domestic facility (as defined in section 415(b) of the FD&C Act) and by the U.S. agent for each foreign facility (section 743(a)(1)(A) of the FD&C Act). This is the party to whom FDA will send the invoice for any fees that are assessed under this section.

C. How much will this fee be?

The fee is based on the number of direct hours spent on such reinspections, including time spent conducting the physical surveillance and/or compliance reinspection at the facility, or whatever components of such an inspection are deemed necessary, making preparations and arrangements for the reinspection, traveling to and from the facility, preparing any reports, analyzing any samples or examining any labels if required, and performing other activities as part of the OAI reinspection until the facility is again determined to be in compliance. The direct hours spent on each such reinspection will be billed at the appropriate hourly rate shown in table 2.

IV. Fees for Non-Compliance With a Recall Order Under Section 743(a)(1)(B)

A. What will cause this fee to be assessed?

The fee will be assessed for not complying with a recall order under section 423(d) (21 U.S.C. 350l(d)) or section 412(f) of the FD&C Act (21 U.S.C. 350a(f)) to cover food recall activities associated with such order performed by the Secretary (and by delegation, FDA) (section 743(a)(1)(B) of the FD&C Act). Non-compliance may include the following: (1) Not initiating a recall as ordered by FDA; (2) not conducting the recall in the manner specified by FDA in the recall order; or (3) not providing FDA with requested information regarding the recall, as ordered by FDA.

B. Who will be responsible for paying this fee?

Section 743(a)(1)(B) of the FD&C Act states that the fee is to be paid by the responsible party for a domestic facility (as defined in section 415(b) of the FD&C Act) and an importer who does not comply with a recall order under section 423 or under section 412(f) of the FD&C Act. In other words, the party paying the fee would be the party that received the recall order.

C. How much will this fee be?

The fee is based on the number of direct hours spent on taking action in response to the firm's failure to comply with a recall order. Types of activities could include conducting recall audit checks, reviewing periodic status reports, analyzing the status reports and the results of the audit checks, conducting inspections, traveling to and from locations, and monitoring product disposition. The direct hours spent on each such recall will be billed at the appropriate hourly rate shown in table 2.

V. How must the fees be paid?

An invoice will be sent to the responsible party for paying the fee after FDA completes the work on which the invoice is based. Payment must be made within 90 days of the invoice date in U.S. currency by check, bank draft, or U.S. postal money order payable to the order of the Food and Drug Administration. Detailed payment information will be included with the invoice when it is issued.

VI. What are the consequences of not paying these fees?

Under section 743(e)(2) of the FD&C Act, any fee that is not paid within 30 days after it is due shall be treated as a claim of the U.S. Government subject to provisions of subchapter II of chapter 37 of title 31, United States Code.

Dated: July 25, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–16184 Filed 8–1–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–0007]

Animal Generic Drug User Fee Rates and Payment Procedures 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 fiscal year (FY) 2018 generic new animal drug user fees. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Animal Generic Drug User Fee Amendments of 2013 (AGDUFA II), authorizes FDA to collect user fees for certain abbreviated applications for generic new animal drugs, for certain generic new animal drug products, and for certain sponsors of such abbreviated applications for generic new animal drugs and/or investigational submissions for generic new animal drugs. This notice establishes the fee rates for FY 2018.

FOR FURTHER INFORMATION CONTACT: Visit FDA's Web site at *https://www.fda.gov/ForIndustry/UserFees/AnimalGenericDrugUserFeeActAGDUFA/default.htm,* or contact Lisa Kable, Center for Veterinary Medicine (HFV–10), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–6888. For general questions, you may also email the Center for Veterinary Medicine (CVM) at *cvmagdufa@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

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

For FY 2014 through FY 2018, the FD&C Act establishes aggregate yearly base revenue amounts for each of these fee categories (21 U.S.C. 379j–21(b)). Base revenue amounts established for fiscal years after FY 2014 are subject to adjustment for workload (21 U.S.C. 379j–21(c)). The target revenue amounts for each fee category for FY 2018, after the adjustment for workload, are as follows: For application fees, the target revenue amount is $2,355,000; for product fees, the target revenue amount is $3,532,000; and for sponsor fees, the target revenue amount is $3,532,000.

