payment levels.

Interested parties such as hospitals, device manufacturers, pharmaceutical companies, and physicians apply for transitional pass-through payment for certain items used with services covered in the outpatient PPS. After we receive all requested information, we evaluate the information to determine if the creation of an additional category of medical devices for transitional pass-through payments is justified. We may request additional information related to the proposed new device category, as needed. We advise the applicant of our decision, and update the outpatient PPS during its next scheduled quarterly payment update cycle to reflect any newly approved device categories. *Form Number:* CMS–10052 (OMB control number 0938–0857); *Frequency:* Occasionally; *Affected Public:* State, Local, and Tribal Governments; *Number of Respondents:* 10; *Total Annual Responses:* 10; *Total Annual Hours:* 160. (For policy questions regarding this collection contact AuSha Washington at 410–786–3736.)

Dated: July 25, 2019.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2019–16224 Filed 7–30–19; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–3505]

Medical Device User Fee Rates for Fiscal Year 2020

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) 2020. The Federal Food, Drug, and Cosmetic Act (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 2020, which apply from October 1, 2019, through September 30, 2020. 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 2020, you should not submit a Small Business Certification Request. This document provides information on how the fees for FY 2020 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: https://www.fda.gov/industry/fda-user-fee-programs/medical-device-user-fee-amendments-mdufa.

For questions relating to the MDUFA Small Business Program, please visit the Center for Devices and Radiological Health's website: https://www.fda.gov/medical-devices/premarket-submissions/reduced-medical-device-user-fees-small-business-determination-sbd-program.

For questions relating to this notice: David Haas, Office of Financial Management, Food and Drug Administration, 4041 Powder Mill Rd., Rm. 62041A, Beltsville, MD 20705, 240–402–9845.

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 2020 is $310,000. From this starting point, this document establishes FY 2020 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 2020 is $4,760. 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 2020

The total revenue amount for FY 2020 is $200,132,014, 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 2020 are described in this document.

Inflation Adjustment

MDUFA specifies that the $200,132,014 is to be adjusted for inflation increases for FY 2020 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 2020 is the sum of one plus the 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 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 2020. The 3-year average is 3.1175 percent (rounded).

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

Fiscal year	2016	2017	2018	3-Year average
Total PC&B	$2,414,728,159	$2,581,551,000	$2,690,678,000	.....
Total FTE	16,381	17,022	17,023	.....
PC&B per FTE	$147,408	$151,660	$158,061	.....
Percent change from previous year	2.2474	2.8845	4.2206	3.1175

The payroll adjustment is 3.1175 percent multiplied by 60 percent, or 1.8705 percent. The statute specifies that the component of the inflation adjustment for non-payroll costs for FY 2020 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)). As a result of a geographical revision made by the Bureau of Labor and Statistics in January 2018,[1] the ''Washington-Baltimore, DC-MD-VA-WV'' index was discontinued and replaced with two separate indices (*i.e.,* ''Washington-Arlington-Alexandria, DC-VA-MD-WV'' and ''Baltimore-Columbia-Towson, MD''). In order to continue applying a CPI that best reflects the geographic region in which FDA is headquartered and that provides the most current data available, the Washington-Arlington-Alexandria index will be used in calculating the relevant adjustment factors for FY 2020 and subsequent years.

Table 2 provides the summary data and the 3-year average percent change in the specified CPI for the Washington-Arlington-Alexandria area. These data are published by the Bureau of Labor Statistics and can be found on their website under series Id CUURS35ASA0 at: *https://data.bls.gov/pdq/SurveyOutputServlet?*

[1] The Bureau of Labor Statistics' Announcement of the geographical revision can be viewed at *https://www.bls.gov/cpi/additional-resources/geographic-revision-2018.htm.*

data_tool=dropmap&series_id=CUURS35ASA0,CUUSS35ASA0.

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

Fiscal year	2016	2017	2018	3-Year average
Annual CPI	253.422	256.221	261.445	.....
Annual Percent Change	1.1003	1.1045	2.0389	.....
3-Year Average Percent Change in CPI	.....	.....	.....	1.4146

The non-pay adjustment is 1.4146 percent multiplied by 40 percent, or 0.5658 percent. Next, the payroll adjustment (1.8705 percent or 0.018705) is added to the non-payroll adjustment (0.5658 percent or .005658), for a total of 2.4363 percent (or 0.024363). To complete the inflation adjustment, 1 (100 percent or 1.0) is added for a total base inflation adjustment of 1.024363 for FY 2020.

