will include presentations by FDA staff and an opportunity for stakeholders to ask questions. If you wish to attend the webinar, FDA asks that you please register through Eventbrite by 12 a.m. EDT, Saturday, August 19, 2017: *https://www.eventbrite.com/e/over-the-counter-monograph-user-fees-stakeholder-meeting-registration-33593404778*. FDA will email the registered attendees a URL to join the webinar at least 1 day before the meeting.

Dated *July 27, 2017.*

**Anna K. Abram,**

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

[FR Doc. 2017–16229 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 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 rates and payment procedures for fiscal year (FY) 2018 animal drug user fees. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Animal Drug User Fee Amendments of 2013 (ADUFA III), authorizes FDA to collect user fees for certain animal drug applications and supplements, for certain animal drug products, for certain establishments where such products are made, and for certain sponsors of such animal drug applications and/or investigational animal drug submissions. This notice establishes the fee rates for FY 2018.

**FOR FURTHER INFORMATION CONTACT:** Visit FDA's Web site at *http://www.fda.gov/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/default.htm* or contact Lisa Kable, Center for Veterinary Medicine (HFV–10), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–6888. For general questions, you may also email the Center for Veterinary Medicine (CVM) at: *cvmadufa@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:**

## I. Background

Section 740 of the FD&C Act (21 U.S.C. 379j–12) establishes four different types of user fees: (1) Fees for certain types of animal drug applications and supplements; (2) annual fees for certain animal drug products; (3) annual fees for certain establishments where such products are made; and (4) annual fees for certain sponsors of animal drug applications and/or investigational animal drug submissions (21 U.S.C. 379j–12(a)). When certain conditions are met, FDA will waive or reduce fees (21 U.S.C. 379j–12(d)).

For FY 2014 through FY 2018, the FD&C Act establishes aggregate yearly base revenue amounts for each fiscal year (21 U.S.C. 379j–12(b)(1)). Base revenue amounts established for years after FY 2014 are subject to adjustment for inflation and workload (21 U.S.C. 379j–12(c)). Fees for applications, establishments, products, and sponsors are to be established each year by FDA so that the percentages of the total revenue that are derived from each type of user fee will be as follows: Revenue from application fees shall be 20 percent of total fee revenue; revenue from product fees shall be 27 percent of total fee revenue; revenue from establishment fees shall be 26 percent of total fee revenue; and revenue from sponsor fees shall be 27 percent of total fee revenue (21 U.S.C. 379j–12(b)(2)).

For FY 2018, the animal drug user fee rates are: $238,100 for an animal drug application; $119,050 for a supplemental animal drug application for which safety or effectiveness data are required and for an animal drug application subject to the criteria set forth in section 512(d)(4) of the FD&C Act (21 U.S.C. 360b(d)(4)); $6,175 for an annual product fee; $88,750 for an annual establishment fee; and $75,150 for an annual sponsor fee. FDA will issue invoices for FY 2018 product, establishment, and sponsor fees by December 31, 2017, and payment will be due by January 31, 2018. The application fee rates are effective for applications 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 application fees and any other animal drug user fees owed under the Animal Drug User Fee program (ADUFA program).

## II. Revenue Amount for FY 2018

### *A. Statutory Fee Revenue Amounts*

ADUFA III, Title I of Public Law 113–14, specifies that the aggregate fee revenue amount for FY 2018 for all animal drug user fee categories is $21,600,000 (21 U.S.C. 379j–12(b)(1)(B)).

### *B. Inflation Adjustment to Fee Revenue Amount*

The fee revenue amount established in ADUFA III for FY 2015 and subsequent fiscal years are subject to an inflation adjustment (21 U.S.C. 379j–12(c)(2)).

The component of the inflation adjustment for payroll costs shall be one plus the average annual percent change in the cost of all personnel compensation and benefits (PC&B) paid per full-time equivalent position (FTE) at FDA for the first three of the four preceding fiscal years, multiplied by the proportion of PC&B costs to total FDA costs for the first three of the four preceding fiscal years (see 21 U.S.C. 379j–12(c)(2)(A) and (B)). The data on total PC&B paid and numbers of FTE paid, from which the average cost per FTE can be derived, are published in FDA's Justification of Estimates for Appropriations Committees.

