by electronic check, credit card, or wire transfer. The preferred method for payments to FDA 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 application, for online electronic payment. The *Pay.gov* feature is available on the FDA website upon receipt of an invoice or after completing the User Fee Cover Sheet and generating the user fee ID number.

Secure electronic payments to FDA 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 an invoice or cover sheet is located, ''Pay Now'' should be selected to be redirected to *Pay.gov*. Electronic payment options are based on the balance due. Payment by credit card is available for balances less than $25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be made using U.S. bank accounts as well as U.S. credit cards.

For payments made by wire transfer, include the unique user fee ID or invoice number to ensure that the payment is applied to the correct fee(s). Without the unique user fee ID or invoice number, the payment may not be applied. The originating financial institution may charge a wire transfer fee. Include applicable wire transfer fees with payment to ensure fees are fully paid. Questions about wire transfer fees should be addressed to the financial institution. The following account information should be used to send payments by wire transfer: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Account No: 75060099, Routing No: 021030004, SWIFT: FRNYUS33.

FDA's tax identification number is 53–0196965. If a fee is not paid in full, the fee will be treated as a claim of the U.S. Government (see section 740(h) of the FD&C Act and 45 CFR part 30), meaning the invoice balance due amount is referred to collections.

B. Application Cover Sheet Procedures

Step One: Create a user account and password. Log on to the ADUFA website at *https://www.fda.gov/industry/animal-drug-user-fee-act-adufa/*animal-drug-user-fee-cover-sheet and, under Application Submission Information, click on ''Create ADUFA User Fee Cover Sheet.'' For security reasons, each firm applying will be assigned an organization identification number, and each user will also be required to set up a user account and password the first time you use this site. Online instructions will walk you through this process.

Step Two: Create an Animal Drug User Fee Cover Sheet, transmit it to the FDA, and print a copy. After logging into your account with your username and password, complete the steps required to create an Animal Drug User Fee Cover Sheet. One cover sheet is needed for each animal drug application or supplement. Once you are satisfied that the data on the cover sheet is accurate and you have finalized the cover sheet, you will be able to transmit it electronically to the FDA and you will be able to print a copy of your cover sheet showing your unique PIN.

Step Three: Send the payment for your application as described in section IX.A above.

Step Four: Submit your application.

C. Product, Establishment, and Sponsor Fees

By December 31, 2026, FDA will issue invoices and payment instructions for product, establishment, and sponsor fees for FY 2027 using this fee schedule. Payment will be due by January 31, 2027. FDA will issue invoices in November 2027 for any products, establishments, and sponsors subject to fees for FY 2027 that qualify for fees after the December 2026 billing.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–15339 Filed 7–29–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–7492]

Medical Device User Fee Rates for Fiscal Year 2027

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the fee rates and payment procedures for medical device user fees for fiscal year (FY) 2027. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Medical Device User Fee Amendments of 2022 (MDUFA V), 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 2027, which apply from October 1, 2026, through September 30, 2027, and provides information on how the fees for FY 2027 were determined, the payment procedures you should follow, and how you may qualify for reduced small business fees.

FOR FURTHER INFORMATION CONTACT: Olufunmilayo Ariyo, Office of Financial Management, Food and Drug Administration, 301–796–7900; or *FDAUserFees@fda.hhs.gov. 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.*

SUPPLEMENTARY INFORMATION:

I. Background

The FD&C Act, as amended by MDUFA V, 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. 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 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 2023 through FY 2027; the base fee for a premarket application received by FDA during FY 2027 is $470,000. From this starting point, this document establishes FY 2027 fee rates for certain types of submissions, and for periodic reporting, by applying criteria specified in the FD&C Act. Under statutorily defined conditions, a qualified applicant may receive a fee waiver or may pay a lower small business fee (see sections 738(a)(3)(B), 738(d) and 738(e) of the FD&C Act). For more information on fee waivers, please see Section IX. Small Business Fee Reductions and Fee Waivers.

