

supported FTE hourly rate excluding travel, \$256/hour, to calculate the portion of the user fee attributable to those activities: $\$256/\text{hour} \times (8 \text{ hours}) = \$2,048$. For the portion of the fee covering onsite evaluation of a domestic VQIP importer, we use the fully supported FTE hourly rate for work requiring domestic travel, \$277/hour, to calculate the portion of the user fee attributable to those activities: $\$277/\text{hour} \times 8 \text{ hours}$ (*i.e.*, one fully supported FTE \times (1 day onsite \times 8 hours)) = \$2,216. Therefore, the total cost of conducting the domestic performance evaluation of a VQIP importer is determined to be $\$2,216 + \$2,048 = \$4,264$.

Coordination of the onsite performance evaluation of a foreign VQIP importer is estimated to take place at an FTE's worksite, so we use the fully supported FTE hourly rate excluding travel, \$256/hour, to calculate the portion of the user fee attributable to those activities: $\$256/\text{hour} \times (10 \text{ hours}) = \$2,560$. For the portion of the fee covering onsite evaluation of a foreign VQIP importer, we use the fully supported FTE hourly rate for work requiring foreign travel, \$330/hour, to calculate the portion of the user fee attributable to those activities: $\$330/\text{hour} \times 24 \text{ hours}$ (*i.e.*, one fully supported FTE \times ((2 travel days \times 8 hours) + (1 day onsite \times 8 hours))) = \$7,920. Therefore, the total cost of conducting the foreign performance evaluation of a VQIP importer is determined to be $\$2,560 + \$7,920 = \$10,480$.

Therefore, the estimated average cost of the work FDA performs in total for approving an application for a VQIP importer in FY22 based on these figures would be $\$7,000 + (\$9,984 \times 0.25) + (\$7,168 \times 0.75) + (\$4,264 \times 0.25) = \$15,938$.

IV. How must the fee be paid?

An invoice will be sent to VQIP importers approved to participate in the program. Payment must be made prior to October 1, 2021, to be eligible for VQIP participation for the benefit year beginning October 1, 2021. FDA will not refund the VQIP user fee for any reason.

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 in the check stub. 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.)

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

The consequences of not paying these fees are outlined in Section J of "FDA's Voluntary Qualified Importer Program; Guidance for Industry" document (available at <https://www.fda.gov/media/92196/download>). If the user fee is not paid before October 1, a VQIP importer will not be eligible to

participate in VQIP. For the first year a VQIP application is approved, if the user fee is not paid before October 1, 2021, you are not eligible to participate in VQIP. If you subsequently pay the user fee, FDA will begin your benefits after we receive the full payment. The user fee may not be paid after December 31, 2021. For a subsequent year, if you do not pay the user fee before October 1, FDA will send a Notice of Intent to Revoke your participation in VQIP. If you do not pay the user fee within 30 days of the date of the Notice of Intent to Revoke, we will revoke your participation in VQIP.

Dated: July 20, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-0661]

Generic Drug User Fee Rates for Fiscal Year 2022

AGENCY: Food and Drug Administration, Health and Human Services (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, and contract manufacturing organization (CMO) facilities; and generic drug applicant program user fees. In this document, FDA is announcing fiscal year (FY) 2022 rates for GDUFA II fees.

FOR FURTHER INFORMATION CONTACT: Lola Olajide, Office of Financial Management, Food and Drug Administration, 4041 Powder Mill Rd., Rm. 61077B, Beltsville, MD 20705-4304, 240-402-4244.

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) through (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 2022, the generic drug fee rates are: ANDA (\$225,712), DMF (\$74,952), domestic API facility (\$42,557) foreign API facility (\$57,557), domestic FDF facility (\$195,012), foreign FDF facility (\$210,012), domestic CMO facility (\$65,004), foreign CMO facility (\$80,004), large size operation generic drug applicant program (\$1,536,856), medium size operation generic drug applicant program (\$614,742), and small business generic drug applicant program (\$153,686). These fees are effective on October 1, 2021, and will remain in effect through September 30, 2022.

II. Fee Revenue Amount for FY 2022

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. The base revenue amount for FY 2022 is \$520,208,640. This is the amount calculated for the prior fiscal year, FY 2021, pursuant to the statute (see section 744B(b)(1) of the FD&C Act). 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 2022 are described in this document.

