DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0806]

Animal Drug User Fee Rates and Payment Procedures for Fiscal Year 2013

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) 2013 animal drug user fees. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Animal Drug User Fee Act of 2003 (ADUFA) and the Animal Drug User Fee Amendments of 2008 (ADUFA II), 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 2013.

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, 7529 Standish Pl., Rockville, MD 20855, 240–276–9718. 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 2009 through FY 2013, the FD&C Act establishes aggregate yearly base revenue amounts for each of these fee categories. Base revenue amounts established for years after FY 2009 are subject to adjustment for workload. Fees for applications, establishments, products, and sponsors are to be established each year by FDA so that the revenue for each fee category will approximate the level established in the statute, after the level has been adjusted for workload.

For FY 2013, the animal drug user fee rates are: $435,200 for an animal drug application; $217,600 for a supplemental animal drug application for which safety or effectiveness data is 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)); $8,640 for an annual product fee; $104,600 for an annual establishment fee; and $87,700 for an annual sponsor fee. FDA will issue invoices for FY 2013 product, establishment, and sponsor fees by December 31, 2012, and these invoices will be due and payable within 30 days of issuance of the invoice. The application fee rates are effective for applications submitted on or after October 1, 2012, and will remain in effect through September 30, 2013. Applications will not be accepted for review until FDA has received full payment of application fees and any other animal drug user fees owed.

II. Revenue Amount for FY 2013

A. Statutory Fee Revenue Amounts

ADUFA II (Pub. L. 110–316 signed by the President on August 14, 2008) specifies that the aggregate revenue amount for FY 2013 for each of the four animal drug user fee categories is $6,061,000 before any adjustment for workload is made. (See 21 U.S.C. 379j–12(b)(1) through (b)(4).)

B. Inflation Adjustment to Fee Revenue Amount

The amounts established in ADUFA II for each year for FY 2009 through FY 2013 include an inflation adjustment; therefore, no further inflation adjustment is required.

C. Workload Adjustment to Inflation Adjusted Fee Revenue Amount

For each FY beginning in FY 2010, ADUFA provides that fee revenue amounts shall be further adjusted to reflect changes in review workload (21 U.S.C. 379j–12(c)(1)).

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, 2002 (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, 2012.

The results of these calculations are presented in the first two columns of table 1 of this document. 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 5 years. Column 5 of table 1 of this document 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 the table the sum of the values in column 5 is added, reflecting a total change in workload of −32% percent for FY 2013. This is the workload adjuster for FY 2013.

TABLE 1—WORKLOAD ADJUSTER CALCULATION (NUMBERS MAY NOT ADD DUE TO ROUNDING)

Application type	Column 1 5-year Avg. (base years)	Column 2 latest 5-year avg.	Column 3 percent change	Column 4 weighting factor	Column 5 weighted percent change
New Animal Drug Applications (NADAs)	28.8	11.4	−60	0.0229	−1
Supplemental NADAs With Safety or Efficacy Data	23.4	11.4	−51	0.0275	−1
Manufacturing Supplements	366.6	394.2	8	0.1222	1
Investigational Study Submissions	336.6	224.0	−33	0.6435	−22
Investigational Protocol Submissions	292.4	148.6	−49	0.1838	−9

TABLE 1—WORKLOAD ADJUSTER CALCULATION (NUMBERS MAY NOT ADD DUE TO ROUNDING)—Continued

Application type	Column 1 5-year Avg. (base years)	Column 2 latest 5-year avg.	Column 3 percent change	Column 4 weighting factor	Column 5 weighted percent change
FY 2013 Workload Adjuster					−32

ADUFA specifies that the workload adjuster may not result in fees that are less than the fee revenue amount in the statute (21 U.S.C. 379j–12(c)(1)(B)). Because applying the FY 2013 workload adjuster would result in fees less than the statutory amount, the workload adjustment will not be applied in FY 2013. As a result, the statutory revenue target amount for each of the four categories of fees remains at $6,061,000 with the new total revenue target for fees in FY 2013 being $24,244,000.