The FD&C Act specifies the base fee for establishment registration for each year from FY 2023 through FY 2027; the base fee for an establishment registration in FY 2027 is $8,465. 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, 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. Total Revenue Amount for FY 2027

The total revenue amount for FY 2027 is $418,343,000, as set forth in the statute prior to the inflation adjustment (see section 738(b)(3) of the FD&C Act). MDUFA V 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 2027 are described in this document.

Inflation Adjustment

MDUFA specifies that the $418,343,000 is to be adjusted for inflation increases for FY 2027 using two separate adjustments: one for payroll costs and one for non-payroll costs (see 738(c)(2)). The base inflation adjustment for FY 2027 is the sum of one plus the two separate adjustments and is compounded as specified in the statute (see section 738(c)(2)(C) and 738(c)(2)(B) of the FD&C Act).

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 (FTE) position at FDA for the first 3 of the 4 preceding FYs, multiplied by 0.60, or 60 percent (see section 738(c)(2)(C)(i)(I) of the FD&C Act).

Table 1 summarizes the actual cost and FTE data for the specified FYs, provides the percent change from the previous fiscal year, and provides the average percent change over the first 3 of the 4 fiscal years preceding FY 2027. The 3-year average is 5.7330 percent (rounded).

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

	FY 2023	FY 2024	FY 2025	3-Year average
Total PC&B	$3,436,513,000	$3,791,729,000	$3,875,940,000	.....
Total FTE	18,729	19,687	19,139	.....
PC&B per FTE	$183,486	$192,601	$202,515	.....
Percent change from previous year	7.0838%	4.9677%	5.1474%	5.7330%

The payroll adjustment is 5.7330 percent multiplied by 60 percent, resulting in 3.4398 percent. The statute specifies that the component of the inflation adjustment for non-payroll costs for FY 2027 is the average annual percent change that occurred in the Consumer Price Index (CPI) for urban consumers (Washington-Arlington-Alexandria, DC-VA-MD-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 section 738(c)(2)(C)(i)(II) of the FD&C Act).

Table 2 provides the summary data and the 3-year average percent change in the specified CPI for the Washington-Arlington-Alexandria area.[1]

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

	2023	2024	2025	3-Year average
Annual CPI	305.317	315.186	321.993	.....
Annual Percent Change	3.1069%	3.2324%	2.1597%	.....
3-Year Average Percent Change in CPI	.....	.....	.....	2.8330%

The non-payroll adjustment is 2.8330 percent multiplied by 40 percent, resulting in 1.1332 percent. Next, the payroll adjustment (3.4398 percent or 0.034398) is added to the non-payroll adjustment (1.1332 percent or 0.011332), for a total of 4.5730 percent (or 0.045730). To complete the inflation adjustment, 1 (100 percent or 1.0) is added for a total base inflation adjustment of 1.045730 for FY 2027. If the base inflation adjustment for a fiscal year is greater than 1.04, such adjustment shall be considered to be equal to 1.04 (see section 738(c)(2)(C)(ii)(II) of the FD&C Act). The total base inflation adjustment for FY 2027 is 1.04.

MDUFA V provides for this inflation adjustment to be compounded for FY 2023 and each subsequent fiscal year (see section 738(c)(2)(B) of the FD&C Act). To complete the compounded inflation adjustment for FY 2027, the FY 2026 compounded adjustment (1.167391) is multiplied by the FY 2027 base inflation adjustment (1.040000) to reach the applicable inflation adjustment of 1.214087 (rounded) for FY 2027. We then multiply the total revenue amount for FY 2027 ($418,343,000) by 1.214087, yielding an inflation adjusted total revenue amount of $507,905,000 (rounded to the nearest thousand dollars).

III. Adjustments to Base Fee Amounts for FY 2027

Under the FD&C Act, all submission fees and the periodic reporting fee are set as a percentage of the standard (full) fee for a premarket application (see section 738(a)(2)(A) and (b)(1)).

