DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–3453]

Medical Device User Fee Rates for Fiscal Year 2025

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) 2025. 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 2025, which apply from October 1, 2024, through September 30, 2025, and provides information on how the fees for FY 2025 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: Olufunmilayo Ariyo, Office of Financial Management, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20903, 240–402–4989; or the User Fee Support Staff at *OO-OFBAP-OFM-UFFS-Government@fda.hhs.gov.*

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 2025 is $445,000. From this starting point, this document establishes FY 2025 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 2025 is $7,100. 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. Total Revenue Amount for FY 2025

The total revenue amount for FY 2025 is $350,746,400, 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 2025 are described in this document.

Inflation Adjustment

MDUFA specifies that the $350,746,400 is to be adjusted for inflation increases for FY 2025 using two separate adjustments: one for payroll costs and one for non-payroll costs (see section 738(c)(2) of the FD&C Act). The base inflation adjustment for FY 2025 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 2025. The 3-year average is 3.8539 percent (rounded).

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

	FY 2021	FY 2022	FY 2023	3-Year average
Total PC&B	$3,039,513,000	$3,165,477,000	$3,436,513,000	
Total FTE	18,501	18,474	18,729	
PC&B per FTE	$164,289	$171,348	$183,486	
Percent change from previous year	0.1811%	4.2967%	7.0838%	3.8539%

The payroll adjustment is 3.8539 percent multiplied by 60 percent, or 2.3123 percent. The statute specifies that the component of the inflation adjustment for non-payroll costs for FY 2025 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. 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.*

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

	2021	2022	2023	3-Year average
Annual CPI	277.728	296.117	305.317	.....
Annual Percent Change	3.9568%	6.6212%	3.1069%	.....
3-Year Average Percent Change in CPI	.....	.....	.....	4.5616%

The non-payroll adjustment is 4.5616 percent multiplied by 40 percent, or 1.8246 percent. Next, the payroll adjustment (2.3123 percent or 0.023123) is added to the non-payroll adjustment (1.8246 percent or 0.018246), for a total of 4.1369 percent (or 0.041369). To complete the inflation adjustment, 1 (100 percent or 1.0) is added for a total base inflation adjustment of 1.041369 for FY 2025. 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 2025 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 2025, the FY 2024 compounded adjustment (1.079318) is multiplied by the FY 2025 base inflation adjustment (1.040000) to reach the applicable inflation adjustment of 1.122491 (rounded) for FY 2025. We then multiply the total revenue amount for FY 2025 ($350,746,400) by 1.122491, yielding an inflation adjusted total revenue amount of $393,710,000 (rounded to the nearest thousand dollars).

III. Adjustments to Base Fee Amounts for FY 2025

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 section 738(a)(2)(A) and (b)(1) of the FD&C Act).

A. Inflation Adjustment

MDUFA specifies that the base fees of $445,000 (premarket application) and $7,100 (establishment registration) are to be adjusted for FY 2025 using the same methodology as that for the total revenue inflation adjustment in section II (see section 738I(2)(D)(i) of the FD&C Act). Multiplying the base fees by the compounded inflation adjustment of 1.122491 yields inflation adjusted base fees of $499,508 (premarket application) and $7,970 (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) of the FD&C Act).

For FY 2025, further adjustments were required to meet the inflation adjusted total revenue amount of $393,710,000. After increasing base fees, on a uniform proportionate basis, and further increasing establishment registration fees, this yields inflation adjusted base fees of $540,783 (premarket application) and $8,716 (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, which is set forth in the statute (see section 738(c)(4) of the FD& C Act). FDA met the FY 2023 Pre-Submission Written Feedback goal, which triggers the performance improvement adjustment for FY 2025.

For FY 2025, the performance improvement adjustment is equal to the product of the pre-submission amount in section 738(c)(4)(B)(i)(I) of the FD&C Act, $15,396,600, and the inflation adjustment under section 738(c)(2)(B) of the FD&C Act, 1.122491. See section 738(c)(4)(A)(i) of the FD&C Act. For FY 2025, the performance improvement adjustment is $17,282,545.

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) of the FD&C Act).

FDA met the FY 2023 statutory hiring threshold of 123 hires, so establishment registration fees will not need to be lowered by the hiring adjustment amount in FY 2025. Since FDA met the FY 2023 Pre-Submission Written Feedback goal, the FY 2027 statutory hiring goal will be 83 hires for fiscal year 2025 (see section 738(c)(5)(D)(iii)(II) of the FD&C Act) and the threshold will be 75 hires for fiscal year 2025 (see section 738(c)(5)(B)(iii)(II) of the FD&C Act).

