



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

May 13, 2011

The Honorable Joseph R. Biden, Jr.
President
United States Senate
Washington, DC 20510

Dear Mr. President:

The Animal Drug User Fee Act of 2003, as amended in 2008, requires the Food and Drug Administration (FDA) to report annually on the financial aspects of its implementation of the Animal Drug User Fee Act (ADUFA). Please find enclosed the Fiscal Year (FY) 2010 report, which documents how FDA met each of the legal conditions specified in ADUFA allowing the FDA to continue collecting and spending the animal drug user fees.

In addition, this report also presents the user fee collections and related expenses for FY 2010, and details the amounts carried forward at the end of the year that remain available to enhance the process for the review of new animal drug applications and submissions. In FY 2010, FDA had net collections of \$15.8 million and spent \$16.6 million in animal drug user fees.

Approximately 57 percent of the fees were spent on personnel compensation and benefits for staff. The remaining 43 percent was spent for other operational expenses including operating support for personnel engaged in the process for the review of animal drug applications and infrastructure for the animal drug review process.

The funds provided by ADUFA are crucial to ensuring FDA has qualified personnel and the appropriate infrastructure to review new animal drugs in a timely manner.

Sincerely,

A handwritten signature in black ink, reading "Kathleen Sebelius". The signature is written in a cursive style with a large, stylized "K" and "S".

Kathleen Sebelius

Enclosure

**FY 2010 ADUFA
FINANCIAL REPORT**

REQUIRED BY THE

**ANIMAL DRUG USER
FEE ACT OF 2003**

AS AMENDED

**FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES**

Executive Summary

The Animal Drug User Fee Act of 2003 (ADUFA), as amended in 2008, requires the Food and Drug Administration (FDA) to report annually on the financial aspects of its implementation of the Act. Required under ADUFA, this is the seventh financial report and covers activities for fiscal year (FY) 2010.

ADUFA, as amended, specifies that the following three legal conditions must be satisfied each fiscal year in order for FDA to collect and spend ADUFA user fees:

1. FDA's overall Salaries and Expenses Appropriation, excluding fees, must exceed FDA's overall FY 2003 Salaries and Expenses Appropriation, excluding fees and adjusted for inflation.
2. Fee collections must be specified in Appropriation Acts.
3. FDA must spend at least as much from appropriated funds for the review of animal drug applications as it spent in FY 2003, adjusted for inflation.

This report explains how FDA met the three legal conditions in FY 2010. The statements and tables in the report provide data on animal drug user fee collections and expenditures for FY 2010. In FY 2010, FDA collected \$15.8 million in animal drug user fees, spent \$16.6 million in user fees for the review process, and carried a cash balance of roughly \$3.2 million forward for future fiscal years.

ADUFA implementation strategies facilitated the recruitment of new review staff in FY 2010. The animal drug user fees and appropriations spent in FY 2010 supported 285 full-time equivalent staff years, including salary and operational expenses to support the staff responsible for the process for the review of animal drug applications. In FY 2011, FDA will spend user fees to continue enhancing the review program and improve communications to meet the challenging performance goals associated with this program in FY 2011.

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BACKGROUND

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by ADUFA, authorizes FDA to collect fees from the animal pharmaceutical industry to augment appropriations spent on FDA's animal drug review process. FDA spends the fee revenues to hire, support, and maintain personnel for the review of animal drug applications to ensure safe and effective drug products reach the American public more quickly.

The Animal Drug User Fee Amendments of 2008 (Title I of Public Law 110-316) amended ADUFA and extended its authorization for an additional five years, through 2013. The reauthorization is referred to as ADUFA II.

Under ADUFA II, approximately one fourth of the revenues continue to be derived from each of four types of fees: (1) fees on certain animal drug applications and supplemental animal drug applications (for which safety or effectiveness data are required); (2) annual fees for certain animal drug products; (3) annual fees for certain establishments that manufacture animal drug products; and (4) annual fees paid by certain animal drug sponsors. The aggregate fee revenue amount, and amounts for each type of fee, are set in statute, with provisions for adjustment. ADUFA II authorizes FDA to set fees for each fiscal year so that the total revenue FDA receives in each category is estimated to equal the statutory amount, after adjustment for workload—and no adjustment for workload was required when FDA set fees for 2010 in August of 2009. FY 2010 is the seventh year of the ADUFA program. FDA set fees for FY 2010 in accordance with the amounts specified in ADUFA II (see 73 FR 53254). Inflation adjustments were built into the statutory fee revenue totals for each of the five years of ADUFA II, so no additional changes are necessary.

ADUFA requires FDA to submit two reports to Congress in each fiscal year: 1) a performance report to be sent within 60 days of the end of the fiscal year, and 2) a financial report is to be sent within 120 days of the end of the fiscal year. The FY 2010 ADUFA Performance Report, that describes FDA's progress in meeting the goals referred to in ADUFA, is being transmitted separately to Congress. This report is the FY 2010 ADUFA Financial Report that addresses the implementation and use of animal drug user fees by FDA during the period of October 1, 2009, through September 30, 2010.

As required by ADUFA, this report discusses the legal conditions that must be satisfied before FDA can collect and spend the animal drug user fees each year. In addition, this report also presents summary statements of FY 2010 fee collections, carryover cash balances, obligations from fees, and total costs of the process for the review of animal drug applications from both fees and appropriations.