A. Inflation Adjustment

MDUFA specifies that the base fees of $470,000 (premarket application) and $8,465 (establishment registration) are to be adjusted for FY 2027 using the same methodology as that for the total revenue inflation adjustment in section II (see section 738(c)(2)(D)(i) of the FD&C Act). Multiplying the base fees by the compounded inflation adjustment of

[1] This data is published by the Bureau of Labor Statistics and can be found on its website at: *https://data.bls.gov/pdq/SurveyOutputServlet?data_tool=dropmap&series_id=CUURS35ASA0,CUUSS35ASA0.*

1.214087 yields inflation adjusted base fees of $570,621 (premarket application) and $10,277 (establishment registration).

B. Further Adjustments To Generate the Inflation-Adjusted Total Revenue Amount

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 section 738(c)(2)(D)(ii) of the FD&C Act). After this adjustment, if necessary, FDA may further increase the base establishment registration fees to generate the inflation-adjusted total revenue amount (see section 738(c)(3)).

For FY 2027, further adjustments were required to meet the inflation adjusted total revenue amount of $507,905,000. After increasing base fees, on a uniform proportionate basis, and further increasing establishment registration fees, this yields inflation adjusted base fees of $636,732 (premarket application) and $11,693 (establishment registration).

C. MDUFA V Adjustments Solely to Registration Fees

MDUFA V has three new potential adjustments that will not change the total revenue amount but may impact collections by increasing or decreasing establishment registration base fees only. These adjustments are the performance improvement adjustment, the hiring adjustment, and the operating reserve adjustment.

1. Performance Improvement Adjustment

Beginning with FY 2025, this adjustment allows FDA to collect fees in addition to the total revenue amount in FYs 2025, 2026, and 2027, if the Agency meets certain performance goals in FYs 2023, 2024, and 2025. If applicable, this provision further increases base establishment registration fee amounts to achieve an increase in total fee collections equal to the applicable performance improvement adjustment amount, which is set forth in the statute (see section 738(c)(4)). FDA met the FY 2025 Pre-Submission Written Feedback goal and the FY 2024 De Novo Decision goal, which determine the amount of the performance improvement adjustment for FY 2027

For FY 2027, the performance improvement adjustment amount is equal to the product of (1) the sum of the pre-submission amount in section 738(c)(4)(B)(i)(III)(cc), $40,572,600 and the de novo classification request amount in section 738(c)(4)(B)(ii)(II)(bb), $11,765,400 and (2) the applicable inflation adjustment under section 738(c)(2)(B), 1.214087. See section 738(c)(4)(A)(iii). Thus, for FY 2027, the performance improvement adjustment is equal to the product of $52,338,000 and 1.214087 which results in $63,542,885.

2. Hiring Adjustment

Beginning with FY 2025, this adjustment provides for the reduction of base establishment registration fees in FYs 2025, 2026, and 2027, if specified hiring goals for FYs 2023, 2024, and 2025 are not met by a certain threshold. The hiring adjustment would serve to decrease the base establishment registration fee amounts, as necessary, to achieve a reduction in total fee collections equal to the hiring adjustment amount, which is set forth in the statute (see section 738(c)(5)).

FDA met the FY 2025 statutory hiring threshold of 75 hires, so establishment registration fees will not need to be lowered by the hiring adjustment amount in FY 2027.

3. Operating Reserve Adjustment

For FYs 2023 to 2027, the operating reserve adjustment requires FDA to decrease base establishment registration fees if the amount of operating reserves of carryover user fees exceeds the ''designated amount'', and such reduction is necessary to provide for not more than such designated amount of operating reserves of carryover user fees (see section 738(c)(6)(A)).

The designated amount is equal to the sum of 13 weeks of operating reserves of carryover user fees plus 1 month of operating reserves, as described in 738(c)(8) (see 738(c)(6)(B)).

To determine the 13-week operating reserves of carryover user fees amount, the FY 2027 inflation-adjusted total revenue amount (from section II), $507,905,000, is added to the inflation-adjusted performance improvement adjustment amount (from section III.C.1), $63,542,885 resulting in $571,447,885. This amount is then divided by 52, and then multiplied by 13. The 13-week operating reserve amount for FY 2027 is $142,861,971.