For FY 2018, the generic new animal drug user fee rates are: $193,000 for each abbreviated application for a generic new animal drug other than those subject to the criteria in section 512(d)(4) of the FD&C Act (21 U.S.C. 360b(d)(4)); $96,500 for each abbreviated application for a generic new animal drug subject to the criteria in section 512(d)(4); $8,195 for each generic new animal drug product; $76,250 for each generic new animal drug sponsor paying 100 percent of the sponsor fee; $57,188 for each generic new animal drug sponsor paying 75 percent of the sponsor fee; and $38,125 for each generic new animal drug sponsor paying 50 percent of the sponsor fee. FDA will issue invoices for

FY 2018 product and sponsor fees by December 31, 2017. These fees will be due by January 31, 2018. The application fee rates are effective for all abbreviated applications for a generic new animal drug submitted on or after October 1, 2017, and will remain in effect through September 30, 2018. Applications will not be accepted for review until FDA has received full payment of related application fees and any other fees owed under the Animal Generic Drug User Fee program (AGDUFA program).

II. Revenue Amount for FY 2018

A. Statutory Fee Revenue Amounts

AGDUFA II, Title II of Public Law 113–14, specifies that the aggregate revenue amount for FY 2018 for abbreviated application fees is $2,117,000 and each of the other two generic new animal drug user fee categories, annual product fees and annual sponsor fees, is $3,175,000 each (see 21 U.S.C. 379j–21(b)).

B. Inflation Adjustment to Fee Revenue Amount

The amounts established in AGDUFA II for each year for FY 2014 through FY 2018 include an inflation adjustment; therefore, no further inflation adjustment is required.

C. Workload Adjustment Fee Revenue Amount

For each FY beginning after FY 2014, AGDUFA II provides that statutory fee revenue amounts shall be further adjusted to reflect changes in review workload. (See 21 U.S.C. 379j–21(c)(2).)

FDA calculated the average number of each of the four types of applications and submissions specified in the workload adjustment provision (abbreviated applications for generic new animal drugs, manufacturing supplemental abbreviated applications for generic new animal drugs, investigational generic new animal drug study submissions, and investigational generic new animal drug protocol submissions) received over the 5-year period that ended on September 30, 2013 (the base years), and the average number of each of these types of applications and submissions over the most recent 5-year period that ended on June 30, 2017.

The results of these calculations are presented in the first two columns in table 1. Column 3 reflects the percent change in workload over the two 5-year periods. Column 4 shows the weighting factor for each type of application, reflecting how much of the total FDA generic new animal drug review workload was accounted for by each type of application or submission in the table during the most recent 5 years. Column 5 is the weighted percent change in each category of workload and was derived by multiplying the weighting factor in each line in column 4 by the percent change from the base years in column 3. At the bottom right of table 1, the sum of the values in column 5 is calculated, reflecting a total change in workload of 51.4457 percent for FY 2018. This is the workload adjuster for FY 2018.

TABLE 1—WORKLOAD ADJUSTER CALCULATION

Application Type	Column 1 5-Year average (base years)	Column 2 Latest 5-Year average	Column 3 Percent change	Column 4 Weighting factor	Column 5 Weighted percent change
Abbreviated New Animal Drug Applications (ANADAs)	25.0	28.00	12.0	0.342876	4.1145
Manufacturing Supplements ANADAs	128.0	155.40	21.4	0.275337	5.8939
Generic Investigational Study Submissions	23.0	51.40	123.5	0.238287	29.4233
Generic Investigational Protocol Submissions	17.2	31.60	83.7	0.143501	12.0140
FY 2018 AGDUFA II Workload Adjuster					51.4457

Over the last year FDA has continued to see more sponsors getting involved in the generic animal drug approval process, including pioneer sponsors. This has contributed to sustained increases in the number of ANADAs, manufacturing supplements, and protocols submitted. Additionally, more sponsors continue to pursue drug approvals that do not qualify for a waiver from the requirement to conduct an in vivo bioequivalence study. For this reason we are seeing a large sustained increase in the number of generic investigational new animal drug study submissions.

As a result, the statutory revenue amount for each category of fees for FY 2018 ($2,117,000 for application fees and $3,175,000 for both product and sponsor fees) must now be increased by 51.4457 percent, for a total fee revenue target in FY 2018 of $12,822,907 for fees from all three categories before the offset for excess collections through FY 2018. The target for application fee revenue before the offset is $2,117,000 × 151.4457 percent, for a total of $3,206,105, rounded to the nearest dollar. The target for product fee revenue before the offset is $3,175,000 × 151.4457 percent, for a total of $4,808,401, rounded to the nearest dollar, and the target for sponsor fee revenue before the offset is the same as for product fees ($4,808,401, rounded to the nearest dollar).