MEETING THE LEGAL CONDITIONS FOR USER FEES IN FY 2010

ADUFA imposes three legal conditions that FDA must satisfy in each fiscal year before the Agency can collect and spend animal drug user fees. A summary of how each of these legal conditions was satisfied in FY 2010 is shown below. Detailed explanations and calculations are described in Appendix A.

The first legal condition. FDA's overall Salaries and Expenses appropriation (excluding user fees) must meet or exceed FDA's FY 2003 Salaries and Expenses appropriation (excluding user fees), including an adjustment for inflation. In FY 2010, FDA's appropriation for salaries and expenses was \$2,344,656,000 excluding user fees. FDA's FY 2003 Salaries and Expenses appropriation, excluding user fees and then adjusted for inflation, was \$1,640,978,300. Because \$2,344,656,000 is greater than \$1,640,978,300 the first legal condition was satisfied.

The second legal condition. The amount of user fees collected for each fiscal year must be specified in that year's Appropriation Acts. The President signed the FY 2010 Agriculture, Rural Development, Food And Drug Administration And Related Agencies Appropriations Act (Public Law 111-80) specifying amounts collectable from fees during FY 2010, on October 21, 2009. It specified that \$17,280,000 shall be derived from animal drug user fees. The Appropriations Act also specified that the fees collected by FDA remain available to FDA until expended. Therefore, the second legal condition for FY 2010 was satisfied.

The third legal condition. User fees may be collected and used only in years when FDA spends at least as much from appropriated funds (excluding user fees) on the process for the review of animal drug applications as it did in FY 2003 adjusted for inflation. This is referred to as the specified minimum in this report. Under ADUFA, the condition is considered met if the total review expense funded by appropriations in any year is no more than three percent below the specified minimum. The specified minimum level for FY 2010 after the adjustment for inflation is \$39,119,319. In FY 2010, FDA obligated \$48,082,679 from appropriations for the review of animal drug applications. Because FDA spent more than the specified minimum amount from appropriations in FY 2010, the third legal condition was satisfied.

USER FEE COLLECTIONS

ADUFA specifies that user fees shall be collected for certain animal drug applications and supplements upon their submission, and annual fees shall be collected for certain products, establishments, and sponsors. The statute also specifies the amount FDA is allowed to collect for each of these categories, and how the fee rates should be adjusted in each fiscal year for increases in workload.

Under ADUFA, fees collected and appropriated, but not spent by the end of a fiscal year, continue to remain available for FDA to spend in future fiscal years. The balances carried forward from year to year are described on page 7.

Table 1 provides a breakout of user fees collected by fee category during the past two fiscal years, and also reflects the amount of open receivables.

TABLE 1
STATEMENT OF ANIMAL DRUG USER FEE COLLECTIONS
AND RECEIVABLES BY FEE SOURCES
AS OF SEPTEMBER 30, 2010

Fees Collected	FY 2009	FY 2010
Application Fees	\$1,970,400	\$3,557,400
Product Fees	\$3,866,125	\$4,620,195
Establishment Fees	\$3,520,703	\$4,357,150
Sponsor Fees	\$3,468,327	\$3,410,692
TOTAL COLLECTIONS	\$12,825,555	\$15,945,437
Fees Receivable		
Product Fees	\$0	\$0
Establishment Fees	\$0	\$0
Sponsor Fees	\$356,414	\$529,208
TOTAL RECEIVABLES	\$356,414	\$529,208

Numbers may not add due to rounding to the nearest dollar.

User fee collections are reported in the year the fee was originally due—referred to as cohort years. For example, a fee originally due in FY 2009, even if it is received in FY 2010, is attributed to FY 2009 collections. In FY 2010, total fee collections for FY 2009 of \$12,904,435 reported in last year's financial report decreased to \$12,825,555 as of September 30, 2010.

The receivables for FY 2009 and FY 2010 are from uncollected product, establishment, and sponsor fees. After 90 days of attempting to collect the delinquent debt, FDA turns these receivables over to the Program Support Center (PSC) of the Office of the Secretary for further attempts at collection. After 180 days of the debt being outstanding, PSC will turn the debt over to the United States Treasury for further collection efforts.

Totals reported for each fiscal year are net of any refunds for that year. In order to ensure the quality of the information provided in this financial report, FDA updates prior year collections and receivables each year.

USER FEE OBLIGATIONS

User fees are expended only for costs necessary to support the process for the review of animal drug applications, as defined in ADUFA. Allowable and excludable costs for the process for the review of animal drug applications are described in Appendix D.

In FY 2010, FDA obligated \$16,600,700 from animal drug user fees. Table 2 provides a breakout of user fee obligations by expense categories during the past two fiscal years.

