addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Bradley Cunningham, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1414, Silver Spring, MD 20993–0002, 301–796–6484.

SUPPLEMENTARY INFORMATION:

I. Background

LASIK is currently one of the most commonly performed elective procedures in the world, as well as the most popular form of refractive surgery that patients choose to correct common vision problems such as nearsightedness, farsightedness, and astigmatism.[1] On April 25, 2008, FDA convened its Ophthalmic Devices Panel of the Medical Devices Advisory Committee to discuss recommendations for modifications to patient labeling of excimer lasers for LASIK as well as other LASIK-related activities. Since the LASIK Advisory Committee meeting, FDA has continued to gather new information pertaining to risks associated with LASIK. This draft guidance recommends content and formatting for patient labeling information for LASIK devices. FDA is issuing this guidance to help ensure that physicians can share and patients can understand information on the benefits and risks of these devices. The recommendations are being made based on concerns the Agency has received regarding patients not receiving and/or understanding key information regarding the benefits and risks of LASIK devices. These labeling recommendations are intended to enhance, but not replace, the physician-patient discussion of the benefits and risks of LASIK devices that uniquely pertain to individual patients.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Laser-Assisted In Situ Keratomileusis (LASIK) Lasers—Patient Labeling Recommendations.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov* or *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.* Persons unable to download an electronic copy of ''Laser-Assisted In Situ Keratomileusis (LASIK) Lasers—Patient Labeling Recommendations'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 16053 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in the following FDA regulations have been approved by OMB as listed in the following table:

21 CFR part	Topic	OMB Control No.
814, subparts A through E	Premarket approval	0910–0231
800, 801, and 809	Medical Device Labeling Regulations	0910–0485

Dated: July 22, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–16166 Filed 7–27–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–1601]

Outsourcing Facility Fee Rates for Fiscal Year 2023

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the fiscal year (FY) 2023 rates for the establishment and reinspection fees related to entities that compound human drugs and elect to register as outsourcing facilities under the Federal Food, Drug, and Cosmetic Act (FD&C Act). The FD&C Act authorizes FDA to assess and collect an annual establishment fee from outsourcing facilities, as well as a reinspection fee for each reinspection of an outsourcing facility. This document establishes the FY 2023 rates for the small business establishment fee ($5,941), the non-small business establishment fee ($18,661), and the reinspection fee ($17,823) for outsourcing facilities; provides information on how the fees for FY 2023 were determined; and describes the payment procedures outsourcing facilities should follow.

DATES: These fee rates are effective October 1, 2022, and will remain in effect through September 30, 2023.

ADDRESSES: Office of Financial Management, Food and Drug Administration, 4041 Powder Mill Rd., Rm. 61075, Beltsville, MD.

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

For questions relating to this notice, contact: Robert Marcarelli, User Fees Support Team at DUF-Budget, Food and Drug Administration, *OO-OFBAP-OFM-DUF-Budget@fda.hhs.gov,* 301–796–7223.

SUPPLEMENTARY INFORMATION:

I. Background

Under section 503B of the FD&C Act (21 U.S.C. 353b), a human drug

[1] Vitale, S., Cotch, M.F., Sperduto, R., Ellwein L., ''Costs of Refractive Correction of Distance Vision Impairment in the United States, 1999–2002,'' *Ophthalmology,* vol. 113, pp. 2163–2170, 2006.

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

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

FDA announced in the **Federal Register** of November 24, 2014 (79 FR 69856), the availability of a final guidance for industry entitled ''Fees for Human Drug Compounding Outsourcing Facilities Under Sections 503B and 744K of the FD&C Act.'' The guidance provides additional information on the annual fees for outsourcing facilities and adjustments required by law, reinspection fees, how to submit payment, the effect of failure to pay fees, and how to qualify as a small business to obtain a reduction of the annual establishment fee. This guidance can be accessed on FDA's website at: *https://www.fda.gov/media/136683/download.*

II. Fees for FY 2023

A. Methodology for Calculating FY 2023 Adjustment Factors

1. Inflation Adjustment Factor

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

Table 1 summarizes the actual cost and FTE data for the specified fiscal years and provides the percent change from the previous fiscal year and the average percent change over the first 3 of the 4 fiscal years preceding FY 2023. The 3-year average is 1.3918 percent.