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) of the FD&C Act). In making this calculation for FYs 2023 to 2026, a certain amount is excluded from the designated amount and is not subject to the decrease (see section 738(c)(6)(C) of the FD&C Act). For FY 2025, this excluded amount is $77,496,161.

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) of the FD&C Act).

To determine the 13-week operating reserves of carryover user fees amount, the FY 2025 inflation-adjusted total revenue amount (from section II), $393,710,000, is added to the inflation-adjusted performance improvement adjustment amount (from section III.C.1), $17,282,545, resulting in $410,992,545. This amount is then divided by 52, and then multiplied by 13. The 13-week operating reserve amount for FY 2025 is $102,748,136.

To determine the 1 month of operating reserves described in section 738(c)(8) of the FD&C Act, the FY 2025 inflation-adjusted total revenue amount of $393,710,000 is added to the inflation-adjusted performance improvement adjustment amount of $17,282,545, resulting in $410,992,545. This amount is then divided by 12. The 1 month of operating reserves for FY 2025 is $34,249,379.

For FY 2025, the designated amount is equal to the 13-week operating reserve of $102,748,136 plus the 1 month of operating reserves of $34,249,379, totaling $136,997,515.

To determine the FY 2024 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 2024) and added the forecasted collections and obligations for the fourth quarter of FY 2024 to generate a full year estimate for FY 2024. The estimated end-of-year FY 2024 operating reserves of carryover user fees is $50,394,972 (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 ($62,498,454). In addition, as noted above, for purposes of the operating reserve adjustment, operating reserves of carryover user fees do not include the estimated $77,496,161 remaining to spend at the end of FY 2024 from the total of $118,000,000 intended to support the Total Product Life Cycle Advisory Program Pilot and Third-Party Review programs.

Because the estimated end-of-year FY 2024 MDUFA operating reserves of carryover user fees amount totaling $50,394,972 does not exceed the FY 2025 designated amount of $136,997,515, FDA will not decrease the base establishment registration fee amounts for FY 2025 to provide for not more than such designated amount.

As there is a performance improvement adjustment for FY 2025, but no hiring adjustment or operating reserve adjustment, establishment registration fees are increased to achieve an increase in total fee collections for FY 2025 equal to the performance improvement adjustment amount of $17,282,545. After so increasing establishment registration fees only, this yields fees of $540,783 (premarket application) and $9,280 (establishment registration).

IV. Calculation of Fee Rates

As noted in section II, the total revenue amount after the applicable inflation adjustment is $393,710,000 (rounded to the nearest thousand dollar). As noted in section III, the performance improvement adjustment solely to registration fees for FY 2025 is $17,282,545. There is no hiring adjustment or operating reserve adjustment for FY 2025.

Table 3A provides fee-paying submission counts, excluding establishment registration, for the last 3 years and the 3-year average. Table 3B provides establishment registration fee-paying submission counts for the most recently completed fiscal year (FY 2023). 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 2025 fee-setting, this would be an average of FY 2021 through FY 2023. FDA received an abnormally high volume of fee-paying establishment registrations due to the COVID–19 pandemic in FY 2020 and FY 2021. The surge in fee-paying establishment registrations has been declining starting in FY 2022, trending back toward pre-pandemic levels. In an effort to normalize the projected volume of establishment registration submissions for the FY 2025 fee-setting calculation, and more accurately project the associated establishment registration revenue, FDA decided to utilize the number of establishment registration fee-paying submission counts from FY 2023.

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

[Excluding establishment registration]

Application type	FY 2021 actual	FY 2022 actual	FY 2023 actual	3 Yr average
Full Fee applications	25	18	31	25
Small Business	5	3	3	4
Panel-Track Supplements	31	21	22	25
Small Business	6	1	5	4
De Novo Classifications	16	23	26	22
Small Business	42	53	68	54
180-Day Supplements	98	93	113	101
Small Business	34	31	12	26
Real-Time Supplements	150	140	138	143
Small Business	20	12	28	20
510(k)s	2,133	2,012	1,943	2,029
Small Business	1,846	1,757	2,031	1,878
30-Day Notice (Note also includes counts for 135 Day Supplements)	843	782	825	817
Small Business	77	67	53	66
513(g)(21 U.S.C. 360c(g)) Request for Classification Information	83	93	82	86
Small Business	53	58	59	57