TABLE 2
STATEMENT OF ANIMAL DRUG USER FEE OBLIGATIONS BY EXPENSE CATEGORIES
AS OF SEPTEMBER 30, 2010

Expense Category	FY 2009	FY 2010
Personnel Compensation and Benefits	\$8,977,105	\$9,380,664
Travel and Transportation	\$188,126	\$363,912
Rent	\$647,855	\$659,000
Communications	\$28,969	\$41,265
Contract Services	\$2,680,976	\$5,080,690
Equipment and Supplies	\$832,567	\$997,485
Other ¹	\$23,602	\$77,684
Total Obligations	\$13,379,200	\$16,600,700

The overall ADUFA process spending from user fees increased 24 percent in FY 2010. This increase in spending was primarily in the Contract Services expense category. These funds were utilized in developing the Electronic Submissions Tool scheduled to be deployed in FY 2011. See the section TOTAL COST OF THE PROCESS FOR THE REVIEW OF ANIMAL DRUG APPLICATIONS, on page 10, for more discussion on the total process costs for ADUFA.

FDA is working to strengthen and expand its capacities to conduct efficient and timely reviews, and to ensure the safety and effectiveness of new animal drugs. FDA dedicated 197 staff-years to the process for the review of animal drug applications in FY 2003, before ADUFA was enacted.

¹Other includes expenses from categories such as rent payments to others, printing & reproduction, and other miscellaneous expenses.

In FY 2010, FDA dedicated a total of 285 full-time equivalents (FTE) to the process for the review of animal drug applications. Animal drug user fees supported other operational expenses such as computers, furniture, supplies, rent, and other infrastructure needs to support these FTEs. During FY 2011, FDA expects to continue to enhance the review program as necessary to meet the challenging performance goals associated with this program in FY 2011.

CARRYOVER BALANCES

Under ADUFA, fees collected, appropriated, and not obligated at the end of a fiscal year remain available to the FDA in future fiscal years. These funds are referred to as carryover balances. The operations in FY 2010 resulted in a net decrease of the carryover balance of \$785,398, from \$4,013,835 to \$3,228,437.

TABLE 3
STATEMENT OF ANIMAL DRUG USER FEE COLLECTIONS,
OBLIGATIONS, AND CARRYOVER BALANCES BY FISCAL YEAR
AS OF SEPTEMBER 30, 2010

Fiscal Year	Beginning Carryover	Net Collection	Obligation	Year-End Carryover
2004	-	\$4,866,475	\$1,083,300	\$3,783,175
2005	\$3,783,175	\$8,301,551	\$8,489,000	\$3,595,726
2006	\$3,595,726	\$11,017,828	\$9,675,678	\$4,937,876
2007	\$4,937,876	\$13,471,861	\$12,270,000	\$6,139,736
2008	\$6,139,736	\$11,420,145	\$13,530,069	\$4,029,812
2009	\$4,029,812	\$13,363,223	\$13,379,200	\$4,013,835
2010	\$4,013,835	\$15,815,302	\$16,600,700	\$3,228,437
2011	\$3,228,437			

Numbers may not add due to rounding to the nearest dollar.

Please note that the balances in Table 3 reflect the cumulative cash from the beginning to the end of each fiscal year, and net cash collected during each fiscal year for all cohort years. The numbers do not include any accounts receivable. Therefore these numbers for FY 2009 and FY 2010 are different from the numbers on page 3, which reflect total net collections for the cohort years only.

COLLECTIONS CEILINGS AND SURPLUS

Under ADUFA II, if cumulative collections through FY 2011, including an estimate for FY 2012, exceed the fee revenue amounts specified in the Appropriations Acts for that period, FDA will reduce the fee rates for FY 2013 by the cumulative amount that fees exceeded the appropriations during that period. The beginning total for the offset includes any remaining ADUFA I collections that were collected after the final adjustment was made when fees were set for FY 2010. Table 4 depicts FY 2010 fee collections realized (the same as Total Collections in the table on page 3), collection ceilings specified in the Appropriations Act, and amounts that must be set aside to be used to offset future collections.

TABLE 4
STATEMENT OF ANIMAL DRUG USER FEES COLLECTED, COLLECTIONS
CEILING, AND AMOUNTS TO OFFSET FUTURE COLLECTIONS
As of September 30, 2010

Fiscal Year	Collections Realized	Collection Ceiling	Amount to Offset Future Collections
2004	\$5,154,700	\$5,000,000	\$154,700
2005	\$8,519,101	\$8,354,000	\$165,101
2006	\$10,901,466	\$11,318,000	\$0
2007	\$13,342,455	\$11,604,000	\$1,738,455
2008	\$11,543,034	\$13,696,000	\$0
2009	\$12,825,555	\$15,260,000	(\$2,434,445)
2010	\$15,945,437	\$17,280,000	(\$1,334,563)
Amount Offset When Fees for FY 2008 Were Determined:			\$320,000
Amount Offset When Fees for FY 2009 Were Determined:			\$1,344,000
Amount Offset When Fees for FY 2010 Were Determined:			\$0

As discussed earlier on page 3, previous cohort year collections realized in FY 2009 have been updated from last year's report. The update reflects net collections for each cohort year through September 30, 2010. Any and all cohort year fees collected subsequent to September 30, 2010 will be reported in the FY 2011 financial report.

RESERVES AND BALANCE AVAILABLE FOR ALLOCATION

Table 5 provides a summary of carryover balances as of September 30, 2010, and anticipated claims on those balances.

The first anticipated claim is the reserve for future offsets of \$394,256 shown above. In addition, prudent operations require that a reserve be kept aside for other potential refunds. For that purpose a total of \$500,000 is being set aside. That leaves a total of \$2,334,181 available for allocation. This amount will fund about 1.4 months of estimated FY 2011 operations from user fee revenue.

