1.428442, which equals $21,427 (rounded to the nearest dollar). There is no reduction in this fee for small businesses.

C. Summary of FY 2027 Fee Rates

TABLE 4—OUTSOURCING FACILITY FEES

Fee category	Fee rates for FY 2027
Qualified Small Business Establishment Fee	$7,142
Non-Small Business Establishment Fee	22,074
Reinspection Fee	21,427

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calendar days after FDA issues the invoice, FDA will consider the submission of registration information to have been withdrawn and adjust the invoice to reflect that no fee is due.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 2026 and wish to maintain their status as an outsourcing facility in FY 2027 must register during the annual registration period that lasts from October 1, 2026, to December 31, 2026. Failure to register and complete payment by December 31, 2026, will result in a loss of status as an outsourcing facility on January 1, 2027. Entities should submit their registration information no later than December 10, 2026, 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. Payments must be made within 30 days of the invoice date.

C. Fee Payment Procedures

Payments made to FDA must be made in U.S. currency drawn on a U.S. bank by electronic check, credit card, or wire transfer. The preferred method for payments to FDA is online using electronic check (Automated Clearing House (ACH), also known as eCheck) or credit card (Discover, VISA, MasterCard, American Express). FDA has partnered with the U.S. Department of the Treasury to utilize *Pay.gov,* a web-based payment application, for online electronic payment. The *Pay.gov* feature is available on the FDA website upon receipt of an invoice.

Secure electronic payments to FDA can be submitted using the User Fees Payment Portal at *https://userfees.fda.gov/pay.* (*Note:* Only full payments are accepted; no partial payments can be made online.) Once an invoice is located, ''Pay Now'' should be selected to be redirected to *Pay.gov*. Electronic payment options are based on the balance due. Payment by credit card is available for balances less than $25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be made using U.S. bank accounts as well as U.S. credit cards.

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

FDA's tax identification number is 53–0196965. If a Reinspection Fee is not paid in full, the fee will be treated as a claim of the U.S. Government (see section 744K(g)(4) of the FD&C Act and 45 CFR part 30), meaning the invoice balance due amount is referred to collections.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–15342 Filed 7–29–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–7712]

Food Safety Modernization Act Third-Party Certification Program User Fee Rate for Fiscal Year 2027

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the fiscal year (FY) 2027 annual fee rate for recognized accreditation bodies and accredited certification bodies, and the initial and renewal fee rate for accreditation bodies applying to be recognized in the third-party certification program authorized by the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the FDA Food Safety Modernization Act (FSMA). We are also announcing the fee rate for certification bodies applying for direct FDA accreditation.

DATES: The fees apply from October 1, 2026, through September 30, 2027.

FOR FURTHER INFORMATION CONTACT: *For Questions Related to FSMA Program Fees: FSMAFeeStaff@fda.hhs.gov. For Questions Related to This Notice:* Olufunmilayo Ariyo, Office of Financial Management, Food and Drug Administration, 301–796–7900; or *FDAUserFees@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 808(b)(1)(A) of the FD&C Act (21 U.S.C. 384d(b)(1)(A)) directed FDA to establish a recognition system for entities that accredit third-party certification bodies to conduct food safety audits and issue food and facility certifications to eligible foreign entities. (For the reasons explained in the third-party certification final rule (80 FR 74570 at 74578 to 74579, November 27, 2015), and for consistency with our regulations for the third-party certification program in 21 CFR parts 1, 11, and 16, this notice uses the term ''third-party certification body'' rather than the term ''third-party auditor'' used in section 808 of the FD&C Act.) Section 808(b)(1)(A)(ii) of the FD&C Act also allowed us to directly accredit certain third-party certification bodies.

Section 808(c)(8) of the FD&C Act directed FDA to establish a reimbursement (user fee) program by which we assess fees and require reimbursement for our work to administer the third-party certification

program. Our regulations pertaining to the user fee program for the third-party certification program can be found at 21 CFR 1.700 through 1.725.

The FY 2027 third-party certification program user fee rates announced in this notice is effective from October 1, 2026, through September 30, 2027.

II. Estimating the Average Cost of a Supported Direct FDA Work Hour for FY 2027

FDA estimates its costs for each activity to establish fee rates (see 21 CFR 1.705(b)).