D. Offset for Excess Collections Through FY 2012

Under the provisions of ADUFA I, which apply to fees collected for FY 2004 through FY 2008, if the amount of fees collected for a FY exceeds the amount of fees specified in appropriation acts for that FY, the excess amount shall be credited to FDA's appropriation account and shall be subtracted from the amount of fees that would otherwise be authorized to be collected in a subsequent FY. (See section 740(g)(4) of the FD&C Act as originally enacted in Public Law 108–130 on November 18, 2003.) In setting ADUFA fees for FY 2008 and FY 2009, offsets totaling $1,664,000 were made under these provisions ($320,000 when FY 2008 fees were set and another $1,344,000 when fees for FY 2009 were set), but offsets totaling $394,256 for this period still need to be made. Table 2 shows the amount of fees specified in FDA's annual appropriation for each year from 2004 through 2008, the amounts FDA has collected for each year; the amount of offset previously taken, and the cumulative difference. FDA will take this difference as an offset against FY 2013 fee collections.

TABLE 2—OFFSETS REMAINING TO BE TAKEN FOR ADUFA I, FY 2004–2008

Fiscal year	Fees appropriated	Fees collected as of 3/31/2012	Excess collections offset when fees were set	Remaining excess collections to be offset
2004	$5,000,000	$5,154,700		$154,700
2005	8,354,000	8,519,101		165,101
2006	11,318,000	10,901,466		0
2007	11,604,000	13,342,455		1,738,455
2008	13,696,000	11,577,312	320,000	0
Totals				[1] 2,058,256
Net Excess Appropriations, to be Offset Against 2013 Collections				394,256

[1] See table 3 of this document for information on additional offset taken in FY 2009.

In addition, under the provisions of ADUFA, as amended by ADUFA II, if the cumulative amount of the fees collected for fiscal years 2009 through 2011, and the amount of fees estimated to be collected under this section for FY 2012, exceeds the cumulative amount appropriated for fees for fiscal years 2009 through 2012, the excess will be subtracted from the amount of fees that FDA would otherwise be authorized to collect for FY 2013 under the FD&C Act (21 U.S.C. 379j–12(g)(4) as amended by ADUFA II).

Table 3 shows the amounts appropriated for each year from FY 2009 through FY 2012, and the amounts FDA has collected for fiscal years 2009, 2010, and 2011 as of March 31, 2012, and the amount that FDA estimated it would collect in FY 2012 when it published the notice of FY 2012 fees in the **Federal Register** on August 1, 2011 (76 FR 45811). The bottom line of Table 3 shows the estimated cumulative amount by which fees collected fell below amounts appropriated for FY 2009 through FY 2012.

TABLE 3—OFFSETS TO BE TAKEN FOR THE ADUFA II PERIOD, FISCAL YEARS 2009–2012

[for FY 2009–2011, fees collected through March 31, 2012; for FY 2012, estimate as August 1, 2011]

Fiscal year	Fees appropriated	Fees collected	Excess collections offset when fees were set	Difference
2009	$15,260,000	$12,893,721	$1,344,000	($2,366,279)
2010	17,280,000	16,609,805		(670,195)
2011	19,448,000	18,342,199		(1,105,801)
2012 estimated	21,768,000	21,768,000		0
Cumulative Difference Less Than Appropriations				(4,142,275)

As can be seen from table 3, no further offset is required for the period 2009 through 2012 since collections have fallen substantially below the amounts appropriated each year and in aggregate. The only offset required at this time is the $394,256 from the ADUFA I period.