TABLE 5
SUMMARY STATEMENT OF CARRYOVER BALANCE
As of September 30, 2010

Status of Carryover Funds	Amount
Reserve for Future Collection Offset	\$394,256
Reserve for Refunds	\$500,000
Available for Allocation	\$2,334,181
TOTAL Carryover Balance	\$3,228,437

**TOTAL COST OF THE PROCESS FOR THE REVIEW
OF ANIMAL DRUG APPLICATIONS**

Table 6 shows the costs for the review of animal drug applications during the past two fiscal years by FDA organizational components. It depicts the full cost of the process for the review of animal drug applications paid from appropriations and user fees. The amounts are based upon obligations recorded at the end of FY 2010.

**TABLE 6
PROCESS FOR THE REVIEW OF ANIMAL DRUG APPLICATIONS – TOTAL COST
AS OF SEPTEMBER 30, 2010**

FDA Component	FY 2009	FY 2010
Center for Veterinary Medicine (CVM)	\$56,692,025	\$57,086,985
Field Inspection and Investigation (ORA)	\$1,886,441	\$2,015,514
Agency General and Administrative Costs	\$4,664,009	\$5,580,880
Total Process Costs	\$63,242,475	\$64,683,379
Obligations from Appropriations	\$49,863,275	\$48,082,679
Obligations from Animal Drug User Fees	\$13,379,200	\$16,600,700

Numbers may not add due to rounding to the nearest dollar.

In FY 2010, FDA experienced a 2.3 percent increase in the costs of the process to review animal drug applications.

A time reporting analysis is performed each year using data from the CVM Activity Time Reporting (ATR) System to determine the percentage of time each organizational component within CVM devoted to activities that are included in the process for the review of animal drug applications, as defined in ADUFA. This facilitates the calculation of process costs.

The field inspection and investigation are pre-approval inspections of manufacturing facilities, investigations of clinical studies, and analytical testing of samples that are counted for the review process for animal drug applications. ORA captures time spent in its field inspection and investigation by using the Field Accomplishments and Compliance Tracking System (FACTS).

The development of the costs associated with the process for the review of animal drug applications is described in more detail in Appendix E.

MANAGEMENT CHALLENGES FOR FY 2011

On August 14, 2008, the President signed Public Law 110-316, the Animal Drug User Fee Amendments of 2008 (ADUFA II). ADUFA II amends and reauthorizes animal drug user fees for an additional five years, FY 2009 through FY 2013. Letters from the Secretary to the Chairmen of the House Committee on Energy and Commerce and the Senate Committee on Health, Education, Labor and Pensions set forth goals and procedures that FDA will strive to meet over the five years of ADUFA II.

To continue to meet the demanding review time goals established under ADUFA II in FY 2011, FDA intends to:

- Continue to provide an “end-review amendment” (ERA) process that enables FDA reviewers to work with the drug sponsor to amend pending submissions in order to achieve a complete review decision. FDA used the ERA process to request additional information on 153 submissions during the first two years of ADUFA II (FY 2009 and FY 2010). Virtually all (151 of 153) of the requests were related to Investigational New Animal Drug (INAD) submissions. In response, ERAs were submitted for 93 percent (142 of 153) of the requests, and 88 percent (125 of 142) of the submissions with ERAs had their reviews end with a favorable outcome in only one review cycle.
- Continue development on an Electronic Submissions Tool that is scheduled to be deployed in the spring of FY 2011. This tool will transform the FDA submission process into a modern, web-friendly environment and will allow FDA to accept INAD and New Animal Drug Application (NADA) submissions from regulated industry in electronic form.
- Continue to strive for the FY 2013 goal to hold 10 public workshops on topics FDA and industry have mutually agreed upon. During FY 2010 FDA conducted three additional workshops for industry as part of its commitments under ADUFA II. Two of the workshops featured the manufacturing chemistry Quality-By-Design approach to enhance the quality and purity of marketed new animal drugs. The third workshop featured scientific exploration of bioequivalence and was co-sponsored by the American Academy of Veterinary Pharmacology and Therapeutics. This workshop addressed challenging scientific bioequivalence concepts relating to the determination of bioequivalence between new animal drugs.
- Continue to improve communications on and enhance the timeliness and predictability of foreign pre-approval inspections. During FY 2010, 10 of 19 sponsors affiliated with foreign facilities submitted annual facilities lists. Of the 10 sponsors submitting annual facilities lists, one submitted a 30-day prior notification. FDA completed 21 foreign inspections in FY 2009, with an average time of 139 days to complete the inspections. FDA completed 19 foreign inspections in FY 2010, with an average time of 106 days to complete the inspections.

- Continue progress on management initiatives that include development of standard operating procedures for review processes, scientific policies for review staff, and implementation of a quality business system.
- Continue to seek qualified candidates to assure adequate staffing to help FDA meet ADUFA II review time goals.
- Continue to provide training and educational opportunities for FDA staff to enhance the knowledge base of the review organization.

