the General Services Administration, Regulatory Secretariat (VPR), 1800 F Street, Room 4041, Washington, DC 20405, telephone (202) 501–4755.

Please cite OMB Control No. 9000–0026, Change Order Accounting, in all correspondence.

Dated: July 28, 2009.

Al Matera,

Director, Office of Acquisition Policy.

[FR Doc. E9–18465 Filed 7–31–09; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0094]

Federal Acquisition Regulation; Submission for OMB Review; Debarment and Suspension

AGENCIES: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice of request for an extension to an existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Federal Acquisition Regulation (FAR) Secretariat will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a currently approved information collection requirement concerning [subject]. A request for public comments was published in the **Federal Register** at 74 FR 18716 on April 24, 2009. No comments were received.

Public comments are particularly invited on: Whether this collection of information is necessary for the proper performance of functions of the FAR, and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

DATES: Submit comments on or before September 2, 2009.

ADDRESSES: Submit comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: FAR Desk Officer, OMB, Room 10102, NEOB, Washington, DC 20503, and a copy to the General Services Administration, Regulatory Secretariat (VPR), 1800 F Street, NW., Room 4041, Washington, DC 20405.

FOR FURTHER INFORMATION CONTACT: Edward Loeb, Contract Policy Division, GSA (202) 501–0650 or via e-mail at *Edward.Loeb@gsa.gov.*

SUPPLEMENTARY INFORMATION:

A. Purpose

The FAR requires contracts to be awarded to only those contractors determined to be responsible. Instances where a firm or its principals have been indicted, convicted, suspended, proposed for debarment, debarred, or had a contract terminated for default are critical factors to be considered by the contracting officer in making a responsible determination, 52.209–5, Certification Responsibility Matters, requires the disclosure of this information.

B. Annual Reporting Burden

Respondents: 89,995.
Responses per Respondent: 12.223.
Annual Responses: 1,100,000.
Hours per Response: 0.0833.
Total Burden Hours: 91,667.
Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat (VPR), 1800 F Street, NW., Room 4041, Washington, DC 20405, telephone (202) 501–4755. Please cite OMB Control No. 9000–0094, Debarment and Suspension, in all correspondence.

Dated: July 28, 2009.

Al Matera,

Director, Office of Acquisition Policy.

[FR Doc. E9–18466 Filed 7–31–09; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0336]

Animal Drug User Fee Rates and Payment Procedures for Fiscal Year 2010

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) 2010 animal drug user fees. The Federal Food, Drug, and Cosmetic Act (the 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, on certain animal drug products, on certain establishments where such products are made, and on certain sponsors of such animal drug applications and/or investigational animal drug submissions. This notice establishes the fee rates for FY 2010.

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 e-mail the Center for Veterinary Medicine (CVM) at: *cvmadufa@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Section 740 of the act (21 U.S.C. 379j-12) establishes four different kinds 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 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 2010, the animal drug user fee rates are: $209,400 for an animal drug application; $145,200 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 act (21 U.S.C. 360b(d)(4)); $6,185 for an annual

product fee; $73,850 for an annual establishment fee; and $57,100 for an annual sponsor fee. FDA will issue invoices for FY 2010 product, establishment, and sponsor fees by December 31, 2009, 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, 2009, and will remain in effect through September 30, 2010. 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 2010

A. Statutory Fee Revenue Amounts

ADUFA II (Public Law 110–316 signed by the President on August 14, 2008) specifies that the aggregate revenue amount for FY 2010 for each of the 4 animal drug user fee categories is $4,320,000, 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; so, 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, 2009.

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 -22% percent for FY 2010. This is the workload adjuster for FY 2010.

TABLE 1.—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 % Change
New Animal Drug Applications (NADAs)	28.80	12.40	-57%	0.0319	-2%
Supplemental NADAs With Safety or Efficacy Data	23.40	13.60	-42%	0.0233	-1%
Manufacturing Supplements	366.6	435.20	19%	0.1605	3%
Investigational Study Submissions	336.60	242.80	-28%	0.5930	-17%
Investigational Protocol Submissions	292.40	204.80	-30%	0.1913	-6%
FY 2010 Workload Adjuster					-22%

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 2010 workload adjuster would result in fees less than the statutory amount, the workload adjustment will not be applied in FY 2010. As a result, the statutory revenue target amount for each of the 4 categories of fees stand at $4,320,000 with the new total revenue target for fees in FY 2010 being $17,280,000.

