Designees under 45 CFR 400.301(c), and Wilson-Fish Grantees (State 2 Agencies) administering or supervising the administration of programs under Title IV of the Act.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ORR–1, Cash and Medical Assistance Program Estimates	55	1	0.60	33

Estimated Total Annual Burden Hours: 33.

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW., Washington, DC 20201. Attention Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov*.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA_SUBMISSION@OMB.EOP.GOV*, Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2017–18254 Filed 8–28–17; 8:45 am]

BILLING CODE 4184–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0007]

Generic Drug User Fee Rates for Fiscal Year 2018

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Generic Drug User Fee Amendments of 2017 (GDUFA II), authorizes FDA 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 the Food and Drug Administration (FDA or Agency) is announcing fiscal year (FY) 2018 rates for GDUFA fees.

FOR FURTHER INFORMATION CONTACT: David Haas, Office of Financial Management, Food and Drug Administration, 8455 Colesville Rd., COLE–14202I, Silver Spring, MD 20993–0002, 240–402–9845.

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) the generic drug applicant program (see section 744B(a)(1)–(5) of the FD&C Act).

GDUFA II fees vary greatly from those in GDUFA I because of two fundamental adjustments to the fee structure:

(1) The revenue base for GDUFA II is $493.6 million versus $323 million in the final year of GDUFA I—ANDAs are the primary workload driver of the program. GDUFA I was built on the assumption that FDA would receive 750 ANDAs per year. Over the first 4 years of GDUFA I, ANDA receipts have averaged approximately 1,000 per year. To address the increased workload, FDA hired additional staff and is projected to spend about $430 million in the final year of GDUFA I. To maintain FDA's current productivity and implement negotiated improvements, GDUFA II stipulates that user fees should total $493.6 million annually adjusted each year for inflation.

(2) GDUFA II will for the first time rely on annual program fees—GDUFA II shifts the fee burden somewhat from facility fees.

For FY 2018, the generic drug fee rates are: ANDA ($171,823), DMF ($47,829), domestic API facility ($45,367), foreign API facility ($60,367), domestic FDF facility ($211,087), foreign FDF facility ($226,087), domestic CMO facility ($70,362), foreign CMO facility ($85,362), large size operation generic drug applicant program ($1,590,792), medium size operation drug applicant program ($636,317), and small business generic drug applicant program ($159,079). These fees are effective on October 1, 2017, and will remain in effect through September 30, 2018.

II. Fee Revenue Amount for FY 2018

The base revenue amount for FY 2018 is $493,600,000, as set in the statute (see section 744B(b)(1) of the FD&C Act). GDUFA II directs FDA to use the yearly revenue amount as a starting point to set the fee rates for each fee type. For more information about GDUFA II, please refer to the FDA Web site (*http://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 2018 are described in this document.

GDUFA II specifies that the $493,600,000 is to be adjusted for inflation increases for FY 2019 through FY 2022 using two separate adjustments—one for personnel compensation and benefits (PC&B) and one for non-PC&B costs (see section 744B(c)(1) of the FD&C Act). Because the adjustment for inflation does not take effect until FY 2019, FDA will not adjust the base revenue amount for inflation in FY 2018.

III. ANDA Fee

Under GDUFA II, the FY 2018 ANDA fee is owed by each applicant that submits an ANDA on or after October 1, 2017. This fee is due on the receipt date of the ANDA. Section 744B(b)(2)(B) specifies that the ANDA fee will make up 33 percent of the $493,600,000, which is $162,888,000.

To calculate the ANDA fee, FDA estimated the number of full application equivalents (FAEs) that will be submitted in FY 2018. An ANDA counts as one FAE; however, 75 percent of the

fee paid for an ANDA 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)(2)(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 if the applicant initially paid a full application fee. One hundred percent of the fee paid for an ANDA shall be refunded if FDA initially receives the ANDA and subsequent to initial receipt, FDA determines that exclusivity should have prevented receipt of the ANDA, and thus FDA determines that the ANDA is no longer received (section 744B(a)(2)(D))(ii) of the FD&C Act).

FDA utilized data from ANDAs submitted from October 1, 2013, to April 30, 2017, to estimate the number of new original ANDAs that will incur filing fees in FY 2018. For FY 2018, the Agency estimates that approximately 938 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 948 for FY 2018.

The FY 2018 application fee is estimated by dividing the number of FAEs that will pay the fee in FY 2018 (948) into the fee revenue amount to be derived from ANDA application fees in FY 2018 ($162,888,000). The result, rounded to the nearest dollar, is a fee of $171,823 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 considers 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 active pharmaceutical ingredient 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 drug master file 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, 2015, to April 30, 2017, and concluded that averaging the number of fee-paying DMFs provided the most accurate model for predicting fee-paying DMFs for FY 2018. FDA is estimating 516 fee-paying DMFs for FY 2018.