To determine the 1 month of operating reserves described in section 738(c)(8) of the FD&C Act, the FY 2027 inflation-adjusted total revenue amount of $507,905,000 is added to the inflation-adjusted performance improvement adjustment amount of $63,542,885, resulting in $571,447,885. This amount is then divided by 12. The 1 month of operating reserves for FY 2027 is $47,620,657.

For FY 2027, the designated amount is equal to the 13-week operating reserve of $142,861,971 plus the 1 month of operating reserves of $47,620,657, totaling $190,482,628.

To determine the FY 2026 end-of-year operating reserves of carryover user fees amount, FDA combined the actual collections and obligations at the end of the third quarter (June 2026) and added the forecasted collections and obligations for the fourth quarter of FY 2026 to generate a full year estimate for FY 2026. The estimated end-of-year FY 2026 operating reserves of carryover user fees is $139,866,752 (Note, this amount includes the 1-month reserve).

Note that under MDUFA V, for the purposes of calculating the operating reserve adjustment, this amount does not include user fee funds considered unappropriated ($26,680,243) or unearned revenue ($89,956,562).

Because the estimated end-of-year FY 2026 MDUFA operating reserves of carryover user fees amount totaling $139,866,752 does not exceed the FY 2027 designated amount of $190,482,628 FDA will not decrease the base establishment registration fee amounts for FY 2027 to provide for not more than such designated amount.

As there is a performance improvement adjustment for FY 2027, but no hiring adjustment or operating reserve adjustment, establishment registration fees are increased to achieve an increase in total fee collections for FY 2027 equal to the performance improvement adjustment amount of $63,542,885. After increasing establishment registration fees only, this yields fees of $636,732 (premarket application) and $13,785 (establishment registration).

IV. Calculation of Fee Rates

As noted in section II, the total revenue amount after the applicable inflation adjustment is $507,905,000 (rounded to the nearest thousand dollars). As noted in section III, the performance improvement adjustment solely to registration fees for FY 2027 is $63,542,885. There is no hiring adjustment or operating reserve adjustment for FY 2027.

Table 3 provides fee-paying submission counts for the last 3 years and the 3-year average. Historically, FDA has estimated the total number of fee-paying submission counts it expects to receive during the next fiscal year by averaging the number of fee-paying submission counts received in the 3 most recently completed fiscal years; for FY 2027 fee-setting, this would be an average of FY 2023 through FY 2025.

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

[Excluding establishment registration]

Application type	FY 2023 actual	FY 2024 actual	FY 2025 actual	3 Yr. average
Full Fee applications	31	20	33	28
Small Business	3	4	3	3
Panel-Track Supplements	22	26	35	28
Small Business	5	2	2	3
De Novo Classifications	26	26	13	22
Small Business	68	47	49	55
180-Day Supplements	113	127	130	123
Small Business	12	15	29	19
Real-Time Supplements	138	157	145	147
Small Business	28	35	42	35
510(k)s	1,943	1,754	1,883	1,860
Small Business	2,031	2,066	2,204	2,100
30-Day Notice (Note also includes counts for 135 Day Supplements)	825	854	893	857
Small Business	53	62	55	57
513(g)(21 U.S.C. 360c(g)) Request for Classification Information	82	65	64	70
Small Business	59	68	54	60
Annual Fee for Periodic Reporting	657	700	713	690
Small Business	22	32	38	31
Establishment Registrations	30,645	30,280	30,214	30,380

The information in table 3 is necessary to estimate the amount of revenue that will be collected based on the fee amounts. Tables 4A and 4B display the FY 2027 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 average of fee-paying submissions, collections are projected to total $449,060,062 which is $58,844,938 lower than the inflation adjusted total revenue amount (in section II). Accordingly, the next step in the fee setting process is to increase the base fee amounts on a uniform proportionate basis to generate the inflation adjusted total revenue amounts (see 738(c)(2)(D)(ii) and table 4A, column three).