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

[Excluding establishment registration]

Application type	FY 2021 actual	FY 2022 actual	FY 2023 actual	3 Yr average
Annual Fee for Periodic Reporting	613	620	657	630
Small Business	84	87	22	64

TABLE 3B—FISCAL YEAR 2023 ACTUAL FEE-PAYING ESTABLISHMENT REGISTRATION SUBMISSIONS

Application type	FY 2023	FY 2025 estimate for registrations
Establishment Registrations	30,645	30,645

The information in tables 3A and 3B is necessary to estimate the amount of revenue that will be collected based on the fee amounts. Tables 4A and 4B display the FY 2025 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, the 3-year average of fee-paying submissions (excluding establishment registration), and the fee-paying establishment registration submissions from FY 2023, collections are projected to total $361,177,583 which is $32,532,417 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) of the FD&C Act and table 4A, column three).

Applying these further adjusted fee rates to the 3-year average of fee-paying submissions, and the fee-paying establishment registration submissions from FY 2023 results in estimated total fee collections of $391,014,947 which is still $2,695,053 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) of the FD&C Act). Accordingly, the base establishment registration fee was increased by $88 for an establishment registration fee rate of $8,716 (see 738(c)(3) of the FD& C Act and table 4B, column three). The performance improvement adjustment amount is $17,282,544. 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 $564 for an establishment registration fee of $9,280. The fees in column three in table 4A and column four in table 4B are those we are establishing for FY 2025, which are the standard fees.

TABLE 4A—FEES NEEDED TO ACHIEVE NEW FY 2025 REVENUE TARGET

Application type	FY 2025 statutory fees (base fees)	FY 2025 inflation adjusted statutory base fees	Adjusted FY 2025 fees to meet revenue target (uniform proportionate increase)	3-Year average of fee-paying submissions	FY 2025 revenue from adjusted fees
Full Fee Applications	$445,000	$499,508	$540,783	25	$13,519,575
Small Business	111,250	124,877	135,196	4	540,784
Panel-Track Supplement	356,000	399,607	432,626	25	10,815,650
Small Business	89,000	99,902	108,157	4	432,628
De Novo Classification Request	133,500	149,583	162,235	22	3,569,170
Small Business	33,375	37,463	40,559	54	2,190,186
180-Day Supplements	66,750	74,926	81,117	101	8,192,817
Small Business	16,688	18,732	20,279	26	527,254
Real-Time Supplements	31,150	34,966	37,855	143	5,413,265
Small Business	7,788	8,741	9,464	20	189,280
510(k)s	20,025	22,478	24,335	2,029	49,375,715
Small Business	5,006	5,619	6,084	1,878	11,425,752
30-Day Notice	7,120	7,992	8,653	817	7,069,501
Small Business	3,560	3,996	4,326	66	285,516
513(g) Request for Classification Information	6,008	6,743	7,301	86	627,886
Small Business	3,004	3,372	3,650	57	208,050
Annual Fee for Periodic Reporting	15,575	17,483	18,927	630	11,924,010
Small Business	3,894	4,371	4,732	64	302,848
Total					126,609,887

TABLE 4B—FEES NEEDED TO ACHIEVE NEW FY 2025 REVENUE TARGET PLUS/MINUS ADJUSTMENTS

Application type	FY 2025 statutory fees (base fees)	FY 2025 inflation adjusted statutory base fees	Adjusted FY 2025 fees to meet inflation adjusted total revenue amount (uniform proportionate increase + further adjustment to establishment registrations)	Adjusted FY 2025 fees to meet inflation adjusted total revenue +/− adjustments	FY 2023 fee-paying submissions	FY 2025 revenue from adjusted fees
Establishment Registrations	$7,100	$7,970	$8,716	$9,280	30,645	$267,101,820

The standard fee (adjusted base amount) for a premarket application, including a BLA, and for a premarket report and a BLA efficacy supplement, is $540,783 for FY 2025. 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 section 738(d)(2)(C) and (e)(2)(C) of the FD&C Act). 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 section 738(d)(2)(C) of the FD&C Act).

The annual fee for establishment registration, after adjustments, is set at $9,280 for FY 2025. For FY 2025, there is no small business waiver for the annual establishment registration fee; all establishments pay the same fee.

