9. *Claudia Gunsch, Ph.D.,* Duke University, Durham, North Carolina.
10. *Nishad Jayasundara, Ph.D.,* Duke University, Durham, North Carolina.
11. *Jakub Kostal, Ph.D.,* George Washington University, Washington, District of Columbia.
12. *Raina M. Maier, Ph.D.,* University of Arizona, Tucson, Arizona.
13. *Stefano Monti, Ph.D.,* Boston University, Boston, Massachusetts.
14. *Ingrid Padilla, Ph.D.,* University of Puerto Rico, Mayagüez, Puerto Rico.
15. *Beate R Ritz, MD, Ph.D.,* University of California Los Angeles, Los Angeles, California.
16. *Zeev Rosenzweig, Ph.D.,* University of Maryland Baltimore County, Baltimore, Maryland.
17. *Tara L Sabo-Attwood, Ph.D.,* University of Florida, Gainesville, Florida.
18. *Maria Reyes Sierra-Alvarez, Ph.D.,* University of Arizona, Tucson, Arizona.
19. *Elsie M. Sunderland, Ph.D.,* Harvard University, Cambridge, Massachusetts.
20. *Justin Teeguarden, Ph.D.,* Department of Energy, Pacific Northwest National Laboratory, Richland, Washington.
21. *Lisa Truong, Ph.D., MBA,* Oregon State University, Corvallis, Oregon.
22. *Paul Westerhoff, Ph.D.,* Arizona State University, Tempe, Arizona.
23. *Timothy R. Zacharewski, Ph.D.,* Michigan State University, East Lansing, Michigan.
24. *Hao Zhu, Ph.D.,* Rutgers University, Camden, New Jersey.

Authority: 7 U.S.C. 136 *et. seq.;* 21 U.S.C. 301 *et seq.;* 5 U.S.C. Appendix

Dated: July 22, 2022.

Michal Freedhoff,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2022–16155 Filed 7–27–22; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0526; FR ID 98395]

Information Collection Being Reviewed by the Federal Communications Commission Under Delegated Authority

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid Office of Management and Budget (OMB) control number.

DATES: Written PRA comments should be submitted on or before September 26, 2022. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicole Ongele, FCC, via email *PRA@fcc.gov* and to *nicole.ongele@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Nicole Ongele, (202) 418–2991.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0526.

Title: Section 69.123, Density Pricing Zone Plans, Expanded Interconnection with Local Telephone Company Facilities.

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit.

Number of Respondents and Responses: 13 respondents; 13 responses.

Estimated Time per Response: 48 hours.

Frequency of Response: On occasion reporting requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. 151, 154(i), 154(j), 201–205, 303(r), and 403.

Total Annual Burden: 624 hours.

Total Annual Cost: $12,090.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: No information of a confidential nature is being sought. However, respondents may request materials or information submitted to the Commission be withheld from public inspection under 47 CFR 0.459 of the Commission's rules.

Needs and Uses: The Commission requires Tier 1 local exchange carriers (LECs) to provide expanded opportunities for third party interconnection with their interstate special access facilities. The LECs are permitted to establish a number of rate zones within study areas in which expanded interconnection are operational. In a previous rulemaking, Fifth Report and Order, CC Docket No. 96–262, the Commission allowed price cap LECs to define the scope and number of zones within a study area. These LECs must file and obtain approval of their pricing plans which will be used by FCC staff to ensure that the rates are just, reasonable and nondiscriminatory.

Federal Communications Commission.

Marlene Dortch,

Secretary. Office of the Secretary.

[FR Doc. 2022–16160 Filed 7–27–22; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–1592]

Food Safety Modernization Act Third-Party Certification Program User Fee Rate 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 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 that is 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 that

are applying to be directly accredited by FDA.

DATES: This fee is effective on October 1, 2022, and will remain in effect through September 30, 2023.

FOR FURTHER INFORMATION CONTACT: Donald Prater, Office of Food Policy and Response, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 3202, Silver Spring, MD 20993, 301–348–3007.

