for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: George Greeley, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6402, Silver Spring, MD 20993–0002, 301–796–2200; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Pediatric Study Plans: Content of and Process for Submitting Initial Pediatric Study Plans and Amended Initial Pediatric Study Plans.'' The purpose of this guidance is to assist sponsors in the submission of an iPSP and any amendments to an iPSP. Specifically, this guidance addresses FDA's current thinking regarding the requirement for sponsors to submit an iPSP under section 505B(e) of the FD&C Act (21 U.S.C. 355c(e)).

This guidance finalizes the draft guidance entitled ''Pediatric Study Plans: Content of and Process for Submitting Initial Pediatric Study Plans and Amended Pediatric Study Plans'' issued March 9, 2016 (81 FR 12508). Changes made took into consideration comments received.

The following topics are addressed in this guidance: (1) Applications that require submission of an iPSP; (2) timelines for iPSP submission; (3) content of the iPSP; (4) the relationship of an agreed iPSP to the requirement to submit a pediatric study plan with a marketing application; (5) content and timing of a requested amendment to an iPSP; (6) what is meant by a non-agreed iPSP; and (7) processes for reaching agreement with FDA on a non-agreed iPSP. This guidance also includes a template that should be used for submission of an iPSP.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Pediatric Study Plans: Content of and Process for Submitting Initial Pediatric Study Plans and Amended Pediatric Study Plans.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required.

However, this guidance refers to previously approved FDA collections of information. These collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014. The collections of information related to expedited review programs for serious conditions have been approved under OMB control number 0910–0765. The collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances,* or *http://www.regulations.gov.*

Dated: July 28, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–16785 Filed 7–31–20; 8:45 am]

BILLING CODE 4164–01–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 2021

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) 2021. 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 2021, which apply from October 1, 2020, through September 30, 2021. 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 2021, you should not submit a Small Business Certification Request. This document provides information on how the fees for FY 2021 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 2021 is $328,000. From this starting point, this document establishes FY 2021 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 2021 is $4,975. 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 2021

The total revenue amount for FY 2021 is $211,748,789, 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 2021 are described in this document.

Inflation Adjustment

MDUFA specifies that the $211,748,789 is to be adjusted for inflation increases for FY 2021 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 2021 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 2021. The 3-year average is 1.2644 percent (rounded).

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

Fiscal year	2017	2018	2019	3-Year average
Total PC&B	$2,581,551,000	$2,690,678,000	$2,620,052,000	.....
Total FTE	17,022	17,023	17,144	.....
PC&B per FTE	$151,660	$158,061	$152,826	.....
Percent change from previous year	2.8845	4.2206	–3.3120	1.2644

The payroll adjustment is 1.2644 percent multiplied by 60 percent, or 0.7586 percent. The statute specifies that the component of the inflation adjustment for non-payroll costs for FY 2021 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 2021 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?data_tool=dropmap&series_id=CUURS35ASA0,CUUSS35ASA0.*

[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.*

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

Fiscal year	2017	2018	2019	3-Year average
Annual CPI	256.221	261.445	264.777	.....
Annual Percent Change	1.1045	2.0389	1.2745	.....
3-Year Average Percent Change in CPI	.....	.....	.....	1.4726

The non-payroll adjustment is 1.4726 percent multiplied by 40 percent, or 0.5890 percent. Next, the payroll adjustment (0.7586 percent or 0.007586) is added to the non-payroll adjustment (0.5890 percent or .005890), for a total of 1.3476 percent (or 0.013476). To complete the inflation adjustment, 1 (100 percent or 1.0) is added for a total base inflation adjustment of 1.013476 for FY 2021.

MDUFA IV provides for this inflation adjustment to be compounded for FY 2021 and each subsequent fiscal year (see 21 U.S.C. 379j(c)(2)(B)(ii)). To complete the compounded inflation adjustment for FY 2021, the FY 2020 compounded adjustment (1.099985) is multiplied by the FY 2021 base inflation adjustment (1.013476) to reach the applicable inflation adjustment of 1.114808 (rounded) for FY 2021. We then multiply the total revenue amount for FY 2021 ($211,748,789) by 1.114808, yielding an inflation adjusted total revenue amount of $236,059,000 (rounded to the nearest thousand dollars).

III. Fees for FY 2021

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 $328,000 (premarket application) and $4,975 (establishment registration) are to be adjusted for FY 2021 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 1.114808 yields inflation adjusted base fees of $365,657 (premarket application) and $5,546 (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 2021.

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

Application type	FY 2017 actual	FY 2018 actual	FY 2019 actual	3-Year average
Full Fee Applications	37	38	32	36
Small Business	6	7	8	7
Panel-Track Supplement	22	23	14	20
Small Business	2	5	4	4
De Novo Classification Request [1]	.....	27	12	20
Small Business [1]	.....	29	37	33
180-Day Supplements	167	133	124	141
Small Business	33	27	23	28
Real-Time Supplements	187	169	213	190
Small Business	19	34	43	32
510(k)s	2,969	2,122	2,069	2,387
Small Business	1,072	1,385	1,558	1,338
30-Day Notice	998	1,058	925	994
Small Business	78	98	111	96
513(g) (21 U.S.C. 360c(g)) Request for Classification Information	93	84	75	84
Small Business	41	33	54	43
Annual Fee for Periodic Reporting [2]	618	624	629	624
Small Business [2]	57	74	96	76
Establishment Registration	27,115	27,544	27,734	27,464

[1] Two-year average for De Novo is based on actuals from available data.
[2] Includes collection of quarter 4 billing for FY 2019 during FY 2020.

