FY 2005 ADUFA
FINANCIAL REPORT

REQUIRED BY THE

ANIMAL DRUG USER FEE ACT OF 2003

October 2006

FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

OCT 13 2006

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

Dear Mr. President:

Enclosed for your consideration is the second annual financial report to Congress required by the Animal Drug User Fee Act of 2003 (ADUFA). This report covers fiscal year 2005, documenting how each of the conditions specified in ADUFA for the continued collection of animal drug user fees was met.

In addition, this report presents the user fee revenues and related expenses for FY 2005, baseline data for FY 2003, and details the amounts carried over at the end of the year that remain available to continue to enhance the process to review new animal drug applications and submissions. In FY 2005, FDA had net collection of $8.3 million and spent $8.5 million animal drug user fees. Slightly more than 50 percent of fees were spent in salaries and benefits for staff. The remainder went toward other operational expenses including support and infrastructure for the animal drug review program. The enhanced infrastructure and the infusion of human resources are critical in 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 resources will enable FDA to substantially strengthen and speed its animal drug review process, while ensuring that only safe and effective animal drugs are available to the public.

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 law requires the Food and Drug Administration (FDA) to report annually on the financial aspects of its implementation of the Animal Drug User Fee Act of 2003 (ADUFA). This is the second financial report required under ADUFA. It covers fiscal year (FY) 2005.

ADUFA (Public Law No. 108-130) was signed into law by the President on November 18, 2003. The Act authorizes FDA to collect fees for certain applications and supplements, establishments, products, and sponsors in support of the review of new animal drugs. On December 8, 2004, the President signed appropriations legislation (Public Law No. 108-447) for FY 2005, which included animal drug user fees for FDA. That action, approximately 3 months into FY 2005, enabled FDA to begin to collect and spend the authorized FY 2005 fees.

ADUFA specifies that the following three conditions must be satisfied each year in order for FDA to collect and spend ADUFA 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 revenues collected 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 describes how the specific statutory conditions or "triggers" were met in FY 2005. The statements and tables in the report also provide baseline data on the expenditures for the animal drug review process in FY 2003.

In FY 2005, FDA collected an additional $8.3 million in animal drug user fees, spent $8.5 million from fee revenues, and carried a balance of $3.6 million forward for future fiscal years. ADUFA implementation strategies facilitated the recruitment of 27 new review staff in FY 2005. The animal drug user fees spent in FY 2005 supported 42 full time equivalent staff years in addition to other operational expenses such as computers, furniture, supplies, rent, and other infrastructure needs. During FY 2006, FDA expects to 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 2006 and beyond.

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BACKGROUND

ADUFA authorized FDA to collect fees from the animal pharmaceutical industry to augment appropriations spent on animal drug review. The collected fees were spent to hire and support additional staff for the review of animal drug applications so that safe and effective drug products would reach the American public promptly. ADUFA was patterned in part after the very successful Prescription Drug User Fee Act (PDUFA).

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 2005 is the second year of the program. After FY 2004, fees are subject to adjustments of inflation and workload. In FY 2005, FDA set fees with a 4.42 percent adjustment for inflation, applying the appropriate provisions of the Act. Following the statutory provisions, no workload adjustment was applied. ADUFA authorizes FDA to set fees for each fiscal year to assure that the total revenue FDA receives from each category equals the statutory amount after the allowable adjustments for inflation and workload.

ADUFA requires FDA to submit two reports to Congress in each fiscal year. A performance report is to be sent within 60 days of the end of the fiscal year, and a financial report is to be sent within 120 days. The FY 2005 ADUFA Performance Report, which discusses FDA's progress in meeting the goals referred to in ADUFA, is being transmitted separately to Congress. This report is the FY 2005 ADUFA Financial Report that addresses the implementation and use of animal drug user fees by FDA during the period of October 1, 2004 through September 30, 2005.

As required by the statute, this report discusses the legal conditions (or "triggers") that must be satisfied before FDA can collect and spend the fees. See Appendix A for calculations and explanations of how the legal conditions were met in FY 2005. 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 Center for Veterinary Medicine (CVM), Office of the Commissioner (OC), and Office of Regulatory Affairs (ORA) in FDA. In addition, this report presents summary statements of FY 2005 fee revenues earned, expenses obligated from animal drug user fees, and total costs of the process for the review of animal drug applications paid by fees and appropriations.