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 2025 rates for all medical device fees.

TABLE 5—MEDICAL DEVICE FEES FOR FY 2025

Application fee type	Standard fee (as a percent of the standard fee for a premarket application)	FY 2025 standard fee	FY 2025 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	$540,783	$135,196
Premarket report (submitted under section 515(c)(2) of the FD&C Act)	100%	540,783	135,196
Efficacy supplement (to an approved BLA under section 351 of the PHS Act)	100%	540,783	135,196
Panel-track supplement	80%	432,626	108,157
De novo classification request	30%	162,235	40,559
180-day supplement	15%	81,117	20,279
Real-time supplement	7%	37,855	9,464
510(k) premarket notification submission	4.5%	24,335	6,084
30-day notice	1.60%	8,653	4,326
513(g) request for classification information	1.35%	7,301	3,650
Annual Fee Type			
Annual fee for periodic reporting on a class III device	3.50%	18,927	4,732
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	9,280	9,280

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 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 must submit the materials showing you qualify as a small business at least 60 days before you send your submission to FDA. For more information on fee waivers or reductions, please see Section IX. Small Business Fee Reductions and Fee Waivers.

Please note that the establishment registration fee is not eligible for a reduced small business fee. For FY 2025, there is no small business waiver for the annual establishment registration fee. As a result, if the establishment registration fee is the only medical device user fee that you will pay in FY 2025, you should not submit a Small Business Certification Request. 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 2024, your status as a small business will expire at the close of business on September 30, 2024. You must re-qualify for FY 2025 in order to pay small business fees during FY 2025.

A. Domestic (U.S.) Businesses

If you are a domestic (U.S.) business and wish to qualify as a small business for FY 2025, submit the following to FDA:

1. A completed MDUFA Small Business Certification Request for a Business Headquartered in the United States (Form FDA 3602). Form FDA 3602 is provided 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 2024, except:

- If you submit your MDUFA Small Business Certification Request for FY 2025 before April 15, 2025, and you have not yet filed your return for 2024, you may use tax year 2023.
- If you submit your MDUFA Small Business Certification Request for FY 2025 on or after April 15, 2025, and have not yet filed your 2024 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, if extant, 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 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 your Form FDA 3602, 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 2025, 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/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 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.

If your firm 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 (2023 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 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.
- 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 your Form FDA 3602A, 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 copy of an MDUFA Foreign Small Business Certification Request 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, 2024, and September 30, 2025, you must pay the fee in effect for FY 2025. 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 2024 or FY 2025 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, 2024. One choice is for applications and fees that will be received on or before September 30, 2024, which are subject to FY 2024 fee rates. A second choice is for applications and fees received on or after October 1, 2024, which are subject to FY 2025 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.

If you prefer to send a check by a courier, the courier may deliver the check to: U.S. Bank, Attn: Government Lockbox 979033, 3180 Rider Trail S, Earth City, MO 63045. (*Note:* This U.S. Bank address is for courier delivery only. If you have any questions concerning courier delivery contact U.S. Bank at 800–495–4981. 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.

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.

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.

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, 3180 Rider Trail S, Earth City, MO 63045. (*Note:* This U.S. Bank address is for courier delivery only. If you have any questions concerning courier delivery, contact U.S. Bank at 800–495–4981. 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.

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 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 2025 until it has completed the steps below to register and pay any applicable fee (see section 738(f)(2) of the FD&C Act).

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 2025 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 979033, St. Louis, MO 63197–9000.

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 979033, 3180 Rider Trail S, Earth City, MO 63045. (*Note:* This U.S. Bank address is for courier delivery only. If you have any questions concerning courier delivery, contact U.S. Bank at 800–495–4981. 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 979033) 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 2025, or To Register a New Establishment for FY 2025

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 2024. 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 Small Business Certification Request and the supporting 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 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 (section 738(d) of the FD&C Act).

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 2025, there is no small business waiver for the annual establishment registration fee; all establishments pay the same fee.

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. FDA has discretion to refund a fee or a portion of the fee. A determination by FDA concerning a refund shall not be reviewable. For more information on qualifying and submitting a refund, see section 738(a)(2)(D) of the FD&C Act.