SUPPLEMENTARY INFORMATION:

I. Background

Section 307 of FSMA (Pub. L. 111–353), Accreditation of Third-Party Auditors, amended the FD&C Act to create a new provision, section 808, under the same name. Section 808 of the FD&C Act (21 U.S.C. 384d) directs FDA to establish a program for accreditation of third-party certification bodies [1] conducting food safety audits and issuing food and facility certifications to eligible foreign entities (including registered foreign food facilities) that meet our applicable requirements. Under this provision, we established a system for FDA to recognize accreditation bodies to accredit certification bodies, except for limited circumstances in which we may directly accredit certification bodies to participate in the third-party certification program.

Section 808(c)(8) of the FD&C Act directs FDA to establish a reimbursement (user fee) program by which FDA assesses fees and requires reimbursement for the work FDA performs to establish and administer the third-party certification program under section 808 of the FD&C Act. The user fee program for the third-party certification program was established by a final rule entitled ''Amendments to Accreditation of Third-Party Certification Bodies To Conduct Food Safety Audits and To Issue Certifications To Provide for the User Fee Program'' (81 FR 90186, December 14, 2016).

The FSMA FY 2023 third-party certification program user fee rate announced in this notice is effective on October 1, 2022, and will remain in effect through September 30, 2023.

[1] For the reasons explained in the third-party certification final rule (80 FR 74570 at 74578–74579, November 27, 2015), and for consistency with the implementing 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(a)(3) of the FD&C Act.

II. Estimating the Average Cost of a Supported Direct FDA Work Hour for FY 2023

FDA must estimate its costs for each activity in order to establish fee rates for FY 2023. In each year, the costs of salary (or personnel compensation) and benefits for FDA employees account for between 50 and 60 percent of the funds available to, and used by, FDA. Almost all the remaining funds (operating funds) available to FDA are used to support FDA employees for paying rent, travel, utility, information technology, and other operating costs.

A. Estimating the Full Cost per Direct Work Hour in FY 2023

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 Agency-wide total cost per FTE requires three primary cost elements: payroll, non-payroll, and rent.

We have used an average of past year cost elements to predict the FY 2023 cost. The FY 2023 FDA-wide average cost for payroll (salaries and benefits) is $173,393; non-payroll (including equipment, supplies, information technology, general and administrative overhead) is $103,078; and rent (including cost allocation analysis and adjustments for other rent and rent-related costs) is $23,944 per paid staff year, excluding travel costs.

Summing the average cost of an FTE for payroll, non-payroll, and rent, brings the FY 2023 average fully supported cost to $300,416 [2] 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 2023 prior to including travel costs as applicable for the activity.

To calculate an hourly rate, FDA must divide the FY 2023 average fully supported cost of $300,416 per FTE by the average number of supported direct FDA work hours in FY 2021 (the last FY for which data are available). See table 1.

[2] Total includes rounding.

TABLE 1—SUPPORTED DIRECT FDA WORK HOURS IN A PAID STAFF YEAR IN FY 2021

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 2023 ($300,416) by the total number of supported direct work hours available for assignment in FY 2021 (1,160) results in an average fully supported cost of $259 (rounded to the nearest dollar), excluding travel costs, per supported direct work hour in FY 2023.

B. Adjusting FY 2021 Travel Costs for Inflation To Estimate FY 2023 Travel Costs

To adjust the hourly rate for FY 2023, FDA must estimate the cost of inflation in each year for FY 2022 and FY 2023. 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) (21 U.S.C. 379h(c)(1))), the statutory method for inflation adjustment in the FD&C Act that FDA has used consistently. FDA previously determined the FY 2022 inflation rate to be 2.2013 percent: this rate was published in the FY 2022 PDUFA user fee rates notice in the **Federal Register** (August 16, 2021, 86 FR 45732). Utilizing the method set forth in section 736(c)(1) of the FD&C Act, FDA has calculated an inflation rate of 2.2013 percent for FY 2022 and 1.6404 percent for FY 2023. FDA intends to use this inflation rate to make inflation adjustments for FY 2023; the derivation of this rate will be published in the **Federal Register** in the FY 2023 notice for the PDUFA user fee rates. The compounded inflation rate for FYs 2022 and 2023 is 1.038778 (or 3.8778 percent) (calculated as 1 plus 2.2013 percent times 1 plus 1.6404 percent).