MEETING THE LEGAL CONDITIONS FOR USER FEES IN FY 2005

ADUFA imposes three legal conditions (or "triggers") that must be satisfied each year before FDA can collect and spend user fees. The calculations on how these conditions were met in FY 2005 are summarized below and explained in more detail 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) with the inflation adjustment. In FY 2005, FDA's budget authority appropriation for salaries and expenses was $1,450,098,000 exclusive of user fees. FDA's FY 2003 total salaries and expenses appropriation, excluding user fees and applying a statutory adjustment for inflation (1.0229), was $1,405,104,635. Since $1,450,098,000 is greater than $1,405,104,635, the first legal condition was satisfied.

The second legal condition. The amount of user fees collected for each fiscal year must be specifically stated in that year's Appropriation Acts. For FY 2005, FDA's Appropriation Act specified that $8,354,000 shall be derived from animal drug user fees, in addition to sums provided in regular appropriations. The Appropriation Act specified that the fees collected remain available until expended. Therefore, the second legal condition 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 for FY 2005 after the adjustment for inflation is $33,496,322. In FY 2005, FDA obligated $34,407,704 from appropriated funds for the reviews of animal drug applications. Since FDA spent more in FY 2005, the third legal condition was satisfied.

Appendix A provides a more detailed explanation on how FDA met each of these three statutory conditions.

USER FEE REVENUES

ADUFA specifies that fee revenues shall be collected for certain animal drug applications, products, establishments, and sponsors. The statute also specifies the amount FDA is allowed to collect for each of these categories, and how they should be adjusted in each fiscal year for inflation and increases in workload. By following the law, FDA is able to establish fees in an effort to assure that the total revenue collected approximates the adjusted statutory total fee amount. The inflation adjustment for FY 2005 was 4.42 percent. This is the greater of the CPI increase during the 12-month period ending June 30, 2004 (3.27 percent) or the increase in pay for FY 2004 for Federal employees stationed in Washington, DC (4.42 percent). Specified review workload has not increased during the most recent 3 year average compared with the average of the base years. ADUFA specifies that the workload adjuster may not result in fees that are less than the inflation-adjusted revenue amount. For this reason, the workload adjustment was not applied in FY 2005. Therefore, FDA set the fees in FY 2005 with a 4.42 percent inflation adjustment and no adjustment for workload.

Under ADUFA, any fees collected and appropriated but not spent by the end of a fiscal year continue to remain available to FDA to spend in future fiscal years. The balance carried forward to the next fiscal year is covered in the section titled Carryover Balances beginning on page 6.

FOOD AND DRUG ADMINISTRATION
STATEMENT OF ANIMAL DRUG USER FEES REVENUES
BY FEE SOURCES
As of September 30, 2005

	FY 2004	FY 2005
Fees Collected:		
Product Fees	$1,422,750	$2,282,900
Establishment Fees	$1,460,950	$2,470,800
Sponsor Fees	$1,096,950	$1,961,101
Application Fees	$1,189,500	$1,252,650
TOTAL COLLECTIONS:	**$5,170,150**	**$7,967,451**
Fees Receivables:		
Product Fees	-	-
Establishment Fees	-	-
Sponsor Fees	$15,450	$96,450
Application Fees	-	-
TOTAL RECEIVABLES:	**$15,450**	**$96,450**
TOTAL REVENUES	**$5,185,600**	**$8,063,901**

Note that user fee revenues are reported in the year the fee was originally due—referred to as cohort years. For example, a fee due for FY 2004, even if it is received in FY 2005, is attributed to FY 2004 revenues. Totals reported for each year are net of any refunds for that year.

The receivables for FY 2004 and FY 2005 are from uncollected sponsor fees, which were turned over to a collection agency. In order to ensure the quality of the information provided in this financial report, FDA updates prior year numbers each year. A summary of FY 2005 waived or reduced fees is provided in Appendix C.

OBLIGATION OF USER FEE REVENUES

User fee revenues 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 defined in Appendix D. In FY 2005, FDA obligated $8,489,000 from animal drug user fee revenues.

FOOD AND DRUG ADMINISTRATION
STATEMENT OF ANIMAL DRUG USER FEES OBLIGATIONS
BY EXPENSE CATEGORY
As of September 30, 2005

Expense Category	FY 2005
Personnel Compensation and Benefits	$4,777,716
Travel and Transportation	$133,247
Rent	$567,000
Communications	$66,114
Contract Services	$2,683,345
Equipment and Supplies	$237,247
Other	$24,331
TOTAL OBLIGATIONS	**$8,489,000**

FDA is working to strengthen and expand our 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. A time reporting analysis is performed each year using data from CVM's Activity Time Reporting (ATR) System to determine the percentage of time each organizational component 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 development of the costs associated with the process for the review of animal drug applications is described in more detail in Appendix E. The time percentages will be recalculated regularly in future years based on process data from CVM's ATR System.

