

**FY 2006 ADUFA
FINANCIAL REPORT**

REQUIRED BY THE

**ANIMAL DRUG USER
FEE ACT OF 2003**

SEPTEMBER 2007

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



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

September 13, 2007

The Honorable Richard Cheney
President of the Senate
United States Senate
Washington, D.C. 20510

Dear Mr. President:

Enclosed for your consideration is the third annual financial report to Congress required by the Animal Drug User Fee Act of 2003 (ADUFA). This report covers fiscal year (FY) 2006, documenting how each of the legal conditions specified in ADUFA allowing the Food and Drug Administration (FDA) to continue collecting and spending the animal drug user fees was met.

In addition, this report presents the user fee collections and related expenses for FY 2006, 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 2006, FDA had net collections of \$11 million and spent \$9.7 million in animal drug user fees. Approximately 70 percent of the fees were spent on personnel compensation and benefits for staff. The remaining 30 percent was spent for other operational expenses including support and infrastructure for the animal drug review process. The infusion of human capital resources possessing the right scientific and technical competencies with appropriate infrastructure and support is critical to enabling FDA to meet the performance goals associated with ADUFA – goals that become increasingly more stringent each year.

We are pleased that Congress enacted ADUFA, which will provide increasing levels of user fees through FY 2008. The additional funding will enable FDA to substantially strengthen its animal drug review process, and continue to ensure new safe and effective animal drugs are available to the public in a timely manner.

Sincerely,

Michael O. Leavitt

Enclosure

Identical letters to:

Speaker of the House of Representatives
Chairman and Ranking Minority Member, Committee on Health, Education, Labor, and
Pensions, United States Senate
Chairman and Ranking Minority Member, Committee on Energy and Commerce,
House of Representatives

EXECUTIVE SUMMARY

The Animal Drug User Fee Act of 2003 (ADUFA) 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 third financial report that covers activities for fiscal year (FY) 2006.

ADUFA (Public Law 108-130) was signed into law by the President on November 18, 2003. It authorizes FDA to collect fees for certain applications and supplements, establishments, products, and sponsors in support of the review of new animal drugs. On November 10, 2005, the President signed appropriations legislation for FY 2006 (Public Law 109-97), which included animal drug user fees for FDA. This action enabled FDA to begin to collect and spend the authorized FY 2006 animal drug user fees.

ADUFA 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.

The report explains how FDA met the three legal conditions in FY 2006. The statements and tables in the report provide data on animal drug fee collections and expenditures for the animal drug review process in FY 2006. In FY 2006, FDA collected \$11 million in animal drug user fees, spent \$9.7 million user fees for the review process, and carried a cash balance of \$4.9 million forward for future fiscal years.

ADUFA implementation strategies facilitated the recruitment of 17 new review staff in FY 2006. The animal drug user fees spent in FY 2006 supported 58 full-time equivalent staff years and in addition, other operational expenses such as computers, furniture, supplies, rent, and other infrastructure needs. In FY 2007, FDA will spend user fees to continue enhancing the review program and recruit the additional review staff necessary to meet the challenging performance goals associated with this program in FY 2007 and beyond.

TABLE OF CONTENTS

BACKGROUND	1
MEETING THE LEGAL CONDITIONS FOR USER FEES IN FY 2006	2
USER FEE COLLECTIONS	3
OBLIGATION OF USER FEE COLLECTIONS	5
CARRYOVER BALANCES	7
TOTAL COST OF THE PROCESS FOR THS REVIEW OF ANIMAL DRUG APPLICATIONS	9
MANAGEMENT PLANS FOR FY 2007	10

APPENDICES

APPENDIX A: CONDITIONS FOR ASSESSMENT AND USE OF FEES

APPENDIX B: NUMBER OF APPLICATIONS PAID BY FEES IN FY 2006

APPENDIX C: WAIVERS AND REDUCTIONS GRANTED

APPENDIX D: ALLOWABLE AND EXCLUDED COSTS FOR THE PROCESS FOR THE
REVIEW OF ANIMAL DRUG APPLICATIONS

APPENDIX E: DEVELOPMENT OF COSTS FOR THE PROCESS FOR THE REVIEW OF
ANIMAL DRUG APPLICATIONS

BACKGROUND

The Animal Drug User Fee Act of 2003 (ADUFA), Public Law 108-130, authorizes the Food and Drug Administration (FDA) to collect fees from the animal pharmaceutical industry to augment appropriations spent on FDA's animal drug review process. FDA spends the collected fees to hire and support additional staff for the review of animal drug applications to ensure safe and effective drug products to reach the American public more quickly.