The average fully supported cost per supported direct FDA work hour, excluding travel costs, of $259 already takes into account inflation as the calculation above is based on FY 2023 predicted costs. FDA will use this base unit fee in determining the hourly fee rate for third-party certification program fees for FY 2023 prior to including travel costs as applicable for the activity. For the purpose of estimating

the fee, we are using the travel cost rate for foreign travel because we anticipate that the vast majority of onsite assessments made by FDA under this program will require foreign travel. In FY 2020,[3] the Office of Regulatory Affairs (ORA) spent a total of $1,449,058 on 171 foreign inspection trips related to FDA's Center for Food Safety and Applied Nutrition and Center for Veterinary Medicine field activities programs, which averaged a total of $8,474 per foreign inspection trip. These trips averaged 3 weeks (or 120 paid hours) per trip. Dividing $8,474 per trip by 120 hours per trip results in an additional cost of $71 (rounded to the nearest dollar) per paid hour spent for foreign inspection travel costs in FY 2020. To adjust $71 for inflationary increases in FY 2021, FY 2022, and FY 2023, FDA must multiply it by the same inflation factor mentioned previously in this document (1.038778 or 3.8778 percent) and the inflation factor for FY 2021[4] (1.013493), which results in an estimated cost of $75 (rounded to the nearest dollar) per paid hour in addition to $259 for a total of $334 per paid hour ($259 plus $75) for each direct hour of work requiring foreign inspection travel. FDA will use this rate in charging fees in FY 2023 when travel is required for the third-party certification program.

TABLE 2—FSMA FEE SCHEDULE FOR FY 2023

Fee category	Fee rates for FY 2023
Hourly rate without travel	$259
Hourly rate if travel is required	334

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. In FY 2023, the only fees that could be collected by FDA under section 808(c)(8) of the FD&C Act are the initial application fee for accreditation bodies seeking recognition, the annual fee for recognized accreditation bodies, the annual fee for certification bodies accredited by a recognized accreditation body, the initial application fee for a certification body seeking direct accreditation from FDA, and the renewal application fee for recognized accreditation bodies. Table 3 provides an overview of the fees for FY 2023.

TABLE 3—FSMA THIRD-PARTY CERTIFICATION PROGRAM USER FEE SCHEDULE FOR FY 2023

Fee category	Fee rates for FY 2023
Initial Application Fee for Accreditation Body Seeking Recognition	$45,040
Annual Fee for Recognized Accreditation Body	2,088
Annual Fee for Accredited Certification Body	2,611
Initial Application Fee for a Certification Body Seeking Direct Accreditation from FDA	45,040
Renewal Application Fee for Recognized Accreditation Body	27,441

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

Section 1.705(a)(1) (21 CFR 1.705(a)(1)) establishes an application fee for accreditation bodies applying for initial recognition that represents the estimated average cost of the work FDA performs in reviewing and evaluating initial 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. These estimates represent FDA's current thinking, and as the program evolves, FDA will continue to reconsider the estimated hours. Based on data we have acquired since starting the program, we estimate that it would take, on average, 80 person-hours to review an accreditation body's submitted 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, $259 per hour, to calculate the portion of the user fee attributable to those activities: $259 per hour multiplied by (80 hours (application review) plus 32 hours (written report)) equals $29,008. FDA employees will likely travel to foreign countries for the onsite performance evaluations because most accreditation bodies are anticipated to be located in foreign countries. For this portion of the fee, we use the fully supported FTE hourly rate for work requiring travel, $334 per hour, to calculate the portion of the user fee attributable to those activities: $334 per hour multiplied by 48 hours (*i.e.,* two fully supported FTEs per trip ((2 travel days multiplied by 8 hours) plus (1 day onsite multiplied by 8 hours))) equaling $16,032. The estimated average cost of the work FDA performs in total for reviewing an initial application for recognition for an accreditation body based on these figures would be $29,008 plus $16,032 equals $45,040. Therefore, the application fee for accreditation bodies applying for recognition in FY 2023 will be $45,040.