In FY 2005, FDA dedicated a total of 259 full time equivalent staff years to the process for the review of animal drug applications, of which 217 were funded by non fee appropriations and 42 were funded by animal drug user fees. The ADUFA program facilitated the recruitment of 27 new review staff in FY 2005 to enhance the animal drug review process. In addition to funding 42 full time equivalent (FTE) staff years in FY 2005, animal drug user fees supported other operational expenses such as computers, furniture, supplies, rent, and other infrastructure needs. During FY 2006, FDA expects to 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 2006 and beyond.

CARRYOVER BALANCES

Under ADUFA, fees collected and appropriated but not obligated by the end of a fiscal year continue to remain available to FDA in future fiscal years. They are referred to as carryover balances. Operations in FY 2005 resulted in a net carryover balance of $3,595,726.

FOOD AND DRUG ADMINISTRATION
STATEMENT OF ANIMAL DRUG USER FEES COLLECTIONS, OBLIGATIONS, AND CARRYOVER BALANCES BY FISCAL YEAR
As of September 30, 2005

Fiscal Year	Beginning Carryover	Net Collections	Obligations	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			

The balances above reflect 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.

COLLECTION CEILINGS AND SURPLUSES

Under ADUFA, the collections in excess of the fee amounts appropriated may be kept and used to reduce fees that would otherwise be assessed in a later fiscal year. The following table depicts FY 2005 net collections, collection ceilings specified in the appropriation, and amounts that may be used to offset future collections.

FOOD AND DRUG ADMINISTRATION
STATEMENT OF ANIMAL DRUG USER FEES COLLECTED, COLLECTION CEILING, AND AMOUNTS TO OFFSET FUTURE COLLECTIONS
As of September 30, 2005

Fiscal Year	Collections Realized	Collection Ceiling	Amounts to Offset Future Collections
2004	$5,170,150	$5,000,000	$170,150*
2005	$7,967,451	$8,354,000	-
		Total:	**$170,150**

* Subject to further reduction as a result of potential Fees Exceed Costs Waiver determinations.

As discussed earlier on page 3, FY 2004 collections realized has been updated from $4,866,475 in last year's report to $5,170,150. The update reflects an additional $303,675 in 2004 fees invoiced and collected by FDA subsequent to September 30, 2004. Additional 2005 fees collected subsequent to September 30, 2005 will be presented in the FY 2006 financial report.

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

The table below shows the costs for the review of animal drug applications for FY 2005 by organizational components. It depicts the full costs of the process for the review of animal drug applications paid from both appropriations and user fee revenues. The amounts are based upon obligations recorded at the end of FY 2005.

FOOD AND DRUG ADMINISTRATION
PROCESS FOR THE REVIEW OF ANIMAL DRUG APPLICATIONS
-- TOTAL COST
As of September 30, 2005

FDA Component	FY 2004	FY 2005
Center for Veterinary Medicine Costs (CVM)	$28,707,661	$37,956,690
Field Inspection and Investigation Costs (ORA)	$1,873,743	$2,185,865
Agency General and Administrative Costs (OC)	$2,275,763	$2,754,149
Total Process Costs	**$32,857,167**	**$42,896,704**
Amount from Appropriations	$31,773,867	$34,407,704
Amount from Fees	$1,083,300	$8,489,000

In FY 2005, FDA experienced increased costs in all components of the process to review animal drug applications. CVM, for example, experienced a 32 percent increase in its process costs reflecting significant progress in hiring the review staff necessary to enhance animal drug review performance in FY 2006 and beyond.

MANAGEMENT CHALLENGES FOR FY 2006

With the second year operating under ADUFA, FDA has improved the review process for new animal drug applications, established the financial program envisioned in the Act, hired additional FDA staff, and prepared guidance for the industry and staff. FDA, working collaboratively with the industry, has also reached beyond the established ADUFA performance goals to reduce the frequency of multiple review cycles in the new animal drug application process.

While FDA's first two years under ADUFA have been highly productive and successful, there are still improvements to make in order to reach the level that will enable us to obtain the comprehensive set of review goals and commitments.

In FY 2006, FDA plans to build on its accomplishments and continue to:

- Hire additional staff necessary to achieve the review capacity specified by ADUFA performance goals for FY 2006 and beyond.
- Advance the work already started on management initiatives (including quality business systems and new information technology systems and solutions).
- Develop improved standard operating procedures for review processes and develop scientific policies for review staff.
- Issue guidance to the industry to clarify current FDA thinking.
- Direct and target training and educational opportunities for staff and management to improve 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, cost-effective improvements in FDA's review of new animal drug applications and submissions. Under the leadership of the President, and in collaboration with the Congress and industry, the FDA looks forward to the continued success and significant improvements in the animal drug review process that ADUFA makes possible.