The FY 2018 DMF fee is determined by dividing the DMF target revenue by the estimated number of fee-paying DMFs in FY 2018. Section 744B(b)(2)(A) specifies that the DMF fees will make up five percent of the $493,600,000, which is $24,680,000. Dividing the DMF revenue amount ($24,680,000) by the estimated fee-paying DMFs (516), and rounding to the nearest dollar, yields a DMF fee of $47,829 for FY 2018.

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 his 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 $493,600,000, which is $98,720,000.

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 for FY 2018, the FDF and CMO facility denominators are 182 FDF domestic, 208 FDF foreign, 71 CMO domestic, and 97 CMO foreign facilities.

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 ($98,720,000), FDA must weight a CMO facility as one-third of an FDF facility. FDA set fees based on the estimate of 182 FDF domestic, 208 FDF foreign, 23.67 CMO domestic (71 multiplied by one-third), and 32.33 CMO foreign facilities (97 multiplied by one-third), which equals 446 total weighted FDF and CMO facilities for FY 2018.

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 ($98,720,000) as follows. The foreign facility fee differential revenue equals the foreign facility fee differential ($15,000) multiplied by the number of FDF foreign facilities (208) plus the foreign facility fee differential ($15,000) multiplied by the number of CMO foreign facilities (97), totaling $4,575,000. This results in foreign fee differential revenue of $4,575,000 from the total FDF and CMO facility fee target collection revenue. Subtracting the foreign facility differential fee revenue ($4,575,000) from the total FDF and CMO facility target collection revenue ($98,720,000) results in a remaining facility fee revenue balance of $94,145,000. To determine the domestic FDF facility fee, FDA divides the $94,145,000 by the total weighted number of FDF and CMO facilities (446), which results in a domestic FDF facility fee of $211,087. The foreign FDF facility fee is $15,000 more than the domestic FDF facility fee, or $226,087.

CMO fees are as follows. 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 $70,362, 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 $85,362.

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 seven percent of $493,600,000 in fee revenue, which is $34,552,000.

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 592. Of the total facilities identified as API facilities, there were 79 domestic facilities and 513 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 (513) 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 $7,695,000 of the total API fee revenue. Subtracting the foreign facility differential fee revenue ($7,695,000) from the total API facility target revenue ($34,552,000) results in a remaining balance of $26,857,000. To determine the domestic API facility fee, we divide the $26,857,000 by the total number of facilities (592), which gives us a domestic API facility fee of $45,367. The foreign API facility fee is $15,000 more than the domestic API facility fee, or $60,367.

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, 2017, 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 $493,600,000 in fee revenue, which is $172,760,000.

To determine the appropriate number of applicants for each tier, the Agency has posted lists of approved ANDAs on the FDA Web site (*http://www.fda.gov/gdufa*) and asked applicants on the list to claim which ANDAs and affiliates belong to the parent company. The original list of approved ANDAs came from the Agency's Document Archiving, Reporting, and Regulatory Tracking System (DARRTS), which included all ANDAs with the status of ''approved'' as of April 30, 2017.

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) unclaimed affiliations—a risk of undercollecting the target revenue if companies do not claim their ANDAs and their affiliates before the Program Fee is calculated; and (3) potential portfolio adjustment—applicants may choose to withdraw some of their approved ANDAs in order to move to a lower tier and reduce their fee exposure. The list of original approved ANDAs from the DARRTS database as of April 30, 2017, shows 339 applicants in the small business tier, 74 applicants in the medium size tier, and 65 applicants in the large size tier. This list also takes into account all the withdrawals, consolidations, and transfer of ownerships from industry as of April 30, 2017. Factoring in all the variables for the first year of GDUFA II, the Agency estimates there will be 258 applicants in the small business tier, 52 applicants in the medium size tier, and 62 applicants in the large size tier for FY 2018.

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 ($172,760,000), 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 25.8 applicants in the small business tier (258 multiplied by 10 percent), 20.8 applicants in the medium size tier (52 multiplied by 40 percent), and 62 applicants in the large size tier, arriving at 108.6 total weighted applicants for FY 2018.

To generate the large size operation GDUFA Program Fee, FDA divides the target revenue amount of $172,760,000 by 108.6, which equals $1,590,792. The medium size operation GDUFA Program Fee is 40 percent of the full fee ($636,317), and the small business operation GDUFA Program Fee is 10 percent of the full fee ($159,079).

IX. Fee Schedule for FY 2018

The fee rates for FY 2018 are set out in table 1.

TABLE 1—FEE SCHEDULE FOR FY 2018

Fee category	Fee rates for FY 2018
Applications:	
Abbreviated New Drug Application (ANDA)	$171,823
Drug Master File (DMF)	47,829
Facilities:	
Active Pharmaceutical Ingredient (API)—Domestic	45,367
API—Foreign	60,367
Finished Dosage Form (FDF)—Domestic	211,087
FDF—Foreign	226,087
Contract Manufacturing Organization (CMO)—Domestic	70,362
CMO—Foreign	85,362
GDUFA Program:	
Large size operation generic drug applicant	1,590,792
Medium size operation generic drug applicant	636,317
Small business operation generic drug applicant	159,079

X. Fee Payment Options and Procedures

The new fee rates are effective October 1, 2017. To pay the ANDA, DMF, API facility, FDF facility, CMO facility, and GDUFA Program Fee, you must complete a Generic Drug User Fee Cover Sheet, available through *https://www.fda.gov/gdufa* and at *https://userfees.fda.gov/OA_HTML/gdufaCAcdLogin.jsp,* and generate a user fee identification (ID) number. 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). Secure electronic payments can be submitted using the User Fees Payment Portal at *https://userfees.fda.gov/pay* (*Note:* Only full payments are accepted. No partial payments can be made online.) Once you search for your invoice, select ''Pay Now'' to be redirected to *Pay.gov.* Note that 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.