FDA is committed to improving the efficiency, quality, and predictability of the new animal drug review process. We are dedicated to exploring new approaches and technologies that offer high quality and cost-effective improvements in FDA's review of NADAs and other submissions. FDA looks forward to the continued success and significant improvements in the animal drug review process that ADUFA II will help make achievable.

CONDITIONS FOR ASSESSMENT AND USE OF FEES

The Federal Food, Drug, and Cosmetic Act (FD&C Act), amended by ADUFA and ADUFA II, specifies three legal conditions that must be met each fiscal year before FDA can collect and spend animal drug user fees. A summary of the legal conditions has been introduced on page 2 of this report. This appendix provides detailed descriptions of these conditions and explanations of how FDA met these conditions in FY 2010.

In order to compare and determine whether the legal conditions are satisfied, FDA must calculate and incorporate adjustment factors (defined in section 739(10) of the FD&C Act, as amended by ADUFA II) in the assessments of the first and the third conditions. The FD&C Act states:

The term “adjustment factor” applicable to a fiscal year refers to the formula set forth in section 735(8) with the base or comparator month being October 2002.

Paragraph 735(8) of the FD&C Act, which is the adjustment factor for the Prescription Drug User Fee Act (PDUFA), states the following definition:

The term “adjustment factor” applicable to a fiscal year is the Consumer Price Index for all urban consumers (all items; United States city average) for October of the preceding fiscal year divided by such Index for October 1996.

For ADUFA II, the base month is October 2002 rather than October 1996, as reflected in the first statutory citation above. The consumer price index for October 2002 was 181.3. The consumer price index for October 2008, October of the fiscal year preceding FY 2010, was 216.573. 216.573 divided by 181.3 equals 1.194556 (rounded to sixth decimal place). That is the adjustment factor for FY 2010.

The **first legal condition** is found in section 740(f)(1) of the FD&C Act. It states:

Fees may not be assessed under subsection (a) for a fiscal year beginning after fiscal year 2003 unless appropriations for salaries and expenses of the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for such fiscal year) are equal to or greater than the amount of appropriations for the salaries and expenses of the Food and Drug Administration for the fiscal year 2003 (excluding the amount of fees appropriated for such fiscal year) multiplied by the adjustment factor applicable to the fiscal year involved.

The first condition requires that FDA's Salaries and Expenses appropriation excluding user fees for FY 2010 must be greater than or equal to FDA's Salaries and Expenses appropriation excluding user fees for FY 2003 multiplied by the adjustment factor for inflation. FDA's Salaries and Expenses appropriation (excluding user fees) for FY 2003 was \$1,373,714,000 after the rescission. Multiplying this amount by the adjustment factor of 1.194556 (rounded to sixth decimal place) equals \$1,640,978,300.

In FY 2010 Congress appropriated \$2,344,656,000 to FDA for salaries and expenses, excluding user fees. Because the FY 2010 Salaries and Expenses appropriation is greater than the adjusted FY 2003 Salaries and Expenses appropriation (\$1,640,978,300), the first legal condition was met.

The **second legal condition** is described in section 740(g)(2)(A)(i) of the FD&C Act. It states that fees:

Shall be retained in each fiscal year in an amount not to exceed the amount specified in Appropriation Acts, or otherwise made available for obligation for such fiscal year

On October 21, 2009, the President signed the FY 2010 Agriculture, Rural Development, Food And Drug Administration, And Related Agencies Appropriations Act (Public Law 111-80), which specified the collectable user fee amount for ADUFA. That law appropriated \$17,280,000 in animal drug user fees. Therefore, the second legal condition was met.

The **third legal condition** is defined in section 740(g)(2)(A)(ii) of the FD&C Act. It states that fees:

Shall only be collected and available to defray increases in the costs of the resources allocated for the process for the review of animal drug applications (including increases in such costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in such process) over such costs, excluding costs paid from fees collected under this section, for fiscal year 2003 multiplied by the adjustment factor.

The third condition requires a minimum spending from appropriations, excluding user fees, on the process of animal drug review. The minimum spending from appropriations is the amount that FDA spent on the process for the review of animal drug applications in FY 2003, adjusted for inflation. FDA must spend at or above this minimum spending level from appropriations.

In FY 2003, the amount spent from appropriations for the process for the review of animal drug applications was \$32,748,000 (rounded to thousand). After applying the adjustment factor of 1.194556 (rounded to sixth decimal place), the minimum appropriation spending level for the process for the review of animal drug applications for FY 2010, excluding user fees, is \$39,119,319.

In FY 2010, FDA obligated \$48,082,679 from appropriations for the process for the review of animal drug applications, which exceeds the specified minimum appropriation spending level. Therefore, FDA met the third condition.

Table 7 shows the amounts FDA spent on the process for the review of animal drug applications from appropriations and user fees for FY 2009 and FY 2010.