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 2021 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 $236,842,961, which is $783,961 higher than the inflation adjusted total revenue amount (in section II). The fees in column two are those we are establishing in FY 2021, which are the standard fees.

TABLE 4—FEES NEEDED TO ACHIEVE NEW FY 2021 REVENUE TARGET

Application type	FY 2021 statutory fees (base fees)	FY 2021 inflation adjusted statutory base fees (standard fees)	3-Year average of fee-paying submissions	FY 2021 revenue from adjusted fees
Full Fee Applications	$328,000	$365,657	36	$13,163,652
Small Business	82,000	91,414	7	639,898
Panel-Track Supplement	246,000	274,243	20	5,484,860
Small Business	61,500	68,561	4	274,244
De Novo Classification Request	98,400	109,697	20	2,193,940
Small Business	24,600	27,424	33	904,992
180-Day Supplements	49,200	54,849	141	7,733,709
Small Business	12,300	13,712	28	383,936
Real-Time Supplements	22,960	25,596	190	4,863,240
Small Business	5,740	6,399	32	204,768
510(k)s	11,152	12,432	2,387	29,675,184
Small Business	2,788	3,108	1,338	4,158,504
30-Day Notice	5,248	5,851	994	5,815,894
Small Business	2,624	2,926	96	280,896
513(g) Request for Classification Information	4,428	4,936	84	414,624
Small Business	2,214	2,468	43	106,124
Annual Fee for Periodic Reporting	11,480	12,798	624	7,985,952
Small Business	2,870	3,200	76	243,200
Establishment Registration	4,975	5,546	27,464	152,315,344
Total				236,842,961

The standard fee (adjusted base amount) for a premarket application, including a BLA, and for a premarket report and a BLA efficacy supplement, is $365,657 for FY 2021. 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 $5,546 for FY 2021. There is no small business rate for the annual establishment registration fee; all establishments pay the same fee.

Table 5 summarizes the FY 2021 rates for all medical device fees.

TABLE 5—MEDICAL DEVICE FEES FOR FY 2021

Application fee type	Standard fee (as a percent of the standard fee for a premarket application)	FY 2021 standard fee	FY 2021 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.	$365,657	$91,414
Premarket report (submitted under section 515(c)(2) of the FD&C Act)	100	365,657	91,414
Efficacy supplement (to an approved BLA under section 351 of the PHS Act)	100	365,657	91,414
Panel-track supplement	75	274,243	68,561
De novo classification request	30	109,697	27,424
180-day supplement	15	54,849	13,712
Real-time supplement	7	25,596	6,399
510(k) premarket notification submission	3.40	12,432	3,108
30-day notice	1.60	5,851	2,926
513(g) request for classification information	1.35	4,936	2,468
Annual Fee Type			
Annual fee for periodic reporting on a class III device	3.50	12,798	3,200
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.	5,546	5,546

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 2020, your status as a small business will expire at the close of business on September 30, 2020. You must re-qualify for FY 2021 in order to pay small business fees during FY 2021.

If you are a domestic (U.S.) business and wish to qualify as a small business for FY 2021, 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 copy of your Federal (U.S.) Income Tax Return for the most recent tax year. The most recent tax year will be 2020, except:

If you submit your MDUFA Small Business Certification Request for FY 2021 before April 15, 2021, and you have not yet filed your return for 2020, you may use tax year 2019.

If you submit your MDUFA Small Business Certification Request for FY 2021 on or after April 15, 2021, and have not yet filed your 2020 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 signed 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 2021, 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 signed copy of the affiliate's Federal (U.S.) Income Tax Return for the most recent tax year (2020 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, 2020, and September 30, 2021, you must pay the fee in effect for FY 2021. 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 2020 or FY 2021 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, 2020. One choice is for applications and fees that will be received on or before September 30, 2020, which are subject to FY 2020 fee rates. A second choice is for applications and fees received on or after October 1, 2020, which are subject to FY 2021 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 that 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 2021 until it has completed the steps below to register and pay any applicable fee (see 21 U.S.C. 379j(f)(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 2021 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 U.S. 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 2021, or To Register a New Establishment for FY 2021

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 2020. 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 29, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020–16793 Filed 7–29–20; 4:15 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0937–0025]

Agency Information Collection Request. 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before October 2, 2020.

ADDRESSES: Submit your comments to *Sherrette.Funn@hhs.gov* or by calling (202) 795–7714.

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0990-New-60D, and project title for reference, to Sherrette Funn, the Reports Clearance Officer, *Sherrette.funn@hhs.gov,* or call 202–795–7714.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and