TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

| Activity; 21 CFR section | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| Content and format of a Medication Guide; § 208.20 | 41 | 1 | 41 | 320 | 13,120 |
| Exemptions and deferrals; § 208.26(a) | 1 | 1 | 1 | 4 | 4 |
| Total | | | 42 | | 13,124 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Upon evaluation of the information collection, we have removed burden we attributed to reporting associated with supplements and other changes to approved abbreviated new drug applications, new drug applications, and biologics license applications (21 CFR 314.70(b)(3)(ii) and 601.12(f)). We now account for burden associated with these regulatory provisions in OMB control numbers 0910–0001 and 0910–0338 and have decreased the burden associated with this collection accordingly.

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

| Activity; 21 CFR section | Number of respondents | Number of disclosures per respondent | Total annual disclosures | Average burden per disclosure [2] | Total hours |
|---|---|---|---|---|---|
| Distribute Medication Guides to authorized dispensers; § 208.24(c) | 191 | 9,000 | 1,719,000 | 1.25 | 2,148,750 |
| Distribute and Dispense Medication Guides to Patients; § 208.24(e) | 88,000 | 5,705 | 502,040,000 | 0.05 (3 minutes) | 25,102,000 |
| Total | | | 503,759,000 | | 27,250,750 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Numbers may not sum due to rounding.

We have decreased our estimated burden associated with disclosures to reflect a decrease in related submissions over the past 3 years.

Dated: September 30, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2022–21840 Filed 10–6–22; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2022–N–2353]**

### Medical Device User Fee Rates for Fiscal Year 2023

**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) 2023. 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 2023, which apply from October 1, 2022, through September 30, 2023, and provides information on how the fees for FY 2023 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 related 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 related to this notice:* Robert Marcarelli, Office of Financial Management, Food and Drug Administration, 4041 Powder Mill Rd, Rm. 61075, Beltsville, MD 20705–4304, 301–796–7223, and the User Fees Support Staff at *OO-OFBAP-OFM-UFSS-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 2023 is $425,000. From this starting point, this document establishes FY 2023 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 21 U.S.C. 379j(d) and (e)). 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 2023 is $6,250. 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 2023

The total revenue amount for FY 2023 is $312,606,000, as set forth in the statute prior to the inflation adjustment (see 21 U.S.C. 379j(b)(3)). 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 2023 are described in this document.

### *Inflation Adjustment*

MDUFA specifies that the $312,606,000 is to be adjusted for inflation increases for FY 2023 using two separate adjustments: one for payroll costs and one for non-payroll costs (see 21 U.S.C. 379j(c)(2)). The base inflation adjustment for FY 2023 is the sum of one plus the two separate adjustments and is compounded as specified in the statute (see 21 U.S.C. 379j(c)(2)(C) and 379j(c)(2)(B)).

The component of the inflation adjustment for payroll costs is the average annual percent change in the cost of all personnel compensation and benefits (PC&B) paid per full-time equivalent position (FTE) at FDA for the first 3 of the 4 preceding FYs, multiplied by 0.60, or 60 percent (see 21 U.S.C. 379j(c)(2)(C)).

Table 1 summarizes the actual cost and FTE data for the specified FYs, 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 2023. The 3-year average is 1.3918 percent (rounded).

Table 1.--FDA PC&Bs Each Year and Percent Change

| | FY 2019 | FY 2020 | FY 2021 | 3-Year Average |
|---|---|---|---|---|
| Total PC&B | $ 2,620,052,000 | $ 2,875,592,000 | $ 3,039,513,000 | |
| Total FTE | $ 17,144 | $ 17,535 | $ 18,501 | |
| PC&B per FTE | $ 152,826 | $ 163,992 | $ 164,289 | |
| Percent Change From Previous Year | -3.3120% | 7.3063% | 0.1811% | 1.3918% |

The payroll adjustment is 1.3918 percent multiplied by 60 percent, or 0.8351 percent. The statute specifies that the component of the inflation adjustment for non-payroll costs for FY 2023 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 21 U.S.C. 379j(c)(2)(C)).