A. Estimating the Full Cost per Direct Work Hour in FY 2027

Full-time Equivalent (FTE) reflects the total number of regular straight-time hours—not including overtime or holiday hours—worked by employees, divided by the number of compensable hours applicable to each fiscal year. Annual leave, sick leave, compensatory time off, and other approved leave categories are considered ''hours worked'' for purposes of defining FTE employment.

In general, the starting point for estimating the full cost per direct work hour is to estimate the cost of an FTE or paid staff year. Calculating an FDA-wide total cost per FTE requires three primary cost elements: payroll, non-payroll, and rent.

We used an average of past year cost elements to predict the FY 2027 cost. The FY 2027 FDA-wide average cost for payroll (salaries and benefits) is $244,029; non-payroll (including equipment, supplies, information technology, general and administrative overhead) is $108,488; and rent (including cost allocation analysis and adjustments for other rent and rent-related costs) is $24,118 per paid staff year, excluding travel costs.

Summing the average cost of an FTE for payroll, non-payroll, and rent brings the FY 2027 average fully supported cost to $376,635 (total includes rounding) per FTE, excluding travel costs. FDA will use this base unit fee in determining the hourly fee rate for third-party certification user fees for FY 2027 before including travel costs as applicable for the activity.

To calculate an hourly rate, we divide the FY 2027 average fully supported cost of $376,635 per FTE by the average number of supported direct FDA work hours in FY 2025 (the last FY for which data are available). See table 1.

TABLE 1—SUPPORTED DIRECT FDA WORK HOURS IN A PAID STAFF YEAR IN FY 2025

Total number of hours in a paid staff year	2,080
Less:	
11 paid holidays	−88
20 days of annual leave	−160
10 days of sick leave	−80
12.5 days of training	−100
22 days of general administration	−176
26.5 days of travel	−212
2 hours of meetings per week	−104
Net Supported Direct FDA Work Hours Available for Assignments	1,160

Dividing the average fully supported FTE cost in FY 2027 ($376,635) by the total number of supported direct work hours available for assignment in FY 2025 (1,160) results in an average fully supported cost of $325 (rounded to the nearest dollar), excluding travel costs, per supported direct work hour in FY 2027.

B. Adjusting FY 2025 Travel Costs for Inflation To Estimate FY 2027 Travel Costs

To adjust the hourly rate for FY 2027, FDA estimates the cost of inflation in each year for FY 2026 and FY 2027. FDA uses the method prescribed for estimating inflationary costs under the Prescription Drug User Fee Act (PDUFA) provisions of the FD&C Act (section 736(c)(1) of the FD&C Act (21 U.S.C. 379h(c)(1))), the statutory method for inflation adjustment in the FD&C Act. FDA previously determined the FY 2026 inflation rate to be 5.0313 percent; this rate was published in the FY 2026 PDUFA user fee rates notice in the **Federal Register** (July 30, 2025, 90 FR 35866). Using the method set forth in section 736(c)(1) of the FD&C Act, FDA has calculated an inflation rate of 5.0313 percent for FY 2026 and 4.7210 percent for FY 2027, and FDA intends to use this inflation rate to make inflation adjustments for FY 2027.

For the purpose of estimating the fee, we are using the travel cost rate for foreign travel because the majority of onsite assessments made by FDA under this program will require foreign travel. In FY 2025, the Office of Inspections and Investigation (OII) spent a total of $2,689,902 on 277 foreign inspection trips (averaging $9,711 per foreign inspection trip) related to FDA's Human Foods Program and Center for Veterinary Medicine field activities programs.[1] These trips averaged 3 weeks (or 120 paid hours) per trip. Dividing $9,711 per trip by 120 hours per trip equals $81 (rounded to the nearest dollar) per paid hour spent for foreign inspection travel costs in FY 2025. To adjust $81 for inflation in FY 2026 and FY 2027, FDA multiplies it by the same inflation factors mentioned previously in this document (1.050313 and 1.047210), which results in an estimated cost of $89 per paid hour. That plus $325 in other costs per average supported direct work hour equals $414 per paid hour for each direct hour of work requiring foreign inspection travel. FDA will use this rate in charging fees in FY 2027 when travel is required for the third-party certification program.