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 Web site after completing the Generic Drug User Fee Cover Sheet and generating the user fee ID number.

Please include the user fee ID number on your check, bank draft, or postal money order and make payable to the order of the Food and Drug Administration. Your payment 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. If you have any questions concerning courier delivery, contact the U.S. Bank at 314–418–4013. This telephone number is only for questions about courier delivery). Please make sure that the FDA post office box number (P.O. Box 979108) is written on the check, bank draft, or postal money order.

If paying by wire transfer, please reference your unique user fee ID number when completing your transfer. Without your unique user fee ID number, the payment may not be applied. If the payment amount is not applied, the invoice amount would be referred to collections. The originating financial institution may charge a wire transfer fee. Please ask your financial institution about the wire transfer fee and include it with your payment to ensure that your fee is fully paid. Use the following account information when sending a payment by wire transfer: U.S. Department of Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, account number: 75060099, routing number: 021030004, SWIFT: FRNYUS33, Beneficiary: FDA, 8455 Colesville Rd., 14th Floor, Silver Spring, MD 20993–0002. If needed, FDA's tax identification number is 53–0196965.

Dated: August 24, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–18377 Filed 8–28–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–0007]

Medical Device User Fee Rates for Fiscal Year 2018

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the fee rates and payment procedures for medical device user fees for fiscal year (FY) 2018. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Medical Device User Fee Amendments of 2017 (MDUFA IV), authorizes FDA to collect user fees for certain medical device submissions and annual fees both for certain periodic reports and for establishments subject to registration. This notice establishes the fee rates for FY 2018, which apply from October 1, 2017, through September 30, 2018. To avoid delay in the review of your application, you should pay the application fee before or at the time you submit your application to FDA. The fee you must pay is the fee that is in effect on the later of the date that your application is received by FDA or the date your fee payment is recognized by the U.S. Treasury. If you want to pay a reduced small business fee, you must qualify as a small business before making your submission to FDA; if you do not qualify as a small business before making your submission to FDA, you will have to pay the higher standard fee. Please note that the establishment registration fee is not eligible for a reduced small business fee. As a result, if the establishment registration fee is the only medical device user fee that you will pay in FY 2018, you should not submit a FY 2018 Small Business Qualification and Certification request. This document provides information on how the fees for FY 2018 were determined, the payment procedures you should follow, and how you may qualify for reduced small business fees.

FOR FURTHER INFORMATION CONTACT:

For information on Medical Device User Fees: Visit FDA's Web site at *https://www.fda.gov/ForIndustry/UserFees/MedicalDeviceUserFee/ucm20081521.htm.*

For questions relating to this notice: Robert Marcarelli, Office of Financial Management, Food and Drug Administration, 8455 Colesville Rd. (COLE–14202F), Silver Spring, MD 20993–0002, 301–796–7223.

SUPPLEMENTARY INFORMATION:

I. Background

Section 738 of the FD&C Act (21 U.S.C. 379j) establishes fees for certain medical device applications, submissions, supplements, notices, and requests (for simplicity, this document refers to these collectively as ''submissions'' or ''applications''); for periodic reporting on class III devices; and for the registration of certain establishments. Under statutorily-defined conditions, a qualified applicant may receive a fee waiver or may pay a lower small business fee (see 21 U.S.C. 379j(d) and (e)).

Under the FD&C Act, the fee rate for each type of submission is set at a specified percentage of the standard fee for a premarket application (a premarket application is a premarket approval application (PMA), a product development protocol (PDP), or a biologics license application (BLA)). The FD&C Act specifies the base fee for a premarket application for each year from FY 2018 through FY 2022; the base fee for a premarket application received by FDA during FY 2018 is $294,000. From this starting point, this document establishes FY 2018 fee rates for certain types of submissions, and for periodic reporting, by applying criteria specified in the FD&C Act.

The FD&C Act specifies the base fee for establishment registration for each year from FY 2018 through FY 2022; the base fee for an establishment registration in FY 2018 is $4,375. There is no reduction in the registration fee for small businesses. Each establishment that is registered (or is required to register) with the Secretary of Health and Human Services under section 510 of the FD&C Act (21 U.S.C. 360) because such establishment is engaged in the manufacture, preparation, propagation, compounding, or processing of a device is required to pay the annual fee for establishment registration.

II. Revenue Amount for FY 2018

The total revenue amount for FY 2018 is $183,280,756, as set forth in the