Table 2 provides the summary data and the 3-year average percent change in the specified CPI for the 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

| | 2019 | 2020 | 2021 | 3-Year Average |
|---|---|---|---|---|
| Annual CPI | 264.78 | 267.16 | 277.73 | |
| Annual Percent Change | 1.2745% | 0.8989% | 3.9568% | 2.0434% |

The non-payroll adjustment is 2.0434 percent multiplied by 40 percent, or 0.8174 percent. Next, the payroll adjustment (0.8351 percent or 0.008351) is added to the non-payroll adjustment (0.8174 percent or 0.008174), for a total of 1.6525 percent (or 0.016525). To complete the inflation adjustment, 1 (100 percent or 1.0) is added for a total base inflation adjustment of 1.016525 for FY 2023.

MDUFA V provides for this inflation adjustment to be compounded for FY 2023 and each subsequent fiscal year (see 21 U.S.C. 379j(c)(2)(B)(ii)). To complete the compounded inflation adjustment for FY 2023, the FY 2022 base adjustment (1.022046) is multiplied by the FY 2023 base inflation adjustment (1.016525) to reach the applicable inflation adjustment of 1.038935 (rounded) for FY 2023. We then multiply the total revenue amount for FY 2023 ($312,606,000) by 1.038935, yielding an inflation-adjusted total revenue amount of $324,777,000 (rounded to the nearest thousand dollar).

## III. Adjustments to Base Fee Amounts for FY 2023

Under the FD&C Act, all submission fees and the periodic reporting fee are set as a percent of the standard (full) fee for a premarket application (see 21 U.S.C. 379j(a)(2)(A)).

### *A. Inflation Adjustment*

MDUFA specifies that the base fees of $425,000 (premarket application) and $6,250 (establishment registration) are to be adjusted for FY 2023 using the same methodology as that for the total revenue inflation adjustment in section

II (see 21 U.S.C. 379j(c)(2)(D)(i)). Multiplying the base fees by the compounded inflation adjustment of 1.038935 yields inflation-adjusted base fees of $441,547 (premarket application) and $6,493 (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 21 U.S.C. 379j(c)(2)(D)(ii)). After this adjustment, if necessary, FDA may further increase the base establishment registration fees to generate the inflation-adjusted total revenue amount (see 21 U.S.C. 379j(c)(3)).

*C. 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. Only the operating reserve adjustment is potentially applicable in FY 2023.

1. Performance Improvement Adjustment

For FY 2023, there is no 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 21 U.S.C. 379j(c)(4)).

2. Hiring Adjustment

For FY 2023, there is no 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 21 U.S.C. 379j(c)(5)).

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 21 U.S.C. 379j(c)(6)). 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 21 U.S.C. 379j(c)(6)(C)). For FY 2023, this excluded amount is $118,000,000.

The designated amount is equal to the sum of 13 weeks of operating reserves of carryover user fees plus 1 month of operating reserves described in 21 U.S.C. 379j(c)(8) (see 21 U.S.C. 379j(c)(6)(B)).

To determine the 13-week operating reserves of carryover user fees amount, the FY 2023 inflation-adjusted total revenue amount, $324,777,000 is divided by 52, and then multiplied by 13. The 13-week operating reserve amount for FY 2023 is $81,194,250.

To determine the 1 month of operating reserves described in 21 U.S.C. 379j(c)(8), the FY 2023 inflation-adjusted total revenue amount of $324,777,000 is divided by 12. The 1 month of operating reserves for FY 2023 is $27,064,750.

For FY 2023, the designated amount is equal to the 13-week operating reserve of $81,194,250 plus the 1 month of operating reserves of $27,064,750, totaling $108,259,000.

To determine the FY 2022 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 2022) and added the forecasted collections and obligations for the fourth quarter of FY 2022 to generate a full year estimate for FY 2022. The estimated end-of-year FY 2022 operating reserves of carryover user fees is $40,290,467. (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 ($57,171,986). In addition, as noted above, for purposes of the operating reserve adjustment, operating reserves of carryover user fees do not include the $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 2022 MDUFA operating reserves of carryover user fees amount totaling $40,290,467 does not exceed the FY 2023 designated amount of $108,259,105, FDA will not decrease the base establishment registration fee amounts for FY 2023 to provide for not more than such designated amount.

## IV. Calculation of Fee Rates

As noted in section II, the total revenue amount after the applicable inflation adjustment is $324,777,000 (rounded to the nearest thousand dollar). As noted in section III, there is no MDUFA V adjustment solely to registration fees for FY 2023.