Table 1 summarizes that 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 of the 4 fiscal years preceding FY 2018. The 3-year average is 2.2354 percent.

TABLE 1—FDA PERSONNEL COMPENSATION AND BENEFITS (PC&B) 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% |

The statute specifies that this 2.2354 percent should be multiplied by the proportion of PC&B costs to total FDA costs. Table 2 shows the amount of PC&B and the total amount obligated by FDA for the same 3 FYs.

TABLE 2—PC&B AS A PERCENT OF TOTAL COSTS AT FDA

| Fiscal year | 2014 | 2015 | 2016 | 3-Year average |
|---|---|---|---|---|
| Total PC&B | $2,054,937,000 | $2,232,304,000 | $2,414,728,159 | ..... |
| Total Costs | $4,298,476,000 | $4,510,565,000 | $4,666,236,000 | ..... |
| PC&B Percent | 47.8062% | 49.4906% | 51.7490 | 49.6819% |

The payroll adjustment is 2.2354 percent multiplied by 49.6819 percent (or 1.1106 percent).

The statute specifies that the portion of the inflation adjustment for non-payroll costs for FY 2018 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 less food and energy; 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 FDA costs (see 21 U.S.C. 379j–12(c)(2)(C)). Table 3 provides the summary data for the percent change in the specified CPI for the Baltimore-Washington area. The data from the Bureau of Labor Statistics is shown in table 3.

TABLE 3—ANNUAL AND 3-YEAR AVERAGE PERCENT CHANGE IN BALTIMORE-WASHINGTON AREA CPI LESS FOOD AND ENERGY

| Year | 2014 | 2015 | 2016 | 3-Year average |
|---|---|---|---|---|
| Annual CPI | 149.581 | 152.242 | 154.702 | ..... |
| Annual Percent Change | 1.7883% | 1.7790% | 1.6158% | 1.7277% |

To calculate the inflation adjustment for non-pay costs, we multiply the 1.7277 percent by the proportion of all costs other than PC&B to total FDA costs. Since 49.6819 percent was obligated for PC&B as shown in table 2, 50.3181 percent is the portion of costs other than PC&B (100 percent − 49.6819 percent = 50.3181 percent). The non-payroll adjustment is 1.7277 percent times 50.3181 percent, or 0.8693 percent.

Next, we add the payroll component (1.1106 percent) to the non-pay component (0.8693 percent), for a total inflation adjustment of 1.9799 percent for FY 2018.

ADUFA III provides for the inflation adjustment to be compounded each fiscal year after FY 2014 (see 21 U.S.C. 379j–12(c)(2)). The factor for FY 2018 (1.9799 percent) is compounded by adding 1 and then multiplying by 1 plus the inflation adjustment factor for FY 2017 (6.0746 percent), as published in the **Federal Register** of July 28, 2016 (81 FR 49664 to 49669), which equals 1.081748 (rounded) (1.019799 × 1.060746) for FY 2018. We then multiply the base revenue amount for FY 2018 ($21,600,000) by 1.081748, yielding an inflation adjusted amount of $23,365,757.

*C. Workload Adjustment to Inflation Adjusted Fee Revenue Amount*

A workload adjustment will be calculated to the inflation adjusted fee revenue amount established in ADUFA III for FY 2015 and subsequent fiscal years (21 U.S.C. 379j–12(c)(3)).

FDA calculated the average number of each of the five types of applications and submissions specified in the workload adjustment provision (animal drug applications, supplemental animal drug applications for which data with respect to safety or efficacy are required, manufacturing supplemental animal drug applications, investigational animal drug study submissions, and investigational 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 June 30, 2017.

The results of these calculations are presented in the first two columns of table 4. 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 animal drug review workload was accounted for by each type of application or submission in the table during the most recent five 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 4 the sum of the values in column 5 is added, reflecting a total change in workload of 5.4599 percent for FY 2018. This is the workload adjuster for FY 2018.

