www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Graham Thompson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1146, Silver Spring, MD 20993–0002, 301–796–5003, Fax: 301–847–8443, *Graham.Thompson@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA is announcing the publication of a report, entitled ''Independent Evaluation of the GDUFA Resource Capacity Planning Adjustment Methodology,'' providing options and recommendations for a methodology to accurately assess changes in the resource needs of the generic drug review program. FDA, in the GDUFA II Commitment Letter [1] (entitled GDUFA Reauthorization Performance Goals and Program Enhancements Fiscal Years 2018–2022), committed to obtaining this report and publishing it before September 30, 2020.

The third authorization of the Prescription Drug User Fee Act (PDUFA III), which began in fiscal year 2003, introduced the concept of a Workload Adjuster. This was a mechanism to ensure that the annual revenue for the program could be adjusted based on workload levels to ensure adequate staffing levels. Since its introduction, several updates have been made to the methodology, including its renaming as the Capacity Planning Adjustment (CPA).

GDUFA does not currently have a methodology analogous to the CPA to enable adjustment of the annual target revenue. The study announced by this notice posits options and recommendations to consider regarding the potential application of an adjustment methodology for the GDUFA program.

FDA commissioned Booz Allen Hamilton to produce this report. The report is publicly available on FDA's website at: *https://www.fda.gov/industry/fda-user-fee-programs/resource-capacity-planning-and-modernized-time-reporting.* FDA will review the public comments on the report.

Dated: July 28, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–16794 Filed 7–31–20; 8:45 am]

BILLING CODE 4164–01–P

[1] Available at: *https://www.fda.gov/media/101052/download.*

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–4119]

Food Safety Modernization Act Third-Party Certification Program User Fee Rate for Fiscal Year 2021

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the fiscal year (FY) 2021 annual fee rate for recognized accreditation bodies and accredited certification bodies, and the 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 October 1, 2020.

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, 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 we assess fees and require 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 2021 third-party certification program user fee rate announced in this notice is effective on October 1, 2020, and will remain in effect through September 30, 2021.

II. Estimating the Average Cost of a Supported Direct FDA Work Hour for FY 2021

FDA must estimate its costs for each activity in order to establish fee rates for FY 2021. 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 of 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 2021

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.

[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.

We have used an average of past year cost elements to predict the FY 2021 cost. The FY 2021 FDA-wide average cost for payroll (salaries and benefits) is $164,103; non-payroll—including equipment, supplies, information technology, general and administrative overhead—is $94,685; and rent, including cost allocation analysis and adjustments for other rent and rent-related costs, is $25,386 per paid staff year, excluding travel costs.

Summing the average cost of an FTE for payroll, non-payroll, and rent, brings the FY 2021 average fully supported cost to $284,174 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 2021 prior to including travel costs as applicable for the activity.

To calculate an hourly rate, FDA must divide the FY 2021 average fully supported cost of $ 284,174 per FTE by the average number of supported direct FDA work hours in FY 2019—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 2019

Total number of hours in a paid staff year	2,080
Less:	
10 paid holidays	−80
20 days of annual leave	−160
10 days of sick leave	−80
12.5 days of training	−100
26.5 days of general administration	−184
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 2021 ($284,174) by the total number of supported direct work hours available for assignment in FY 2019 (1,160) results in an average fully supported cost of $245 (rounded to the nearest dollar), excluding travel costs, per supported direct work hour in FY 2021.

B. Adjusting FY 2019 Travel Costs for Inflation to Estimate FY 2021 Travel Costs

To adjust the hourly rate for FY 2021, FDA must estimate the cost of inflation in each year for FY 2020 and FY 2021. 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 2020 inflation rate to be 2.3964 percent; this rate was published in the FY 2020 PDUFA user fee rates notice in the **Federal Register** (August 2, 2019, 84 FR 37882). Utilizing the method set forth in section 736(c)(1) of the FD&C Act, FDA has calculated an inflation rate of 2.3964 percent for FY 2020 and 1.3493 percent for FY 2021, and FDA intends to use this inflation rate to make inflation adjustments for FY 2021; the derivation of this rate will be published in the **Federal Register** in the FY 2021 notice for the PDUFA user fee rates. The compounded inflation rate for FYs 2020 and 2021, therefore, is 1.037780 (or 3.7780 percent) (calculated as 1 plus 2.3964 percent times 1 plus 1.3493 percent).

The average fully supported cost per supported direct FDA work hour, excluding travel costs, of $245 already takes into account inflation as the calculation above is based on FY 2021 predicted costs. FDA will use this base unit fee in determining the hourly fee rate for third-party certification program fees for FY 2021 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 2019, the Office of Regulatory Affairs spent a total of $3,506,000 on 463 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 $7,572 per foreign inspection trip. These trips averaged 3 weeks (or 120 paid hours) per trip. Dividing $7,572 per trip by 120 hours per trip results in a total and an additional cost of $63 (rounded to the nearest dollar) per paid hour spent for foreign inspection travel costs in FY 2019. To adjust $63 for inflationary increases in FY 2020 and FY 2021, FDA must multiply it by the same inflation factor mentioned previously in this document (1.037780 or 3.7780 percent), which results in an estimated cost of $65 (rounded to the nearest dollar) per paid hour in addition to $245 for a total of $310 per paid hour ($245 plus $65) for each direct hour of work requiring foreign inspection travel. FDA will use this rate in charging fees in FY 2021 when travel is required for the third-party certification program.