A. Inflation Adjustment

The base revenue amount for FY 2022 is \$520,208,640. This is the amount calculated for the prior fiscal year, FY 2021, pursuant to the statute (see section 744B(b)(1) of the FD&C Act). GDUFA II specifies that the

\$520,208,640 is to be adjusted for inflation increases for FY 2022 using two separate adjustments—one for personnel compensation and benefits (PC&B) and one for non-PC&B costs (see sections 744B(c)(1)(B) and (C) of the FD&C Act).

The component of the inflation adjustment for PC&B costs shall be one plus the average annual percent change in the cost of all PC&B paid per full-time equivalent position (FTE) at FDA for the first 3 of the 4 preceding fiscal years, multiplied by the proportion of PC&B costs to total FDA costs of human generic drug activities for the first 3 of the preceding 4 fiscal years (see section 744B(c)(1)(B) of the FD&C Act).

Table 1 summarizes the actual cost and total FTEs for the specified fiscal years, and provides the percent change from the previous fiscal year and the average percent change over the first 3 of the 4 fiscal years preceding FY 2022. The 3-year average is 2.7383 percent.

TABLE 1—FDA PERSONNEL COMPENSATION AND BENEFITS (PC&B) EACH YEAR AND PERCENT CHANGE

Fiscal year	2018	2019	2020	3-Year average
Total PC&B	\$2,690,678,000	\$2,620,052,000	\$2,875,592,000
Total FTEs	17,023	17,144	17,535
PC&B per FTE	\$158,061	\$152,826	\$163,992
Percent Change from Previous Year	4.2206	-3.3120	7.3063	2.7383

The statute specifies that this 2.7383 percent should be multiplied by the proportion of PC&B expended for

human generic drug activities for the first 3 of the preceding 4 fiscal years. Table 2 shows the amount of PC&B and

the total amount obligated for human generic drug activities from FY 2018 through FY 2020.

TABLE 2—PC&B AS A PERCENT OF FEE REVENUES SPENT ON THE PROCESS OF HUMAN GENERIC DRUG APPLICATIONS OVER THE LAST 3 YEARS

Fiscal year	2018	2019	2020	3-Year average
PC&B	\$332,617,643	\$356,874,114	\$397,392,785
Non-PC&B	\$276,911,265	\$290,439,277	\$300,692,399
Total Costs	\$609,528,908	\$647,313,391	\$698,085,185
PC&B Percent	54.5696	55.1316	56.9261	55.5424
Non-PC&B Percent	45.4304	44.8684	43.0739	44.4576

The payroll adjustment is 2.7383 percent multiplied by 55.5424 percent (or 1.5209 percent).

The statute specifies that the portion of the inflation adjustment for non-PC&B costs for FY 2022 is the average annual percent change that occurred in the Consumer Price Index (CPI) for urban consumers (Washington-Baltimore, DC-MD-VA-WV; not seasonally adjusted; all items; annual index) for the first 3 of the preceding 4 years of available data multiplied by the proportion of all costs other than PC&B costs to total costs of human generic

drug activities (see section 744B(c)(1)(C) of the FD&C Act). As a result of a geographical revision made by the Bureau of Labor and Statistics in January 2018,¹ the Washington-Baltimore, DC-MD-VA-WV index was discontinued and replaced with two separate indices (*i.e.*, Washington-Arlington-Alexandria, DC-VA-MD-WV and Baltimore-Columbia-Towson, MD).

¹ The Bureau of Labor Statistics' announcement of the geographical revision can be viewed at <https://www.bls.gov/cpi/additional-resources/geographic-revision-2018.htm>.

In order to continue applying a CPI that best reflects the geographic region in which FDA is headquartered and that provides the most current data available, the Washington-Arlington-Alexandria index will be used in calculating the relevant adjustment factors for FY 2022 and subsequent years. Table 3 provides the summary data for the percent change in the specified CPI. The data are published by

the Bureau of Labor Statistics and can be found on its website at: [https://](https://data.bls.gov/pdq/SurveyOutputServlet?data_)

data.bls.gov/pdq/SurveyOutputServlet?data_

[tool=dropmap&series](https://data.bls.gov/pdq/SurveyOutputServlet?data_)
[id=CUURS35ASA0,GUUSS35ASA0.](https://data.bls.gov/pdq/SurveyOutputServlet?data_)

TABLE 3—ANNUAL AND 3-YEAR AVERAGE PERCENT CHANGE IN CPI FOR WASHINGTON-ARLINGTON-ALEXANDRIA AREA

Year	2018	2019	2020	3-Year average
Annual CPI	261.445	264.777	267.157
Annual Percent Change	2.0389	1.2745	0.8989	1.4041

To calculate the inflation adjustment for non-pay costs, we multiply the 3-year average percent change in the CPI (1.4041 percent) by the proportion of all costs other than PC&B to total costs of human generic drug activities obligated. Because 55.5424 percent was obligated for PC&B as shown in table 2, 44.4576 percent is the portion of costs other than PC&B. The non-pay adjustment is 1.4041 percent times 44.4576 percent, or 0.6242 percent.