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 work FDA performs to monitor performance of a single recognized accreditation body and annualizes that over the average term of recognition. At this time, we assume an average term of recognition of 5 years. We also assume that FDA will monitor 10 percent of recognized accreditation bodies onsite. As the program proceeds, we will adjust the term of recognition as appropriate. We estimate that for one performance evaluation of a recognized accreditation body, it would take, on average (taking into account that not all recognized accreditation bodies would be monitored onsite), 22 hours for FDA 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 the work FDA performs to monitor performance of a single recognized accreditation body would be $7,770 ($259 per hour multiplied by (22 hours (records review) plus 8 hours (written report))) plus $2,672 ($334 per hour multiplied by 8 hours (onsite evaluation)), which is $10,442. Annualizing this amount over 5 years would lead to an annual fee for recognized accreditation bodies of $2,088 for FY 2023.

[3] FDA will be using FY 2020 numbers for the foreign inspection travel costs due to the limited number of inspections done in FY 2021 due to travel restrictions caused by the COVID–19 Pandemic.

[4] FDA previously determined the FY 2021 inflation rate to be 1.3493 percent; this rate was published in the FY 2021 PDUFA user fee rates notice in the **Federal Register** (August 3, 2020, 85 FR 46651).

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 work FDA performs to monitor performance of a single certification body accredited by a recognized accreditation body and annualizes that over the average term of accreditation. At this time, we assume an average term of accreditation of 4 years. This 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 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 the work FDA performs to monitor performance of a single accredited certification body would be $7,770 ($259 per hour multiplied by (22 hours (records review) plus 8 hours (written report))) plus $2,672 ($334 per hour multiplied by 8 hours (onsite evaluation)), which is $10,442. Annualizing this amount over 4 years would lead to an annual fee for accredited certification bodies of $2,611 for FY 2023.

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

Section 1.705(a)(3) establishes an application fee for certification bodies applying for direct accreditation from FDA that represents the estimated average cost of the work FDA performs in reviewing 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. These estimates represent FDA's current thinking, and as the program evolves, FDA will reconsider the estimated hours. We estimate that it would take, on average, 80 person-hours to review a certification body's submitted 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 are likely to review applications and prepare reports from their worksites, so we use the fully supported FTE hourly rate excluding travel, $259 per hour, to calculate the portion of the user fee attributable to those activities: $259 per hour multiplied by (80 hours (application review) plus 32 hours (written report)) equals $29,008. FDA employees will likely travel to foreign countries for the onsite performance evaluations because most certification bodies are anticipated to be located in foreign countries. For this portion of the fee we use the fully supported FTE hourly rate for work requiring travel, $334 per hour, to calculate the portion of the user fee attributable to those activities: $334 per hour multiplied by 48 hours (*i.e.,* two fully supported FTEs for travel ((2 travel days of 8 hours each) plus (1 day onsite for 8 hours))) equaling $16,032. The estimated average cost of the work FDA performs in total for reviewing an initial application for direct accreditation of a certification body based on these figures would be $29,008 plus $16,032 equaling $45,040. Therefore, the application fee for certification bodies applying for direct accreditation from FDA in FY 2023 will be $45,040.

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

Section 1.705(a)(2) establishes a renewal application fee for recognized accreditation bodies that represents the estimated average cost of the work FDA performs in reviewing and evaluating 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. These estimates represent FDA's current thinking, and as the program evolves, FDA will reconsider the estimated hours. 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 (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 are likely to review renewal applications and prepare reports from their worksites, so we use the fully supported FTE hourly rate excluding travel, $259 per hour, to calculate the portion of the user fee attributable to those activities: $259 per hour multiplied by (43 hours (application review) plus 32 hours (written report)) equaling $19,425. FDA employees will likely travel to foreign countries for the onsite performance evaluations because most certification bodies are anticipated to be located in foreign countries. For this portion of the fee we use the fully supported FTE hourly rate for work requiring travel, $334 per hour, to calculate the portion of the user fee attributable to those activities: $334 per hour multiplied by 24 hours (*i.e.,* fully supported FTE multiplied by travel ((2 travel days for 8 hours each) plus (1 day onsite for 8 hours))) equaling $8,016. The estimated average cost of the work FDA performs in total for reviewing a renewal application for recognition of an accreditation body based on these figures would be $19,425 plus $8,016 equals $27,441. Therefore, the renewal application fee for recognized accreditation bodies in FY 2023 will be $27,441.