Table 3 provides the last 3 years of fee-paying submission counts and the 3-year average. These numbers are used to project the fee-paying submission counts that FDA will receive in FY 2023.

Table 3.--Three-Year Average of Fee-Paying Submissions[1]

| Application Type | FY 2019 Actual | FY 2020 Actual | FY 2021 Actual | 3-Year Average |
|---|---|---|---|---|
| Full Fee Applications | 32 | 29 | 25 | 29 |
| Small Business | 8 | 7 | 5 | 7 |
| Panel-Track Supplement | 15 | 23 | 31 | 23 |
| Small Business | 4 | 6 | 6 | 5 |
| De Novo Classification Request | 16 | 20 | 16 | 17 |
| Small Business | 39 | 47 | 42 | 43 |
| 180-Day Supplements | 125 | 124 | 98 | 116 |
| Small Business | 24 | 20 | 34 | 26 |
| Real-Time Supplements | 209 | 175 | 150 | 178 |
| Small Business | 43 | 28 | 20 | 30 |
| 510(k)s | 2,082 | 2,048 | 2,133 | 2,088 |
| Small Business | 1,573 | 1,667 | 1,846 | 1,695 |
| 30-Day Notice | 924 | 870 | 843 | 879 |
| Small Business | 110 | 104 | 77 | 97 |
| 513(g) (21 U.S.C. 360c(g)) Request for Classification Information | 78 | 96 | 83 | 86 |
| Small Business | 54 | 57 | 53 | 55 |
| Annual Fee for Periodic Reporting | 640 | 622 | 613 | 625 |
| Small Business[2] | 98 | 95 | 84 | 92 |
| Establishment Registration | 27,728 | 41,942 | 33,812 | 34,494 |

[1] Includes collection of quarter 4 billing for FYs 2019, 2020, and 2021 during FY 2021.

The information in table 3 is necessary to estimate the amount of revenue that will be collected based on the fee amounts. Table 4 displays the FY 2023 base fees set in statute (column one) and the inflation-adjusted base fees (per calculations in section III.A.) (column two). Using the inflation-adjusted fees and the 3-year averages of fee-paying submissions, collections are projected to total $330,787,011, which is $6,010,011 higher than the inflation-adjusted total revenue amount (in section II). The fees in column two are those FDA is establishing in FY 2023. The fees in column two are the standard fees.

Table 4.--Fees Needed to Achieve New FY 2023 Revenue Target

| Application Type | FY 2023 Statutory Fees (Base Fees) | FY 2023 Inflation Adjusted Statutory Base Fees (Standard Fees) | 3-Year Average of Fee-Paying Submissions | FY 2023 Revenue from Adjusted Fees |
|---|---|---|---|---|
| Full Fee Applications | $425,000 | $441,547 | 29 | $12,804,863 |
| Small Business | $106,250 | $110,387 | 7 | $772,709 |
| Panel-Track Supplement | $340,000 | $353,238 | 23 | $8,124,474 |
| Small Business | $85,000 | $88,309 | 5 | $441,545 |
| De Novo Classification Request | $127,500 | $132,464 | 17 | $2,251,888 |
| Small Business | $31,875 | $33,116 | 43 | $1,423,988 |
| 180-Day Supplements | $63,750 | $66,232 | 116 | $7,682,912 |
| Small Business | $15,938 | $16,558 | 26 | $430,508 |
| Real-Time Supplements | $29,750 | $30,908 | 178 | $5,501,624 |
| Small Business | $7,438 | $7,727 | 30 | $231,810 |
| 510(k)s | $19,125 | $19,870 | 2,088 | $41,488,560 |
| Small Business | $4,781 | $4,967 | 1,695 | $8,419,065 |
| 30-Day Notice | $6,800 | $7,065 | 879 | $6,210,135 |
| Small Business | $3,400 | $3,532 | 97 | $342,604 |
| 513(g) Request for Classification Information | $5,738 | $5,961 | 86 | $512,646 |
| Small Business | $2,869 | $2,980 | 55 | $163,900 |
| Annual Fee for Periodic Reporting | $14,875 | $15,454 | 625 | $9,658,750 |
| Small Business | $3,719 | $3,864 | 92 | $355,488 |
| Establishment Registration | $6,250 | $6,493 | 34,494 | $223,969,542 |
| Total | | | | $330,787,011 |

The standard fee (adjusted base amount) for a premarket application, including a BLA, and for a premarket report and a BLA efficacy supplement, is $441,547 for FY 2023. 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; and
- For a 513(g) request for classification information, 1.35 percent of the standard fee.