Appendix A

CONDITIONS FOR ASSESSMENT AND USE OF FEES

The Food, Drug, and Cosmetic Act (the Act) specifies three major conditions that must be met in each fiscal year before the animal drug user fees can be collected and spent. A summary of these legal conditions has been introduced on page 2. Appendix A provides descriptions of these legal conditions and explanations of how they were accomplished in FY 2005.

In order to make parallel comparisons to determine whether the statutory conditions are satisfied, an adjustment factor which is defined in section 739(10) of the Act must be calculated and incorporated in the assessment of conditions one and three. It 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 contains 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 in particular, the base year is 2003 rather than 1997. The consumer price index for April 2003 was 183.8. The consumer price index for April 2004, the fiscal year preceding FY 2005, was 188.0. If dividing 188.0 by 183.8, it equals to 1.0229. That is the adjustment factor for FY 2005.

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.

This condition requires that FDA's total Salaries and Expenses appropriation (excluding user fees) in each fiscal year must be greater than or equal to FDA's FY 2003 Salaries and Expenses appropriation (excluding user fees) multiplied by the adjustment factor. FDA's total FY 2003 Salaries and Expenses appropriation (excluding user fees) was $1,373,714,000 (the actual amount after the rescission). Multiplying this amount by the adjustment factor of

1.0229 results in an adjusted FY 2003 Salaries and Expenses appropriation of $1,405,104,635.

In FY 2005, FDA's total Salaries and Expenses appropriation (excluding user fees) was $1,450,098,000 after the 0.80% rescission which was equivalent to $11,694,000. Since the FY 2005 total appropriation is greater than the adjusted FY 2003 appropriation by $44,993,365, 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…"

The President signed the Appropriation Act that specified the collectable user fees for FY 2005 on December 8, 2004 (Public Law No. 108-447). The provision of the law approved FDA to collect up to $8,354,000 from animal drug user fees. Thus, the second 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.

In addition, section 740(g)(2)(B) of the Act also states:

> 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)(I) are more than 3 percent below the level specified in subparagraph (A)(ii), and fees assessed for the fiscal year following the 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, FDA's actual total obligation 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 1.0229, the minimum appropriation spending for the process for the review of animal drug applications, excluding user fees, is $33,496,322[1].

[1] Number may be different due to rounding. The adjustment factor in this report is shown and rounded at the fourth decimal place – 1.0229. $33,496,322 is calculated from the adjustment factor with full decimal places.

In FY 2005 FDA obligated $34,407,704 from appropriations for the process for the review of animal drug applications. That amount is $911,382 or 2.7 percent above the spending minimum. Therefore, the third condition was achieved.

The table below shows the amounts FDA spent on the process for the review of animal drug applications in FY 2004 and FY 2005. It also shows the portions of the total obligations that were spent from the appropriation funds and user fee revenues.

FOOD AND DRUG ADMINISTRATION
OBLIGATIONS FOR THE PROCESS FOR THE REVIEW OF ANIMAL DRUG APPLICATIONS
As of September 30, 2005

	FY 2004	FY 2005
From Appropriations	$31,773,867	$34,407,704
From User Fee Revenues	$1,083,300	$8,489,000
Total Obligations	$32,857,167	$42,896,704

Appendix B

SUMMARY OF NUMBER OF APPLICATION FEES PAID IN FY 2005

ADUFA established four fee categories and sets fee revenue for each category. Based on the statutory revenue amounts and estimated numbers of fees that would be paid in each category, FDA established fees for FY 2005 in August 2004. The highest fee was for an animal drug application – $119,300. A supplemental animal drug application (for which new safety or effectiveness data are required) must be 50 percent of an animal drug application fee according to ADUFA, which was $59,650. The other categories of ADUFA fees are animal drug product, animal drug establishment, and animal drug sponsor fees, each of which must be paid annually. They are $3,085, $42,600, and $32,150, respectively.

The table below summarizes the number and type of fees received in FY 2005 and the number and type of fees that FDA assumed it would receive in FY 2005 when ADUFA fees for FY 2005 were established in August 2004.

NUMBERS OF ANIMAL DRUG USER FEES COLLECTED AND ANTICIPATED IN FY 2005
As of September 30, 2005

User Fee Category	Number of Fees Actually Collected in FY 2005	Number of Fees Anticipated When FY 2005 Fee Rates Were Established
Animal Drug Application Fees		
Application	6	11.5
Supplemental Application	9	12
Product Fees	740	677
Establishment Fees	58	49
Sponsor Fees	61	65

The number of fees reported in the table is net of refunds as of September 30, 2005.

