FY 2004 ADUFA
FINANCIAL REPORT

REQUIRED BY THE

ANIMAL DRUG USER FEE ACT OF 2003

January 2005

FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

April 28,2005

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

Dear Mr. President:

Enclosed for your consideration is the first annual financial report to Congress required by the Animal Drug User Fee Act of 2003 (ADUFA). This report covers fiscal year (FY) 2004, documenting how each of the conditions specified in ADUFA for the continued collection of animal drug user fees was met.

The report also presents the user fee revenues and related expenses for FY 2004, baseline data for FY 2003, and details the amounts carried over at the end of the year that remain available. For FY 2004, FDA collected $4.9 million in user fees, and spent $1.1 million. Over 30 percent of the fees were spent for salaries and benefits for additional staff, and the remainder went toward increased support and infrastructure for the animal drug review program. This 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. These 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,

/s/

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 FDA's first financial report required under this Act, and it covers fiscal year (FY) 2004.

ADUFA (Public Law 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 January 23, 2004, the President signed appropriations legislation (Public Law 108-199) for FY 2004 which included animal drug user fees for FDA. That action, approximately 4 months into FY 2004, enabled FDA to begin to collect and spend the authorized 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 2004. The statements and tables included in this report also provide baseline data on the expenditures for the animal drug review process in FY 2003.

For FY 2004, FDA collected $4.9 million in fees, spent $1.1 million from ADUFA revenues, and carried the balance of $3.8 million forward for use in FY 2005. The funds spent in FY 2004 facilitated the recruitment of over 20 new staff resulting in additional 7 staff years to the animal drug review process and to pay for start-up expenses such as space, computers, furniture, supplies, rent, and other infrastructure needs. Most of the additional staffs were hired toward the end of the fiscal year, and FDA utilized only a small fraction of a staff year for each person hired. During FY 2005, FDA expects to spend user fees to pay for about 30 more staff years to conduct and support animal drug reviews than were used in FY 2003, positioning the agency to be able to meet the challenging performance goals associated with this program in FY 2005 and beyond. Hiring to accomplish the substantial increase in review staff necessary to meet the ADUFA goals was well underway by the end of FY 2004.

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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 fees were to be used 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 more quickly. 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 amount is set in statute, and then adjusted each year for both cumulative inflation and changes in drug review workload. Since FY 2004 is the first year of the program, there are no adjustments for workload or inflation on the revenue amounts. However, these adjustments will be made to the statutory revenue amounts each year after FY 2004. ADUFA authorizes FDA to set fees for each fiscal year so that the total revenue FDA receives from each category equals the statutory amount after the 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 2004 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 FDA's FY 2004 ADUFA Financial Report, covering the period of October 1, 2003, through September 30, 2004.

As required by statute, this report presents the legal conditions (or "triggers") that must be satisfied before FDA can collect and spend the fees, and FDA's calculations showing how those conditions were met for FY 2004 (Appendix A). This report also describes (Appendix D) the process for the review of animal drug applications, as defined in ADUFA—a process that includes portions of activities in FDA's Center for Veterinary Medicine (CVM), Office of the Commissioner, and Office of Regulatory Affairs. This report presents FY 2004 revenues and obligations from user fees, and a summary statement of user fees by sources (application, establishment, product, and sponsor fees). The total costs of the process for the review of animal drug applications, as defined in ADUFA, are also presented – both the costs paid from fee revenues and the costs paid from appropriations.

In keeping with the requirements of the Chief Financial Officers Act of 1990, the Office of the Inspector General (OIG), Department of Health and Human Services, audits FDA's annual financial statements. The audit covers all of FDA's financial systems and funds, including ADUFA revenues and expenses. The OIG issued unqualified audit opinions on FDA's financial statements for fiscal years 2003 and 2004. This is the most favorable category of audit opinion.

MEETING THE LEGAL CONDITIONS FOR USER FEES IN FY 2004

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 2004 are summarized below and explained in greater detail in Appendix A.

The first condition is that FDA's overall Salaries and Expenses Appropriation (excluding user fees) must meet or exceed FDA's overall FY 2003 Salaries and Expenses Appropriation (excluding user fees and adjusted for inflation). In FY 2004, FDA's overall Salaries and Expenses Appropriation totaled $1,386,962,000, exclusive of user fees. FDA's FY 2003 total Salaries and Expenses Appropriation, excluding user fees, was $1,382,702,000. Since the FY 2004 amount is greater than the FY 2003 amount, the first condition was met.

The second condition is that the amount of user fees collected each year must be specifically included in the Appropriation Acts. For FY 2004, FDA's Appropriation Act specified that $5,000,000 would come from ADUFA fees, in addition to sums provided in regular appropriations. The Appropriation Act specified that the fees collected could remain available until expended. Therefore, the second condition was met.

The third condition is that user fees may be collected and used only in years when FDA also uses a specified minimum amount of appropriated funds for the review of animal drug applications. The specified minimum is the amount FDA spent on the review of animal drug applications from appropriations (exclusive of user fees) in FY 2003, adjusted for inflation. Under ADUFA, this condition is considered met if costs funded by appropriations in any year are not more than 3 percent below the specified minimum. The specified minimum, adjusted for inflation for FY 2004, is $32,748,388. In FY 2004, FDA obligated $31,773,867 from appropriated funds for the reviews of animal drug applications, which is 2.97 percent less than the trigger. Since 2.97 percent is less than 3 percent, the third condition has been met.