ADUFA was patterned in part after the Prescription Drug User Fee Act. Under ADUFA, fees are derived from animal drug applications, supplemental animal drug applications (for which safety or effectiveness data are required), animal drug products, animal drug establishments, and animal drug sponsors. The aggregate fee revenue is set in statute, and then adjusted in each fiscal year for both cumulative inflation and changes in drug review workload. FY 2006 is the third year of the ADUFA program. After FY 2004, fees are subject each year to adjustments for inflation and workload. FDA set fees for FY 2006 with an 8.29 percent adjustment for cumulative inflation. Changes in workload in FY 2005 and FY 2006 resulted in no adjustment based on workload provision in ADUFA. ADUFA authorizes FDA to set fees for each fiscal year so that the total revenue FDA receives in each category equals the statutory amount after adjustments for inflation and workload.

ADUFA requires FDA to submit two reports to Congress in each fiscal year: 1) a performance report sent within 60 days of the end of the fiscal year, and 2) a financial report sent within 120 days of the end of the fiscal year. The FY 2006 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 2006 ADUFA Financial Report that addresses the implementation and use of animal drug user fees by FDA during the period of October 1, 2005 through September 30, 2006.

As required by ADUFA, this report also discusses the legal conditions that FDA must satisfy before it can collect and spend the animal drug user fees each year. Please refer to Appendix A for calculations and explanations of how FDA satisfied the legal conditions in FY 2006. Furthermore, this report describes in Appendix D the process for the review of animal drug applications, as defined in ADUFA – a process that includes portions of activities in the Center for Veterinary Medicine (CVM), the Office of the Commissioner (OC), and the Office of Regulatory Affairs (ORA) in FDA. In addition, this report presents summary statements of FY 2006 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 2006

ADUFA imposes three legal conditions that must be satisfied in each fiscal year before FDA can collect and spend animal drug user fees. A summary of how each of these legal conditions was satisfied in FY 2006 are shown below. Detailed explanations and calculations are described in Appendix A.

The first legal condition. FDA's budget authority appropriation for salaries and expenses (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 2006, FDA's budget authority appropriation for salaries and expenses was \$1,486,801,000, excluding user fees. FDA's FY 2003 salaries and expenses appropriation, excluding user fees and then adjusted for inflation, was \$1,454,432,777. Because \$1,486,801,000 is greater than \$1,454,432,777, 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. For FY 2006, FDA's Appropriation Act specified that \$11,318,000 shall be derived from animal drug user fees. The Appropriation Act also specified that the fees collected by FDA remain available to FDA until expended. Therefore, the second legal condition for FY 2006 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 3 percent below the specified minimum. The specified minimum level for FY 2006 after the adjustment for inflation is \$34,672,257. In FY 2006, FDA obligated \$36,636,831 from appropriations for the reviews of animal drug applications. Because FDA spent more in FY 2006, the third legal condition was satisfied.

USER FEE COLLECTIONS

ADUFA specifies that the user fees shall be collected for certain animal drug applications and supplements, 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 inflation and 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.

The following table provides a breakout of user fees collected and receivables by fee sources during the past two fiscal years.

**FOOD AND DRUG ADMINISTRATION
STATEMENT OF ANIMAL DRUG USER FEE COLLECTIONS
AND RECEIVABLES BY FEE SOURCES
AS OF SEPTEMBER 30, 2006**

FEE SOURCES	FY 2005	FY 2006
FEE COLLECTIONS		
Application Fees	\$1,371,950	\$2,049,300
Product Fees	\$2,455,658	\$2,885,770
Establishment Fees	\$2,598,600	\$2,853,600
Sponsor Fees	\$2,121,851	\$2,664,000
TOTAL COLLECTIONS	\$8,548,059	\$10,452,670
FEE RECEIVABLES		
Product Fees	\$0	\$3,905
Establishment Fees	\$0	\$61,255
Sponsor Fees	\$160,750	\$355,200
TOTAL RECEIVABLES	\$160,750	\$420,360

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 2005, even if it is received in FY 2006, is attributed to FY 2005 collections. In FY 2006, FDA received \$580,608 that was attributed to FY 2005 collections. Therefore, FDA increased its FY 2005 fee collections of \$7,967,451 reported from last year to \$8,548,059.