To complete the inflation adjustment for FY 2022, we add the PC&B component (1.5209 percent) to the non-PC&B component (0.6242 percent) for a total inflation adjustment of 2.1451 percent (rounded), and then add 1, making an inflation adjustment multiple of 1.021451. We then multiply the base revenue amount for FY 2022 (\$520,208,640) by 1.021451, yielding an inflation-adjusted amount of \$531,367,636.

B. Final Year Adjustment

For FY 2022, FDA may, in addition to the inflation adjustment, further increase the fee revenue and fees established if such an adjustment is necessary to provide for not more than 3 months of operating reserves of carryover user fees for human generic drug activities for the first 3 months of FY 2023. To determine whether a final year adjustment applies, FDA calculates operating reserves of carryover and its estimated balance as of the beginning of FY 2023.

After running analyses on the projected collections and obligations for FY 2021 and FY 2022, FDA estimates available carryover balance will be \$63,131,283 as of the beginning of FY 2023. FDA estimates the cost of operations per week is \$10,202,769; thus, the projected available carryover balance of \$63,131,283 at the beginning of FY 2023 represents approximately 6 weeks of operating reserves. Per the statute, FDA could raise the fee revenue by \$59,301,948 (12 weeks × \$10,202,769 minus projected carryover of \$63,131,283) for the final year adjustment. FDA recognizes that adding \$59,301,948 to the fee revenue in FY 2022 may pose as a burden to the

regulated industry. In light of this, and in light of the fact that the legislative language authorizing the final year adjustment allows FDA discretion in whether to make this adjustment for a full 3 months of operating reserves or for a shorter period, FDA has decided to make the final year adjustment to allow for only 7 weeks of operating reserves. Accordingly, the final year adjustment will be \$8,288,102 (7 × \$10,202,769 less projected carryover of \$63,131,283). Adding this amount to the inflation adjusted amount of \$531,367,636 results in a total revenue target of \$539,656,000 (rounded to the nearest thousand dollars).

III. ANDA Filing Fee

Under GDUFA II, the FY 2022 ANDA filing fee is owed by each applicant that submits an ANDA on or after October 1, 2021. This fee is due on the submission date of the ANDA. Section 744B(b)(2)(B) of the FD&C Act specifies that the ANDA fee will make up 33 percent of the \$539,656,000, which is \$178,086,480.

To calculate the ANDA fee, FDA estimated the number of full application equivalents (FAEs) that will be submitted in FY 2022. The submissions are broken down into three categories: New originals (submissions that have not been received by FDA previously); submissions that FDA refused to receive (RTR) for reasons other than failure to pay fees; and applications that are resubmitted after an RTR decision for reasons other than failure to pay fees. An ANDA counts as one FAE; however, 75 percent of the fee paid for an ANDA that has been RTR shall be refunded according to GDUFA II if: (1) The ANDA is refused for a cause other than failure to pay fees or (2) the ANDA has been withdrawn prior to receipt (section 744B(a)(3)(D)(i) of the FD&C Act). Therefore, an ANDA that is considered not to have been received by FDA due to reasons other than failure to pay fees or withdrawn prior to receipt counts as one-fourth of an FAE. After an ANDA has been RTR, the applicant has the option of resubmitting. For user fee purposes, these resubmissions are equivalent to new original

submissions—ANDA resubmissions are charged the full amount for an application (one FAE).

FDA utilized data from ANDAs submitted from October 1, 2019, to April 30, 2021, to estimate the number of new original ANDAs that will incur filing fees in FY 2022. For FY 2022, the Agency estimates that approximately 788 new original ANDAs will be submitted and incur filing fees. Not all of the new original ANDAs will be received by the Agency and some of those not received will be resubmitted in the same fiscal year. Therefore, the Agency expects that the FAE count for ANDAs will be 789 for FY 2022.