Applying these further adjusted fee rates to the 3-year average of fee-paying submissions, results in estimated total fee collections of $501,089,079 which is still $6,815,921 lower than the inflation adjusted total revenue amount (in Section II). The next step in the fee setting process, after the adjustment in (2)(D) is done, is to increase the base establishment registration fee amount as necessary for total fee collections to generate the inflation adjusted total revenue amount, as adjusted under paragraph (2) (see 738(c)(3)). Accordingly, the base establishment registration fee was increased by $225 for an establishment registration fee rate of $11,693 (see 738(c)(3) and table 4B, column three). The performance improvement adjustment amount is $63,542,885. Per statute, the establishment registration fee is further adjusted to account for the performance improvement adjustment amount. The inflation adjusted establishment registration fee is increased by $2,092 for an establishment registration fee of $13,785. The fees in column three in table 4A and column four in table 4B are those we are establishing for FY 2027, which are the standard fees.

TABLE 4A—FEES NEEDED TO ACHIEVE NEW FY 2027 REVENUE TARGET

Application type	FY 2027 statutory fees (base fees)	FY 2027 inflation adjusted statutory base fees	2027 Fees adjusted to meet revenue target (uniform proportionate increase)	3-Year average of fee-paying submissions	FY 2027 revenue from adjusted fees
Full Fee Application	$470,000	$570,621	$636,732	28	$17,828,496
Small Business	117,500	142,655	159,183	3	477,549
Panel-Track Supplement	376,000	456,497	509,386	28	14,262,808
Small Business	94,000	114,124	127,347	3	382,041
De Novo Classification Request	141,000	171,186	191,020	22	4,202,440
Small Business	35,250	42,797	47,755	55	2,626,525
180-Day Supplement	70,500	85,593	95,510	123	11,747,730
Small Business	17,625	21,398	23,878	19	453,682
Real-Time Supplement	32,900	39,943	44,571	147	6,551,937
Small Business	8,225	9,986	11,143	35	390,005
510(k) Premarket Notification Submission	21,150	25,678	28,653	1,860	53,294,580
Small Business	5,288	6,419	7,163	2,100	15,042,300
30-Day Notice	7,520	9,130	10,188	857	8,731,116
Small Business	3,760	4,565	5,094	57	290,358
513(g) Request for Classification Information	6,345	7,703	8,596	70	601,720
Small Business	3,173	3,852	4,298	60	257,880
Annual Fee for Periodic Reporting	16,450	19,972	22,286	690	15,377,340

TABLE 4A—FEES NEEDED TO ACHIEVE NEW FY 2027 REVENUE TARGET—Continued

Application type	FY 2027 statutory fees (base fees)	FY 2027 inflation adjusted statutory base fees	2027 Fees adjusted to meet revenue target (uniform proportionate increase)	3-Year average of fee-paying submissions	FY 2027 revenue from adjusted fees
Small Business	4,113	4,993	5,572	31	172,732
Total					152,691,239

TABLE 4B—FEES NEEDED TO ACHIEVE NEW FY 2027 REVENUE TARGET PLUS/MINUS ADJUSTMENTS

Application type	FY 2027 statutory fees (base fees)	FY 2027 inflation adjusted statutory base fees	Adjusted FY 2027 fees to meet inflation adjusted total revenue amount (uniform proportionate increase + further adjustment to establishment registrations)	Adjusted FY 2027 fees to meet inflation adjusted total revenue +/− adjustments	3-Year average of fee-paying submissions	FY 2027 revenue from adjusted fees
Establishment Registrations	$8,465	$10,277	$11,693	$13,785	30,380	$355,233,340 [1]

[1] Excludes additional collections from the performance improvement adjustment.

The standard fee (adjusted base amount) for a premarket application, including a BLA, and for a premarket report and a BLA efficacy supplement, is $636,732 for FY 2027.

The fees set by reference to the standard fee for a premarket application are:

- For a panel-track supplement, 80 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, 4.5 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

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 738(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 738(d)(2)(C)).

The annual fee for establishment registration, after adjustments, is set at $13,785 for FY 2027. For FY 2027, FDA may, but is not required to, grant a waiver of the fee for annual establishment registration (excluding the initial registration) to applicants that qualify as a small business if FDA finds that the establishment is a small business and paying the fee for such a year represents a financial hardship to the establishment as determined by FDA. For more information on reduced fees and waivers for small businesses, please see Section IX. Small Business Fee Reductions and Fee Waivers.