E. Final Year Adjustment

Under the provisions of ADUFA, as amended, the Secretary may, in addition to the workload adjustment and offset, further increase the fees and fee revenues if such an adjustment is necessary to provide up to 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 2014. (See 21 U.S.C. 379j–12(c)(2).) The rationale for the amount of this increase shall be contained in the annual notice establishing fee revenues and fees for FY 2013 (See section 740(c)(2) of the FD&C Act.) Table 4 in this document estimates the amount of carryover reserve FDA currently estimates to have available at the end of FY 2013. It begins with the balance available at the end of FY 2011, rounded to the nearest thousand dollars, adds the net prior year collections for the 6 months ending March 31, 2012, and subtracts the amount it will have to use to cover the offset it will make when 2013 fees are set. In addition, FDA is keeping aside a reserve of $1,400,000 for potential refunds, and a net of $379,000 for the last 2 years of ADUFA II. The amount of carry-over balance FDA expects to have available for obligation at the end of FY 2013 is $3,694,000, as shown in the last line of table 4.

TABLE 4—ESTIMATED CARRYOVER BALANCE AT THE END OF FY 2013, AFTER ADJUSTMENTS

Total Carryover Balance End of FY 2011	$4,664,000
Net Prior Year Fees Collected After 9/30/2011 (3/31/2012)	445,000
Used for Offset in 2013	(394,000)
Reserve for Refunds in 2012 and 2013	(1,400,000)
Estimated Change to Carryover Balance at the End of FY 2012	636,000
Estimated Change to Carryover Balance at the End of FY 2013	(257,000)
Estimated 2013 End of FY Carryover Balance	3,694,000

Table 5 estimates the amount of funds FDA anticipates that it will need from animal drug user fees in order to operate for the first 3 months of FY 2014.

TABLE 5—ESTIMATED FEE REVENUE NEEDED TO SUSTAIN FY 2013 OPERATIONS FOR THE FIRST 3 MONTHS OF FY 2014

Estimated Total Spending from Fees in FY 2013	$19,652,000
Estimated FY 2014 Inflation Costs at 2.01%	395,000
Estimated FY 2014 Funds to Sustain FY 2013 Operations	20,047,000
Estimated Fees Needed for 3 Months in FY 2014	5,012,000
Estimated End-of-FY 2013 Carryover Balance	3,694,000
Additional Revenue Needed for 3 Months in FY 2013	1,318,000

FDA expects to collect and spend a total of $19,652,000 in FY 2013, rounding to the nearest thousand dollars, after making adjustments for the offset of $394,256 and for likely revenue shortfalls below the $24,244,000 amount authorized for collection from ADUFA fee in that year. To maintain FY 2013 operations in FY 2014, FDA is applying an anticipated inflation rate of 2.01 percent to the amount of fee revenues FDA expects to obligate in FY 2013. This 2.01 percent is the statutory inflation adjustment to be applied to PDUFA and several other user fee programs in FY 2013, and the only statutory inflation adjustment for FDA available at this time; its derivation is published elsewhere in this issue of the **Federal Register** where the FY 2013 fees for the PDUFA user fee program is published. FDA expects to obligate a total of $20,047,000 in FY 2014—or a total of about $5,012,000 during the first 3 months of FY 2014, rounded to the nearest thousand dollars. The available carryover balance at the beginning of FY 2013 is estimated at $3,694,000 (rounded to the nearest thousand dollars). Thus FDA would need an additional $1,318,000 ($5,012,000 minus $3,694,000 rounded to the nearest thousand dollars) as the final year adjustment to assure sufficient operating reserves for the first 3 months of FY 2014.

FDA recognizes that adding $1,318,000 to the fee revenue costs in FY 2013 poses a substantial burden on the regulated industry at a time when it is undergoing financial strain. In light of this, and in light of the fact that the legislative language authorizing the final year adjustment allows FDA discretion in whether to make this adjustment for a full 3 months of operating reserves or for a shorter period, FDA has decided to balance its own risks with the amount of burden the final year adjustment would place on the industry. In making this decision, FDA has decided to assume more risk, making the final year adjustment to allow for only 2 months of operating reserves instead of 3 months. Accordingly FDA will make the final year adjustment for a lesser amount, as derived in table 6 of this document.