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 Prevous Year	−3.3120%	7.3063%	0.1811%	1.3918%

Section 744K(c)(2)(A)(ii) of the FD&C Act specifies that this 1.3918 percent should be multiplied by the proportion of PC&B to total costs of an average FDA FTE for the same 3 fiscal years.

TABLE 2—FDA PC&BS AS A PERCENT OF FDA TOTAL COSTS OF AN AVERAGE FTE

	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 Costs	$5,663,389,000	$6,039,320,747	$6,105,480,000	
PC&B Percent	46.2630%	47.6145%	49.7834%	47.8870%

The payroll adjustment is 1.3918 percent multiplied by 47.8870 percent, or 0.6665 percent.

Section 744K(c)(2)(A)(iii) of the FD&C Act specifies that the portion of the inflation adjustment for non-payroll costs for FY 2023 is equal to the average annual percent change in the Consumer Price Index (CPI) for urban consumers (U.S. City Average; Not Seasonally Adjusted; All items; Annual Index) for the first 3 years of the preceding 4 years of available data, multiplied by the proportion of all non-PC&B costs to total costs of an average FDA FTE for the same period.

Table 2 provides the summary data for the percent change in the specified CPI for U.S. cities. These data are published by the Bureau of Labor Statistics and can be found on its website: *https://data.bls.gov/cgi-bin/surveymost?cu. The data can be viewed* by checking the box marked ''U.S. city average, All items—CUUR0000SA0'' and then selecting ''Retrieve Data.''

TABLE 3—ANNUAL AND 3-YEAR AVERAGE PERCENT CHANGE IN U.S. CITY AVERAGE CPI

	2019	2020	2021	3-Year average
Annual CPI	255.66	258.81	270.97	.....
Annual Percent Change	1.8120%	1.2337%	4.6980%	2.5812%

Section 744K(c)(2)(A)(iii) of the FD&C Act specifies that this 2.5812 percent should be multiplied by the proportion of all non-PC&B costs to total costs of an average FTE for the same 3 fiscal years. The proportion of all non-PC&B costs to total costs of an average FDA FTE for FYs 2019 to 2021 is 52.1130 percent (100 percent minus 47.8870 percent equals 52.1130 percent). Therefore, the non-pay adjustment is 2.5812 percent times 52.1130 percent, or 1.3451 percent.

The PC&B component (0.6665 percent) is added to the non-PC&B component (1.3451 percent), for a total inflation adjustment of 2.0116 percent (rounded). Section 744K(c)(2)(A)(i) of the FD&C Act specifies that one is added to that figure, making the inflation adjustment 1.020116.

Section 744K(c)(2)(B) of the FD&C Act provides for this inflation adjustment to be compounded after FY 2015. This factor for FY 2023 (2.0116 percent) is compounded by adding one to it, and then multiplying it by one plus the inflation adjustment factor for FY 2022 (16.4796 percent), as published in the **Federal Register** on July 28, 2021 (86 FR 40588). The result of this multiplication of the inflation factors for the 8 years since FY 2015 (1.020116×1.164796) becomes the inflation adjustment for FY 2023. For FY 2023, the inflation adjustment is 18.8227 percent (rounded). We then add one, making the FY 2023 inflation adjustment factor 1.188227.

2. Small Business Adjustment Factor

Section 744K(c)(3) of the FD&C Act specifies that in addition to the inflation adjustment factor, the establishment fee for non-small businesses is to be further adjusted for a small business adjustment factor. Section 744K(c)(3)(B) of the FD&C Act provides that the small business adjustment factor is the adjustment to the establishment fee for non-small businesses that is necessary to achieve total fees equaling the amount that FDA would have collected if no entity qualified for the small business exception in section 744K(c)(4) of the FD&C Act. Additionally, section 744K(c)(5)(A) states that in establishing the small business adjustment factor for a fiscal year, FDA shall provide for the crediting of fees from the previous year to the next year if FDA overestimated the amount of the small business adjustment factor for such previous fiscal year.

Therefore, to calculate the small business adjustment to the establishment fee for non-small businesses for FY 2023, FDA must estimate: (1) the number of outsourcing facilities that will pay the reduced fee for small businesses for FY 2023 and (2) the total fee revenue it would have collected if no entity had qualified for the small business exception (*i.e.,* if each entity that registers as an outsourcing facility for FY 2023 were to pay the inflation-adjusted fee amount of $17,823).