III. Adjustment for Excess Collections in Previous Years

Under the provisions of ADUFA, if the agency collects more fees than were provided for in appropriations in any year, FDA is required to reduce its anticipated fee collections in a subsequent fiscal year by that amount (21 U.S.C. 379j-12(g)(4)) prior to its amendment under ADUFA II). Table 2 of this document shows the amount of collections realized and the amount provided in appropriations acts, and the amount to be offset in a subsequent year, as of the end of the latest complete fiscal year, 2008, which is the final year of ADUFA.

TABLE 2.—FEES COLLECTED, FEES APPROPRIATED, AND OFFSET FOR FUTURE COLLECTIONS—AS OF SEPTEMBER 30, 2008

Fiscal Year Cohort	Fees Collected	Fees Appropriated	Amount to Offset Future Collections
2004	$5,154,700	$5,000,000	$154,700

TABLE 2.—FEES COLLECTED, FEES APPROPRIATED, AND OFFSET FOR FUTURE COLLECTIONS—AS OF SEPTEMBER 30, 2008—Continued

Fiscal Year Cohort	Fees Collected	Fees Appropriated	Amount to Offset Future Collections
2005	$8,519,101	$8,354,000	$165,101
2006	$10,945,866	$11,318,000	$0
2007	$13,189,060	$11,604,000	$1,585,060[1]
2008	$11,177,600	$13,696,000	$0
Total			$1,904,861
Amount Offset When Fees for FY 2008 Were Determined			$320,000
Amount Offset When Fees for FY 2009 Were Determined			$1,344,000[2]
Remaining Balance to Be Offset When FY 2013 Fees Are Set			$240,861

[1] Some fees for FY 2007 were collected at the end of FY 2008 and were therefore not reflected in the **Federal Register** document announcing animal drug user fee rates and payment procedures for FY 2009 (September 15, 2008; 73 FR 53254). These additional fees amount to $240,861 and represent the remaining balance to be offset.

[2] The amount shown in the corresponding chart last year was $1,342,316 (73 FR 53254). When the reduction was taken this amount was divided by 4, so it could be distributed among the 4 categories of fees (application fees, establishment fees, product fees and sponsor fees) and then it was rounded to the nearest thousand dollars, which amounted to $336,000, for each of these categories. Thus, the total reduction actually taken in FY 2009 was $336,000 times 4, or a total of $1,344,000.

When ADUFA fees were established for FY 2008 and FY 2009, the amount of fee revenues for each year was reduced by $320,000 and $1,344,000 of collections in excess of appropriations, respectively. That leaves a total of $240,861 collected under ADUFA I remaining to be offset. ADUFA II amended the annual offset provision of ADUFA I to require one offset when FY 2013 fees are set in August of 2012, if aggregate collections from FY 2009 through 2011 plus the amount of fees estimated to be collected for FY 2012 exceed aggregate appropriations over the same period (21 U.S.C. 379j-12(g)(4), as amended by ADUFA II). FDA will include the remaining $240,861 in excess collections from FY 2004 through FY 2008 in the calculations when it determines whether or not there will be an offset in FY 2013, the final year of ADUFA II. FDA is not offsetting for excess collections at this time.

IV. Application Fee Calculations for FY 2010

The terms ''animal drug application'' and ''supplemental animal drug application'' are defined in section 739 of the 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 $4,320,000 in fee revenue for FY 2010. This is the amount set out in the statute and no adjustments are required for FY 2010. 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) 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 $4,320,000, FDA must first make some assumptions about the number of fee-paying applications and supplements the agency will receive in FY 2010.

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 2010, FDA is assuming that the number of applications that will pay fees in FY 2010 will equal the average number of submissions over the 4 most recent years (including an estimate for the current year). 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 6 years of experience with this program.

Over the past 4 years, the average number of animal drug applications that would have been subject to the full fee was 8.25, including the number for the most recent year, estimated at 6. 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 act that would have been subject to half of the full fee was 13.25, including the number for the most recent year, estimated at 9.

