estimated total annual burden for followup reports of new medical information is shown in row 2 of table 1 of this document.

As previously noted, section 761(e)(1) of the act requires that responsible persons maintain records related to dietary supplement adverse event reports they receive, whether or not the adverse event is serious. Under the statute, the records must be retained for a period of 6 years. The draft guidance provides FDA's recommendations as to what records industry should maintain to satisfy the statutory recordkeeping requirement.

The guidance recommends that the responsible person document its attempts to obtain the minimum data elements for a serious adverse event report. Along with these records, the guidance recommends that the responsible person keep the following other records: (1) Communications between the responsible person and the initial reporter of the adverse event and with any other person(s) who provided information about the adverse event; (2) (for serious adverse events only) the responsible person's serious adverse event report to FDA on MedWatch Form 3500A, with attachments; (3) any new medical information about the adverse event received by the responsible person; (4) (for serious adverse events only) any reports to FDA of new medical information related to the serious adverse event report. We estimate that assembling and filing these records, including any necessary photocopying, will take approximately 0.5 hours per adverse event report received by the responsible person.

Once the documents pertaining to an adverse event report have been assembled and filed, FDA expects the records retention burden to be minimal, as the agency believes most establishments would normally keep this kind of record for at least several years after receiving the report, as a matter of usual and customary business practice. FDA requests comment on current adverse event recordkeeping practices in the dietary supplement industry, including the length of time such records are typically kept.

According to a 2001 report by the Office of the Inspector General, between 1994–1999 FDA received 2,547 adverse event reports involving dietary supplements, or about 500 reports per year, on average. According to the report, the actual number of adverse events relating to dietary supplements is likely to be at least 100 times that many, or more than 50,000 adverse events per year. Given that we have limited data on how many adverse events will be reported each year to the responsible person, we are using the 50,000 per year figure as an upper-bound estimate of reporting. This is almost certainly an overestimate of the number of reports the firms will receive, as it is unlikely that every adverse event that occurs will be reported to the responsible person. FDA requests comments on this estimate.

We estimated in the economic impact analysis of the Dietary Supplement Good Manufacturing Practices final rule (the GMP final rule) (72 FR 34752, June 25, 2007) that there are 1,460 manufacturers, packers, and holders of dietary supplements (72 FR 34752 at 34920). We assume that the estimated 50,000 adverse event reports related to dietary supplements will be spread evenly among these firms. The estimate of the number of manufacturers, packers, and holders of dietary supplements from the GMP final rule is FDA's best estimate of the number of firms that are ''responsible persons'' who must comply with the recordkeeping requirements of the DSNDCPA; however, it is not a precise estimate because the number of dietary supplement establishments covered by the GMP final rule is likely to be larger than the number of ''responsible persons,'' where a ''responsible person'' is a dietary supplement manufacturer, packer, or distributor whose name is listed on the label of a dietary supplement marketed in the United States (see section 761(b)(1) of the act). Thus, FDA's estimate for the number of respondents in table 2 may be over inclusive. FDA requests comments on the number of firms that would be subject to the recordkeeping requirements of the DSNDCPA.

The estimated total annual recordkeeping burden under the statute and this guidance is shown in table 2 of this document.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records[2]	Hours per Record	Total Hours
Dietary supplement adverse event records (21 U.S.C. 379aa–1(e)(1))	1,460	4.2465	50,000	0.5	25,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

[2] For purposes of estimating the number of records and hours per record, a ''record'' means all records kept for an individual adverse event report received by the responsible person.

Dated: September 8, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–21454 Filed 9–12–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0480]

Animal Drug User Fee Rates and Payment Procedures for Fiscal Year 2009

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) 2009 for user fees under the Animal Drug User Fee Act program (ADUFA). The Federal Food, Drug, and Cosmetic Act (the act), as amended by the Animal Drug User Fee Act of 2003 (ADUFA I), and the Animal Drug User Fee Amendments of 2008 (ADUFA II), authorizes FDA to collect user fees for certain animal drug applications, 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 2009.

For FY 2009, the animal drug user fee rates are: $246,300 for an animal drug application; $123,150 for a supplemental animal drug application for which safety or effectiveness data is required and for an animal drug application subject to certain criteria; $4,925 for an annual product fee; $59,450 for an annual establishment fee; and $52,700 for an annual sponsor fee. FDA will issue invoices for FY 2009 product, establishment, and sponsor fees by December 31, 2008, and these invoices will be due and payable on or before January 31, 2009. FDA will issue invoices in November 2009 for any products, establishments, and sponsors that are subject to fees for FY 2009 but that qualified for fees after the December 2008 billing.