D. Offset for Excess Collections Through FY 2017

Under the provisions of the FD&C Act, if the sum of the cumulative amount of the fees collected for FY 2014 through FY 2016, and the amount of fees estimated to be collected for FY 2017, exceeds the cumulative amount appropriated for fees for FY 2014 through FY 2017, the excess shall be credited to FDA's appropriation account and subtracted from the amount of fees that FDA would otherwise be authorized to collect for FY 2018 (see section 741(g)(4) of the FD&C Act).

Table 2 shows the amounts specified in appropriation acts for each year from FY 2014 through FY 2017, and the amounts FDA has collected for FY 2014, FY 2015, FY 2016, and FY 2017 as of June 30, 2017, and an additional $11,810,000 (rounded to the nearest thousand dollars) that FDA estimates it will collect in FY 2017 based on historical data. Table 2 shows the estimated cumulative difference between AGDUFA II fee amounts specified in appropriation acts for FY 2014 through FY 2017 and AGDUFA II fee amounts collected.

TABLE 2—OFFSETS TO BE TAKEN FOR AGDUFA II

Fiscal year	Collections realized	Collection amount specified in appropriation acts	Amount in excess of collection amount specified in appropriation acts
2014	$8,388,928	$7,328,000	$1,060,928
2015	9,982,041	6,944,000	3,038,041
2016	8,541,304	9,705,000	−1,163,696
2017	11,810,000	11,341,000	469,000
Net Balance to be Offset When Fees are Set for FY 2018	.....	.....	3,404,273

Note: FY 2017 ''Collections Realized'' is the amount FDA estimates it will collect in FY 2017 based on historical data.

The cumulative fees collected for FY 2014 through FY 2017 are estimated to be $3,404,273 greater than the cumulative fee amounts specified in appropriation acts during this same period. Reducing the workload adjusted amount of $12,822,907 by the AGDUFA II offset of $3,404,273 results in an amount of $9,419,000 (rounded to the nearest thousand dollars), before the final year adjustment.

Reducing the fees to achieve the offset-adjusted target revenue (as a percentage of workload-adjusted target revenue) yields the following revenue by fee type: The target for application fee revenue after the offset is $9,419,000 × 25 percent, for a total of $2,355,000, rounded to the nearest thousand. The target for product fee revenue after the offset is $9,419,000 × 37.5 percent, for a total of $3,532,000, rounded to the nearest thousand, and the target for sponsor fee revenue after the offset is the same as for product fees ($3,532,000, rounded to the nearest thousand).

E. Final Year Adjustment

Under the provisions of the FD&C Act, for FY 2018 the Secretary of Health and Human Services may, in addition to the workload adjustment, further increase the fees if such an adjustment is necessary to provide for not more than 3 months of operating reserves of carryover user fees for the process for the review of abbreviated applications for generic new animal drugs for the first 3 months of FY 2019. If such an adjustment is necessary, the rationale for the amount of this increase shall be contained in the annual notice establishing fees for FY 2018 (see section 741(c)(3) of the FD&C Act).

After calculating the operating reserves and estimating the balance as of the beginning of FY 2019, FDA estimates that the AGDUFA program will have sufficient funds for the operating reserves; thus, FDA will not be performing a final year adjustment for FY 2019 because FDA has determined such an adjustment to be unnecessary.

III. Abbreviated Application Fee Calculations for FY 2018

A. Application Fee Revenues and Numbers of Fee-Paying Applications

Each person that submits an abbreviated application for a generic new animal drug shall be subject to an application fee, with limited exceptions (21 U.S.C. 379j–21(a)(1)). The term ''abbreviated application for a generic new animal drug'' means an abbreviated application for the approval of any generic new animal drug submitted under section 512(b)(2) (21 U.S.C. 379j–21(k)(1)). The application fees are to be set so that they will generate $2,355,000 in fee revenue for FY 2018.

To set fees for abbreviated applications for generic new animal drugs to realize $2,355,000, FDA must first make some assumptions about the number of fee-paying abbreviated applications it will receive during FY 2018.