TABLE 6—ESTIMATED FEE REVENUE NEEDED TO SUSTAIN FY 2013 OPERATIONS FOR THE FIRST 2 MONTHS OF FY 2014

Estimated Total Spending from Fees in FY 2013	$19,652,000
Estimated FY 2014 Inflation Costs at 2.01%	395,000
Estimated FY 2014 Funds to Sustain FY 2013 Operations	20,047,000
Estimated Fees Needed for 2 Months in FY 2014	3,341,000
Estimated End-of-FY 2013 Carryover Balance	3,694,000
Additional Revenue Needed for 2 Months in FY 2013	0

Accordingly FDA will make no final year adjustment in the ADUFA fee revenue amount. In making this decision, FDA is assuming that it will have the revenues to operate in FY 2013 as proposed in the President's budget request for FDA. Should a significant reduction below that amount occur, FDA will have to make larger expenditures of user fee reserves to sustain the animal drug review program in FY 2013, to make up for appropriation reductions, and will have less carryover balance at the end of FY 2013 than estimated in this document. If such a reduction in appropriated funds should occur, FDA is reserving the right to revise the fees it is setting for FY 2013, due to the need to assess a final year adjustment in such circumstances. If that fact only becomes known after the start of FY 2013, FDA may publish a revised fee schedule with increased FY 2013 fees, and advise any who have paid fees at the lower rate that they will have to make another payment to make up the difference between the fees published in this document and the higher fees necessitated by the need to impose a final year adjustment.

F. FY 2013 Fee Revenue Amounts

The final estimate of fee revenue for ADUFA fees for FY 2013 is shown in table 7 in this document. The statutory amount of $6,061,000 for each of the fee components is reduced by a total of $98,564—one fourth of the total offset amount of $394,256. No final year adjustment is made. The total is then rounded to the nearest thousand dollars,

for a total of $5,962,000 to come from each fee component.

TABLE 7—ESTIMATE OF TOTAL ADUFA FEE REVENUE FOR FY 2013

Fee components	Application fees	Establishment fees	Product fees	Sponsor fees	Total
Amount in ADUFA II	$6,061,000	$6,061,000	$6,061,000	$6,061,000	$24,244,000
Reduction for Offset	(98,564)	(98,564)	(98,564)	(98,564)	(394,256)
Final Year Adjustment	0	0	0	0	0
Total	5,962,436	5,962,436	5,962,436	5,962,436	23,849,744
Total Rounded	5,962,000	5,962,000	5,962,000	5,962,000	23,848,000

III. Application Fee Calculations for FY 2013

The terms ''animal drug application'' and ''supplemental animal drug application'' are defined in section 739 of the FD&C Act (21 U.S.C. 379j–11(1) and (2)).

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

The application fee must be paid for any animal drug application or supplemental animal drug application that is subject to fees under ADUFA and that is submitted on or after September 1, 2003. The application fees are to be set so that they will generate $5,962,000 in fee revenue for FY 2013. This is the amount set out in the statute and adjusted for the offset with no final year adjustment. 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. (See 21 U.S.C. 379j–12(a)(1)(A)(ii), as amended by ADUFA II.)

To set animal drug application fees and supplemental animal drug application fees to realize $5,962,000, FDA must first make some assumptions about the number of fee-paying applications and supplements the Agency will receive in FY 2013.

The Agency knows the number of applications that have been submitted in previous years. That number fluctuates significantly from year to year. In estimating the fee revenue to be generated by animal drug application fees in FY 2013, FDA is assuming that the number of applications that will pay fees in FY 2013 will equal the average number of submissions over the 5 most recent completed years (FY 2007–FY 2011). This may not fully account for possible year to year fluctuations in numbers of fee-paying applications, but FDA believes that this is a reasonable approach after 9 years of experience with this program.

Over the 5 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 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 11.0.