Table 5 summarizes the FY 2027 rates for all medical device fees.

TABLE 5—MEDICAL DEVICE FEES FOR FY 2027

Application fee type	Standard fee (as a percentage of the standard fee for a premarket application)	FY 2027 standard fee	FY 2027 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.	$636,732	$159,183
Premarket Report (submitted under section 515(c)(2) of the FD&C Act)	100%	636,732	159,183
Efficacy Supplement (to an approved BLA under section 351 of the PHS Act)	100%	636,732	159,183
Panel-Track Supplement	80%	509,386	127,347
De Novo Classification Request	30%	191,020	47,755
180-Day Supplement	15%	95,510	23,878
Real-Time Supplement	7%	44,571	11,143
510(k) Premarket Notification Submission	4.5%	28,653	7,163
30-Day Notice	1.60%	10,188	5,094
513(g) Request for Classification Information	1.35%	8,596	4,298
Annual Fee Type:			
Annual Fee for Periodic Reporting on a class III device	3.50%	22,286	5,572

TABLE 5—MEDICAL DEVICE FEES FOR FY 2027—Continued

Application fee type	Standard fee (as a percentage of the standard fee for a premarket application)	FY 2027 standard fee	FY 2027 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.	13,785	13,785

V. 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 your most recent tax year, you may qualify for reduced small business fees. If your business, including your affiliates, has gross receipts or sales of no more than $30 million for your most recent tax year, 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 must submit the materials showing you qualify as a small business at least 60 days before any applicable fee is due to FDA. For more information on fee waivers or reductions, please see Section IX. Small Business Fee Reductions and Fee Waivers.

For FY 2027, FDA may, but is not required to, grant a waiver of the annual establishment registration fee (excluding the initial registration) to applicants that qualify as a small business if FDA finds that the establishment is a small business and paying the fee for such a year represents a financial hardship to the establishment as determined by FDA. For the purpose of the annual registration fee waiver, a small business is defined as one with $1,000,000 or less in gross receipts or sales in the most recent Federal (U.S.) income tax return (including the returns of its affiliates).[1]

If your business qualified as a small business for FY 2026, your status as a small business will expire at the close of business on September 30, 2026. You must re-qualify for FY 2027 in order to pay small business fees during FY 2027.

A. Domestic (U.S.) Businesses

If you are a domestic (U.S.) business and wish to qualify as a small business for FY 2027, submit the following to FDA:

1. A completed MDUFA Small Business Request form. The most current FDA Form may be found in the FDA Forms database: *https://www.fda.gov/about-fda/reports-manuals-forms/forms.*

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 2026, except:

- If you submit your MDUFA Small Business Request for FY 2027 before April 15, 2027, and you have not yet filed your return for 2026, you may use tax year 2025.
- If you submit your MDUFA Small Business Request for FY 2027 on or after April 15, 2027, and have not yet filed your 2026 return because you obtained an extension, you may submit your most recent tax 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, if extant, of the country in which the business 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 during which these receipts or sales were 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 your affiliate is headquartered in a country without a National Taxing Authority, please contact the Division of Industry and Consumer Education at 800–638–2041 or 301–796–7100 or email at *DICE@fda.hhs.gov.*

4. Once you have completed and signed the most current FDA Form for a MDUFA Small Business Request, submit your form and your supporting documentation (copies of the Federal (U.S.) income tax returns), using the instructions which are available at the following website: *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm577696.htm.*

If you need assistance, please contact the Division of Industry and Consumer Education at 800–638–2041 or 301–796–7100 or email at *DICE@fda.hhs.gov.*

B. Foreign Businesses

If you are a foreign business, and wish to qualify as a small business for FY 2027, submit the following:

1. A completed MDUFA Small Business Request form. The most current FDA Form is provided in the FDA Forms database: *https://www.fda.gov/about-fda/reports-manuals-forms/forms.*

2. A National Taxing Authority Certification, completed by, and bearing the official seal of, the National Taxing Authority, if extant, of the country in which the business 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 during which these receipts or sales were collected.