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 new 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 new 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 payables in FY 2005, as well as the value of each granted.

WAIVERS AND REDUCTIONS GRANTED AND USED
BY FEE CATEGORY IN FY 2005
As of September 30, 2005

Fee Category	Applications & Supplements	Products	Establishments	Sponsors	Total
Significant Barrier to Innovation	-	-	-	11	11
Fees Exceed Costs	-	-	-	-	-
Free Choice Feeds	1	-	-	2	3
Minor Use or Minor Species	3	5	2	38	48
Small Business	-	-	-	-	-
TOTAL - Exemptions Granted	**4**	5	**2**	**51**	**62**

VALUE OF WAIVERS AND REDUCTIONS GRANTED AND USED IN FY 2005
As of September 30, 2005

Fee Category	Fee Rate	Number Used	Value
Application	$119,300	1	$119,300
Supplemental Application	$59,650	3	$178,950
Product	$3,085	5	$15,425
Establishment	$42,600	2	$85,200
Sponsor	$32,150	51	$1,639,650
Total		**62**	**$2,038,525**

The waivers and the reductions presented in the table above were fees that were otherwise due and payable in FY 2005, 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, 2005 (and therefore the waiver was not used), or the waivers were for FY 2005 fees that were invoiced after the close of the fiscal year. We expect that these will result in the waiver of fees that would otherwise have been collected in FY 2006, and their impact will be reflected in the FY 2006 ADUFA Financial Report.

In addition to the waivers and reductions shown above, on September 30, 2005, there were six waiver requests pending relating to fees payable in FY 2004 and three waiver requests pending relating to fees payable in FY 2005 that were requested on the basis that fees assessed exceed FDA's costs.

In FY 2005 FDA also denied 18 applications for waivers and reductions. The following is a summary of the waiver requests that were denied:

- 2 for application or supplement fees
- 5 product fees
- 7 sponsor fees
- 4 establishment fees

Appendix D

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 the Animal Drug User Fee Act of 2003 (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 - 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
- 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 new animal drug applications, supplemental animal drug applications, investigational animal drug submissions, 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
- 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 premarket applications
- FDA sponsored conferences/workshops related to premarket 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)
- 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

Appendix E

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 the Office of the Commissioner (OC). These organizations correspond to the cost categories presented on the Statement of Costs for the Process for the Review of Animal Drug Applications as follows:

Cost Category	FDA Organization
Costs for the Review of New Animal Drug Applications, Supplemental Animal Drug Applications and Investigational New Animal Drug Submissions	CVM
Costs for Field Preapproval Inspection and Investigation	ORA
Costs for Agency General and Administrative	OC

The costs were accumulated using activity time reporting 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 Act, a portion of the costs within each of the three organizations listed above was identified as part 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 SOPs 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 60 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 FY 2004. It combined the support responsibilities and resources previously located both in the centers and in the Office of the Commissioner, and ensured effective and efficient services in a competitive market environment.

Prior to FY 2004, many of the Office of Shared Services FTEs and resources were originated in the organizations that are associated with the animal drug review process. In FY 2005, 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 2005

The time reporting system operated by CVM indicated 56 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 Office of Regulatory Affairs (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 the fiscal years 2004 and 2005.

FOOD AND DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS
COSTS OF THE REVIEW PROCESS FOR ANIMAL DRUG APPLICATIONS
As of September 30, 2005

Cost Component	FY 2004	FY 2005
Staff Years Utilized	14	14
ORA Average Salary and Benefits	$86,376	$93,594
Salary and Benefits	$1,209,263	$1,310,313
Operations, Rent, and Shared Services	$664,481	$875,551
Total	**$1,873,744**	**$2,185,864**

AGENCY GENERAL AND ADMINISTRATIVE COSTS

The Agency general and administrative costs are incurred in the FDA's Office of the Commissioner (OC). During FY 2005, 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 Office of the Commissioner costs by the total salary obligations of the Agency, excluding the Office of the Commissioner. That percentage is then multiplied by the total salaries (excluding benefits) applicable to the process for the review of animal drugs in CVM and ORA to arrive at the total General and Administrative Costs.

Using this methodology, $2,275,763 and $2,754,149 in general and administrative obligations were dedicated to the animal drug review process in FY 2004 and FY 2005, respectively. They are the total costs including funds obligated from both appropriations and from fees. The Agency general and administrative intends to retain a low overhead for the review process of the animal drug applications. They account for approximately 6.9 percent in FY 2004 and 6.4 percent in FY 2005 of the total review costs.