MDUFA IV provides for this inflation adjustment to be compounded for FY 2020 and each subsequent fiscal year (see 21 U.S.C. 379j(c)(2)(B)(ii)). To complete the compounded inflation adjustment for FY 2020, the FY 2019 compounded adjustment (1.073823) is multiplied by the FY 2020 base inflation adjustment (1.024363) to reach the applicable inflation adjustment of 1.099985 (rounded) for FY 2020. We then multiply the total revenue amount for FY 2020 ($200,132,014) by 1.099985, yielding an inflation adjusted total revenue amount of $220,142,000 (rounded to the nearest thousand dollars).

III. Fees for FY 2020

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 $310,000 (premarket application) and $4,760 (establishment registration) are to be adjusted for FY 2020 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 the base fees by the compounded inflation adjustment of 1.099985 yields inflation adjusted base fees of $340,995 (premarket application) and $5,236 (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 2020.

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

Application type	FY 2016 actual	FY 2017 actual	FY 2018 actual	3-Year average
Full Fee Applications	37	37	38	37
Small Business	10	6	7	8
Panel-Track Supplement	17	22	23	21
Small Business	1	2	5	3
De Novo Classification Request [1]	.....	.....	27	27
Small Business [1]	.....	.....	29	29
180-Day Supplements	115	167	133	138
Small Business	16	33	27	25
Real-Time Supplements	179	187	169	178
Small Business	27	19	34	27
510(k)s	2,583	2,969	2,122	2,558
Small Business	1,002	1,072	1,385	1,153
30-Day Notice	926	998	1,058	994
Small Business	76	78	98	84
513(g) (21 U.S.C. 360c(g)) Request for Classification Information	68	93	84	82
Small Business	46	41	33	40
Annual Fee for Periodic Reporting [2]	586	618	624	609
Small Business [2]	75	57	74	69
Establishment Registration	26,043	27,115	27,544	26,901

[1] Three-year average for De Novo is based on estimate for FY 2020.
[2] Includes collection of quarter 4 billing for FY 2018 during FY 2019.

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 2020 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, collections are projected to total $221,603,174, which is $1,461,174 higher than the inflation adjusted total revenue amount (in section II). The fees in column two are

those we are establishing in FY 2020, which are the standard fees.

TABLE 4—FEES NEEDED TO ACHIEVE NEW FY 2020 REVENUE TARGET

Application type	FY 2020 statutory fees (base fees)	FY 2020 inflation adjusted statutory base fees (standard fees)	3-Year average of fee-paying submissions	FY 2020 revenue from adjusted fees
Full Fee Applications	$310,000	$340,995	37	$12,616,815
Small Business	77,500	85,249	8	681,992
Panel-Track Supplement	232,500	255,747	21	5,370,687
Small Business	58,125	63,937	3	191,811
De Novo Classification Request	93,000	102,299	27	2,762,073
Small Business	23,250	25,575	29	741,675
180-Day Supplements	46,500	51,149	138	7,058,562
Small Business	11,625	12,787	25	319,675
Real-Time Supplements	21,700	23,870	178	4,248,860
Small Business	5,425	5,968	27	161,136
510(k)s	10,540	11,594	2,558	29,657,452
Small Business	2,635	2,899	1,153	3,342,547
30-Day Notice	4,960	5,456	994	5,423,264
Small Business	2,480	2,728	84	229,152
513(g) Request for Classification Information	4,185	4,603	82	377,446
Small Business	2,093	2,302	40	92,080
Annual Fee for Periodic Reporting	10,850	11,935	609	7,268,415
Small Business	2,713	2,984	69	205,896
Establishment Registration	4,760	5,236	26,901	140,853,636
Total	.....	.....	.....	221,603,174

The standard fee (adjusted base amount) for a premarket application, including a BLA, and for a premarket report and a BLA efficacy supplement, is $340,995 for FY 2020. 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 $5,236 for FY 2020. There is no small business rate for the annual establishment registration fee; all establishments pay the same fee.

Table 5 summarizes the FY 2020 rates for all medical device fees.