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

The annual fee for establishment registration, after adjustment, is set at $6,493 for FY 2023. For FY 2023, 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 2023 rates for all medical device fees.

Table 5.--Medical Device Fees for FY 2023

| Application Fee Type | Standard Fee (as a percent of the standard fee for a premarket application) | FY 2023 Standard Fee | FY 2023 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 | $441,547 | $110,387 |
| Premarket report (submitted under section 515(c)(2) of the FD&C Act) | 100% | $441,547 | $110,387 |
| Efficacy supplement (to an approved BLA under section 351 of the PHS Act) | 100% | $441,547 | $110,387 |
| Panel-track supplement | 80% | $353,238 | $88,309 |
| De novo classification request | 30% | $132,464 | $33,116 |
| 180-day supplement | 15% | $66,232 | $16,558 |
| Real-time supplement | 7% | $30,908 | $7,727 |
| 510(k) premarket notification submission | 4.5% | $19,870 | $4,967 |
| 30-day notice | 1.60% | $7,065 | $3,532 |
| 513(g) request for classification information | 1.35% | $5,961 | $2,980 |
| Annual Fee Type | | | |
| Annual fee for periodic reporting on a class III device | 3.50% | $15,454 | $3,864 |
| 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 | $6,493 | $6,493 |

## 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 should 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. As a result, if the establishment registration fee is the only medical device user fee that you will pay in FY 2023, 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 2022, your status as a small business will expire at the close of business on September 30, 2022. You must re-qualify for FY 2023 in order to pay small business fees during FY 2023.

### *A. Domestic (U.S.) Businesses*

If you are a domestic (U.S.) business and wish to qualify as a small business for FY 2023, 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/downloads/AboutFDA/ReportsManualsForms/Forms/UCM573420.pdf.*

2. A signed copy of your Federal (U.S.) Income Tax Return for the most recent tax year. The most recent tax year will be 2022, except:

If you submit your MDUFA Small Business Certification Request for FY 2023 before April 15, 2023, and you have not yet filed your return for 2022, you may use tax year 2021.

If you submit your MDUFA Small Business Certification Request for FY 2023 on or after April 15, 2023, and have not yet filed your 2022 return because you obtained an extension, you may submit your most recent return filed prior to the extension.

3. For each of your affiliates, either:

- If the affiliate is a domestic (U.S.) business, a signed copy of the affiliate's Federal (U.S.) Income Tax Return for the most recent tax year, or
- If the affiliate is a foreign business and cannot submit a Federal (U.S.) Income Tax Return, a National Taxing Authority Certification completed by, and bearing the official seal of, the National Taxing Authority of the country in which the firm is

headquartered. The National Taxing Authority is the foreign equivalent of the U.S. Internal Revenue Service. This certification must show the amount of gross receipts or sales for the most recent tax year, in both U.S. dollars and the local currency of the country, the exchange rate used in converting the local currency to U.S. dollars, and the dates of the gross receipts or sales collected. The business must also submit a statement signed by the head of the business's firm or by its chief financial officer that the business has submitted certifications for all of its affiliates, identifying the name of each affiliate, or that the business has no affiliates.

4. Once you have completed your Form FDA 3602, print and sign the form. Mail the completed form and your supporting documentation (copies of the Federal (U.S.) income tax returns) to Medical Device User Fee Small Business Certification Request mailing address, which is 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 2023, submit the following:

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

2. A National Taxing Authority Certification completed by, and bearing the official seal of, the National Taxing Authority of the country in which the firm is headquartered. This certification must show the amount of gross receipts or sales for the most recent tax year, in both U.S. dollars and the local currency of the country, the exchange rate used in converting the local currency to U.S. dollars, and the dates of the gross receipts or sales collected.