The FY 2022 application fee is estimated by dividing the number of FAEs that will pay the fee in FY 2022 (789) into the fee revenue amount to be derived from ANDA application fees in FY 2022 (\$178,086,480). The result, rounded to the nearest dollar, is a fee of \$225,712 per ANDA.

The statute provides that those ANDAs that include information about the production of active pharmaceutical ingredients other than by reference to a DMF will pay an additional fee that is based on the number of such active pharmaceutical ingredients and the number of facilities proposed to produce those ingredients (see section 744B(a)(3)(F) of the FD&C Act). FDA anticipates that this additional fee is unlikely to be assessed often; therefore, FDA has not included projections concerning the amount of this fee in calculating the fees for ANDAs.

IV. DMF Fee

Under GDUFA II, the DMF fee is owed by each person that owns a type II API DMF that is referenced, on or after October 1, 2012, in a generic drug submission by an initial letter of authorization. This is a one-time fee for each DMF. This fee is due on the earlier of the date on which the first generic drug submission is submitted that references the associated DMF or the date on which the DMF holder requests the initial completeness assessment. Under section 744B(a)(2)(D)(iii) of the FD&C Act, if a DMF has successfully undergone an initial completeness

assessment and the fee is paid, the DMF will be placed on a publicly available list documenting DMFs available for reference.

To calculate the DMF fee, FDA assessed the volume of DMF submissions over time. The Agency assessed DMFs from October 1, 2019, to April 30, 2021, and concluded that averaging the number of fee-paying DMFs provided the most accurate model for predicting fee-paying DMFs for FY 2022. The monthly average of paid DMF submissions the Agency received in FY 2020 and FY 2021 is 30. To determine the FY 2022 projected number of fee-paying DMFs, the average of 30 DMF submissions is multiplied by 12 months, which results in 360 estimated FY 2022 fee-paying DMFs. FDA is estimating 360 fee-paying DMFs for FY 2022.

The FY 2022 DMF fee is determined by dividing the DMF target revenue by the estimated number of fee-paying DMFs in FY 2022. Section 744B(b)(2)(A) of the FD&C Act specifies that the DMF fees will make up 5 percent of the \$539,656,000, which is \$26,982,800. Dividing the DMF revenue amount (\$26,982,800) by the estimated fee-paying DMFs (360), and rounding to the nearest dollar, yields a DMF fee of \$74,952 for FY 2022.

V. Foreign Facility Fee Differential

Under GDUFA II, the fee for a facility located outside the United States and its territories and possessions shall be \$15,000 higher than the amount of the fee for a facility located in the United States and its territories and possessions. The basis for this differential is the extra cost incurred by conducting an inspection outside the United States and its territories and possessions.

VI. FDF and CMO Facility Fees

Under GDUFA II, the annual FDF facility fee is owed by each person who owns an FDF facility that is identified in at least one approved generic drug submission owned by that person or its affiliates. The CMO facility fee is owed by each person who owns an FDF facility that is identified in at least one approved ANDA but is not identified in an approved ANDA held by the owner of that facility or its affiliates. These fees are due no later than the first business day on or after October 1 of each such year. Section 744B(b)(2)(C) of the FD&C Act specifies that the FDF and CMO facility fee revenue will make up 20 percent of the \$539,656,000, which is \$107,931,200.

To calculate the fees, data from FDA's Integrity Services (IS) were utilized as the primary source of facility

information for determining the denominators of each facility fee type. IS is the master data steward for all facility information provided in generic drug submissions received by FDA. A facility's reference status in an approved generic drug submission is extracted directly from submission data rather than relying on data from self-identification. This information provided the number of facilities referenced as FDF manufacturers in at least one approved generic drug submission. Based on FDA's IS data, the FDF and CMO facility denominators are 181 FDF domestic, 279 FDF foreign, 88 CMO domestic, and 104 CMO foreign facilities for FY 2022.

GDUFA II specifies that the CMO facility fee is to be equal to one-third the amount of the FDF facility fee. Therefore, to generate the target collection revenue amount from FDF and CMO facility fees (\$107,931,200), FDA must weight a CMO facility as one-third of an FDF facility. FDA set fees based on the estimate of 181 FDF domestic, 279 FDF foreign, 29.33 CMO domestic (88 multiplied by one-third), and 34.67 CMO foreign facilities (104 multiplied by one-third), which equals 524 total weighted FDF and CMO facilities for FY 2022.