Thus, for FY 2010, FDA estimates receipt of 8.25 fee paying original applications and 13.25 fee-paying supplemental animal drug applications and applications subject to the criteria set forth is section 512(d)(4) of the act which pay half of the full fee.

B. Fee Rates for FY 2010

FDA must set the fee rates for FY 2010 so that the estimated 8.25 applications that pay the full fee and the estimated 13.25 supplements and applications subject to the criteria set forth in section 512(d)(4) of the act that pay half of the full fee will generate a total of $4,320,000. To generate this amount, the fee for an animal drug application, rounded to the nearest hundred dollars, will have to be $290,400, 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 act will have to be $145,200.

V. Product Fee Calculations for FY 2010

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 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 $4,320,000 in fee revenue for FY 2010. This is the amount set out in the statute and no adjustments are required for FY 2010.

To set animal drug product fees to realize $4,320,000, FDA must make some assumptions about the number of products for which these fees will be paid in FY 2010. FDA developed data on all animal drug products that have been submitted for listing under section 510 of the 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 July 2009, FDA estimates that there are a total of 776 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 776 products will be subject to this fee in FY 2010.

In estimating the fee revenue to be generated by animal drug product fees in FY 2010, FDA is assuming that 10 percent of the products invoiced, or about 77.6, will not pay fees in FY 2010 due to fee waivers and reductions. Based on experience with other user fee programs and the first 6 years of ADUFA, FDA believes that this is a reasonable basis for estimating the number of fee-paying products in FY 2010.

Accordingly, the agency estimates that a total of 698.4 (776 minus 77.6) products will be subject to product fees in FY 2010.

B. Product Fee Rates for FY 2010

FDA must set the fee rates for FY 2010 so that the estimated 698.4 products that pay fees will generate a total of $4,320,000. To generate this amount will require the fee for an animal drug product, rounded to the nearest 5 dollars, to be $6,185.

VI. Establishment Fee Calculations for FY 2010

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 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 1 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 $4,320,000 in fee revenue for FY 2010. This is the amount set out in the statute and no adjustments are required for FY 2010.

To set animal drug establishment fees to realize $4,320,000, FDA must make some assumptions about the number of establishments for which these fees will be paid in FY 2010. 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 July 2009, FDA estimates that there are a total of 65 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 65 establishments will be subject to this fee in FY 2010.

In estimating the fee revenue to be generated by animal drug establishment fees in FY 2010, FDA is assuming that 10 percent of the establishments invoiced, or 6.5, will not pay fees in FY 2010 due to fee waivers and reductions. Based on experience with the first 6 years of ADUFA, FDA believes that this is a reasonable basis for estimating the number of fee-paying establishments in FY 2010.

Accordingly, the agency estimates that a total of 58.5 establishments (65 minus 6.5) will be subject to establishment fees in FY 2010.

B. Establishment Fee Rates for FY 2010

FDA must set the fee rates for FY 2010 so that the estimated 58.5 establishments that pay fees will generate a total of $4,320,000. To generate this amount will require the fee for an animal drug establishment, rounded to the nearest 50 dollars, to be $73,850.

VII. Sponsor Fee Calculations for FY 2010

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 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 $4,320,000 in fee revenue for FY 2010. This is the amount set out in the statute, and no adjustments are required for FY 2010.

To set animal drug sponsor fees to realize $4,320,000, FDA must make some assumptions about the number of sponsors who will pay these fees in FY 2010. Based on the number of firms that would have met this definition in each of the past 6 years, FDA estimates that a total of 161 sponsors will meet this definition in FY 2010.

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)(C)). Based on the agency's experience to date with sponsor fees, FDA's current best estimate is that an additional 20 percent will qualify for other waivers or reductions, for a total of 53 percent of the sponsors invoiced, or 85.3, who will not pay fees in FY 2010 due to fee waivers and reductions. FDA believes that this is a reasonable basis for estimating the number of fee-paying sponsors in FY 2010.

Accordingly, the agency estimates that a total of 75.7 sponsors (161 minus 85.3) will be subject to and pay sponsor fees in FY 2010.

B. Sponsor Fee Rates for FY 2010

FDA must set the fee rates for FY 2010 so that the estimated 75.7 sponsors that pay fees will generate a total of $4,320,000. To generate this amount will require the fee for an animal drug sponsor, rounded to the nearest 50 dollars, to be $57,100.