TABLE 5—MEDICAL DEVICE FEES FOR FY 2020

Application fee type	Standard fee (as a percent of the standard fee for a premarket application)	FY 2020 standard fee	FY 2020 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.	$340,995	$85,249
Premarket report (submitted under section 515(c)(2) of the FD&C Act)	100	340,995	85,249
Efficacy supplement (to an approved BLA under section 351 of the PHS Act)	100	340,995	85,249
Panel-track supplement	75	255,747	63,937
De novo classification request	30	102,299	25,575
180-day supplement	15	51,149	12,787
Real-time supplement	7	23,870	5,968
510(k) premarket notification submission	3.40	11,594	2,899
30-day notice	1.60	5,456	2,728
513(g) request for classification information	1.35	4,603	2,302
Annual Fee Type			
Annual fee for periodic reporting on a class III device	3.50	11,935	2,984

TABLE 5—MEDICAL DEVICE FEES FOR FY 2020—Continued

Application fee type	Standard fee (as a percent of the standard fee for a premarket application)	FY 2020 standard fee	FY 2020 small business fee
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(14)).	Base fee specified in statute.	5,236	5,236

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 2019, your status as a small business will expire at the close of business on September 30, 2019. You must re-qualify for FY 2020 in order to pay small business fees during FY 2020.

If you are a domestic (U.S.) business and wish to qualify as a small business for FY 2020, you must submit the following to FDA:

1. A completed MDUFA Small Business Certification Request For a Business Headquartered in the U.S. (Form FDA 3602). Form FDA 3602 is provided in the FDA Forms database: *https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM573420.pdf.*

2. A signed certified copy of your Federal (U.S.) Income Tax Return for the most recent tax year. The most recent tax year will be 2019, except:

If you submit your MDUFA Small Business Certification Request for FY 2020 before April 15, 2020, and you have not yet filed your return for 2019, you may use tax year 2018.

If you submit your MDUFA Small Business Certification Request for FY 2020 on or after April 15, 2020, and have not yet filed your 2019 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 business must also submit a statement signed by the head of the business's firm or by its chief financial officer that the business has submitted certifications for all of its affiliates, identifying the name of each affiliate, or that the business has no affiliates.

If you are a foreign business, and wish to qualify as a small business for FY 2020, you must submit the following:

1. A completed MDUFA Foreign Small Business Certification Request For a Business Headquartered Outside the United States (Form FDA 3602A). Form FDA 3602A is provided in the FDA Forms database: *https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM573423.pdf.*

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 (2019 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 business must also submit a statement signed by the head of the business'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 business 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, 2019, and September 30, 2020, you must pay the fee in effect for FY 2020. 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 2019 or FY 2020 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, 2019. One choice is for applications and fees that will be received on or before September 30, 2019, which are subject to FY 2019 fee rates. A second choice is for applications and fees received on or after October 1, 2019, which are subject to FY 2020 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 the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Acct. No. 75060099, Routing No. 021030004, SWIFT: FRNYUS33.

FDA records the official application receipt date as the later of the following: (1) The date the application was received by the FDA Document Control Center for the reviewing 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/cdrhsubmissionaddress.*

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.

VII. Procedures for Paying Annual Establishment Registration Fees

To pay the annual establishment registration fee, firms must access the Device Facility User Fee (DFUF) website at *https://userfees.fda.gov/OA_HTML/furls.jsp.* (FDA has verified the website address, but FDA is not responsible for any subsequent changes to the website 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 2020 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 website listed previously in this section. After creating a user name and password, log into the Establishment Registration User Fee FY 2020 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 the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Acct. No. 75060099, Routing No. 021030004, SWIFT: FRNYUS33. If needed, FDA's tax identification number is 53–0196965.

C. Complete the Information Online To Update Your Establishment's Annual Registration for FY 2020, or To Register a New Establishment for FY 2020

Go to the Center for Devices and Radiological Health's website at *https://www.fda.gov/medical-devices/how-study-and-market-your-device/device-registration-and-listing* 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 2019. Manufacturers of licensed biologics should register in the Biologics Establishment Registration (BER) system at *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-establishment-registration.*

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: July 26, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–16270 Filed 7–30–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–0007]

Outsourcing Facility Fee Rates for Fiscal Year 2020

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the fiscal year (FY) 2020 rates for the establishment and re-inspection fees related to entities that compound human drugs and elect to register as outsourcing facilities under the Federal Food, Drug, and Cosmetic Act (FD&C Act). The FD&C Act authorizes FDA to assess and collect an annual establishment fee from outsourcing facilities, as well as a re-inspection fee for each re-inspection of an outsourcing facility. This document establishes the FY 2020 rates for the small business establishment fee ($5,599), the non-small business establishment fee ($18,288), and the re-inspection fee ($16,798) for outsourcing facilities; provides information on how the fees for FY 2020 were determined; and describes the payment procedures outsourcing facilities should follow. These fee rates are effective October 1, 2019, and will remain in effect through September 30, 2020.