TABLE 4—WORKLOAD ADJUSTER CALCULATION

[Numbers may not add due to rounding]

| 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 |
|---|---|---|---|---|---|
| New Animal Drug Applications (NADAs) | 9.8000 | 16.0 | 63.2653 | 0.030373 | 1.9216 |
| Supplemental NADAs with Safety or Efficacy Data | 9.6000 | 10.6 | 10.4167 | 0.026491 | 0.2759 |
| Manufacturing Supplements | 361.0000 | 334.6 | −7.3130 | 0.162018 | −1.1848 |
| Investigational Study Submissions | 216.4000 | 189.8 | −12.2921 | 0.579781 | −7.1267 |
| Investigational Protocol Submissions | 133.6000 | 210.4 | 57.4850 | 0.201337 | 11.5739 |

TABLE 4—WORKLOAD ADJUSTER CALCULATION—Continued

[Numbers may not add due to rounding]

| 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 |
|---|---|---|---|---|---|
| FY 2018 Workload Adjuster | | | | | 5.4599 |

FDA experienced an increase in the number of new animal drug applications (NADAs) and supplemental NADAs with safety or effectiveness data. Over the last several years FDA has seen an increase in the number of animal drug products brought by animal drug sponsors for review in the drug evaluation process. These new animal drug products come from both existing animal drug sponsors as well as sponsors new to the animal drug market. The increase in new animal drug products has contributed to an increase in the number of protocol submissions and NADAs submitted for many novel drug classes and novel indications for both food-producing animals and companion animals. FDA can expect that the increases in reviewed protocols will lead in the near future to an increase in the number of Investigational Study Submissions and NADAs or supplemental NADAs as sponsors work their products through the regulatory review process. Additionally, FDA has seen an increase in the number of animal drug sponsors pursuing multiple changes to their existing NADAs (*e.g.,* new indications, new species, changes in dosage). For this reason we are seeing an increase in the number of supplemental NADAs with safety or effectiveness data. The increases in these submissions are consistent with an overall increase in workload including all submissions and communications with sponsors. In addition, CVM is not seeing a corresponding decrease in any of the other submission types that might have served to offset workload. As a result, the statutory revenue amount after the inflation adjustment ($23,365,757) must now be increased by 5.4599 percent to reflect the changes in review workload (workload adjustment), for a total fee revenue target of $24,641,504.

*D. Offset for Excess Collections Through FY 2017*

Under section 740(g)(4) 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 under the FD&C Act. (21 U.S.C. 379j–12(g)(4)).

Table 5 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 $21,941,000 (rounded to the nearest thousand dollars) that FDA estimates it will collect in FY 2017 based on historical data. Table 5 shows the estimated cumulative difference between ADUFA fee amounts specified in appropriation acts for FY 2014 through FY 2017 and ADUFA fee amounts collected.

TABLE 5—OFFSETS TO BE TAKEN FOR ADUFA III

| Fiscal year | Collections realized | Collection amount specified in appropriation acts | Amount in excess of collection amount specified in appropriation acts |
|---|---|---|---|
| 2014 | $27,184,831 | $23,600,000 | $3,584,831 |
| 2015 | 24,535,338 | 22,464,000 | 2,071,338 |
| 2016 | 25,442,477 | 22,818,000 | 2,624,477 |
| 2017 | 21,941,000 | 23,673,000 | −1,732,000 |
| Net Balance to be Offset When Fees are Set for FY 2018 | | | 6,548,646 |

**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 $6,548,646 greater than the cumulative fee amounts specified in appropriation acts during this same period. Reducing the inflation and workload adjusted amount of $24,641,504 by the ADUFA III offset of $6,548,646 results in an amount of $18,093,000 (rounded to the nearest thousand), before the final year adjustment.

*E. Final Year Adjustment*

Under section 740(c)(4) of the FD&C Act, for FY 2018 the Secretary of Health and Human Services (the Secretary) may, in addition to the inflation and workload adjustments, 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 animal drug applications for the first 3 months of FY 2019. If such an adjustment is necessary, the rationale for the amount of this increase must be included in the annual notice establishing fees for FY 2018 (21 U.S.C. 379j–12(c)(4)).