3. For each of your affiliates, either:

- If the affiliate is a domestic (U.S.) business, a signed copy of the affiliate's Federal (U.S.) Income Tax Return for the most recent tax year (2021 or later), or
- If the affiliate is a foreign business and cannot submit a Federal (U.S.) Income Tax Return, a National Taxing Authority Certification completed by, and bearing the official seal of, the National Taxing Authority, of the country in which the firm is headquartered. The National Taxing Authority is the foreign equivalent of the U.S. Internal Revenue Service. This certification must show the amount of gross receipts or sales for the most recent tax year, in both U.S. dollars and the local currency of the country, the exchange rate used in converting the local currency to U.S. dollars, and the dates for the gross receipts or sales collected. The business must also submit a statement signed by the head of the business's firm or by its chief financial officer that the applicant has submitted certifications for all of its affiliates, identifying the name of each affiliate, or that the business has no affiliates.

4. Once you have completed your Form FDA 3602A, print and sign the form. Mail the completed form and your supporting documentation including the following to CDRH's Medical Device User Fee Small Business Certification Request address, which is 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, 2022, and September 30, 2023, you must pay the fee in effect for FY 2023. 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 2022 or FY 2023 apply. FDA must receive the correct fee at the time that an application is submitted or the application will not be accepted for fling 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, 2022. One choice is for applications and fees that will be received on or before September 30, 2022, which are subject to FY 2022 fee rates. A second choice is for applications and fees received on or after October 1, 2023, which are subject to FY 2023 fee rates.) After completing data entry, print a copy of the Medical Device User Fee cover sheet and note the unique PIN located in the upper right-hand corner of the printed cover sheet.

*B. Electronically Transmit a Copy of the Printed Cover Sheet With the PIN*

When you are satisfied that the data on the cover sheet is accurate, electronically transmit that data to FDA according to instructions on the screen. Applicants are required to set up a user account and password to assure data security in the creation and electronic submission of cover sheets.

*C. Submit Payment for the Completed Medical Device User Fee Cover Sheet*

1. The preferred payment method is online using electronic check (Automated Clearing House (ACH) also known as eCheck) or credit card (Discover, VISA, MasterCard, American Express). FDA has partnered with the U.S. Department of the Treasury to utilize *Pay.gov,* a web-based payment system, for online electronic payment. You may make a payment via electronic check or credit card after submitting your cover sheet. Secure electronic payments can be submitted using the User Fees Payment Portal at *https://userfees.fda.gov/pay. Note:* Only full payments are accepted. No partial payments can be made online. Once you search for your invoice, select ''Pay Now'' to be redirected to *Pay.gov.* Electronic payment options are based on the balance due. Payment by credit card is available for balances that are less than $25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be made using U.S bank accounts as well as U.S. credit cards.

2. If paying with a paper check:

• All paper checks must be in U.S. currency from a U.S. bank and made payable to the Food and Drug Administration. If needed, FDA's tax identification number is 53–0196965.

• Please write your application's unique PIN (from the upper right-hand corner of your completed Medical Device User Fee cover sheet) on your check.

• *Mail the paper check and a copy of the completed cover sheet to:* Food and Drug Administration, P.O. Box 979033, St. Louis, MO 63197–9000. (Please note that this address is for payments of application and annual report fees only and is not to be used for payment of annual establishment registration fees.)

If you prefer to send a check by a courier, the courier may deliver the check to: U.S. Bank, Attn: Government Lockbox 979033, 1005 Convention Plaza, St. Louis, MO 63101. (*Note:* This U.S. Bank address is for courier delivery only. If you have any questions concerning courier delivery, contact U.S. Bank at 314–418–4013. This telephone number is only for questions about courier delivery).

3. If paying with a wire transfer:

• Please include your application's unique PIN (from the upper right-hand corner of your completed Medical Device User Fee cover sheet) in your wire transfer. Without the PIN, your payment may not be applied to your cover sheet and review of your application may be delayed.

• The originating financial institution may charge a wire transfer fee. If the financial institution charges a wire transfer fee, it is required that you add that amount to the payment to ensure that the invoice is paid in full.

Use the following account information when sending a wire transfer: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St, New York, NY 10045, Acct. No. 75060099, Routing No. 021030004, SWIFT: FRNYUS33.