With respect to (1), FDA estimates that 10 entities will qualify for small business exceptions and will pay the reduced fee for FY 2023. With respect to (2), to estimate the total number of entities that will register as outsourcing facilities for FY 2023, FDA used data submitted by outsourcing facilities through the voluntary registration process, which began in December 2013. Accordingly, FDA estimates that 78 outsourcing facilities, including 10 small businesses, will be registered with FDA in FY 2023.

If the projected 78 outsourcing facilities paid the full inflation-adjusted fee of $17,823, this would result in total revenue of $1,390,194 in FY 2023 ($17,823 \times 78$). However, 10 of the entities that are expected to register as outsourcing facilities for FY 2023 are projected to qualify for the small business exception and to pay one-third of the full fee ($5,941 \times 10$), totaling $59,410 instead of paying the full fee ($17,823 \times 10$), which would total $178,230. This would leave a potential shortfall of $118,820 ($178,230 minus $59,410).

Additionally, section 744K(c)(5)(A) of the FD&C Act states that in establishing the small business adjustment factor for a fiscal year, FDA shall provide for the crediting of fees from the previous year to the next year if FDA overestimated the amount of the small business adjustment factor for such previous fiscal year. FDA has determined that it is appropriate to credit excess fees collected from the last completed fiscal year, due to the inability to conclusively determine the amount of excess fees from the fiscal year that is in progress at the time this calculation is made. This crediting is done by comparing the small business adjustment factor for the last completed fiscal year, FY 2021 ($2,441), to what would have been the small business adjustment factor for FY 2021 ($1,582) if FDA had estimated perfectly.

The calculation for what the small business adjustment would have been if FDA had estimated perfectly begins by determining the total target collections ($15{,}000 \times$ (inflation adjustment factor) $\times$ (number of registrants). For the most recent complete fiscal year, FY 2021, this was $1,400,970 ($17{,}085 \times 82$). The actual FY 2021 revenue from the 82 total registrants (*i.e.,* 72 registrants paying FY 2021 non-small business establishment fee and 10 small business registrants) paying establishment fees is $1,287,070. $1,287,070 is calculated as follows: (FY 2021 Non-Small Business Establishment Fee adjusted for inflation only) $\times$ (total number of registrants in FY 2021 paying Non-Small Business Establishment Fee) + (FY 2021 Small Business Establishment Fee) $\times$ (total number of small business registrants in FY 2021 paying Small Business Establishment Fee). $\$17{,}085 \times 72 + \$5{,}695 \times 10 = \$1{,}287{,}070$. This left a shortfall of $113,900 from the estimated total target collection amount ($1,400,970 minus $1,287,070). This amount ($113,900) divided by the total number of registrants in FY 2021 paying Standard Establishment Fee (72) equals $1,582.

The difference between the small business adjustment factor used in FY 2021 and the small business adjustment factor that would have been used had FDA estimated perfectly is $859 ($2,441 minus $1,582). The $859 (rounded to the nearest dollar) is then multiplied by the number of actual registrants who paid the standard fee for FY 2021 (72), which provides us a total excess collection of $61,831 in FY 2021.

Therefore, to calculate the small business adjustment factor for FY 2023, FDA subtracts $61,831from the projected shortfall of $118,820 for FY 2023 to arrive at the numerator for the small business adjustment amount, which equals $56,989. This number divided by 68 (the number of expected non-small businesses for FY 2023) is the

small business adjustment amount for FY 2023, which is $838 (rounded to the nearest dollar).

B. FY 2023 Rates for Small Business Establishment Fee, Non-Small Business Establishment Fee, and Reinspection Fee

1. Establishment Fee for Qualified Small Businesses [1]

The amount of the establishment fee for a qualified small business is equal to $15,000 multiplied by the inflation adjustment factor for that fiscal year, divided by 3 (see section 744K(c)(4)(A) and (c)(1)(A) of the FD&C Act). The inflation adjustment factor for FY 2023 is 1.188227. See section II.A.1 of this document for the methodology used to calculate the FY 2023 inflation adjustment factor. Therefore, the establishment fee for a qualified small business for FY 2023 is one third of $17,823, which equals $5,941 (rounded to the nearest dollar).