After calculating the operating reserves and estimating the balance as of the beginning of FY 2019, FDA estimates that the ADUFA 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.

*F. FY 2018 Fee Revenue Amounts*

ADUFA III specifies that the revenue amount of $18,093,000 for FY 2018 is to be divided as follows: 20 percent, or a total of $3,619,000 (rounded to the nearest thousand dollars), is to come from application fees; 27 percent, or a total of $4,885,000 (rounded to the nearest thousand dollars), is to come from product fees; 26 percent, or a total of $4,704,000 (rounded to the nearest thousand dollars), is to come from establishment fees; and 27 percent, or a total of $4,885,000 (rounded to the nearest thousand dollars), is to come from sponsor fees (21 U.S.C. 379j–12(b)).

## III. Application Fee Calculations for FY 2018

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

Each person that submits an animal drug application or a supplemental animal drug application shall be subject to an application fee, with limited exceptions (see 21 U.S.C. 379j–12(a)(1)). The term ''animal drug application'' means an application for approval of any new animal drug submitted under section 512(b)(1) of the FD&C Act (21 U.S.C. 379j–11(1)). A ''supplemental animal drug application'' is defined as a request to the Secretary to approve a change in an animal drug application which has been approved, or a request to the Secretary to approve a change to an application approved under section 512(c)(2) of the FD&C Act for which data with respect to safety or effectiveness are required (21 U.S.C. 379j–11(2)). The application fees are to be set so that they will generate $3,619,000 in fee revenue for FY 2018. The fee for a supplemental animal drug application for which safety or effectiveness data are required and for an animal drug application subject to criteria set forth in section 512(d)(4) of the FD&C Act is to be set at 50 percent of the animal drug application fee (21 U.S.C. 379j–12(a)(1)(A)(ii)).

To set animal drug application fees and supplemental animal drug application fees to realize $3,619,000 FDA must first make some assumptions about the number of fee-paying applications and supplements the Agency will receive in FY 2018.

The Agency knows the number of applications that have been submitted in previous years. That number fluctuates from year to year. In estimating the fee revenue to be generated by animal drug application fees in FY 2018, FDA is assuming that the number of applications that will pay fees in FY 2018 will equal the average number of submissions over the five most recent completed years of the ADUFA program (FY 2012 to FY 2016). FDA believes that this is a reasonable approach after 13 completed years of experience with this program.

Over the five most recent completed years, the average number of animal drug applications that would have been subject to the full fee was 8.2. Over this same period, the average number of supplemental applications for which safety or effectiveness data are required and applications subject to the criteria set forth in section 512(d)(4) of the FD&C Act that would have been subject to half of the full fee was 14.0.

*B. Application Fee Rates for FY 2018*

FDA must set the fee rates for FY 2018 so that the estimated 8.2 applications that pay the full fee and the estimated 14.0 supplemental applications for which safety or effectiveness data are required and applications subject to the criteria set forth in section 512(d)(4) of the FD&C Act that pay half of the full fee will generate a total of $3,619,000. To generate this amount, the fee for an animal drug application, rounded to the nearest $100, will have to be $238,100, and the fee for a supplemental animal drug application for which safety or effectiveness data are required and for applications subject to the criteria set forth in section 512(d)(4) of the FD&C Act will have to be $119,050.

## IV. Product Fee Calculations for FY 2018

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

The animal drug product fee (also referred to as the product fee) must be paid annually by the person named as the applicant in a new animal drug application or supplemental new animal drug application for an animal drug product submitted for listing under section 510 of the FD&C Act (21 U.S.C. 360), and who had an animal drug application or supplemental animal drug application pending at FDA after September 1, 2003 (21 U.S.C. 379j–12(a)(2)). The term ''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 animal drug application or a supplemental animal drug application has been approved (21 U.S.C. 379j–11(3)). The product fees are to be set so that they will generate $4,885,000 in fee revenue for FY 2018.