The receivables for FY 2005 and FY 2006 are from uncollected product, establishment, and sponsor fees. FDA has turned these receivables over to a collection agency.

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.

OBLIGATION OF USER FEE COLLECTIONS

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 identified in Appendix D.

In FY 2006, FDA obligated \$9,675,678 from animal drug user fees. The following table provides a breakout of user fee obligations by expense categories during the past 2 fiscal years.

**FOOD AND DRUG ADMINISTRATION
STATEMENT OF ANIMAL DRUG USER FEE OBLIGATIONS BY EXPENSE CATEGORIES
AS OF SEPTEMBER 30, 2006**

Expense Category	FY 2005	FY 2006
Personnel Compensation and Benefits	\$4,777,716	\$6,725,480
Travel and Transportation	\$133,247	\$158,106
Rent	\$567,000	\$627,500
Communications	\$66,114	\$218,917
Contract Services	\$2,683,345	\$1,732,132
Equipment and Supplies	\$237,247	\$179,293
Other ¹	\$24,331	\$34,251
Total Obligations	\$8,489,000	\$9,675,678

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

The overall ADUFA process spending of the user fees increased by 14 percent. The largest increase is in the personnel compensation and benefits category, which reflects the significant progress made in hiring additional review staff. See the section TOTAL COST OF THE PROCESS FOR THE REVIEW OF ANIMAL DRUG APPLICATIONS, on page 9, 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 the 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.

In FY 2006, FDA dedicated a total of 258 full time equivalent (FTE) positions to the process for the review of animal drug applications, of which 58 were funded by animal drug user fees. The ADUFA program facilitated the recruitment of 17 new review staff in FY 2006 to enhance the animal drug review process. In addition to funding 58 FTEs in FY 2006, animal drug user fees supported other operational expenses such as computers, furniture, supplies, rent, and other infrastructure needs. During FY 2007, FDA expects to continue to enhance the review program and recruit additional review staff necessary to meet the challenging performance goals associated with this program in FY 2007 and beyond.

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 2006 resulted in a net carryover balance of \$4,937,876.

FOOD AND DRUG ADMINISTRATION STATEMENT OF ANIMAL DRUG USER FEE COLLECTIONS, OBLIGATIONS, AND CARRYOVER BALANCES BY FISCAL YEAR AS OF SEPTEMBER 30, 2006

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			

Please note that the balances in the table 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 account receivables.

COLLECTIONS CEILINGS AND SURPLUS

Under ADUFA, the collections in excess of the fee amounts specified in the Appropriation Act may be kept and used to reduce the fee rates in a later fiscal year. The following table depicts FY 2006 collections realized¹, collection ceilings specified in the Appropriation Act, and amounts that may be used to offset future collections.

¹ Collections realized are the same as the net collections in the collection table on page 3.

**FOOD AND DRUG ADMINISTRATION
STATEMENT OF ANIMAL DRUG USER FEE COLLECTED, COLLECTIONS
CEILING, AND AMOUNTS TO OFFSET FUTURE COLLECTIONS
As of September 30, 2006**

Fiscal Year	Collections Realized	Collection Ceiling	Amount to Offset Future Collections
2004	\$5,154,700	\$5,000,000	\$154,700
2005	\$8,548,059	\$8,354,000	\$194,059
2006	\$10,452,670	\$11,318,000	-
Total:			\$348,759

\$348,759 may also be subject to further reduction as a result of potential Fees Exceed Costs Waiver determinations by FDA.

As discussed earlier on page 3, FY 2005 collections realized has been updated from \$7,967,451 in last year's report to \$8,548,059. The update reflects an additional \$580,608 in FY 2005 cohort year fees collected by FDA subsequent to September 30, 2005. Additional 2006 cohort year fees collected subsequent to September 30, 2007 will be reported in the FY 2007 financial report.

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

The table below shows the costs for the review of animal drug applications during the past 2 fiscal years by FDA organizational components. It depicts the full costs 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 2006.