**TABLE 7
OBLIGATIONS FOR THE PROCESS FOR THE REVIEW OF
ANIMAL DRUG APPLICATIONS
AS OF SEPTEMBER 30, 2010**

	FY 2009	FY 2010
From Appropriations	\$49,863,275	\$48,082,679
From Fee Revenues	\$13,379,200	\$16,600,700
Total Obligations	\$63,242,475	\$64,683,379

NUMBER OF FEES PAID IN FY 2010

ADUFA II established four fee categories and sets fee revenue for each category. Based on the statutory revenues and estimated numbers of fees that would be paid in each category, FDA published the FY 2010 fee rates for all categories in August 2009¹. In FY 2010, the highest fee was for an animal drug application – \$290,400. Under ADUFA, as amended, the fee for a supplemental animal drug application (for which safety or effectiveness data are required) or an animal drug application subject to the criteria set forth in section 512(d)(4) of the FD&C Act must be one-half of the full animal drug application fee, which was \$145,200 for FY 2010. The other fee categories under ADUFA are animal drug products, animal drug establishments, and animal drug sponsor fees, each of which must be paid annually. They are \$6,185, \$73,850, and \$57,100, respectively.

Table 8 summarizes the number and type of fees actually received in FY 2010 for cohort year 2010 in comparison to what the FDA estimated it would receive in FY 2010 when the agency established ADUFA fees for FY 2010 in August 2009.

TABLE 8
NUMBERS OF ANIMAL DRUG USER FEES COLLECTED AND ANTICIPATED IN FY 2010
AS OF SEPTEMBER 30, 2010

User Fee Category	# of Fees Actually Collected in FY 2010	# of Fees Anticipated in September 2009 when FY 2010 Fees were set
Animal Drug Applications	19	21.5
Full Application Fees	7	8.25
Half Application Fees ²	12	13.25
Products	747	698.4
Establishments	59	58.5
Sponsors	59.73	75.7

¹FDA published FY 2010 animal drug user fee rates in the federal register notice – August 3, 2009 (74 FR 38429 <http://edocket.access.gpo.gov/2009/pdf/E9-18459.pdf>)

² Half application fees include supplemental animal drug applications (for which safety or effectiveness data are required) and an animal drug application subject to the criteria set forth in section 512(d)(4) of the FD&C Act.

WAIVERS AND REDUCTIONS GRANTED

ADUFA II directs FDA to waive or reduce fees in five different circumstances when:

- the assessment of the fee would present a significant barrier to innovation because of limited resources available to such person or other circumstances;
- the fees to be paid by such person will exceed the anticipated present and future costs incurred by FDA in conducting the process for the review of animal drug applications for such person;
- the animal drug application or the supplemental animal drug application is intended solely to provide for use of the animal drug in a free-choice medicated feed;
- the animal drug application or the supplemental animal drug application is intended solely to provide for a minor use or minor species indication; or
- the sponsor involved is a small business submitting its first animal drug application to FDA for review.

Tables 9 and 10 summarize the waivers and the reductions actions taken by FDA for fees payable in FY 2010, as well as the value of each granted. Please note that the waivers and the reductions granted in the tables below are for cohort year 2010 only.

**TABLE 9
WAIVERS AND REDUCTIONS GRANTED AND USED BY FEE CATEGORY IN FY 2010
AS OF SEPTEMBER 30, 2010**

Reason	Application & Supplement	Product	Establishment	Sponsor	Total
Significant Barrier to Innovation	0	0	0	33	33
Free Choice Feeds	0	0	0	2	2
Minor Use or Minor Species	0	10	3	47	60
Small Business	2	0	0	0	2
Total	2	10	3	82	97

TABLE 10
VALUE OF WAIVERS AND REDUCTIONS GRANTED AND USED IN FY 2010
AS OF SEPTEMBER 30, 2010

Fee Category	Fee Rate	Number	Value
Full Application Fee	\$290,400	2	\$580,800
Half Application Fee	\$145,200	0	\$0
Products	\$6,185	10	\$61,850
Establishments	\$73,850	3	\$221,550
Sponsors	\$57,100	82	\$4,682,200
Total		97	\$5,546,400

The waivers and the reductions presented in table 10 were fees that were due and payable in FY 2010, and reflect revenue that would otherwise have been collected by FDA.

In addition to the waivers and reductions shown in table 10, on September 30, 2010, there were three waiver requests pending relating to fees payable in FY 2010 that were requested on the basis that fees assessed exceed FDA's costs.

In FY 2010, FDA denied one application for sponsor fee waiver and reduction.

**ALLOWABLE AND EXCLUDED COSTS FOR THE PROCESS
FOR THE REVIEW OF ANIMAL DRUG APPLICATIONS**

The FD&C Act as amended defines the process for the review of animal drug applications and the costs that may be included in that process. Fees may only be spent for activities that are included in this definition, although fee-generating activities are only a small subset of the activities that are included in this definition. Using the statutory definition and the methodologies described in Appendix E, the agency identified those activities that were applicable to the process for the review of animal drug applications.

Because over 96 percent of the amounts obligated by FDA each year are expended within 2 years, obligations represent an accurate measure of costs.

ADUFA RELATED COSTS

INCLUDED ACTIVITIES

[Section 739(8)] *The term ‘process for the review of animal drug applications’ means the following activities of the Secretary with respect to the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.*

[Section 739(8)(A)] *The activities necessary for the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.*

This encompasses, among other things, the review of the following types of information:

- with respect to NADAs—original applications, pre- and post-market supplements, chemistry reports, reactivations, Veterinary Master Files, Public Master Files, and application-related correspondence;
- with respect to INADs—initial submissions, reauthorization requests, Emergency/Compassionate Use requests, protocols with or without data, and studies with or without data; and
- with respect to Abbreviated New Animal Drug Applications (ANADAs)—supplements that request a change to an approved ANADA and for which data with respect to safety or effectiveness are required.