VIII. Fee Schedule for FY 2010

The fee rates for FY 2010 are summarized in table 3 of this document.

TABLE 3.—FY 2010 FEE RATES

Animal Drug User Fee Category	Fee Rate for FY 2010
Animal Drug Application Fees	
Animal Drug Application	$290,400
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 Act	$145,200
Animal Drug Product Fee	$6,185
Animal Drug Establishment Fee[1]	$73,850
Animal Drug Sponsor Fee[2]	$57,100

[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.

IX. Procedures for Paying the FY 2010 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, 2009. 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 (FEDEX) or United Parcel Service (UPS), 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 314–418–4821. 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/AnimalDrugUserFeeAct ADUFA/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 IX.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, 2009, FDA will issue invoices and payment instructions for product, establishment, and sponsor fees for FY 2010 using this Fee Schedule. Payment will be due and payable within 30 days of issuance of the invoice. FDA will issue invoices in November 2010 for any products, establishments, and sponsors subject to fees for FY 2010 that qualify for fees after the December 2009 billing.

Dated: July 28, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–18459 Filed 7–31–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0340]

Animal Generic Drug User Fee Rates and Payment Procedures for Fiscal Year 2010

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) 2010 generic new animal drug user fees. The Federal Food, Drug, and Cosmetic Act (the 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, on certain generic new animal drug products, and on 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 2010.

For FY 2010, the generic animal drug user fee rates are: $75,000 for each abbreviated application for a generic new animal drug; $3,255 for each generic new animal drug product; $54,050 for each generic new animal drug sponsor paying 100 percent of the sponsor fee; $40,537 for each generic new animal drug sponsor paying 75 percent of the sponsor fee; and $27,025 for a generic new animal drug sponsor paying 50 percent of the sponsor fee. FDA will issue invoices for FY 2010 product and sponsor fees by December 31, 2009. These fees will be due and payable within 30 days of the issuance of the invoices.

The application fee rates are effective for all abbreviated applications for a generic new animal drug submitted on or after October 1, 2009, and will remain in effect through September 30, 2010. Applications will not be accepted for review until the FDA has received full payment of related application fees and any other fees owed under the Animal Generic Drug User Fee program.

FOR FURTHER INFORMATION CONTACT: Visit the FDA Web site at *http://www.fda.gov/ForIndustry/UserFees/AnimalGenericDrugUserFeeActAGDUFA/default.htm* or contact Bryan Walsh, Center for Veterinary Medicine (HFV–10), Food and Drug Administration, 7529 Standish Pl., Rockville, MD 20855, 240–276–9730. For general questions, you may also e-mail the Center for Veterinary Medicine (CVM) at: *cvmagdufa@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Section 741 of the act (21 U.S.C. 379j–21) establishes three different kinds 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 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.

II. Revenue Amount for FY 2010

A. Statutory Fee Revenue Amounts

AGDUFA (Title II of Public Law 110–316 signed by the President on August 14, 2008) specifies that the aggregate revenue amount for FY 2010 for abbreviated application fees is $1,532,000 and each of the other two generic new animal drug user fee categories, annual product fees and annual sponsor fees, is $1,787,000 each, before any adjustment for workload is made (see 21 U.S.C. 379j–21(b)).

B. Inflation Adjustment to Fee Revenue Amount

The amounts established in AGDUFA for each year for FY 2009 through FY 2013 include an inflation adjustment, so no inflation adjustment is required.

C. Workload Adjustment to Inflation Adjusted Fee Revenue Amount

For each FY beginning after FY 2009, AGDUFA provides that statutory fee revenue amounts shall be further adjusted to reflect changes in review workload (21 U.S.C. 379j–21(c)(1)).

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 ended on September 30, 2008 (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, 2009.

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 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 of table 1 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 negative 11.2 percent for FY 2010. This is the workload adjuster for FY2010.

TABLE 1.—WORKLOAD ADJUSTER CALCULATION

Application type	Column 1 5-Year Avg. (Base Years)	Column 2 Latest 5-Year Avg.	Column 3 Percent Change	Column 4 Weighting Factor	Colum 5 Weighted Percent Change
Abbreviated New Animal Drug Applications (ANADAs)	44.20	38.00	-14%	59%	-8.3%