FOOD AND DRUG ADMINISTRATION PROCESS FOR THE REVIEW OF ANIMAL DRUG APPLICATIONS – TOTAL COST AS OF SEPTEMBER 30, 2006

FDA Component	FY 2005	FY 2006
Center for Veterinary Medicine	\$37,956,690	\$40,975,359
Field Inspection and Investigation	\$2,185,865	\$2,298,089
Agency General and Administrative Costs	\$2,754,149	\$3,039,062
Total Process Costs	\$42,896,704	\$46,312,509
Obligations from Appropriations	\$34,407,704	\$36,636,831
Obligations from Animal Drug User Fees	\$8,489,000	\$9,675,678

In FY 2006, the FDA experienced increased costs in all components of the process to review animal drug applications. This increase is a result of progress made by FDA to ensure the enhancement of the animal drug review performance in FY 2006 and beyond.

A time reporting analysis is performed each year using data from FDA's CVM Activity Time Reporting 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. FDA's ORA captures time spent in its field inspection and investigation by using the Field Accomplishments and Compliance Tracking System.

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 PLANS FOR FY 2007

FDA's first 3 years under ADUFA have been highly productive and successful. Since FY 2004, FDA has met or exceeded all of the review performance goals established under ADUFA. This has been accomplished by such measures as hiring a substantial number of additional FDA staff, staff development activities, and the development and dissemination of guidance, policy, and procedural documents. These actions are an integral part of FDA's commitment to improving the efficiency, quality, and predictability of the new animal drug review process to meet more demanding review time goals established under ADUFA for FY 2007 and FY 2008.

In FY 2007, FDA plans to build on its accomplishments to:

- Advance progress already made on management initiatives (including quality business systems).
- Refine, update, and develop new standard operating procedures for review and scientific processes.
- Issue guidance to industry to explain current FDA thinking related to the new animal drug review process.
- 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. The agency is dedicated to exploring new approaches and technologies that offer high quality and cost-effective improvements in FDA's review of new animal drug applications and submissions. FDA looks forward to the continued success and significant improvements in the animal drug review process that ADUFA will help make achievable.

CONDITIONS FOR ASSESSMENT AND USE OF FEES

The Federal Food, Drug, and Cosmetic Act (the Act), as amended by ADUFA, specifies three legal conditions that must be met in 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. Appendix A provides descriptions of these conditions and explanations of how FDA accomplished these conditions in FY 2006 in more detail.

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 Act) in the assessments of the first and the third conditions. The 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 year being 2003.

Paragraph 735(8) of the Act 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 April of the preceding fiscal year divided by such Index for April 1997.

For ADUFA, the base year is 2003 rather than 1997. The consumer price index for April 2003 was 183.8. The consumer price index for April 2005, the fiscal year preceding FY 2006, was 194.6. $194.6 \div 183.8 = 1.0588$ (rounded to fourth decimal place). That is the adjustment factor for FY 2006.

The **first legal condition** is found in section 740(f)(1) of the 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 2006 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 1.0588 (rounded to fourth decimal place) equals to \$1,454,432,777¹.

In FY 2006, Congress appropriated \$1,486,801,000 after 1.0 percent rescission (equivalent to \$14,816,000) to FDA for salaries and expenses, excluding user fees. Because the FY 2006 Salaries and Expenses appropriation is greater than the adjusted FY 2003 Salaries and Expenses appropriation by \$32,368,223, the first legal condition was satisfied.

The **second legal condition** is described in section 740(g)(2)(A)(i) of the 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, and ... ”

On November 10, 2005, the President signed the FY 2006 Appropriation Act, Public Law 109-97, that specified the collectable user fees amount for ADUFA. That provision approved FDA to collect \$11,318,000 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 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 what 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.

Under ADUFA, the condition is considered satisfied if spending for the animal drug review process in any year is no more than 3 percent below the minimum spending level from appropriations.

It states in section 740(g)(2)(B) of the Act:

The Secretary shall be considered to have met the requirements of subparagraph (A)(ii) in any fiscal year if the costs funded by appropriations and allocated for the process for the review of animal drug applications –

(i) are not more than 3 percent below the level specified in subparagraph (A)(ii); or

(ii) are more than 3 percent below the level specified in subparagraph (A)(ii), and fees assessed for the fiscal year following the

¹ Number may be different due to rounding. The adjustment factor in this report is shown and rounded to the fourth decimal place. \$1,454,432,777 is calculated from the adjustment factor with full decimal places.

subsequent fiscal year are decreased by the amount in excess of 3 percent by which such costs fell below the level specified in subparagraph (A)(ii); and
 (II) such costs are not more than 5 percent below the level specified in subparagraph (A)(ii).