Furthermore, the activities necessary for the review of NADAs, supplemental animal drug applications, and INADs include among other activities:

- agency initiated action related to these applications and submissions;

- general NADA and INAD activities that do not directly relate to a pending submission, such as staff training and administrative support;
- administrative processing of these applications and submissions;
- maintenance and support of automated systems that track these applications and submissions; and
- quality assurance and quality control standards and policy development activities related to the review of these applications and submissions.

[Section 739(8)(B)] *The issuance of action letters which approve animal drug applications or supplemental animal drug applications or which set forth in detail the specific deficiencies in animal drug applications, supplemental animal drug applications, or investigational animal drug submissions and, where appropriate, the actions necessary to place such applications, supplements or submissions in condition for approval.*

This includes activities such as the issuance of deficiency letters, meetings with applicants to discuss such letters, and review of the responses.

[Section 739(8)(C)] *The inspection of animal drug establishments and other facilities undertaken as part of the Secretary's review of pending animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.*

[Section 739(8)(D)] *Monitoring of research conducted in connection with the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.*

This includes monitoring of clinical and other research conducted in connection with the review of these applications and submissions.

[Section 739(8)(E)] *The development of regulations and policy related to the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.*

This includes activities such as development of drug-specific, cross-cutting, special control, program-related guidance, and Standard Operating Procedures.

[Section 739(8)(F)] *Development of standards for products subject to review.*

This includes FDA's activities on national and international standards development for products subject to review.

[Section 739(8)(G)] *Meetings between the agency and the animal drug sponsor.*

This includes activities such as:

- informal consultation in person and via phone, mail, e-mail, and facsimile;

- meetings between FDA and sponsors, such as pre-submission conferences;
- use of Advisory Committees and outside experts in the review of pre-market applications; and
- FDA sponsored conferences/workshops related to pre-market submissions.

[Section 739(8)(H)] *Review of advertising and labeling prior to approval of an animal drug application or supplemental animal drug application, but not after such application has been approved.*

[Section 739(9)] *The term 'costs of resources allocated for the process for the review of animal drug applications' means the expenses incurred in connection with the process for the review of animal drug applications for—*

[Section 739(9)(A)] *officers and employees of the Food and Drug Administration, contractors of the Food and Drug Administration, advisory committees consulted with respect to the review of specific animal drug applications, supplemental animal drug applications, or investigational animal drug submissions, and costs related to such officers, employees, committees, and contractors, including costs for travel, education, and recruitment and other personnel activities,*

This includes costs management and administrative services related to the process for the review of animal drug applications, as well as costs for personnel development and training such as:

- scientific, clinical, and statistical training;
- managerial and other administrative training;
- policy/regulatory training;
- professional development (coursework, attendance at professional meetings, library resources); and
- site visit program for premarket reviewers.

[Section 739(9)(B)] *management of information, and the acquisition, maintenance, and repair of computer resources,*

[Section 739(9)(C)] *leasing, maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies, and*

[Section 739(9)(D)] *collecting fees under section 740 and accounting for resources allocated for the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.*

This includes all forms of information management and infrastructure acquisitions in support of the process for the review of animal drug applications and in support of user fee collections and accounting.

EXCLUDED ACTIVITIES

- Review of ANADAs
- Enforcement policy development
- Post-approval surveillance and compliance activities
- Post-approval activities relating to the review of advertising
- Inspections unrelated to the process for review of animal drug applications
- Research unrelated to the process for review of animal drug applications

**DEVELOPMENT OF COSTS FOR THE PROCESS FOR
THE REVIEW OF ANIMAL DRUG APPLICATIONS**

GENERAL METHODOLOGY

The costs associated with the process for the review of animal drug applications are based on obligations recorded within FDA's CVM, ORA, and Office of the Commissioner (OC). These organizations correspond to the cost categories presented as follows:

<u>Cost Category</u>	<u>FDA Organization</u>
Costs for the Review of NADAs, Supplemental Animal Drug Applications and INADs	CVM
Costs for Field Pre-approval Inspection and Investigation	ORA
Costs for Agency General and Administrative	OC

The costs were derived mostly from time reporting systems in CVM and ORA, and were calculated for OC as described in more detail in this Appendix. Using the definitions of costs and activities included in the process for the review of animal drug applications in the ADUFA, as explained in the discussion in Appendix D, the cost categories within each organization listed above were identified as parts of the animal drug review process.

CENTER COSTS

Costs are accumulated for CVM in FDA's financial system in cost centers corresponding to the organizational components at the office level within CVM. Most CVM components involved in the animal drug review process perform a mixture of activities—some included in the definition of the process for the review of animal drug applications, and some not included (see Appendix D). The activities involved in the process for the review of animal drug applications are categorized into three areas: 1) direct process activities, such as submission specific work; 2) indirect process and support activities, such as standard operating procedures and application review support; and 3) center-wide support activities. CVM's ATR System supports the allocations for all three areas.

CVM's ATR

CVM developed and implemented a total time reporting system as part of a multi-year Activity Based Costing initiative. The ATR has a robust Activity Dictionary developed by CVM employees, describing the work "activities" of the Center employees.