To calculate the fee for domestic facilities, FDA first determines the total fee revenue that will result from the foreign facility differential by subtracting the fee revenue resulting from the foreign facility fee differential from the target collection revenue amount (\$107,931,200) as follows. The foreign facility fee differential revenue equals the foreign facility fee differential (\$15,000) multiplied by the number of FDF foreign facilities (279) plus the foreign facility fee differential (\$15,000) multiplied by the number of CMO foreign facilities (104), totaling \$5,745,000. This results in foreign fee differential revenue of \$5,745,000 from the total FDF and CMO facility fee target collection revenue. Subtracting the foreign facility differential fee revenue (\$5,745,000) from the total FDF and CMO facility target collection revenue (\$107,931,200) results in a remaining facility fee revenue balance of \$102,186,200. To determine the domestic FDF facility fee, FDA divides the \$102,186,200 by the total weighted number of FDF and CMO facilities (524), which results in a domestic FDF facility fee of \$195,012. The foreign FDF facility fee is \$15,000 more than the domestic FDF facility fee, or \$210,012.

According to GDUFA II, the domestic CMO fee is calculated as one-third the amount of the domestic FDF facility fee. Therefore, the domestic CMO fee is

\$65,004, rounded to the nearest dollar. The foreign CMO fee is calculated as the domestic CMO fee plus the foreign fee differential of \$15,000. Therefore, the foreign CMO fee is \$80,004.

VII. API Facility Fee

Under GDUFA II, the annual API facility fee is owed by each person who owns a facility that is identified in: (1) At least one approved generic drug submission or (2) in a Type II API DMF referenced in at least one approved generic drug submission. These fees are due no later than the first business day on or after October 1 of each such year. Section 744B(b)(2)(D) of the FD&C Act specifies the API facility fee will make up 7 percent of \$539,656,000 in fee revenue, which is \$37,775,920.

To calculate the API facility fee, data from FDA's IS were utilized as the primary source of facility information for determining the denominator. As stated above, IS is the master data steward for all facility information provided in generic drug submissions received by FDA. A facility's reference status in an approved generic drug submission is extracted directly from submission data rather than relying on data from self-identification. This information provided the number of facilities referenced as API manufacturers in at least one approved generic drug submission.

The total number of API facilities identified was 679; of that number, 87 were domestic and 592 were foreign facilities. The foreign facility differential is \$15,000. To calculate the fee for domestic facilities, FDA must first subtract the fee revenue that will result from the foreign facility fee differential. FDA takes the foreign facility differential (\$15,000) and multiplies it by the number of foreign facilities (592) to determine the total fee revenue that will result from the foreign facility differential. As a result of that calculation, the foreign fee differential revenue will make up \$8,880,000 of the total API fee revenue. Subtracting the foreign facility differential fee revenue (\$8,880,000) from the total API facility target revenue (\$37,775,920) results in a remaining balance of \$28,895,920. To determine the domestic API facility fee, we divide the \$28,895,920 by the total number of facilities (679), which gives us a domestic API facility fee of \$42,557. The foreign API facility fee is \$15,000 more than the domestic API facility fee, or \$57,557.

VIII. Generic Drug Applicant Program Fee

Under GDUFA II, if a person and its affiliates own at least one but not more

than five approved ANDAs on October 1, 2021, the person and its affiliates shall owe a small business GDUFA program fee. If a person and its affiliates own at least 6 but not more than 19 approved ANDAs, the person and its affiliates shall owe a medium size operation GDUFA program fee. If a person and its affiliates own at least 20 approved ANDAs, the person and its affiliates shall owe a large size operation GDUFA program fee. These fees are due no later than the first business day on or after October 1 of each such year. Section 744B(b)(2)(E) of the FD&C Act specifies the GDUFA program fee will make up 35 percent of \$539,656,000 in fee revenue, which is \$188,879,600.

To determine the appropriate number of parent companies for each tier, the Agency asked companies to claim their ANDAs and affiliates in the Center for Drug Evaluation and Research (CDER) NextGen Portal. The companies were able to confirm relationships currently present in the Agency’s records, while also reporting newly approved ANDAs, newly acquired ANDAs, and new affiliations.