2. Establishment Fee for Non-Small Businesses

Under section 744K(c) of the FD&C Act, the amount of the establishment fee for a non-small business is equal to $15,000 multiplied by the inflation adjustment factor for that fiscal year, plus the small business adjustment factor for that fiscal year, and plus or minus an adjustment factor to account for over or under collections due to the small business adjustment factor in the prior year. The inflation adjustment factor for FY 2023 is 1.188227. The small business adjustment amount for FY 2023 is $838. See section II.A.2 of this document for the methodology used to calculate the small business adjustment factor for FY 2023. Therefore, the establishment fee for a non-small business for FY 2023 is $15,000 multiplied by 1.188227plus $838, which equals $18,661 (rounded to the nearest dollar).

3. Reinspection Fee

Section 744K(c)(1)(B) of the FD&C Act provides that the amount of the FY 2023 reinspection fee is equal to $15,000, multiplied by the inflation adjustment factor for that fiscal year. The inflation adjustment factor for FY 2023 is 1.188227. Therefore, the reinspection fee for FY 2023 is $15,000 multiplied by 1.188227, which equals $17,823 (rounded to the nearest dollar). There is no reduction in this fee for small businesses.

C. Summary of FY 2023 Fee Rates

TABLE 4—OUTSOURCING FACILITY FEES

Qualified Small Business Establishment Fee	$5,941.00
Non-Small Business Establishment Fee	18,661.00
Reinspection Fee	17,823.00

III. Fee Payment Options and Procedures

A. Establishment Fee

Once an entity submits registration information and FDA has determined that the information is complete, the entity will incur the annual establishment fee. FDA will send an invoice to the entity, via email to the email address indicated in the registration file. The invoice will contain information regarding the obligation incurred, the amount owed, and payment procedures. A facility will not be registered as an outsourcing facility until it has paid the annual establishment fee under section 744K of the FD&C Act. Accordingly, it is important that facilities seeking to operate as outsourcing facilities pay all fees immediately upon receiving an invoice. If an entity does not pay the full invoiced amount within 15 calendar days after FDA issues the invoice, FDA will consider the submission of registration information to have been withdrawn and adjust the invoice to reflect that no fee is due.

Outsourcing facilities that registered in FY 2022 and wish to maintain their status as an outsourcing facility in FY 2023 must register during the annual registration period that lasts from October 1, 2022, to December 31, 2022. Failure to register and complete payment by December 31, 2022, will result in a loss of status as an outsourcing facility on January 1, 2023. Entities should submit their registration information no later than December 10, 2022, to allow enough time for review of the registration information, invoicing, and payment of fees before the end of the registration period.

B. Reinspection Fee

FDA will issue invoices for each reinspection after the conclusion of the reinspection, via email to the email address indicated in the registration file or via regular mail if email is not an option. Invoices must be paid within 30 days.

C. Fee Payment Procedures

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). 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, click ''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 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*: Checks must be in U.S. currency from a U.S. bank and made payable to the Food and Drug Administration. Payments can be mailed to: Food and Drug Administration, P.O. Box 979033, St. Louis, MO 63197–9000. Include invoice number on check. 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, 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 the U.S. Bank at 314–418–4013).

3. When paying by wire transfer, the invoice number must be included. Without the invoice number the payment may not be applied. Regarding reinspection fees, if the payment amount is not applied, the invoice amount will 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 the outsourcing facility 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.

[1] To qualify for a small business reduction of the FY 2023 establishment fee, entities had to submit their exception requests by April 30, 2022. See section 744K(c)(4)(B) of the FD&C Act. The time for requesting a small business exception for FY 2023 has now passed. An entity that wishes to request a small business exception for FY 2024 should consult section 744K(c)(4) of the FD&C Act and section III.D of FDA's guidance for industry entitled ''Fees for Human Drug Compounding Outsourcing Facilities Under sections 503B and 744K of the FD&C Act,'' which can be accessed on FDA's website at *https://www.fda.gov/media/136683/download.*

Dated: July 22, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–16170 Filed 7–27–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–1607]

Animal Drug User Fee Rates and Payment Procedures for Fiscal Year 2023

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the fee rates and payment procedures for fiscal year (FY) 2023 animal drug user fees. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Animal Drug User Fee Amendments of 2018 (ADUFA IV), authorizes FDA to collect user fees for certain animal drug applications and supplemental animal drug applications, for certain animal drug products, for certain establishments where such products are made, and for certain sponsors of such animal drug applications and/or investigational animal drug submissions. This notice establishes the fee rates for FY 2023.