The Agency knows the number of applications that have been submitted in previous years. That number fluctuates from year to year. FDA is making estimates and applying different assumptions for two types of full fee submissions: Original submissions of abbreviated applications for generic new animal drugs and ''reactivated'' submissions of abbreviated applications for generic new animal drugs. Any original submissions of abbreviated applications for generic new animal drugs that were received by FDA before July 1, 2008, were not assessed fees (21 U.S.C. 379j–21(a)(1)(A)). Some of these non-fee-paying submissions were later resubmitted on or after July 1 because the initial submission was not approved by FDA (*i.e.,* FDA marked the submission as incomplete and requested additional non-administrative information) or because the original submission was withdrawn by the sponsor. Abbreviated applications for generic new animal drugs resubmitted on or after July 1, 2008, are subject to user fees. In this notice, FDA refers to these resubmitted applications as ''reactivated'' applications.

Also, under AGDUFA II, an abbreviated application for an animal generic drug subject to the criteria in section 512(d)(4) of the FD&C Act and submitted on or after October 1, 2013, shall be subject to 50 percent of the fee applicable to all other abbreviated applications for a generic new animal drug (21 U.S.C. 379j–21(a)(1)(C)(ii)).

Regarding original submissions of abbreviated applications for generic new animal drugs, FDA is assuming that the number of applications that will pay fees in FY 2018 will equal the average number of submissions over the 5 most recently completed years of the AGDUFA program (FY 2012–FY 2016). FDA believes that this is a reasonable approach after 8 complete years of experience with this program.

The average number of original submissions of abbreviated applications for generic new animal drugs over the 5 most recently completed years is 10 applications not subject to the criteria in section 512(d)(4) of the FD&C Act and 4.4 submissions subject to the criteria in section 512(d)(4). Each of the submissions described under section 512(d)(4) of the FD&C Act pays 50 percent of the fee paid by the other applications and will be counted as one half of a fee. Adding all of the applications not subject to the criteria in section 512(d)(4) of the FD&C Act and 50 percent of the number that are subject to such criteria results in a total of 12.2 anticipated full fees.

In prior years, FDA had estimated the number of reactivations of abbreviated applications for generic new animal drugs that had been originally submitted prior to July 1, 2008. Over the years, that number has decreased to the point that

FDA no longer expects to receive any reactivations of applications initially submitted prior to July 1, 2008, and will include no provision for them in its fee estimates. Should such a submission be made, the submitter will be expected to pay the appropriate fee.

Based on the previous assumptions, FDA is estimating that it will receive a total of 12.2 fee-paying generic new animal drug applications in FY 2018 (10 original applications paying a full fee and 4.4 applications paying a half fee).

B. Application Fee Rates for FY 2018

FDA must set the fee rates for FY 2018 so that the estimated 12.2 abbreviated applications that pay the fee will generate a total of $2,355,000. To generate this amount, the fee for a generic new animal drug application, rounded to the nearest hundred dollars, will have to be $193,000, and for those applications that are subject to the criteria set forth in section 512(d)(4) of the FD&C Act, 50 percent of that amount, or $96,500.

IV. Generic New Animal Drug Product Fee Calculations for FY 2018

A. Product Fee Revenues and Numbers of Fee-Paying Products

The generic new animal drug product fee (also referred to as the product fee) must be paid annually by the person named as the applicant in an abbreviated application or supplemental abbreviated application for a generic new animal drug product submitted for listing under section 510 of the FD&C Act (21 U.S.C. 360), and who had an abbreviated application or supplemental abbreviated application for a generic new animal drug product pending at FDA after September 1, 2008 (see 21 U.S.C. 379j–21(a)(2)). The term ''generic new animal drug product'' means each specific strength or potency of a particular active ingredient or ingredients in final dosage form marketed by a particular manufacturer or distributor, which is uniquely identified by the labeler code and product code portions of the national drug code, and for which an abbreviated application for a generic new animal drug or supplemental abbreviated application for a generic new animal drug has been approved (21 U.S.C. 379j–21(k)(6)). The product fees are to be set so that they will generate $3,532,000 in fee revenue for FY 2018.

To set generic new animal drug product fees to realize $3,532,000, FDA must make some assumptions about the number of products for which these fees will be paid in FY 2018. FDA gathered data on all generic new animal drug products that have been submitted for listing under section 510 of the FD&C Act and matched this to the list of all persons who FDA estimated would have an abbreviated new animal drug application or supplemental abbreviated application pending after September 1, 2008. As of June 2017, FDA estimates a total of 431 products submitted for listing by persons who had an abbreviated application for a generic new animal drug or supplemental abbreviated application for a generic new animal drug pending after September 1, 2008. Based on this, FDA believes that a total of 431 products will be subject to this fee in FY 2018.