[1] Effective October 1st, 2024, FDA implemented a reorganization to establish a unified Humans Foods Program and restructured its field operations, formerly the Office of Regulatory Affairs and now the Office of Inspections and Investigations (OII). The establishment of the Human Foods Program allows us to most effectively deliver on our mission to protect and promote public health through science-based approaches to prevent foodborne illness, reduce diet-related chronic disease, and ensure the safety of chemicals in our food. For more information, see *https://www.fda.gov/news-events/press-announcements/fdas-unified-human-foods-program-new-model-field-operations-and-other-modernization-efforts-go.*

TABLE 2—FSMA FEE SCHEDULE FOR FY 2027

Fee category	Fee rates for FY 2027
Hourly rate without travel	$325
Hourly rate if travel is required	414

III. Fees for Accreditation Bodies and Certification Bodies in the Third-Party Certification Program Under Section 808(c)(8) of the FD&C Act

The third-party certification program assesses application fees and annual

fees. Specifically, FDA can collect an initial application fee for accreditation bodies seeking recognition, an annual fee for recognized accreditation bodies, an annual fee for certification bodies accredited by a recognized accreditation body, an initial application fee for a certification body seeking direct accreditation from FDA, and a renewal application fee for recognized accreditation bodies. Table 3 provides an overview of the fees for FY 2027.

TABLE 3—FSMA THIRD-PARTY CERTIFICATION PROGRAM USER FEE SCHEDULE FOR FY 2027

Fee category	Fee rates for FY 2027
Initial Application Fee for Accreditation Body Seeking Recognition	$56,272
Annual Fee for Recognized Accreditation Body	2,612
Annual Fee for Accredited Certification Body	3,266
Initial Application Fee for a Certification Body Seeking Direct Accreditation from FDA	56,272
Renewal Application Fee for Recognized Accreditation Body	34,311

A. Application Fee for Accreditation Bodies Applying for Recognition in the Third-Party Certification Program Under Section 808(c)(8) of the FD&C Act

Our regulations, at § 1.705(a)(1), require an application fee for accreditation bodies applying for recognition; that fee covers the estimated average cost of the work FDA performs in reviewing and evaluating applications for recognition of accreditation bodies.

The fee is based on the fully supported FTE hourly rates and estimates of the number of hours it would take FDA to perform relevant activities. Based on our data since starting the program, we estimate that it would take, on average, 80 person-hours to review an accreditation body's application, 48 person-hours for an onsite performance evaluation of the applicant (including travel and other steps necessary for a fully supported FTE to complete an onsite assessment), and 32 person-hours to prepare a written report documenting the onsite assessment.

FDA employees review applications and prepare reports from their worksites, so we use the fully supported FTE hourly rate excluding travel ($325 per hour) to calculate the user fee attributable to those activities: $325/hour × (80 hours (application review) + 32 hours (written report)) = $36,400. We use the fully supported FTE hourly rate for work requiring travel ($414 per hour) to calculate the user fee for onsite performance evaluations, since historically most accreditation bodies are in foreign countries: $414/hour × 48 hours (*i.e.,* two fully supported FTEs × ((2 travel days × 8 hours) + (1 day onsite × 8 hours))) = $19,872. The estimated average cost of our total work for reviewing an application for recognition for an accreditation body based on these figures would be $36,400 + $19,872 = $56,272. Therefore, the application fee for accreditation bodies applying for recognition in FY 2027 will be $56,272.

B. Annual Fee for Accreditation Bodies Participating in the Third-Party Certification Program Under Section 808(c)(8) of the FD&C Act

To calculate the annual fee for each recognized accreditation body, FDA takes the estimated average cost of our work to monitor performance of a single recognized accreditation body and annualizes that over the average term of recognition. We assume an average term of recognition of 5 years. We also assume that FDA will monitor 10 percent of recognized accreditation bodies onsite. We estimate that one performance evaluation of a recognized accreditation body would take, on average, 22 hours to conduct records review, 8 hours to prepare a report detailing the records review and onsite performance evaluation, and 8 hours of onsite performance evaluation. Using the fully supported FTE hourly rates in table 2, the estimated average cost of our work to monitor performance of a single recognized accreditation body would be $9,750 ($325/hour × (22 hours (records review) + 8 hours (written report))) plus $3,312 ($414/hour × 8 hours (onsite evaluation)), which is $13,062. Annualizing this amount over 5 years leads to an annual fee for recognized accreditation bodies of $2,612 for FY 2027.