FDA records the official application receipt date as the later of the following: (1) the date the application was received by the FDA Document Control Center for the reviewing Center or (2) the date the U.S. Treasury recognizes the payment.

### *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. (Please note that this address is for payments of application and annual report fees only and is not to be used for payment of annual establishment registration fees.)

To send a check by a courier, the courier must deliver the check and printed copy of the cover sheet to U.S. Bank, Attn: Government Lockbox 979033, 1005 Convention Plaza, St. Louis, MO 63101. (*Note:* This U.S. Bank address is for courier delivery only. If you have any questions concerning courier delivery, contact U.S. Bank at 314–418–4013. This telephone number is only for questions about courier delivery).

3. When paying by a wire transfer, it is required that the invoice number is included; without the invoice number, the payment may not be applied. If the payment amount is not applied, the invoice amount would be referred to collections. The originating financial institution may charge a wire transfer fee. If the financial institution charges a wire transfer fee, it is required that you add that amount to the payment to ensure that the invoice is paid in full.

Use the following account information when sending a wire transfer: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St, New York, NY 10045, Acct. No. 75060099, Routing No. 021030004, SWIFT: FRNYUS33.

## 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 2023 until it has completed the steps below to register and pay any applicable fee (see 21 U.S.C. 379j(f)(2)).

Companies that do not manufacture any product other than a licensed biologic are required to register in the Blood Establishment Registration (BER) system. FDA's Center for Biologics Evaluation and Research (CBER) will send establishment registration fee invoices annually to these companies.

### *A. Submit a DFUF Order With a PIN From FDA Before Registering or Submitting Payment*

To submit a DFUF order, you must create or have previously created a user account and password for the user fee website listed previously in this section. After creating a user name and password, log into the Establishment Registration User Fee FY 2023 store. Complete the DFUF order by entering the number of establishments you are registering that require payment. When you are satisfied that the information in the order is accurate, electronically transmit that data to FDA according to instructions on the screen. Print a copy of the final DFUF order and note the unique PIN located in the upper right-hand corner of the printed order.

*B. Pay for Your DFUF Order*

Unless paying by U.S. credit card, all payments must be in U. S. currency and drawn on a U.S. bank.

1. *If paying by credit card or electronic check (ACH or eCheck):* The DFUF order will include payment information, including details on how you can pay online using a credit card or electronic check. Follow the instructions provided to make an electronic payment.

2. *If paying with a paper check:* The check must be in U.S. currency and drawn on a U.S. bank, and mailed to: Food and Drug Administration, P.O. Box 979108, St. Louis, MO 63197–9000. (*Note:* This address is different from the address for payments of application and annual report fees and is to be used only for payment of annual establishment registration fees.)

If a check is sent by a courier that requests a street address, the courier can deliver the check to: U.S. Bank, Attn: Government Lockbox 979108, 1005 Convention Plaza, St. Louis, MO 63101. (*Note:* This U.S. Bank address is for courier delivery only. If you have any questions concerning courier delivery, contact U.S. Bank at 314–418–4013. This telephone number is only for questions about courier delivery.)

Please make sure that both of the following are written on your check: (1) the FDA post office box number (P.O. Box 979108) and (2) the PIN that is printed on your order. Include a copy of your printed order when you mail your check.

3. *If paying with a wire transfer:* Wire transfers may also be used to pay annual establishment registration fees. To send a wire transfer, please read and comply with the following information:

Include your order's unique PIN (in the upper right-hand corner of your completed DFUF order) in your wire transfer. Without the PIN, your payment may not be applied to your facility and your registration may be delayed.

The originating financial institution may charge a wire transfer fee. If the financial institution charges a wire transfer fee, it is required that you add that amount to the payment to ensure that the invoice is paid in full. Use the following account information when sending a wire transfer: U.S. Dept. of the Treasury, TREAS NYC, 33 Liberty St, New York, NY 10045, Acct. No. 75060099, Routing No. 021030004, SWIFT: FRNYUS33. If needed, FDA's tax identification number is 53–0196965.

*C. Complete the Information Online To Update Your Establishment's Annual Registration for FY 2023, or To Register a New Establishment for FY 2023*

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 2022. 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 (see 21 U.S.C. 379j(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*

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 21 U.S.C. 379j(a)(2)(D).

Dated: October 4, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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