In estimating the fee revenue to be generated by generic new animal drug product fees in FY 2018, FDA is assuming that less than two products invoiced will qualify for minor use/minor species fee waiver (see 21 U.S.C. 379j–21(d)). FDA has kept this estimate at zero percent this year, based on historical data over the past 5 completed years of the AGDUFA program.

Accordingly, the Agency estimates that a total of 431 products will be subject to product fees in FY 2018.

B. Product Fee Rates for FY 2018

FDA must set the fee rates for FY 2018 so that the estimated 431 products that pay fees will generate a total of $3,532,000. To generate this amount will require the fee for a generic new animal drug product, rounded to the nearest $5, to be $8,195.

V. Generic New Animal Drug Sponsor Fee Calculations for FY 2018

A. Sponsor Fee Revenues and Numbers of Fee-Paying Sponsors

The generic new animal drug sponsor fee (also referred to as the sponsor fee) must be paid annually by each person who: (1) Is named as the applicant in an abbreviated application for a generic new animal drug, except for an approved application for which all subject products have been removed from listing under section 510 of the FD&C Act, or has submitted an investigational submission for a generic new animal drug that has not been terminated or otherwise rendered inactive and (2) had an abbreviated application for a generic new animal drug, supplemental abbreviated application for a generic new animal drug, or investigational submission for a generic new animal drug pending at FDA after September 1, 2008 (see 21 U.S.C. 379j–21(k)(7) and 379j–21(a)(3), respectively). A generic new animal drug sponsor is subject to only one such fee each fiscal year (see 21 U.S.C. 379j–21(a)(3)(C)). Applicants with more than six approved abbreviated applications will pay 100 percent of the sponsor fee; applicants with more than one and fewer than seven approved abbreviated applications will pay 75 percent of the sponsor fee; and applicants with one or fewer approved abbreviated applications will pay 50 percent of the sponsor fee (see 21 U.S.C. 379j–21(a)(3)(C)). The sponsor fees are to be set so that they will generate $3,532,000 in fee revenue for FY 2018.

To set generic new animal drug sponsor fees to realize $3,532,000, FDA must make some assumptions about the number of sponsors who will pay these fees in FY 2018. FDA now has 8 complete years of experience collecting these sponsor fees. Based on the number of firms that meet this definition and the average number of firms paying fees at each level over the 5 most recently completed years of the AGDUFA program (FY 2012 through FY 2016), FDA estimates that in FY 2018, 14 sponsors will pay 100 percent fees, 17 sponsors will pay 75 percent fees, and 42 sponsors will pay 50 percent fees. That totals the equivalent of 47.75 full sponsor fees (14×100 percent or 14, plus 17×75 percent or 12.75, plus 42×50 percent or 21).

FDA estimates that about 3 percent of all of these sponsors, or 1.43, may qualify for a minor use/minor species fee waiver (see 21 U.S.C. 379j–21(d)). FDA has kept the estimate of the percentage of sponsors that will not pay fees at 3 percent this year, based on historical data over the past 5 completed years of the AGDUFA program.

Accordingly, the Agency estimates that the equivalent of 46.32 full sponsor fees (47.75 minus 1.43) are likely to be paid in FY 2018.

B. Sponsor Fee Rates for FY 2018

FDA must set the fee rates for FY 2018 so that the estimated equivalent of 46.32 full sponsor fees will generate a total of $3,532,000. To generate this amount will require the 100 percent fee for a generic new animal drug sponsor, rounded to the nearest $50, to be $76,250. Accordingly, the fee for those paying 75 percent of the full sponsor fee will be $57,188, and the fee for those paying 50 percent of the full sponsor fee will be $38,125.

VI. Fee Schedule for FY 2018

The fee rates for FY 2018 are summarized in table 3.

TABLE 3—FY 2018 FEE RATES

Generic new animal drug user fee category	Fee rate for FY 2018
Abbreviated Application Fee for Generic New Animal Drug except those subject to the criteria in section 512(d)(4)	$193,000
Abbreviated Application Fee for Generic New Animal Drug subject to the criteria in section 512(d)(4)	96,500
Generic New Animal Drug Product Fee	8,195
100 Percent Generic New Animal Drug Sponsor Fee [1]	76,250
75 Percent Generic New Animal Drug Sponsor Fee [1]	57,188
50 Percent Generic New Animal Drug Sponsor Fee [1]	38,125

[1] An animal drug sponsor is subject to only one fee each fiscal year.