In determining the appropriate number of approved ANDAs, the Agency has factored in a number of variables that could affect the collection of the target revenue: (1) Inactive ANDAs—applicants who have not submitted an annual report for one or more of their approved applications within the past 2 years; (2) Program Fee Arrears List—parent companies that are on the arrears list for any fiscal year; (3) Center for Biologics Evaluation and Research (CBER) approved ANDAs—applicants and their affiliates with CBER-approved ANDAs in addition to CDER’s approved ANDAs; and (4) withdrawals of approved ANDAs by April 1st—applicants who have submitted a written request for withdrawal of approval by April 1st of the previous fiscal year. The list of original approved ANDAs from the Generic Drug Review Platform as of April 30, 2021, shows 291 applicants in the small business tier, 76 applicants in the medium size tier, and 76 applicants in the large size tier. Factoring in all the variables for the fourth year of GDUFA II, the Agency estimates there will be 203 applicants in the small business tier, 69 applicants in the medium size tier, and 75 applicants in the large size tier for FY 2022.

To calculate the GDUFA program fee, GDUFA II provides that large size operation generic drug applicants pay the full fee, medium size operation applicants pay two-fifths of the full fee, and small business applicants pay one-tenth of the full fee. To generate the

target collection revenue amount from GDUFA program fees (\$188,879,600), we must weigh medium and small tiered applicants as a subset of a large size operation generic drug applicant. FDA will set fees based on the weighted estimate of 20.30 applicants in the small business tier (203 multiplied by 10 percent), 27.6 applicants in the medium size tier (69 multiplied by 40 percent), and 75 applicants in the large size tier, arriving at 122.90 total weighted applicants for FY 2022.

To generate the large size operation GDUFA program fee, FDA divides the target revenue amount of \$188,879,600 by 122.90, which equals \$1,536,856. The medium size operation GDUFA program fee is 40 percent of the full fee (\$614,742), and the small business operation GDUFA program fee is 10 percent of the full fee (\$153,686).

IX. Fee Schedule for FY 2022

The fee rates for FY 2022 are set out in table 4.

TABLE 4—FEE SCHEDULE FOR FY 2022

Fee category	Fees rates for FY 2022
Applications:	
Abbreviated New Drug Application (ANDA)	\$225,712
Drug Master File (DMF)	74,952
Facilities:	
Active Pharmaceutical Ingredient (API)—Domestic	42,557
API—Foreign	57,557
Finished Dosage Form (FDF)—Domestic	195,012
FDF—Foreign	210,012
Contract Manufacturing Organization (CMO)—Domestic	65,004
CMO—Foreign	80,004
GDUFA Program:	
Large size operation generic drug applicant ...	1,536,856
Medium size operation generic drug applicant	614,742
Small business operation generic drug applicant	153,686

X. Fee Payment Options and Procedures

The new fee rates are effective October 1, 2021. To pay the ANDA, DMF, API facility, FDF facility, CMO facility, and GDUFA program fees, a Generic Drug User Fee Cover Sheet must be completed, available at <https://www.fda.gov/gdufa> and http://userfees.fda.gov/OA_HTML/gdufaCAcdLogin.jsp, and a user fee identification (ID) number must be generated. Payment must be made in

U.S. currency drawn on a U.S. bank by electronic check, check, bank draft, U.S. postal money order, credit card, or wire transfer. The preferred payment method is online using electronic check (Automated Clearing House (ACH), also known as eCheck) or credit card (Discover, VISA, MasterCard, American Express). FDA has partnered with the U.S. Department of the Treasury to utilize *Pay.gov*, a web-based payment application, for online electronic payment. The *Pay.gov* feature is available on the FDA website after completing the Generic Drug User Fee Cover Sheet and generating the user fee ID number.

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 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.

The user fee ID number must be included on the check, bank draft, or postal money order and must be made payable to the order of the Food and Drug Administration. Payments can be mailed to: Food and Drug Administration, P.O. Box 979108, St. Louis, MO 63197–9000. If checks are to be sent by a courier that requests a street address, the courier can deliver checks to: U.S. Bank, Attention: Government Lockbox 979108, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This U.S. Bank address is for courier delivery only. For questions concerning courier delivery, U.S. Bank can be contacted at 314–418–4013. This telephone number is only for questions about courier delivery.) The FDA post office box number (P.O. Box 979108) must be written on the check, bank draft, or postal money order.