C. Annual Fee for Certification Bodies Accredited by a Recognized Accreditation Body in the Third-Party Certification Program Under Section 808(c)(8) of the FD&C Act

To calculate the annual fee for a certification body accredited by a recognized accreditation body, FDA takes the estimated average cost of our work to monitor performance of a single certification body accredited by a recognized accreditation body and annualizes that over the average term of accreditation. We assume an average term of accreditation of 4 years. We estimate that FDA would conduct, on average, the same activities for the same amount of time to monitor certification bodies accredited by a recognized accreditation body as we would to monitor an accreditation body recognized by FDA. Using the fully supported FTE hourly rates in table 2, the estimated average cost of our work to monitor performance of a single accredited certification body would be $9,750 ($325/hour × (22 hours (records review) + 8 hours (written report))) plus $3,312 ($414/hour × 8 hours (onsite evaluation)), which is $13,062. Annualizing this amount over 4 years leads to an annual fee for accredited certification bodies of $3,266 for FY 2027.

D. Initial Application Fee for Certification Bodies Seeking Direct Accreditation From FDA in the Third-Party Certification Program Under Section 808(c)(8) of the FD&C Act

Our regulations, at § 1.705(a)(3), require an application fee for certification bodies applying for direct accreditation from FDA to cover the estimated average cost of our work to review and evaluating initial applications for direct accreditation of certification bodies.

The fee is based on the fully supported FTE hourly rates and estimates of the number of hours it would take FDA to perform relevant activities. We estimate that it would take, on average, 80 person-hours to review a certification body's application, 48 person-hours for an onsite performance evaluation of the applicant, and 32 person-hours to prepare a written report documenting the onsite assessment.

FDA employees are likely to review applications and prepare reports from their worksites, so we use the fully supported FTE hourly rate excluding travel, $325 per hour, to calculate the portion of the user fee attributable to those activities: $325/hour × (80 hours (application review) + 32 hours (written report)) = $36,400. For the portion of the

fee attributable to onsite performance evaluations, we use the fully supported FTE hourly rate for work requiring travel ($414 per hour) since historically most certification bodies are in foreign countries: $414/hour × 48 hours (*i.e.,* two fully supported FTEs × ((2 travel days × 8 hours) + (1 day onsite × 8 hours))) = $19,872. The estimated average cost of our work to review an application for direct accreditation of a certification body is $36,400 + $19,872 = $56,272. Therefore, the application fee for certification bodies applying for direct accreditation from FDA in FY 2027 will be $56,272

E. Renewal Application Fee for Accreditation Bodies Participating in the Third-Party Certification Program Under Section 808(c)(8) of the FD&C Act

Our regulations, at § 1.705(a)(2), require a renewal application fee for recognized accreditation bodies to cover the estimated average cost of our work to review and evaluate renewal applications for recognition of accreditation bodies.

The fee is based on the fully supported FTE hourly rates and estimates of the number of hours it would take FDA to perform relevant activities. We estimate that it would take, on average, 43 person-hours to review an accreditation body's submitted renewal application, 24 person-hours for an onsite performance evaluation of the applicant, and 32 person-hours to prepare a written report documenting the onsite assessment.

FDA employees are likely to review renewal applications and prepare reports from their worksites, so we use the fully supported FTE hourly rate excluding travel ($325 per hour) to calculate the portion of the user fee attributable to those activities: $325/hour × (43 hours (application review) + 32 hours (written report)) = $24,375. For the portion of the fee attributable to onsite performance evaluations, we use the fully supported FTE hourly rate for work requiring travel ($414 per hour) since historically most accreditation bodies are in foreign countries: $414/hour × 24 hours (*i.e.,* fully supported FTE × ((2 travel days × 8 hours) + (1 day onsite × 8 hours))) = $9,936. The estimated average cost of our work for reviewing a renewal application for recognition of an accreditation body is $24,375 + $9,936 = $34,311. Therefore, the renewal application fee for recognized accreditation bodies in FY 2027 will be $34,311.