If your business is headquartered in a country without a National Taxing Authority, please contact the Division of Industry and Consumer Education at 800–638–2041 or 301–796–7100 or email at *DICE@fda.hhs.gov.*

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 (2025 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, if extant, of the country in which the business is headquartered. The National Taxing

[1] See Medical Device User Fee Small Business Qualification and Determination guidance (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-user-fee-small-business-qualification-and-determination*).

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 during which these receipts or sales were 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.

- If your affiliate is headquartered in a country without a National Taxing Authority, please contact the Division of Industry and Consumer Education at 800–638–2041 or 301–796–7100 or email at *DICE@fda.hhs.gov.*

4. Once you have completed and signed the most current MDUFA Small Business request, submit your form and your supporting documentation, including the following, using the instructions which are available at the following website: *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm577696.htm.*

- A copy of the most recent Federal (U.S.) income tax return for each of your affiliates headquartered in the U.S. and
- A National Taxing Authority Certification for each of your foreign affiliates.

If you need assistance, please contact the Division of Industry and Consumer Education at 800–638–2041 or 301–796–7100 or email at *DICE@fda.hhs.gov.*

VI. 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, 2026, and September 30, 2027, you must pay the fee in effect for FY 2027. To avoid delay in the review of your application, you should pay the application fee at the time you submit your application to FDA. 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 2026 or FY 2027 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.

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, 2026. One choice is for applications and fees that will be received on or before September 30, 2026, which are subject to FY 2026 fee rates. A second choice is for applications and fees received on or after October 1, 2026, which are subject to FY 2027 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

Payments made to FDA must be made in U.S. currency drawn on a U.S. bank by electronic check, credit card, or wire transfer. The preferred method for payments to FDA 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 application, for online electronic payment. The *Pay.gov* feature is available on the FDA website upon receipt of an invoice or after completing the User Fee Cover Sheet and generating the user fee ID number.

Secure electronic payments to FDA 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 an invoice or cover sheet is located, ''Pay Now'' should be selected to be redirected to *Pay.gov.* Electronic payment options are based on the balance due. Payment by credit card is available for balances less than $25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be made using U.S. bank accounts as well as U.S. credit cards.

For payments made by wire transfer, include the unique user fee ID or invoice number to ensure that the payment is applied to the correct fee(s). Without the unique user fee ID or invoice number, the payment may not be applied. The originating financial institution may charge a wire transfer fee. Include applicable wire transfer fees with payment to ensure fees are fully paid. Questions about wire transfer fees should be addressed to the financial institution. The following account information should be used to send payments by wire transfer: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Account No: 75060099, Routing No: 021030004, SWIFT: FRNYUS33.

FDA's tax identification number is 53–0196965. If a fee is not paid in full, the fee will be treated as a claim of the United States Government (see 738(i) of the FD&C Act and 45 CFR part 30), meaning the invoice balance due amount is referred to collections.

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.

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.*

VII. 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.

Payments made to FDA must be made in U.S. currency drawn on a U.S. bank by electronic check, credit card, or wire transfer. The preferred method for payments to FDA 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 application, for online electronic payment. The *Pay.gov*feature is available on the FDA website upon receipt of an invoice or after completing the User Fee Cover Sheet and generating the user fee ID number.

Secure electronic payments to FDA 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 an invoice or cover sheet is located, ''Pay Now'' should be selected to be redirected to *Pay.gov*. Electronic payment options are based on the balance due. Payment by credit card is available for balances less than $25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be made using U.S. bank accounts as well as U.S. credit cards.

For payments made by wire transfer, include the unique user fee ID or invoice number to ensure that the payment is applied to the correct fee(s). Without the unique user fee ID or invoice number, the payment may not be applied. The originating financial institution may charge a wire transfer fee. Include applicable wire transfer fees with payment to ensure fees are fully paid. Questions about wire transfer fees should be addressed to the financial institution. The following account information should be used to send payments by wire transfer: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Account No: 75060099, Routing No: 021030004, SWIFT: FRNYUS33.