The application fee rates are effective for applications submitted on or after October 1, 2008, and will remain in effect through September 30, 2009. Applications will not be accepted for review until FDA has received full payment of application fees and any other animal drug user fees owed.

FOR FURTHER INFORMATION CONTACT: Visit the FDA Web site at *http://www.fda.gov/oc/adufa* or contact Roxanne Schweitzer, Center for Veterinary Medicine (HFV–10), Food and Drug Administration, 7529 Standish Pl., Rockville, MD 20855, 240–276–9705. For general questions, you may also e-mail the Center for Veterinary Medicine 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 (section 740(a) of the act). When certain conditions are met, FDA will waive or reduce fees (section 740(d) of the act).

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, products, establishments, 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 2009

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 2009 for each of the four animal drug user fee categories is $3,815,000, before any adjustment for workload is made (see section 740(b)(1) through (b)(4) of the act).

B. Inflation Adjustment to Fee Revenue Amount

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

C. Workload Adjustment to Fee Revenue Amount

For each FY beginning after FY 2009, ADUFA II provides that statutory fee revenue amounts shall be further adjusted to reflect changes in review workload (section 740(c)(1) of the act). No workload adjustment is to be made in fee revenue amounts for FY 2009.

III. Adjustment for Excess Collections in Previous Years

Under the provisions of ADUFA I, 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 year by that amount (section 740(g)(4) of the act). Table 1 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, 2007.

TABLE 1—FEES COLLECTED, FEES APPROPRIATED, AND OFFSET FOR FUTURE COLLECTIONS AS OF SEPTEMBER 30, 2007

Fiscal Year	Collections Realized	Fees Appropriated	Amount to Offset Future Collections
2004	$5,154,700	$5,000,000	$154,700
2005	$8,519,101	$8,354,000	$165,101
2006	$10,945,866	$11,318,000	$0
2007	$12,946,515	$11,604,000	$1,342,515
Total			$1,662,316
Amount offset when fees for FY 2008 were determined			$320,000
Remaining balance to be offset in FY 2009			$1,342,316

When ADUFA fees were established for FY 2008, the amount of fee revenues for FY 2008 was reduced by a total of $320,000 of excess collections. That leaves a total of $1,342,316 to be offset against FY 2009 revenue collections, lowering the net amount that would otherwise be collected. One-fourth of this amount, rounded to the nearest thousand, or $336,000, rounded to the nearest thousand dollars, will be subtracted from the statutory fee revenue amounts for each of the four fee categories in setting the FY 2009 adjusted revenue amount for each fee category. Thus, after adjustment for prior-year excess collections, the adjusted FY 2009 revenue target for each fee category is as follows:

Application Fee Revenue Amount: $3,479,000 ($3,815,000 minus $336,000)

Establishment Fee Revenue Amount: $3,479,000 ($3,815,000 minus $336,000)

Product Fee Revenue Amount: $3,479,000 ($3,815,000 minus $336,000)

Sponsor Fee Revenue Amount: $3,479,000 ($3,815,000 minus $336,000)

Thus, the adjusted revenue amount from all four categories after this adjustment totals $13,916,000.

IV. Application Fee Calculations for FY 2009

The terms ''animal drug applications'' and ''supplemental animal drug applications'' are defined in section 739(1) and (2) 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 $3,479,000 in fee revenue for FY 2009. This is the amount set out in the statute after it has been adjusted for excess collections in previous years as set out in section III of this document. 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 act (21 U.S.C. 360b(d)(4)) is to be set at 50 percent of the animal drug application fee (see section 740(a)(1)(A)(ii) of the act, as amended by ADUFA II).

To set animal drug application fees and supplemental animal drug application fees to realize $3,479,000, FDA must first make some assumptions about the number of fee-paying applications and supplements it will receive in FY 2009.

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 2009, FDA is assuming that the number of applications that will pay fees in FY 2009 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 5 years of experience with this program.

Over the past 4 years, the average number of animal drug applications that have been subject to the full fee was 7.5, including the number for the most recent year, which is estimated at 4. Over this same period, the average number of supplemental applications and applications subject to the criteria set forth in section 512(d)(4) that would have been subject to half of the full fee was 13.25, including the number for the most recent year, which is estimated at 9.

Thus, for FY 2009, FDA estimates receipt of 7.5 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), which pay half of the full fee.

B. Fee Rates for FY 2009

FDA must set the fee rates for FY 2009 so that the estimated 7.5 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) that pay half of the full fee will generate a total of $3,479,000. To generate this amount, the fee for an animal drug application, rounded to the nearest hundred dollars, will have to be $246,300, 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) will have to be $123,150.