FOR FURTHER INFORMATION CONTACT:

For more information on human drug compounding and outsourcing facility fees: Visit FDA's website at: *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/default.htm.*

For questions relating to this notice: Melissa Hurley, Office of Financial Management, Food and Drug Administration, 4041 Powder Mill Rd., Rm. 61075, Beltsville, MD 20705–4304, 240–402–4585.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Quality and Security Act (DQSA) contains important provisions relating to the oversight of compounding human drugs. Title I of this law, the Compounding Quality Act, created a new section 503B in the FD&C Act (21 U.S.C. 353b). Under section 503B of the FD&C Act, a human drug compounder can become an ''outsourcing facility.''

Outsourcing facilities, as defined in section 503B(d)(4) of the FD&C Act, are facilities that meet all of the conditions described in section 503B(a), including registering with FDA as an outsourcing facility and paying an annual establishment fee. If the conditions of section 503B are met, a drug compounded by or under the direct supervision of a licensed pharmacist in an outsourcing facility is exempt from three sections of the FD&C Act: (1) Section 502(f)(1) (21 U.S.C. 352(f)(1)) concerning the labeling of drugs with adequate directions for use; (2) section 505 (21 U.S.C. 355) concerning the approval of human drug products under new drug applications (NDAs) or abbreviated new drug applications (ANDAs); and (3) section 582 (21 U.S.C. 360eee–1) concerning drug supply chain security requirements. Drugs compounded in outsourcing facilities are not exempt from the requirements of section 501(a)(2)(B) of the FD&C Act (21 U.S.C. 351(a)(2)(B)) concerning current good manufacturing practice requirements for drugs.

Section 744K of the FD&C Act (21 U.S.C. 379j–62) authorizes FDA to assess and collect the following fees associated with outsourcing facilities: (1) An annual establishment fee from each outsourcing facility and (2) a re-inspection fee from each outsourcing facility subject to a re-inspection (see section 744K(a)(1) of the FD&C Act). Under statutorily defined conditions, a qualified applicant may pay a reduced small business establishment fee (see section 744K(c)(4) of the FD&C Act).

FDA announced in the **Federal Register** of November 24, 2014 (79 FR 69856), the availability of a final guidance for industry entitled ''Fees for Human Drug Compounding Outsourcing Facilities Under Sections 503B and 744K of the FD&C Act.'' The guidance provides additional information on the annual fees for outsourcing facilities and adjustments required by law, re-inspection fees, how to submit payment, the effect of failure to pay fees, and how to qualify as a small business to obtain a reduction of the annual establishment fee. This guidance can be accessed on FDA's website at: *https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM391102.pdf.*

II. Fees for FY 2020

A. Methodology for Calculating FY 2020 Adjustment Factors

1. Inflation Adjustment Factor

Section 744K(c)(2) of the FD&C Act specifies the annual inflation adjustment for outsourcing facility fees. The inflation adjustment has two components: One based on FDA's payroll costs and one based on FDA's non-payroll costs for the first 3 of the 4 previous fiscal years. The payroll component of the annual inflation adjustment is calculated by taking the average change in FDA's per-full time equivalent (FTE) personnel compensation and benefits (PC&B) in the first 3 of the 4 previous fiscal years (see section 744K(c)(2)(A)(ii) of the FD&C Act). FDA's total annual spending on PC&B is divided by the total number of FTEs per fiscal year to determine the average PC&B per FTE.

Table 1 summarizes the actual cost and FTE data for the specified fiscal years, and provides the percent change from the previous fiscal year and the average percent change over the first 3 of the 4 fiscal years preceding FY 2020. The 3-year average is 3.1175 percent.

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

Fiscal year	2016	2017	2018	3-year average
Total PC&B	$2,414,728,159	$2,581,551,000	$2,690,678,000	
Total FTE	16,381	17,022	17,023	
PC&B per FTE	$147,408	$151,660	$158,061	
Percent change from previous year	2.2474%	2.8845%	4.2206%	3.1175%

Section 744K(c)(2)(A)(ii) of the FD&C Act specifies that this 3.1175 percent should be multiplied by the proportion of PC&B to total costs of an average FDA FTE for the same 3 fiscal years.