VII. Procedures for Paying FY 2018 Generic New Animal Drug User Fees

A. Abbreviated Application Fees and Payment Instructions

The FY 2018 fee established in the new fee schedule must be paid for an abbreviated new animal drug application subject to fees under AGDUFA II that is submitted on or after October 1, 2017. 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* or the *Pay.gov* payment option is available to you after you submit a cover sheet. (**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 write your application's unique Payment Identification Number, beginning with the letters ''AG'', on the upper right-hand corner of your completed Animal Generic Drug User Fee Cover Sheet. Also write the FDA post office box number (P.O. Box 979033) on the enclosed check, bank draft, or money order. Mail the payment and a copy of the completed Animal Generic Drug User Fee Cover Sheet to: Food and Drug Administration, P.O. Box 979033, 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. 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. 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. 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, Beneficiary: FDA, 8455 Colesville Rd., 14th Floor, Silver Spring, MD 20993–0002.

To send a check by a courier such as Federal Express, the courier must deliver the check and printed copy of the cover sheet to: U.S. Bank, Attn: Government Lockbox 979033, 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.)

It is important that the fee arrives at the bank at least a day or two before the abbreviated application arrives at FDA's Center for Veterinary Medicine (CVM). FDA records the official abbreviated application receipt date as the later of the following: The date the application was received by CVM, or the date U.S. Bank notifies FDA that your payment in the full amount has been received, or when the U.S. Department of the Treasury notifies FDA of payment. U.S. Bank and the United States Treasury are required to notify FDA within 1 working day, using the Payment Identification Number described previously.

The tax identification number of FDA is 53–0196965. (**Note:** In no case should the payment for the fee be submitted to FDA with the application.)

B. Application Cover Sheet Procedures

Step One—Create a user account and password. Log onto the AGDUFA Web site at *http://www.fda.gov/ForIndustry/UserFees/AnimalGenericDrugUserFeeActAGDUFA/ucm137049.htm* and scroll down the page until you find the link ''Create AGDUFA User Fee Cover Sheet.'' Select that link and follow the directions. For security reasons, each firm submitting an application will be assigned an organization identification number, and each user will also be required to set up a user account and password the first time you use this site. Online instructions will walk you through this process.

Step Two—Create an Animal Generic Drug User Fee Cover Sheet, transmit it to FDA, and print a copy. After logging into your account with your user name and password, complete the steps required to create an Animal Generic Drug User Fee Cover Sheet. One cover sheet is needed for each abbreviated animal drug application. Once you are satisfied that the data on the cover sheet is accurate and you have finalized the cover sheet, you will be able to transmit it electronically to FDA and you will be able to print a copy of your cover sheet showing your unique Payment Identification Number.

Step Three—Send the payment for your application as described in section VII.A of this document.

Step Four—Please submit your application and a copy of the completed Animal Generic Drug User Fee Cover Sheet to the following address: Food and Drug Administration, Center for Veterinary Medicine, Document Control Unit (HFV–199), 7500 Standish Pl., Rockville, MD 20855.

C. Product and Sponsor Fees

By December 31, 2017, FDA will issue invoices and payment instructions for product and sponsor fees for FY 2018 using this fee schedule. Fees will be due by January 31, 2018. FDA will issue invoices in November 2018 for any products and sponsors subject to fees for

FY 2018 that qualify for fees after the December 2017 billing.

Dated: July 26, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–16181 Filed 8–1–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–0007]

Outsourcing Facility Fee Rates for Fiscal Year 2018

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the fiscal year (FY) 2018 rates for the establishment and re-inspection fees related to entities that compound human drugs and elect to register as outsourcing facilities under the Federal Food, Drug, and Cosmetic Act (the FD&C Act). The FD&C Act authorizes FDA to assess and collect an annual establishment fee from outsourcing facilities, as well as a re-inspection fee for each re-inspection of an outsourcing facility. This document establishes the FY 2018 rates for the small business establishment fee ($5,364), the non-small business establishment fee ($17,364), and the re-inspection fee ($16,093) for outsourcing facilities; provides information on how the fees for FY 2018 were determined; and describes the payment procedures outsourcing facilities should follow. These fee rates are effective October 1, 2017, and will remain in effect through September 30, 2018.