IV. Estimated Fees for Accreditation Bodies and Certification Bodies in Other Fee Categories for FY 2027

Our regulations, at § 1.705(a)(4), require application fees for certification bodies applying for renewal of direct accreditation, while § 1.705(b)(2) requires annual fees for certification bodies directly accredited by FDA.

Although to date we have not directly accredited any certification bodies under the Third-Party Certification Program, FDA notifies the public of the program fee schedule annually (21 CFR 1.710). Therefore, we are providing estimates of annual fees and renewal applications for directly accredited certification bodies, based on the fully supported FTE hourly rates for FY 2026 and estimates of the number of hours it would take FDA to perform relevant activities as outlined in the Final Regulatory Impact Analysis for the Third-Party Certification regulation. Table 4 provides an overview of the estimated fees for these other categories.

TABLE 4—ESTIMATED FEE RATES FOR OTHER FEE CATEGORIES UNDER THE FSMA THIRD-PARTY CERTIFICATION PROGRAM

Fee category	Estimated fee rates for FY 2027
Renewal application fee for directly accredited certification body	$34,311
Annual fee for certification body directly accredited by FDA	26,960

V. How must the fees be paid?

Accreditation bodies seeking recognition must submit the application fee with the application (21 CFR 1.715(a)). For recognized accreditation bodies and accredited certification bodies, an invoice will be sent annually. Payments made to FDA must be made, within 30 days of the invoice date, in U.S. currency drawn on a U.S. bank by electronic check, credit card, or wire transfer. The preferred method for payments to FDA is online using electronic check (Automated Clearing House (ACH), also known as eCheck) or credit card (Discover, VISA, MasterCard, American Express). FDA has partnered with the U.S. Department of the Treasury to utilize *Pay.gov,* a web-based payment application, for online electronic payment. The *Pay.gov* feature is available on the FDA website upon receipt of an invoice.

Secure electronic payments to FDA can be submitted using the User Fees Payment Portal at *https://userfees.fda.gov/pay.* (*Note:* Only full payments are accepted; no partial payments can be made online.) Once an invoice is located, ''Pay Now'' should be selected to be redirected to *Pay.gov.* Electronic payment options are based on the balance due. Payment by credit card is available for balances less than $25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be made using U.S. bank accounts or U.S. credit cards.

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

FDA's tax identification number is 53–0196965.

VI. What are the consequences of not paying this fee?

The consequences of not paying these fees are outlined in 21 CFR 1.725. If FDA does not receive an application fee with an application for recognition, the application will be considered incomplete, and FDA will not review the application. If a recognized accreditation body fails to submit its annual user fee within 30 days of the due date, we will suspend its recognition. If the recognized accreditation body fails to submit its annual user fee within 90 days of the due date, we will revoke its recognition. If an accredited certification body fails to pay its annual fee within 30 days of the due date, we will suspend its accreditation. If the accredited certification body fails to pay its annual

fee within 90 days of the due date, we will withdraw its accreditation.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–15337 Filed 7–29–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–7498]

Animal Generic Drug User Fee Program Rates and Payment Procedures for Fiscal Year 2027

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the fee rates and payment procedures for fiscal year (FY) 2027 generic new animal drug program user fees. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Animal Generic Drug User Fee Amendments of 2023 (AGDUFA IV), authorizes FDA to collect user fees for certain abbreviated applications for generic new animal drugs, for certain generic new animal drug products, for certain sponsors of such abbreviated applications for generic new animal drugs and/or investigational submissions for generic new animal drugs (JINADs), and for certain submissions related to JINAD files. This notice establishes the fee rates for FY 2027.

DATES: The application fee rates are effective for all abbreviated applications for a generic new animal drug submitted on or after October 1, 2026, and will remain in effect through September 30, 2027. The fee rates for requests to establish a JINAD file, and for certain submissions to JINAD files established prior to October 1, 2023, are effective on October 1, 2026, and will remain in effect through September 30, 2027.