In FY 2003, the costs from appropriations for the process for the review of animal drug applications were \$32,748,000 (rounded to thousand). After applying the adjustment factor of 1.0588 (rounded to fourth decimal place), the minimum appropriation spending level for the process for the review of animal drug applications for FY 2006, excluding user fees, is \$34,672,257².

In FY 2006, FDA obligated \$36,636,831 from appropriations for the process for the review of animal drug applications, which is \$1,964,574 or 5.7 percent above the minimum appropriation spending level. Therefore, FDA met the third condition.

The table below shows the amounts FDA spent on the process for the review of animal drug applications from appropriations and user fees for FY 2005 and FY 2006.

**FOOD AND DRUG ADMINISTRATION
 OBLIGATIONS FOR THE PROCESS FOR THE REVIEW OF
 ANIMAL DRUG APPLICATIONS
 AS OF SEPTEMBER 30, 2006**

	FY 2005	FY 2006
From Appropriations	\$34,407,704	\$36,636,831
From Fee Revenues	\$8,489,000	\$9,675,678
Total Obligations	\$42,896,704	\$46,312,509

² Number may be different due to rounding. The adjustment factor in this report is shown and rounded to the fourth decimal place . \$34,672,257 is calculated from the adjustment factor with full decimal places.

NUMBER OF APPLICATIONS PAID BY FEES IN FY 2006

ADUFA 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 2006 fee rates all categories in August 2005¹. In FY 2006, the highest fee was for an animal drug application – \$151,800. A supplemental animal drug application (for which safety or effectiveness data are required) must be 50 percent of an animal drug application fee according to ADUFA, which was \$75,900. 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 \$3,905, \$49,200, and \$44,400, respectively.

The table below summarizes the number and type of fees actually received in FY 2006 for cohort year 2006 in comparison to what the FDA estimated it would receive in FY 2006 when ADUFA fees for FY 2006 were established in August 2005.

**FOOD AND DRUG ADMINISTRATION
NUMBERS OF ANIMAL DRUG USER FEES COLLECTED AND ANTICIPATED IN FY 2006
AS OF SEPTEMBER 30, 2006**

User Fee Category	# of Fees Actually Collected in FY 2006	# of Fees Anticipated to Establish FY 2006 Fees
Animal Drug Applications		
Applications	7	12
Supplemental Applications	13	11.7
Products	740	693
Establishments	58	55
Sponsors	60	61

¹ FDA published FY 2006 animal drug user fee rates in the federal register notice – August 1, 2005 (70 FR 44101).

APPENDIX C

WAIVERS AND REDUCTIONS GRANTED

ADUFA 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.

The tables below summarize the waivers and the reductions actions taken by FDA for fees payable in FY 2006, 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 2006 only.

WAIVERS AND REDUCTIONS GRANTED AND USED BY FEE CATEGORY IN FY 2006 AS OF SEPTEMBER 30, 2006

Reason	Application & Supplement	Product	Establishment	Sponsor	Total
Significant Barrier to Innovation	-	-	-	15	15
Fees Exceed Costs	-	-	-	-	0
Free Choice Feeds	-	-	-	2	2
Minor Use or Minor Species	3	5	2	42	52
Small Business	2	-	-	-	2
Total	5	5	2	59	71

**VALUE OF WAIVERS AND REDUCTIONS GRANTED AND USED IN FY 2006
AS OF SEPTEMBER 30, 2006**

Fee Category	Fee Rate	Number	Value
Applications	\$151,800	4	\$607,200
Supplemental Applications	\$75,900	1	\$75,900
Products	\$3,905	5	\$19,525
Establishments	\$49,200	2	\$98,400
Sponsors	\$44,400	59	\$2,619,600
Total		71	\$3,420,625

The waivers and the reductions presented in the table above were fees that were otherwise due and payable in FY 2006, and reflect revenue that would otherwise have been collected by FDA. FDA also approved other fee waivers, but the corresponding applications were not submitted as of September 30, 2006 (and therefore the waiver was not used), or the waivers were for FY 2006 fees that were invoiced after the close of the fiscal year. The agency expects that these will result in the waiver of fees that would otherwise have been collected in FY 2007, and their impact will be reflected in the FY 2007 ADUFA Financial Report.

In addition to the waivers and reductions shown above, on September 30, 2006, there were four waiver requests pending relating to fees payable in FY 2006 that were requested on the basis that fees assessed exceed FDA's costs.