DATES: The application fee rates are effective for applications submitted on or after October 1, 2022, and will remain in effect through September 30, 2023.

FOR FURTHER INFORMATION CONTACT: Visit FDA's website at *https://www.fda.gov/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/default.htm* or contact Lisa Kable, Center for Veterinary Medicine (HFV–10), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–6888, *Lisa.Kable@fda.hhs.gov*. For general questions, you may also email FDA's Center for Veterinary Medicine (CVM) at: *cvmadufa@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Section 740 of the FD&C Act (21 U.S.C. 379j–12), as amended by ADUFA IV, establishes four different types of user fees: (1) fees for certain types of animal drug applications and supplemental animal drug applications; (2) annual fees for certain animal drug products; (3) annual fees for certain establishments where such products are made; and (4) annual fees for certain sponsors of animal drug applications and/or investigational animal drug submissions (21 U.S.C. 379j–12(a)). When certain conditions are met, FDA will waive or reduce fees (21 U.S.C. 379j–12(d)).

For FYs 2019 through 2023, the FD&C Act establishes the base revenue amount for each fiscal year (21 U.S.C. 379j–12(b)(1)). Base revenue amounts are subject to adjustment for inflation and workload (21 U.S.C. 379j–12(c)(2) and (3)). Beginning with FY 2021, the annual fee revenue amounts are also subject to adjustment to reduce workload-based increases by the amount of certain excess collections or to account for certain collection shortfalls (21 U.S.C. 379j–12(c)(3) and (g)(5)). Fees for applications, products, establishments, and sponsors are to be established each year by FDA so that the percentages of the total revenue that are derived from each type of user fee will be as follows: (1) revenue from application fees shall be 20 percent of total fee revenue; (2) revenue from product fees shall be 27 percent of total fee revenue; (3) revenue from establishment fees shall be 26 percent of total fee revenue; and (4) revenue from sponsor fees shall be 27 percent of total fee revenue (21 U.S.C. 379j–12(b)(2)). The target revenue amounts for each fee category for FY 2023, are as follows: for application fees, the target revenue amount is $6,428,800; for product fees, the target revenue amount is $8,678,880; for establishment fees, the target revenue amount is $8,357,440 and for sponsor fees, the target revenue amount is $8,678,880.

For FY 2023, the animal drug user fee rates are: $659,364 for an animal drug application; $329,682 for a supplemental animal drug application for which safety or effectiveness data are required and for an animal drug application subject to the criteria set forth in section 512(d)(4) of the FD&C Act (21 U.S.C. 360b(d)(4)); $11,375 for the annual product fee; $167,149 for the annual establishment fee; and $149,636 for an annual sponsor fee. FDA will issue invoices for FY 2023 product, establishment, and sponsor fees by December 31, 2022, and payment will be due by January 31, 2023. The application fee rates are effective for applications submitted on or after October 1, 2022, and will remain in effect through September 30, 2023. Applications will not be accepted for review until FDA has received full payment of application fees and any other animal drug user fees owed under the ADUFA program.

II. Revenue Amount for FY 2023

A. Statutory Fee Revenue Amounts

ADUFA IV, Title I of Public Law 115–234, specifies that the aggregate base fee revenue amount for FY 2023 for all animal drug user fee categories is $29,931,240 (21 U.S.C. 379j–12(b)(1)(B)).

B. Inflation Adjustment to Fee Revenue Amount

ADUFA IV specifies that the annual fee revenue amount is to be adjusted for inflation increases for FY 2020 and subsequent fiscal years, using two separate adjustments—one for personnel compensation and benefits (PC&B) and one for non-PC&B costs (21 U.S.C. 379j–12(c)(2)(A)(ii) and (iii)). The component of the inflation adjustment for payroll costs shall be one plus the average annual percent change in the cost of all PC&B paid per full-time equivalent position (FTE) at FDA for the first 3 of the 4 preceding fiscal years of available data, multiplied by the average proportion of PC&B costs to total FDA costs for the first 3 of the 4 preceding fiscal years of available data. The data on total PC&B paid and numbers of FTE paid, from which the average cost per FTE can be derived, are published in FDA's Justification of Estimates for Appropriations Committees.

Table 1 summarizes the actual cost and FTE data for the specified fiscal years, 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.

TABLE 1—FDA PC&B 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	