FOR FURTHER INFORMATION CONTACT: Visit FDA's website at: *https://www.fda.gov/industry/fda-user-fee-programs/animal-generic-drug-user-fee-act-agdufa.* For general questions, email FDA's Center for Veterinary Medicine (CVM) at: *cvmagdufa@fda.hhs.gov. For questions relating to this notice:* Olufunmilayo Ariyo, Office of Financial Management, Food and Drug Administration, 301–796–7900; or *FDAUserFees@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 741(a) of the FD&C Act (21 U.S.C. 379j–21(a)), establishes four different types of generic new animal drug user fees: (1) fees for certain abbreviated applications for generic new animal drugs; (2) annual fees for certain generic new animal drug products; (3) annual fees for certain sponsors of abbreviated applications for generic new animal drugs and/or investigational submissions for generic new animal drugs; and (4) JINAD file fees. When certain conditions are met, section 741(d) of the FD&C Act authorizes FDA to waive or reduce fees for generic new animal drugs intended solely to provide for a minor use or minor species indication.

Section 741(b)(1) of the FD&C Act establishes a base revenue amount for each fiscal year. Per section 741(c)(2) and (3) of the FD&C Act, the base revenue amounts established for fiscal years after FY 2024 are subject to adjustment for inflation and workload. Beginning FY 2026, the annual fee revenue amounts are also subject to adjustment to reduce workload-based increases by the amount of certain excess collections. Section 741(b) of the FD&C Act establishes fees each year so that the percentage allocations for each of the fee categories is as follows: 20 percent shall be derived from fees for abbreviated applications for a generic new animal drug and JINAD file fees; 40 percent shall be derived from fees for generic new animal drug products; and 40 percent shall be derived from fees for generic new animal drug sponsors. The target revenue amounts for each fee category for FY 2027 are as follows: for application and/or JINAD file fees, the target revenue amount is $5,696,000; for product fees, the target revenue amount is $11,392,000; and for sponsor fees, the target revenue amount is $11,392,000.

For FY 2027, the AGDUFA rates are: $132,614 for each abbreviated application for a generic new animal drug other than those subject to the criteria in section 512(d)(4) of the FD&C Act (21 U.S.C. 360b(d)(4)); $66,307 for each abbreviated application for a generic new animal drug subject to the criteria in section 512(d)(4) of the FD&C Act; $50,000 for each JINAD file request or certain submissions to established JINAD files; $15,670 for each generic new animal drug product; $264,009 for each generic new animal drug sponsor paying 100 percent of the sponsor fee; $198,007 for each generic new animal drug sponsor paying 75 percent of the sponsor fee; and $132,005 for each generic new animal drug sponsor paying 50 percent of the sponsor fee. FDA will issue invoices for FY 2027 product and sponsor fees by December 31, 2026, and payment will be due by January 31, 2027. The application fee rates are effective for all abbreviated applications for a generic new animal drug submitted on or after October 1, 2026, and will remain in effect through September 30, 2027. The fee rate for requests to establish a JINAD file, and for certain submissions to JINAD files established prior to October 1, 2023, is effective on October 1, 2026, and will remain in effect through September 30, 2027.

Applications will not be accepted for review until FDA has received full payment of application fees and any other fees owed under the AGDUFA program. Similarly, a request to establish a JINAD file or a submission to an existing JINAD file will not be accepted for action by FDA until FDA has received full payment of all fees owed under the AGDUFA program.

II. Fee Revenue Amount for FY 2027

A. Statutory Fee Revenue Amounts

Section 741(b)(1) of the FD&C Act specifies that the base fee revenue amount for FY 2027 for all generic animal drug user fee categories totals $25,000,000.

B. Inflation Adjustment to Fee Revenue Amount

Section 741(c)(2)(A) of the FD&C Act specifies that the annual fee revenue amount is to be adjusted for inflation increases for FY 2025 and subsequent fiscal years using two separate factors—one for personnel compensation and benefits (PC&B) costs and one for non-PC&B costs.

Section 741(c)(2)(A)(ii) of the FD&C Act specifies 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, per full-time equivalent (FTE) position of FDA, for the first 3 of the preceding 4 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 total PC&B costs per FTE for the specified fiscal years, provides the percentage change from the previous fiscal year, and provides the average percentage change over the first 3 of the 4 fiscal years preceding FY 2027. The 3-year average is 5.7330 percent.