TABLE 2—FSMA FEE SCHEDULE FOR FY 2021

Fee category	Fee rates for FY 2021
Hourly rate without travel	$245
Hourly rate if travel is required	310

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 2021, 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, and the initial application fee for a certification body seeking direct accreditation from FDA. Table 3 provides an overview of the fees for FY 2021.

TABLE 3—FSMA THIRD-PARTY CERTIFICATION PROGRAM USER FEE SCHEDULE FOR FY 2021

Fee category	Fee rates for FY 2021
Initial Application Fee for Accreditation Body Seeking Recognition	$42,320
Annual Fee for Recognized Accreditation Body	1,966
Annual Fee for Accredited Certification Body	2,458
Initial Application Fee for a Certification Body Seeking Direct Accreditation from FDA	42,320

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, $245/hour, to calculate the portion of the user fee attributable to those activities: $245/hour × (80 hours (application review) + 32 hours (written report)) = $27,440. 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, $310/hour, to calculate the portion of the user fee attributable to those activities: $310/hour × 48 hours (*i.e.,* two fully supported FTEs × ((2 travel days × 8 hours) + (1 day onsite × 8 hours))) = $14,880. 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 $27,440 + $14,880 = $42,320. Therefore, the application fee for accreditation bodies applying for recognition in FY 2021 will be $42,320.

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 $7,350 ($245/hour × (22 hours (records review) + 8 hours (written report))) plus $2,480 ($310/hour × 8 hours (on-site evaluation)), which is $9,830. Annualizing this amount over 5 years would lead to an annual fee for recognized accreditation bodies of $1,966 for FY 2021.

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 $7,350 ($245/hour × (22 hours (records review) + 8 hours (written report))) plus $2,480 ($310/hour × 8 hours (on-site evaluation)), which is $9,830. Annualizing this amount over 4 years would lead to an annual fee for accredited certification bodies of $2,458 for FY 2021.

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, $245/hour, to calculate the portion of the user fee attributable to those activities: $245/hour × (80 hours (application review) + 32 hours (written report)) = $27,440. 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, $310/hour, to calculate the portion of the user fee attributable to those activities: $310/hour × 48 hours (*i.e.,* two fully supported FTEs × ((2 travel days × 8 hours) + (1 day onsite × 8 hours))) = $14,880. 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 $27,440 + $14,880 = $42,320. Therefore, the application fee for certification bodies applying for direct accreditation from FDA in FY 2021 will be $42,320.

IV. Estimated Fees for Accreditation Bodies and Certification Bodies in Other Fee Categories for FY 2021

Section 1.705(a) also establishes application fees for recognized accreditation bodies submitting renewal applications and 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 2021, for transparency and planning purposes, we have provided an estimate of what these fees would be for FY 2021 based on the fully supported FTE hourly rates for FY 2021 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 2021
Renewal application fee for recognized accreditation body	$25,195
Renewal application fee for directly accredited certification body	25,195
Annual fee for certification body directly accredited by FDA	20,240

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 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 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 29, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020–16846 Filed 7–30–20; 11:15 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1692]

Generic Drug User Fee Rates for Fiscal Year 2021

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Federal Food, Drug, and Cosmetic Act (FD&C Act or statute), as amended by the Generic Drug User Fee Amendments of 2017 (GDUFA II), authorizes the Food and Drug Administration (FDA, Agency, or we) to assess and collect fees for abbreviated new drug applications (ANDAs), drug master files (DMFs), generic drug active pharmaceutical ingredient (API) facilities, finished dosage form (FDF) facilities, contract manufacturing organization (CMO) facilities, and generic drug applicant program user fees. In this document, FDA is announcing fiscal year (FY) 2021 rates for GDUFA II fees.

FOR FURTHER INFORMATION CONTACT: Andrew Bank, Office of Financial Management, Food and Drug Administration, 4041 Powder Mill Rd., Rm. 62019A, Beltsville, MD 20705–4304, 301–796–0292.

SUPPLEMENTARY INFORMATION:

I. Background

Sections 744A and 744B of the FD&C Act (21 U.S.C. 379j–41 and 379j–42) establish fees associated with human generic drug products. Fees are assessed on: (1) Certain types of applications for human generic drug products; (2) certain facilities where APIs and FDFs are produced; (3) certain DMFs associated with human generic drug products; and (4) generic drug applicants who have approved ANDAs (the program fee) (see section 744B(a)(2)–(5) of the FD&C Act).

GDUFA II provides that user fees should total $493,600,000 annually adjusted each year for inflation. For FY 2021, the generic drug fee rates are: ANDA ($196,868), DMF ($69,921), domestic API facility ($41,671), foreign API facility ($56,671), domestic FDF facility ($184,022), foreign FDF facility ($199,022), domestic CMO facility ($61,341), foreign CMO facility ($76,341), large size operation generic drug applicant program ($1,542,993), medium size operation generic drug applicant program ($617,197), and small business generic drug applicant program ($154,299). These fees are effective on October 1, 2020, and will remain in effect through September 30, 2021.

II. Fee Revenue Amount for FY 2021

GDUFA II directs FDA to use the yearly revenue amount determined under the statute as a starting point to set the fee rates for each fee type. For more information about GDUFA II, please refer to the FDA website (*https://www.fda.gov/gdufa*). The ANDA, DMF, API facility, FDF facility, CMO facility, and generic drug applicant program fee (GDUFA program fee) calculations for FY 2021 are described in this document.

The base revenue amount for FY 2021 is $513,223,160. This is the amount