B. Fee Rates for FY 2013

FDA must set the fee rates for FY 2013 so that the estimated 8.2 applications that pay the full fee and the estimated 11.0 supplemental applications 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 $5,962,000. To generate this amount, the fee for an animal drug application, rounded to the nearest hundred dollars, will have to be $435,200, 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 $217,600.

IV. Product Fee Calculations for FY 2013

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. (See 21 U.S.C. 379j–12(a)(2).) The term ''animal drug product'' is defined in 21 U.S.C. 379j–11(3). The product fees are to be set so that they will generate $5,962,000 in fee revenue for FY 2013. This is the amount set out in the statute and adjusted for the offset with no final year adjustment.

To set animal drug product fees to realize $5,962,000, FDA must make some assumptions about the number of products for which these fees will be paid in FY 2013. 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 2012, FDA estimates that there are a total of 767 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 767 products will be subject to this fee in FY 2013.

In estimating the fee revenue to be generated by animal drug product fees in FY 2013, FDA is again assuming that 10 percent of the products invoiced, or 77, will not pay fees in FY 2013 due to fee waivers and reductions. Based on experience with other user fee programs and the first 9 years of ADUFA, FDA believes that this is a reasonable basis for estimating the number of fee-paying products in FY 2013.

Accordingly, the Agency estimates that a total of 690 (767 minus 77) products will be subject to product fees in FY 2013.

B. Product Fee Rates for FY 2013

FDA must set the fee rates for FY 2013 so that the estimated 690 products that pay fees will generate a total of $5,962,000. To generate this amount will require the fee for an animal drug product, rounded to the nearest 5 dollars, to be $8,640.

V. Establishment Fee Calculations for FY 2013

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. (See 21 U.S.C. 379j–12(a)(3).) The term ''animal drug establishment'' is defined in 21 U.S.C. 379j–11(4). The establishment fees are to be set so that they will generate $5,962,000 in fee revenue for FY 2013. This is the amount set out in the statute and adjusted for the offset with no final year adjustment.

To set animal drug establishment fees to realize $5,962,000, FDA must make some assumptions about the number of establishments for which these fees will be paid in FY 2013. 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 2012, FDA estimates that there are a total of 63 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 63 establishments will be subject to this fee in FY 2013.

In estimating the fee revenue to be generated by animal drug establishment fees in FY 2013, FDA is assuming that 10 percent of the establishments invoiced, or 6, will not pay fees in FY 2013 due to fee waivers and reductions. Based on experience with the first 9 years of ADUFA, FDA believes that this is a reasonable basis for estimating the number of fee-paying establishments in FY 2013.

Accordingly, the Agency estimates that a total of 57 establishments (63 minus 6) will be subject to establishment fees in FY 2013.

B. Establishment Fee Rates for FY 2013

FDA must set the fee rates for FY 2013 so that the estimated 57 establishments that pay fees will generate a total of $5,962,000. To generate this amount will require the fee for an animal drug establishment, rounded to the nearest 50 dollars, to be $104,600.

VI. Sponsor Fee Calculations for FY 2013

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 $5,962,000 in fee revenue for FY 2013. This is the amount set out in the statute and adjusted for the offset with no final year adjustment.

To set animal drug sponsor fees to realize $5,962,000, FDA must make some assumptions about the number of sponsors who will pay these fees in FY 2013. Based on the number of firms that would have met this definition in each of the past 9 years, FDA estimates that a total of 171 sponsors will meet this definition in FY 2013.

Careful review indicates that about one third or 33 percent of all of these sponsors will qualify for minor use/minor species 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 27 percent will qualify for other waivers or reductions, for a total of 60 percent of the sponsors invoiced, or 103, who will not pay fees in FY 2013 due to fee waivers and reductions. FDA believes that this is a reasonable basis for estimating the number of fee-paying sponsors in FY 2013.

Accordingly, the Agency estimates that a total of 68 sponsors (171 minus 103) will be subject to and pay sponsor fees in FY 2013.