Dated: July 26, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–16883 Filed 7–30–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–3423]

Biosimilar User Fee Rates for Fiscal Year 2025

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the rates for biosimilar user fees for fiscal year (FY) 2025. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Biosimilar User Fee Amendments of 2022 (BsUFA III), authorizes FDA to assess and collect user fees for certain activities in connection with biosimilar biological product development; review of certain applications for approval of biosimilar biological products; and each biosimilar biological product approved in a biosimilar biological product application. BsUFA III directs FDA to establish, before the beginning of each fiscal year, the amount of initial and annual biosimilar biological product development (BPD) fees, the reactivation fee, and the biosimilar biological product application and program fees for such year. These fees apply to the period from October 1, 2024, through September 30, 2025.

FOR FURTHER INFORMATION CONTACT: Olufunmilayo Ariyo, Office of Financial Management, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 240–402–4989, and the User Fees Support Staff at *OO-OFBAP-OFM-UFSS-Government@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Sections 744G, 744H, and 744I of the FD&C Act (21 U.S.C. 379j–51, 379j–52, and 379j–53), as amended by BsUFA III, authorize the collection of fees for biosimilar biological products. Under section 744H(a)(1)(A) of the FD&C Act, the initial BPD fee for a product is due when the sponsor submits an investigational new drug (IND) application that FDA determines is intended to support a biosimilar biological product application or within 7 calendar days after FDA grants the first BPD meeting, whichever occurs first. A sponsor who has paid the initial BPD fee is considered to be participating in FDA's BPD program for that product.

Under section 744H(a)(1)(B) of the FD&C Act, once a sponsor has paid the initial BPD fee for a product, the annual BPD fee is assessed beginning with the next fiscal year. The annual BPD fee is assessed for the product each fiscal year until the sponsor submits a marketing application for the product that is accepted for filing, the sponsor discontinues participation in FDA's BPD program for the product, or the sponsor has been administratively removed from the BPD program for the product.

Under section 744H(a)(1)(D) of the FD&C Act, if a sponsor has discontinued participation in FDA's BPD program or has been administratively removed from the BPD program for a product and wants to reengage with FDA on development of the product, the sponsor must pay all annual BPD fees previously assessed for such product and still owed, and a reactivation fee to resume participation in the program. The sponsor must pay the reactivation fee by the earlier of the following dates: (1) no later than 7 calendar days after FDA grants the sponsor's request for a BPD meeting for that product or (2) upon the date of submission by the sponsor of an IND describing an investigation that FDA determines is intended to support a biosimilar biological product application for that product. The sponsor will be assessed an annual BPD fee beginning in the next fiscal year after payment of the reactivation fee.

BsUFA III also authorizes fees for certain biosimilar biological product applications and for each biosimilar biological product identified in an approved biosimilar biological product application (section 744H(a)(2) and (3) of the FD&C Act). Under certain conditions, FDA will grant a small business a waiver of the biosimilar biological product application fee (section 744H(d)(1) of the FD&C Act).

For FY 2023 through FY 2027, the base revenue amounts for the total revenues from all BsUFA fees are established by BsUFA III. For FY 2025, the base revenue amount is the FY 2024 total revenue amount excluding any operating reserve adjustment, which equates to the amount of $51,058,823. The FY 2025 base revenue amount is to be adjusted by the inflation adjustment, strategic hiring and retention adjustment, capacity planning adjustment (CPA), operating reserve adjustment, and the additional dollar amount. Each of these adjustments will be discussed in the sections below.

This document provides fee rates for FY 2025 for the initial and annual BPD fee ($10,000), for the reactivation fee ($20,000), for an application requiring clinical data ($1,471,118) for an application not requiring clinical data ($735,559) and for the program fee ($256,168). These fees are effective on October 1, 2024, and will remain in effect through September 30, 2025. For applications that are submitted on or after October 1, 2024, the new fee schedule must be used.

II. Fee Revenue Amount for FY 2025

The base revenue amount for FY 2025 is $51,058,823 prior to adjustments for inflation, strategic hiring and retention, capacity planning, operating reserves, and the additional dollar amount (see section 744H(b) and (c) of the FD&C Act).

A. FY 2025 Statutory Fee Revenue Adjustments for Inflation

BsUFA III specifies that the $51,058,823 is to be adjusted for inflation increases for FY 2025 using two separate adjustments: one for personnel compensation and benefits (PC&B) and one for non-PC&B costs (see section 744H(c)(1) of the FD&C Act).

The component of the inflation adjustment for payroll costs shall be the average annual percent change in the cost of all PC&B paid per full-time