V. Product Fee Calculations for FY 2009

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 an animal drug application or supplemental 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 before FDA after September 1, 2003 (see section 740(a)(2) of the act). The term ''animal drug product'' is defined in section 739(3) of the act. The product fees are to be set so that they will generate $3,479,000 in fee revenue for FY 2009. This is the amount set out in the statute after it has been adjusted for excess collections in previous years as set out in section III of this document.

To set animal drug product fees to realize $3,479,000, FDA must make some assumptions about the number of products for which these fees will be paid in FY 2009. 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 August 2008, FDA estimates that there are a total of 785 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 785 products will be subject to this fee in FY 2009.

In estimating the fee revenue to be generated by animal drug product fees in FY 2009, FDA is assuming that 10 percent of the products invoiced, or about 78.5, will not pay fees in FY 2009 due to fee waivers and reductions. Based on experience with other user fee programs and the first 5 years of ADUFA, FDA believes that this is a reasonable basis for estimating the number of fee-paying products in FY 2009.

Accordingly, the agency estimates that fees for a total of 706.5 products (785 minus 78.5) will be paid in FY 2009.

B. Product Fee Rates for FY 2009

FDA must set the fee rates for FY 2009 so that the estimated 706.5 products for which fees will be paid will generate a total of $3,479,000. To generate this amount will require the fee for an animal drug product, rounded to the nearest 5 dollars, to be $4,925.

VI. Establishment Fee Calculations for FY 2009

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 before FDA after September 1, 2003; and (4) whose establishment engaged in the manufacture of the animal drug product during the FY (see section 740(a)(3) of the act). An establishment subject to animal drug establishment fees is assessed only one such fee per FY (see section 740(a)(3) of the act). The term ''animal drug establishment'' is defined in section 739(4) of the act. The establishment fees are to be set so that they will generate $3,479,000 in fee revenue for FY 2009. This is the amount set out in the statute after it has been adjusted for excess collections in previous years as set out in section III of this document.

To set animal drug establishment fees to realize $3,479,000, FDA must make some assumptions about the number of establishments for which these fees will

be paid in FY 2009. 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 August 2008, 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 2009.

In estimating the fee revenue to be generated by animal drug establishment fees in FY 2009, FDA is assuming that 10 percent of the establishments invoiced, or 6.5, will not pay fees in FY 2009 due to fee waivers and reductions. Based on experience with the first 5 years of ADUFA, FDA believes that this is a reasonable basis for estimating the number of fee-paying establishments in FY 2009.

Accordingly, the agency estimates that fees for a total of 58.5 establishments (65 minus 6.5) will be paid in FY 2009.

B. Establishment Fee Rates for FY 2009

FDA must set the fee rates for FY 2009 so that the estimated 58.5 establishments for which fees will be paid will generate a total of $3,479,000. To generate this amount will require the fee for an animal drug establishment, rounded to the nearest 50 dollars, to be $59,450.

VII. Sponsor Fee Calculations for FY 2009

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 that has not been withdrawn 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 before FDA after September 1, 2003 (see sections 739(6) and 740(a)(4) of the act). An animal drug sponsor is subject to only one such fee each FY (see section 740(a)(4) of the act). The sponsor fees are to be set so that they will generate $3,479,000 in fee revenue for FY 2009. This is the amount set out in the statute after it has been adjusted for excess collections in previous years as set out in section III of this document.

To set animal drug sponsor fees to realize $3,479,000, FDA must make some assumptions about the number of sponsors who will pay these fees in FY 2009. Based on the number of firms that would have met this definition as of August 2008, FDA estimates that a total of 140 sponsors will meet this definition in FY 2009.

Careful review indicates that about one-third or 33 percent of all of these sponsors will qualify for a minor use/minor species waiver or reduction (section 740(d)(1)(C) of the act). Based on the agency's experience 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 74 sponsors, who will not pay fees in FY 2009 due to fee waivers and reductions. FDA believes that this is a reasonable basis for estimating the number of fee-paying sponsors in FY 2009.

Accordingly, the agency estimates that a total of 66 sponsors (140 minus 74) will pay sponsor fees in FY 2009.

B. Sponsor Fee Rates for FY 2009

FDA must set the fee rates for FY 2009 so that the estimated 66 sponsors that pay fees will generate a total of $3,479,000. To generate this amount will require the fee for an animal drug sponsor, rounded to the nearest 50 dollars, to be $52,700.

VIII. Fee Schedule for FY 2009

The fee rates for FY 2009 are summarized in table 2 of this document.