IV. Estimated Fees for Accreditation Bodies and Certification Bodies in Other Fee Categories for FY 2023

Section 1.705(a) also establishes application fees for certification bodies applying for renewal of direct accreditation. Section 1.705(b) also establishes annual fees for certification bodies directly accredited by FDA.

Although we will not be collecting these other fees in FY 2023, for transparency and planning purposes, we have provided an estimate of what these fees would be for FY 2023 based on the fully supported FTE hourly rates for FY 2023 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 other fee categories.

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

Fee category	Estimated fee rates for FY 2023
Renewal application fee for directly accredited certification body	$27,441
Annual fee for certification body directly accredited by FDA	21,648

V. How must the fee be paid?

Accreditation bodies seeking initial recognition must submit the application fee with the application. For recognized accreditation bodies and accredited certification bodies, an invoice will be sent annually. Payment must be made within 30 days of the receipt invoice date. The payment must be made in U.S. currency from a U.S. bank by one of the following methods: wire transfer, electronically, check, bank draft, or U.S. postal money order made payable to the Food and Drug Administration. The preferred payment method is online using an 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 (*Pay.gov*) at *https://userfees.fda.gov/pay.* (Note: only full payments are accepted. No partial payments can be made online.) Once you have found 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 only 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. When paying by check, bank draft, or U.S. postal money order, please include the invoice number. Also write the FDA post office box number (P.O. Box 979108) on the enclosed check, bank draft, or money order. Mail the payment including the invoice number on the check stub to: Food and Drug Administration, P.O. Box 979108, St. Louis, MO 63197–9000.

When paying by wire transfer, it is required that the invoice number is included; without the invoice number, the payment may not be applied. The originating financial institution may charge a wire transfer fee. If the financial institution charges a wire transfer fee, it is required to add that amount to the payment to ensure that the invoice is paid in full. For international wire transfers, please inquire with the financial institutions prior to submitting the payment. 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, Account Name: Food and Drug Administration, Account No.: 75060099, Routing No.: 021030004, Swift No.: FRNYUS33.

To send a check by a courier such as Federal Express, the courier must deliver the check to: U.S. Bank, Attn: Government Lockbox 979108, 1005 Convention Plaza, St. Louis, MO 63101. (Note: this address is for courier delivery only. If you have any questions concerning courier delivery, contact U.S. Bank at 314–418–4013. This phone number is only for questions about courier delivery.) The tax identification number of FDA is 53–0196965. (Note: invoice copies do not need to be submitted to FDA with the payments.)

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.

Dated: July 22, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–16171 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–1620]

Animal Generic 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, Agency, or we) is announcing the fee rates and payment procedures for fiscal year (FY) 2023 generic new animal drug user fees. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Animal Generic Drug User Fee Amendments of 2018 (AGDUFA III), authorizes FDA to collect user fees for certain abbreviated applications for generic new animal drugs, for certain generic new animal drug products, and for certain sponsors of abbreviated applications for generic new animal drugs and/or investigational submissions for generic new animal drugs. This notice establishes the fee rates for FY 2023.

DATES: The application fee rates are effective for all abbreviated applications for a generic new animal drug 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/AnimalGenericDrugUserFeeActAGDUFA/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: *cvmagdufa@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

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

For FYs 2019 through 2023, the FD&C Act establishes the base revenue amount for each fiscal year (21 U.S.C. 379j–21(b)(1)). Base revenue amounts are subject to adjustment for inflation and workload (21 U.S.C. 379j–21(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 (21 U.S.C. 379j–21(c)(3)(B)). Fees for applications, products, 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) 25 percent shall be derived from fees for abbreviated applications for a generic new animal drug; (2) 37.5 percent shall be derived from fees for generic new animal drug products; and (3) 37.5 percent shall be derived from fees for generic new animal drug sponsors (21 U.S.C. 379j–