In FY 2006 FDA denied 6 applications for waivers and reductions. The followings are the waiver requests that were denied:

- one for application fees,
- four for sponsor fees,
- one for establishment fees.

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

The Federal Food, Drug, and Cosmetic Act (the Act), as amended by ADUFA, Public Law No. 108-130, 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 two 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 New Animal Drug Applications (NADA) - original applications, pre- and post-market supplements, chemistry reports, reactivations, Veterinary Master Files, Public Master Files, and application-related correspondence;
- with respect to investigational new animal drugs (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, INADs, and among other activities includes:

- 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 such activities after an animal drug 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.*

These sections include 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 Center for Veterinary Medicine (CVM), Office of Regulatory Affairs (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 New Animal Drug Applications, Supplemental Animal Drug Applications and Investigational New Animal Drug Submissions	CVM
Costs for Field Pre-approval Inspection and Investigation	ORA
Costs for Agency General and Administrative	OC

The costs were accumulated using activity time tracking systems in CVM and ORA, and were extrapolated for OC. Using the definitions of costs and activities included in the process for the review of animal drug applications in the ADUFA, 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 Activity Time Reporting (ATR) System supports the allocations for all three areas.

CVM'S ACTIVITY TIME REPORTING SYSTEM (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 on October 6, 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. For a representation of this, please refer to Appendix D – Allowable and Excluded Costs for the Process for the Review of Animal Drug Applications.

FDA Centers are very payroll intensive organizations – about 61 percent of all FDA funds go to pay for employee salaries and benefits, and almost all other costs are directly supporting these employees. Thus the percent of time reported as having been expended on allowable animal drug review process activities for each cost center was then applied to all costs incurred for that cost center for the entire fiscal year.

CENTER-WIDE EXPENSES

A number of center-wide expenses are paid from the central accounts rather than being charged directly to a specific center. These costs include rent for facilities that house CVM staff, telecommunications and utility costs, computer equipment and support costs, facilities repair and maintenance, part of extramural and service contracts, and Shared Services costs. For the costs that are chargeable to the center, a weighted average of the process activity percentage methodology was utilized.

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 Fiscal Year (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 Full Time Equivalent employees and resources were originated in the organizations that are associated with the animal drug review process. In FY 2006, 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.

CENTER TIME REPORTING RESULTS FOR FY 2006

The time reporting system operated by CVM indicated 58 percent of all time spent in the Center was dedicated to the process for the review of animal drug applications as defined in ADUFA.

FIELD INSPECTION AND INVESTIGATION COSTS

FDA’s ORA incurs all field inspection, investigation, and laboratory analyses costs. ORA costs are incurred in both district offices (the "field") and headquarters offices. In FY 2000, the agency began to track the accumulated ORA costs through a new system, called the Field Accomplishments and Compliance Tracking System [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, applies the total number of user fee related staff-years to the average salary cost in ORA to arrive at ORA user fee related salary costs. 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. The following table summarizes the calculation of ORA costs for the review of animal drug applications for FY 2005 and FY 2006.

**FOOD AND DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS
COSTS OF THE REVIEW PROCESS FOR ANIMAL DRUG APPLICATIONS
AS OF SEPTEMBER 30, 2006**

Cost Component	FY 2005	FY 2006
Staff Years Utilized	14	14
ORA Average Salary and Benefits	\$93,594	\$99,675
Salary and Benefits	\$1,310,313	\$1,395,453
Operating and Other Costs ¹	\$875,551	\$902,636
Grand Total	\$2,185,864	\$2,298,089

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

AGENCY GENERAL AND ADMINISTRATIVE COSTS

The agency general and administrative costs are incurred in the FDA's OC. During FY 2006, OC was comprised of the following offices:

- Immediate Office of the Commissioner
- Office of Chief Counsel
- Office of the Administrative Law Judge
- Office of Equal Employment Opportunity and Diversity Management
- Office of Science and Health Coordination
- Office of International Activities and Strategic Initiatives
- Office of Crisis Management
- Office of Legislation
- Office of External Relations
- Office of Policy and Planning
- Office of Management

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 \$3,039,062 in general and administrative costs to the animal drug review process in FY 2006. The costs are total costs obligated from appropriations and user fees. FDA intends to maintain a low overhead cost for the review process of the animal drug applications. General and administrative costs are approximately 6.6 percent of FY 2006 total animal drug review process costs.