TABLE 2—FY 2009 FEE RATES

Animal Drug User Fee Category	Fee Rate for FY 2009
Animal Drug Application Fee	
Animal drug application	$246,300
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	$123,150
Animal drug product fee	$4,925
Animal drug establishment fee[1]	$59,450
Animal drug sponsor fee[2]	$52,700

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

IX. Procedures for Paying the FY 2009 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 supplemental animal drug application subject to fees under ADUFA II that is submitted after September 30, 2008. Payment must be made in U.S. currency by check, bank draft, 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 Now'' button on the cover sheet). On your check, bank draft, or U.S. postal money order, or wire transfer, please write your application's unique Payment Identification Number, 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 via wire transfer, send payment to US Department of Treasury, TREAS, NYC, 33 Liberty St. New York, NY 10045, Account Name: Food and Drug Administration, Account Number: 75060099, Routing Number: 021030004, Swift Number: FRNYUS33. If payment is made via Pay.gov, you will first create and submit a cover sheet for your organization, then click on the ''Pay Now'' button. You will then be taken to the Pay.gov site to make your payment electronically.

If you prefer to send a check by a courier such as FEDEX or UPS, the courier may deliver the check and printed copy of the cover sheet to: US Bank, Attn: Government Lockbox

953877, 1005 Convention Plaza, St. Louis, Missouri 63101. (Note: This address is for courier delivery only. If you have any questions concerning courier delivery contact the US Bank at 314–418–4821. This phone 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 check 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 Center for Veterinary Medicine (CVM). FDA records the official application receipt date as the later of the following: the date the application was received by CVM, or the date US Bank notifies FDA that your check in the full amount of the payment due has been received, or when the United States Treasury notifies FDA of receipt of an electronic payment. US Bank and the United States Treasury are required to notify FDA within 1 working day, using the Payment Identification Number described previously.

B. Application Cover Sheet Procedures

Step One—Create a user account and password. Log onto the ADUFA Web site at *http://www.fda.gov/oc/adufa* and, under the ''Forms'' heading, click on the link ''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 they use this site. Online instructions will walk you through this process.

Step Two—Create an Animal Drug User Fee Cover Sheet, transmit it to FDA, and print a copy. After logging into your account with your user name and password, complete the steps required to create an Animal 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 Payment Identification Number.

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, 2008, FDA will issue invoices and payment instructions for product, establishment, and sponsor fees for FY 2009 using this fee schedule. Payment will be due and payable on or before January 31, 2009. FDA will issue invoices in November 2009 for any products, establishments, and sponsors subject to fees for FY 2009 but that qualified for fees after the December 2008 billing.

Dated: September 8, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0479]

Generic New Animal Drug User Fee Rates and Payment Procedures for Fiscal Year 2009

AGENCY: Food and Drug Administration

ACTION: Notice

SUMMARY: The Food and Drug Administration (FDA) is announcing the rates and payment procedures for fiscal year (FY) 2009 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 a generic new animal drug, 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 2009.

For FY 2009, the generic new animal drug user fee rates are: $41,400 for each abbreviated application for a generic new animal drug; $3,005 for each generic new animal drug product; $56,350 for each generic new animal drug sponsor paying 100 percent of the sponsor fee; $42,265 for each generic new animal drug sponsor paying 75 percent of the sponsor fee; and $28,175 for a generic new animal drug sponsor paying 50 percent of the sponsor fee. FDA will issue invoices for FY 2009 product and sponsor fees by December 31, 2008, or within 30 days of enactment of an appropriation for these fees, whichever is later. 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 generic new animal drugs submitted on or after July 1, 2008, and will remain in effect through September 30, 2009. However, FDA may not collect application fees until enactment of an appropriation for these fees. Within 30 days of enactment of an appropriation for these fees, FDA will issue invoices for applications received on or after July 1, 2008, and will publish a **Federal Register** notice stating that for the remainder of fiscal year 2009 FDA will not accept any further abbreviated applications for generic new animal drugs for review until FDA has received full payment of application fees and any other generic new animal drug user fees owed. That **Federal Register** notice will also provide instructions for payment of abbreviated applications for generic new animal drug fees.

FOR FURTHER INFORMATION CONTACT: Visit the FDA Web site at *http://www.fda.gov/oc/agdufa* or contact Roxanne Schweitzer, Center for Veterinary Medicine (HFV–10), Food and Drug Administration, 7529 Standish Place, Rockville, MD 20855, 240–276–9705. For general questions, you may also e-mail the Center for Veterinary Medicine 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 are subject to adjustment 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