FOR FURTHER INFORMATION CONTACT: For more information on human drug compounding and outsourcing facility fees, visit FDA's Web site at: *http://www.fda.gov/Drugs/GuidanceCompliance RegulatoryInformation/PharmacyCompounding/default.htm.*

For questions relating to this notice: Rachel Richter, Office of Financial Management, Food and Drug Administration, 8455 Colesville Rd., COLE–14216, Silver Spring, MD 20993–0002, 301–796–7111.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Quality and Security Act (DQSA) contains important provisions relating to the oversight of compounding human drugs. Title I of this law, the Compounding Quality Act, created a new section 503B in the FD&C Act (21 U.S.C. 353b). Under section 503B of the FD&C Act, a human drug compounder can become an ''outsourcing facility.''

Outsourcing facilities, as defined in section 503B(d)(4) of the FD&C Act, are facilities that meet all of the conditions described in section 503B(a), including registering with FDA as an outsourcing facility and paying an annual establishment fee. If the conditions of section 503B are met, a drug compounded by or under the direct supervision of a licensed pharmacist in an outsourcing facility is exempt from three sections of the FD&C Act: (1) Section 502(f)(1) (21 U.S.C. 352(f)(1)) concerning the labeling of drugs with adequate directions for use; (2) section 505 (21 U.S.C. 355) concerning the approval of human drug products under new drug applications (NDAs) or abbreviated new drug applications (ANDAs); and (3) section 582 (21 U.S.C. 360eee-1) concerning drug supply chain security requirements. Drugs compounded in outsourcing facilities are not exempt from the requirements of section 501(a)(2)(B) of the FD&C Act (21 U.S.C. 351(a)(2)(B)) concerning current good manufacturing practice requirements for drugs.

Section 744K of the FD&C Act (21 U.S.C. 379j–62) authorizes FDA to assess and collect the following fees associated with outsourcing facilities: (1) An annual establishment fee from each outsourcing facility and (2) a re-inspection fee from each outsourcing facility subject to a re-inspection (see section 744K(a)(1) of the FD&C Act). Under statutorily defined conditions, a qualified applicant may pay a reduced small business establishment fee (see section 744K(c)(4) of the FD&C Act).

FDA announced in the **Federal Register** of November 24, 2014 (79 FR 69856), the availability of a final guidance for industry entitled ''Fees for Human Drug Compounding Outsourcing Facilities Under Sections 503B and 744K of the FD&C Act.'' The guidance provides additional information on the annual fees for outsourcing facilities and adjustments required by law, re-inspection fees, how to submit payment, the effect of failure to pay fees, and how to qualify as a small business to obtain a reduction of the annual establishment fee. This guidance can be accessed on FDA's Web site at: *https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM391102.pdf.*

II. Fees for FY 2018

A. Methodology for Calculating FY 2018 Adjustment Factors

1. Inflation Adjustment Factor

Section 744K(c)(2) of the FD&C Act specifies the annual inflation adjustment for outsourcing facility fees. The inflation adjustment has two components: One based on FDA's payroll costs and one based on FDA's non-payroll costs for the first 3 of the 4 previous fiscal years. The payroll component of the annual inflation adjustment is calculated by taking the average change in FDA's per-full time equivalent (FTE) personnel compensation and benefits (PC&B) in the first 3 of the 4 previous fiscal years (see section 744K(c)(2)(A)(ii) of the FD&C Act). FDA's total annual spending on PC&B is divided by the total number of FTEs per fiscal year to determine the average PC&B per FTE.

Table 1 summarizes the actual cost and FTE data 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 2018. The 3-year average is 2.2354 percent.

TABLE 1—FDA PC&BS EACH YEAR AND PERCENT CHANGE

Fiscal year	2014	2015	2016	3-Year average
Total PC&B	$2,054,937,000	$2,232,304,000	$2,414,728,159	.....
Total FTE	14,555	15,484	16,381	.....
PC&B per FTE	$141,184	$144,168	$147,408	.....
Percent change from previous year	2.3451%	2.1136%	2.2474%	2.2354%

Section 744K(c)(2)(A)(ii) of the FD&C Act specifies that this 2.2354 percent should be multiplied by the proportion of PC&B to total costs of an average FDA FTE for the same 3 fiscal years.