The system was implemented center-wide in October 2003. All CVM employees report their time in ATR.

Using the Activity Dictionary in conjunction with the definition of the process for the review of animal drug applications in ADUFA, CVM was able to attribute activity time reported by its employees to direct and indirect process and support activities as distinguished from non-process activities. These activity definitions are consistent with the allowable costs for the process of the review of animal drug applications as detailed in Appendix D.

AGENCY-WIDE EXPENSES

A number of agency-wide expenses are paid from the central accounts rather than from funds allocated to a specific center. These costs include rent for facilities that house CVM staff, telecommunications and utility costs, some computer equipment and support costs, facilities repair and maintenance costs, part of extramural and service contract costs, and costs of the Office of Shared Services, which supports all FDA programs and activities. For these agency-wide costs that are chargeable to the center, we assumed that a percentage of them are chargeable to the process for the review of animal drug applications. That percentage was the amount of time reported for allowable activities (direct and indirect) in the center, as a percentage of total time reported for all center direct and indirect activities.

In support of the President's Management Agenda and the Secretary's Goal of "One-HHS", FDA was requested to consolidate its administrative functions (including facilities, procurement, finance, EEO, and IT services) to carry out more efficient realignment of the resources, which would provide high quality administrative services from a single organization. FDA created an Office of Shared Services in FY 2004. It combined the support responsibilities and resources previously located both in the centers and in OC, and ensured effective and efficient services in a competitive market environment.

Prior to FY 2004, many of the Office of Shared Services FTE employees and resources were performed in CVM, ORA, and OC. In FY 2010, resources expended by the Office of Shared Services in supporting the animal drug review process are reported as if they were incurred in CVM, ORA, or OC, for comparability to the FY 2003 base year.

FIELD INSPECTION AND INVESTIGATION COSTS

ORA incur all field inspection, investigation, and laboratory analyses costs. ORA costs are incurred in both district offices (the "field") and headquarters offices, which are tracked in FACTS. FACTS is a time and activity tracking system that captures time spent in a variety of categories, including pre-approval inspections of manufacturing facilities, investigations of clinical studies, and analytical testing of samples, which are all part of the review process for animal drug applications.

Total direct hours reported in FACTS are used to calculate the total number of staff-years required by ORA to perform these activities. In addition to the direct time, an allocation of support time is also included to represent the work done by the ORA administrative and management personnel. The agency, then, multiplies the total number of staff-years used in the process for the review of animal drug applications by the average salary cost in ORA to arrive at ORA salary costs for work that is a part of the process for the review of animal drug applications as defined in ADUFA. The final step is to allocate ORA obligations for operations and rent to the animal drug review process based upon the ratio of user fee related staff-years to total ORA staff-years. Table 11 summarizes the calculation of ORA costs for the review of animal drug applications for FY 2009 and FY 2010.

TABLE 11
OFFICE OF REGULATORY AFFAIRS
COSTS OF THE REVIEW PROCESS FOR ANIMAL DRUG APPLICATIONS
AS OF SEPTEMBER 30, 2009 AND 2010

Cost Component	FY 2009	FY 2010
Staff Years Utilized	10	10
ORA Average Salary and Benefits	\$107,401	\$108,065
Salary and Benefits (Staff Years times ORA Average Salary and Benefits)	\$1,074,010	\$1,080,650
Operating and Other Costs ¹	\$812,431	\$934,864
Grand Total (salary/benefits and operating/other costs)	\$1,886,441	\$2,015,514

¹ Other costs are central, GSA rent, rent-related, and Shared Services costs that are applicable to the process for the review of device applications.

ORA costs for the process for the review of animal drug applications described above include total process costs, including costs paid from appropriations and costs paid from fee revenues.

AGENCY GENERAL AND ADMINISTRATIVE COSTS

The agency general and administrative costs are incurred in the FDA's OC. At the end of FY 2010, OC was comprised of the following offices:

- Immediate Office of the Commissioner
- Office of the Chief Counsel
- Office of the Chief of Staff
- Office of the Administrative Law Judge
- Office of Equal Employment Opportunity and Diversity Management
- Office of International Programs
- Office of Administration
- Office of Policy, Planning and Budget
- Office of Special Medical Programs
- Office of Legislation
- Office of the Counselor to the Commissioner
- Office of Women's Health
- Office of Foods
- Office of the Chief Scientist
- Office of External Affairs

The OC costs applicable to the process for the review of animal drugs were calculated using a method prescribed by the Division of Cost Determination Management, Office of Finance, Office of the Secretary, Department of Health and Human Services. The method uses the percentage derived by dividing total OC costs by the total FDA salary expenses (excluding benefits) after subtracting the salary expense (excluding benefits) from OC. That percentage is then multiplied by the sum of salaries (excluding benefits) applicable to the process for the review of animal drug applications in CVM and ORA to derive the applicable general and administrative costs.

Using this methodology, FDA dedicated \$5,580,880 in general and administrative costs to the animal drug review process in FY 2010. The costs are total costs obligated from appropriations and user fees. FDA strives to maintain a low overhead cost for the review process of the animal drug applications. General and administrative costs are approximately 8.6 percent of FY 2010 total animal drug review process costs.