For payments made by wire transfer, the unique user fee ID number must be referenced. Without the unique user fee ID number, the payment may not be applied. If the payment amount is not applied, the invoice amount will be referred to collections. The originating financial institution may charge a wire transfer fee. Applicable wire transfer fees must be included 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 number: 75060099, routing number: 021030004, SWIFT: FRNYUS33. FDA's tax identification number is 53-0196965.

Dated: July 20, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-0649]

Determination That CECLOR CD (Cefaclor Extended-Release Tablets) 375 Milligrams and 500 Milligrams Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness, Except the Indication of Secondary Bacterial Infections of Acute Bronchitis, Which Was Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) has determined that CECLOR CD (cefaclor extended-release tablets) 375 milligrams (mg) and 500 mg were not withdrawn from sale for reasons of safety or effectiveness, except with respect to the indication of secondary bacterial infections of acute bronchitis (SBIAB) that was withdrawn for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to suspend approval of any abbreviated new drug application (ANDA) that refers to this drug product and has removed the indication for SBIAB. This determination also will allow FDA to continue to approve ANDAs that refer to these drug products as long as they meet relevant legal and regulatory requirements. However, the Agency will not accept or approve ANDAs for CECLOR CD (cefaclor extended-release tablets) 375 mg and 500 mg that include SBIAB as an indication.

FOR FURTHER INFORMATION CONTACT:

Stacy Kane, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6236, Silver Spring, MD 20993-0002, 301-796-8363, Stacy.Kane@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) Has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and, with certain exceptions, labeling as the listed drug, which is a version of the drug that was previously approved and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is known generally as the "Orange Book." Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

Under § 314.161(a)(2), the Agency must also determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness if ANDAs that referred to the listed drug have already been approved prior to its market withdrawal. If the Agency determines that a listed drug was withdrawn from sale for reasons of safety or effectiveness, and there are approved ANDAs that reference that listed drug, FDA will initiate a proceeding to determine whether the suspension of the ANDAs is also required (21 CFR 314.161(d)).

CECLOR CD (cefaclor extended-release tablets) 375 mg and 500 mg are the subject of NDA 050673 held by Eli Lilly and Co., and initially approved on June 28, 1996. CECLOR CD (cefaclor extended-release tablets) is indicated for the treatment of patients with the

following mild to moderate infections when caused by susceptible strains of the designated microorganisms:

- Acute bacterial exacerbations of chronic bronchitis due to *Haemophilus influenzae* (non- β -lactamase-producing strains only), *Moraxella catarrhalis* (including β -lactamase-producing strains) or *Streptococcus pneumoniae*.
- Secondary bacterial infections of acute bronchitis due to *H. influenzae* (non- β -lactamase-producing strains only), *M. catarrhalis* (including β -lactamase-producing strains), or *S. pneumoniae*.
- Pharyngitis and tonsillitis due to *Streptococcus pyogenes*.
- Uncomplicated skin and skin structure infections due to *Staphylococcus aureus* (methicillin-susceptible).

On June 13, 2005, Eli Lilly and Co. submitted a request to the Agency to withdraw approval of NDA 050673, CECLOR CD (cefaclor extended-release tablets), 375 mg and 500 mg, under 21 CFR 314.150(c). The Agency published a **Federal Register** notice on April 22, 2014, withdrawing approval of NDA 050673, effective May 22, 2014.¹

After reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that CECLOR CD (cefaclor extended-release tablets), 375 mg and 500 mg, were not withdrawn from sale for reasons of safety or effectiveness, except with respect to the indication for SBIAB.

Based on a review of relevant information, FDA has concluded that the SBIAB indication is not appropriate because most cases of SBIAB are considered to be viral or noninfectious. As an antibacterial drug, CECLOR CD (cefaclor extended-release tablets) is not considered to be effective to treat SBIAB. Such use of CECLOR CD (cefaclor extended-release tablets) would likely result in inappropriate antibacterial drug use. Accordingly, for the treatment of SBIAB, the benefit-risk profile of CECLOR CD (cefaclor extended-release tablets) is unfavorable and does not support approval of these products (or ANDAs referencing them) for this indication. For the remaining indications, the Agency has determined that CECLOR CD (cefaclor extended-release tablets) continues to have a favorable benefit-risk profile.

Accordingly, the Agency will continue to list CECLOR CD (cefaclor extended-release tablets), 375 mg and 500 mg, in the "Discontinued Drug Product List" section of the Orange Book. The approved ANDA has

¹ See 79 FR 22501 (April 22, 2014).