To set animal drug product fees to realize $4,885,000, FDA must make some assumptions about the number of products for which these fees will be paid in FY 2018. FDA developed data on all 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 had an animal drug application or supplement pending after September 1, 2003. As of June 2017, FDA estimates that there are a total of 815 products submitted for listing by persons who had an animal drug application or supplemental animal drug application pending after September 1, 2003. Based on this, FDA estimates that a total of 815 products will be subject to this fee in FY 2018.

In estimating the fee revenue to be generated by animal drug product fees in FY 2018, FDA is assuming that 3 percent of the products invoiced, or 24, will not pay fees in FY 2018 due to fee waivers and reductions. FDA has kept this estimate at 3 percent this year, based on historical data over the past five completed years of the ADUFA program. Based on experience over the first 13 completed years of the ADUFA program, FDA believes that this is a reasonable basis for estimating the number of fee-paying products in FY 2018.

Accordingly, the Agency estimates that a total of 791 (815 minus 24) 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 791 products that pay fees will generate a total of $4,885,000. To generate this amount will require the fee for an animal drug product, rounded to the nearest $5, to be $6,175.

## V. Establishment Fee Calculations for FY 2018

*A. Establishment Fee Revenues and Numbers of Fee-Paying Establishments*

The animal drug establishment fee (also referred to as the establishment fee) must be paid annually by the person who: (1) Owns or operates, directly or through an affiliate, an animal drug establishment; (2) is named as the applicant in an animal drug application or supplemental animal drug application for an animal drug product submitted for listing under section 510 of the FD&C Act; (3) had an animal drug application or

supplemental animal drug application pending at FDA after September 1, 2003; and (4) whose establishment engaged in the manufacture of the animal drug product during the fiscal year (see 21 U.S.C. 379j–12(a)(3)). An establishment subject to animal drug establishment fees is assessed only one such fee per fiscal year. The term ''animal drug establishment'' is defined as a foreign or domestic place of business which is at one general physical location consisting of one or more buildings all of which are within 5 miles of each other, at which one or more animal drug products are manufactured in final dosage form (21 U.S.C. 379j–11(4)). The establishment fees are to be set so that they will generate $4,704,000 in fee revenue for FY 2018.

To set animal drug establishment fees to realize $4,704,000, FDA must make some assumptions about the number of establishments for which these fees will be paid in FY 2018. FDA developed data on all animal drug establishments and matched this to the list of all persons who had an animal drug application or supplement pending after September 1, 2003. As of June 2017, FDA estimates that there are a total of 60 establishments owned or operated by persons who had an animal drug application or supplemental animal drug application pending after September 1, 2003. Based on this, FDA believes that 60 establishments will be subject to this fee in FY 2018.

In estimating the fee revenue to be generated by animal drug establishment fees in FY 2018, FDA is assuming that 11 percent of the establishments invoiced, or seven, will not pay fees in FY 2018 due to fee waivers and reductions. FDA has kept this estimate at 11 percent this year, based on historical data over the past 5 completed years. Based on experience over the past 13 completed years of the ADUFA program, FDA believes that this is a reasonable basis for estimating the number of fee-paying establishments in FY 2018.

Accordingly, the Agency estimates that a total of 53 establishments (60 minus 7) will be subject to establishment fees in FY 2018.

*B. Establishment Fee Rates for FY 2018*

FDA must set the fee rates for FY 2018 so that the estimated 53 establishments that pay fees will generate a total of $4,704,000. To generate this amount will require the fee for an animal drug establishment, rounded to the nearest $50, to be $88,750.

## VI. Sponsor Fee Calculations for FY 2018

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

The 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 animal drug application, 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 animal drug submission that has not been terminated or otherwise rendered inactive and (2) had an animal drug application, supplemental animal drug application, or investigational animal drug submission pending at FDA after September 1, 2003 (see 21 U.S.C. 379j–11(6) and 379j–12(a)(4)). An animal drug sponsor is subject to only one such fee each fiscal year (see 21 U.S.C. 379j–12(a)(4)). The sponsor fees are to be set so that they will generate $4,885,000 in fee revenue for FY 2018.