B. Sponsor Fee Rates for FY 2013

FDA must set the fee rates for FY 2013 so that the estimated 68 sponsors that pay fees will generate a total of $5,962,000. To generate this amount will require the fee for an animal drug sponsor, rounded to the nearest 50 dollars, to be $87,700.

VII. Fee Schedule for FY 2013

The fee rates for FY 2013 are summarized in table 8 of this document.

TABLE 8—FY 2013 FEE RATES

Animal drug user fee category	Fee rate for FY 2013
Animal Drug Application Fees:	
Animal Drug Application	$435,200
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	217,600
Animal Drug Product Fee	8,640
Animal Drug Establishment Fee[1]	104,600
Animal Drug Sponsor Fee[2]	87,700

[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 2013 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 that is submitted after September 30, 2012. Payment must be made in U.S. currency by check, bank draft, or U.S. postal money order payable to the order of the Food and Drug Administration, by wire transfer, or electronically using Pay.gov. (The Pay.gov payment option is available to you after you submit a cover sheet. Click the ''Pay Now'' button.) On your check, bank draft, or U.S. postal money order, please write your application's unique Payment Identification Number (PIN), beginning with the letters AD, from 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 953877) on the enclosed check, bank draft, or money order. Your payment and a copy of the completed Animal Drug User Fee Cover Sheet can be mailed to: Food and Drug

Administration, P.O. Box 953877, St. Louis, MO 63195–3877.

If payment is made by wire transfer, send payment to: 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. You are responsible for any administrative costs associated with the processing of a wire transfer. Contact your bank or financial institution regarding additional fees.

If you prefer to send a check by a courier such as Federal Express or United Parcel Service, the courier may deliver the check and printed copy of the cover sheet to: U.S. Bank, Attn: Government Lockbox 953877, 1005 Convention Plaza, St. Louis, MO 63101. (**NOTE:** This 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.)

The tax identification number of the Food and Drug Administration is 530196965. (**NOTE:** In no case should the payment for the fee be submitted to FDA with the application.)

It is helpful if 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.

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 click ''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 of this document.

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, 2012, FDA will issue invoices and payment instructions for product, establishment, and sponsor fees for FY 2013 using this Fee Schedule. Payment will be due and payable within 30 days of issuance of the invoice. FDA will issue invoices in November 2013 for any products, establishments, and sponsors subject to fees for FY 2013 that qualify for fees after the December 2012 billing.

Dated: July 26, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0807]

Animal Generic Drug User Fee Rates and Payment Procedures for Fiscal Year 2013

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) 2013 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 Act of 2008 (AGDUFA), 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 2013.

FOR FURTHER INFORMATION CONTACT: Visit the FDA Web site at *http://www.fda.gov/ForIndustry/UserFees/AnimalGenericDrugUserFeeActAGDUFA/default.htm* or contact Lisa Kable, Center for Veterinary Medicine (HFV–10), Food and Drug Administration, 7529 Standish Pl., Rockville, MD 20855, 240–276–9718. 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 2009 through FY 2013, the FD&C Act establishes aggregate yearly base revenue amounts for each of these fee categories. Base revenue amounts established for years after FY 2009 may be adjusted for workload. Fees for applications, products, and sponsors are to be established each year by FDA so that the revenue for each fee category will approximate the level established in the statute, after the level has been adjusted for workload.

For FY 2013, the generic new animal drug user fee rates are: $148,300 for each abbreviated application for a generic new animal drug; $6,515 for each generic new animal drug product; $63,000 for each generic new animal drug sponsor paying 100 percent of the sponsor fee; $47,250 for each generic new animal drug sponsor paying 75 percent of the sponsor fee; and $31,500 for each generic new animal drug sponsor paying 50 percent of the sponsor fee. FDA will issue invoices for FY 2013 product and sponsor fees by December 31, 2012. These fees will be due and payable within 30 days of the issuance of the invoices. The