FDA's tax identification number is 53–0196965. If a fee is not paid in full, the fee will be treated as a claim of the United States Government (see 738(i) of the FD&C Act and 45 CFR part 30), meaning the invoice balance due amount is referred to collections.

VIII. 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 is published 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 2027 until it has completed the steps below to register and pay any applicable fee (see 738(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 username and password, log into the Establishment Registration User Fee FY 2027 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.

If you have an approved small business waiver, please contact *FDAUserFees@fda.hhs.gov* for further instructions.

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 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. Include applicable wire transfer fees with payment to ensure fees are fully paid. Questions about wire transfer fees should be addressed to the financial institution. The following account information should be used to send payments by wire transfer: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Account No: 75060099, Routing No: 021030004, SWIFT: FRNYUS33.

FDA's tax identification number is 53–0196965. If a fee is not paid in full, the fee will be treated as a claim of the United States Government (see section 738(i) of the FD&C Act and 45 CFR part 30), meaning the invoice balance due amount is referred to collections.

C. Complete the Information Online To Update Your Establishment's Annual Registration for FY 2027, or To Register a New Establishment for FY 2027

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 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 2026. Manufacturers of licensed biologics should register in the electronic Blood Establishment Registration (eBER) 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 eBER 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.

IX. Small Business Fee Reductions and Fee Waivers

To qualify for reduced fees for small businesses or a small business fee waiver, please see the requirements for qualification provided in Section V. How To Qualify as a Small Business for Purposes of Medical Device Fees. The applicant should submit a MDUFA Small Business Request form and the supporting materials showing you qualify as a small business at least 60 days before any applicable fee is due 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 you need assistance, please contact the Division of Industry and Consumer Education at 800–638–2041 or 301–796–7100 or email at *DICE@fda.hhs.gov.*

A. Premarket Approval Fee Reduction or Waiver

A small business applicant may request to pay a reduced rate for premarket approval fees. An applicant may also request a fee waiver for their first premarket application or premarket report (738(d)).

B. Premarket Notification Submission Fee Reduction

A small business applicant may request to pay a reduced rate for a premarket notification submission.

C. Annual Establishment Registration Fee Waiver

For FY 2027, FDA may, but is not required to, grant a waiver of the annual establishment registration fee (excluding the initial registration) to applicants that qualify as a small business if FDA finds that the establishment is a small business and paying the fee for such a year represents a financial hardship to the establishment as determined by FDA.

X. Refunds

To qualify for consideration for a refund, a person shall submit to FDA a written request for a refund not later than 180 days after such fee is due. For more information on qualifying and submitting a refund, see section 738(a)(2)(D) of the FD&C Act (21 U.S.C. 379j(a)(2)(D)).

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–7397]

Outsourcing Facility Fee Rates for Fiscal Year 2027

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the fiscal year (FY) 2027 rates for the establishment and reinspection 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 reinspection fee for each reinspection of an outsourcing facility. This document establishes the FY 2027 rates for the small business establishment fee ($7,142), the non-small business establishment fee ($22,074), and the reinspection fee ($21,427) for outsourcing facilities; provides information on how the fees for FY 2027 were determined; and describes the payment procedures outsourcing facilities should follow.

DATES: These fee rates are effective October 1, 2026, and will remain in effect through September 30, 2027.

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/guidance-compliance-regulatory-information/human-drug-compounding. For questions relating to this notice:* Olufunmilayo Ariyo, Office of Financial Management, Food and Drug Administration, 301–796–7900; or *FDAUserFees@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Under section 503B of the FD&C Act (21 U.S.C. 353b), a human drug compounder can register with FDA as an ''outsourcing facility.'' Outsourcing facilities, as defined in section 503B(d)(4), are, in part, facilities that meet all 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 or abbreviated new drug applications; 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 reinspection fee from each outsourcing facility subject to a reinspection (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, reinspection 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/media/136683/download.*