To set animal drug sponsor fees to realize $4,885,000, FDA must make some assumptions about the number of sponsors who will pay these fees in FY 2018. Based on the number of firms that would have met this definition in each of the past 13 completed years of the ADUFA program, FDA estimates that a total of 198 sponsors will meet this definition in FY 2018.

A review of our records indicates that 35 percent of these sponsors will qualify for a minor use/minor species fee waiver or reduction (21 U.S.C. 379j–12(d)(1)(D)). Based on the Agency's experience to date with sponsor fees, FDA's current best estimate is that an additional 32 percent will qualify for other waivers or reductions, for a total of 67 percent of the sponsors invoiced, or 133, who will not pay fees in FY 2018 due to fee waivers and reductions. FDA has kept this estimate at 67 percent this year, based on historical data over the past 5 completed years of the ADUFA program. FDA believes that this is a reasonable basis for estimating the number of fee-paying sponsors in FY 2018.

Accordingly, the Agency estimates that a total of 65 sponsors (198 minus 133) will be subject to and pay sponsor fees in FY 2018.

*B. Sponsor Fee Rates for FY 2018*

FDA must set the fee rates for FY 2018 so that the estimated 65 sponsors that pay fees will generate a total of $4,885,000. To generate this amount will require the fee for an animal drug sponsor, rounded to the nearest $50, to be $75,150.

## VII. Fee Schedule for FY 2018

The fee rates for FY 2018 are summarized in Table 6.

TABLE 6—FY 2018 FEE RATES

| Animal drug user fee category | Fee rate for FY 2018 |
|---|---|
| Animal Drug Application Fees: | |
| Animal Drug Application | $238,100 |
| Supplemental Animal Drug Application for Which Safety or Effectiveness Data are Required or Animal Drug Application Subject to the Criteria Set Forth in Section 512(d)(4) of the FD&C Act | 119,050 |
| Animal Drug Product Fee | 6,175 |
| Animal Drug Establishment Fee[1] | 88,750 |
| Animal Drug Sponsor Fee[2] | 75,150 |

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

## VIII. Procedures for Paying the FY 2018 Fees

*A. Application Fees and Payment Instructions*

The appropriate application fee established in the new fee schedule must be paid for an animal drug application or supplement subject to fees under ADUFA III that is submitted on or after October 1, 2017. The payment must be made in U.S. currency 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 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 search for and find 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 that are 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 (PIN), beginning with the letters AD, on the upper right-hand corner of your completed Animal 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 Drug User Fee Cover Sheet to: Food and Drug Administration, P.O. Box 979033, St. Louis, MO 63197–9000. When paying by wire transfer, the invoice number needs to be 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 payment by wire transfer: U.S. Department of Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, FDA Deposit Account Number: 75060099, U.S. Department of Treasury routing/transit number: 021030004, SWIFT Number: 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 telephone 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 application arrives at FDA's CVM. FDA records the official application receipt date as the later of the following: The date the application was received by FDA's CVM, or the date U.S. Bank notifies FDA that your payment in the full amount has been received, or when the U.S. Treasury notifies FDA of receipt of an electronic or wire transfer payment. U.S. Bank and the U.S. Treasury are required to notify FDA within 1 working day, using the PIN 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 on to the ADUFA Web site at *http://www.fda.gov/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/default.htm* and, under Tools and Resources, click ''The Animal Drug User Fee Cover Sheet'' and then select ''Create ADUFA User Fee Cover Sheet.'' 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 Drug User 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 Drug User Fee Cover Sheet. One cover sheet is needed for each animal drug application or supplement. 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 PIN.

Step Three—Send the payment for your application as described in section VIII.A.

Step Four—Please submit your application and a copy of the completed Animal 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, Establishment, and Sponsor Fees*

By December 31, 2017, FDA will issue invoices and payment instructions for product, establishment, and sponsor fees for FY 2018 using this fee schedule. Payment will be due by January 31, 2018. FDA will issue invoices in November 2018 for any products, establishments, 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. 2017–16180 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–2011–D–0689]**

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; De Novo Classification Process (Evaluation of Automatic Class III Designation)

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by September 1, 2017.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All