Appendix A provides more details on the calculations of how these statutory conditions were met.

USER FEE REVENUES

ADUFA specifies that fee revenues shall be collected from application, product, establishment, and sponsor fees. The statute specifies the revenue amount for each of these categories. Since FY 2004 is the first year of the program, there are no adjustments for workload or inflation on the revenue amounts. However, these adjustments will be made to the statutory revenue amounts each year after FY 2004.

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 year is covered in the section on carryover balances beginning on page 6.

FOOD AND DRUG ADMINISTRATION
STATEMENT OF ADUFA USER FEE REVENUES BY FEE SOURCE
As of September 30, 2004

	FY 2004
Fees Collected:	
Product Fees	$1,340,489
Establishment Fees	$1,317,249
Sponsor Fees	$988,737
Application Fees	$1,220,000
TOTAL FEES COLLECTED:	**$4,866,475**
Fees Receivable:	
Product Fees	$0
Establishment Fees	$0
Sponsor Fees	$30,900
Application Fees	$0
TOTAL FEES COLLECTED:	**$30,900**
Total User Fee Revenues:	**$4,897,375**

Note that user fee revenues are reported in the year the fee was originally due – referred to as the cohort year. For example, a fee due in 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 (as of September 30th), but do not take into account any refunds that may be made after September 30th. Information on the number of application fees received in FY 2004 is provided in Appendix B.

The fees receivable of $30,900 is due to unpaid invoices for two sponsor fees that were due in June 2004. The fees receivable are over 90 days old, and both have been turned over to a collection agency. A summary of FY 2004 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 2004, FDA obligated $1,083,300 from animal drug user fee revenues.

FOOD AND DRUG ADMINISTRATION
STATEMENT OF ADUFA USER FEE OBLIGATIONS
BY EXPENSE CATEGORY
As of September 30, 2004

Expense Category	FY 2004
Personnel Compensation and Benefits	$308,328
Travel and Transportation	$1,534
Rent	$100,000
Communications	$25,012
Contract Services	$281,421
Equipment and Supplies	$362,849
Other	$4,156
TOTAL OBLIGATIONS	**$1,083,300**

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 was performed using data from CVM's Activity Time Reporting (ATR) System, during a part of FY 2004, 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 facilitated 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.

For FY 2004, FDA dedicated 204 staff-years to the process for the review of animal drug applications. The implementation of ADUFA, which began subsequent to appropriation of the user fees in late January, facilitated the recruitment of over 20 new staff resulting in approximately 7 more staff-years than in FY 2003. Most of CVM's additional staff were hired toward the end of FY 2004. The impact of their full-year costs will not be incurred until FY 2005. In FY 2005, FDA expects to utilize about 30 more staff years than in FY 2003, as the Agency further increases its staffing to the levels that will be necessary to meet the ADUFA performance goals, which become increasingly more stringent each year.

As indicated in the table above, the remaining expenses were devoted to FTE support in the reviewing organizations within CVM and new staff start-up expenses such as space, computers, furniture, supplies, rent, and other infrastructure needs.

CARRYOVER BALANCES

Under ADUFA, any fees collected and appropriated but not obligated by the end of a fiscal year continue to remain available to FDA in future fiscal years. These revenues are referred to as carryover balances. Operations in FY 2004 resulted in a net carryover balance of $3,783,175.

The table below captures the carryover balance for FY 2004, and will be updated in future fiscal years.

FOOD AND DRUG ADMINISTRATION
STATEMENT OF ADUFA COLLECTIONS, OBLIGATIONS, AND CARRYOVER BALANCES BY FISCAL YEAR
As of September 30, 2004

Fiscal Year	Beginning Carryover	Net Collections	Obligations	Year-End Carryover
2004	-	$4,866,475	$1,083,300	$3,783,175
2005	$3,783,175			

The balances above reflect cumulative cash at the beginning/end of each fiscal year, and net cash collected during each fiscal year for all cohort years. The figures do not include the accounts receivables.

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 2004's net collections, collection ceilings specified in the appropriation, and amounts that may be used to offset future collections.

FOOD AND DRUG ADMINISTRATION
STATEMENT OF ADUFA FEES COLLECTED, COLLECTION CEILING, AND AMOUNTS TO OFFSET FUTURE COLLECTIONS
As of September 30, 2004

Fiscal Year	Collections Realized	Collection Ceiling	Amounts to Offset Future Collections
2004	$4,866,475	$5,000,000	-
		Total:	-

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

The following table demonstrates the costs for the review of animal drug applications for FY 2004 by organizational components. It depicts the full cost of the process for the review of animal drug applications, including costs paid from both appropriations and user fee revenues. The amounts are based upon obligations recorded as of the end of FY 2004, which FDA believes is an accurate measure of costs.

FOOD AND DRUG ADMINISTRATION
PROCESS FOR THE REVIEW OF ANIMAL DRUG APPLICATIONS
TOTAL COST
As of September 30, 2004

FDA Component	FY 2003	FY 2004
Center for Veterinary Medicine Costs (CVM)	$28,683,712	$28,707,661
Field Inspection and Investigation Costs (ORA)	$1,820,921	$1,873,743
Agency General and Administrative Costs (OC)	$2,243,755	$2,275,763
Total Process Costs	**$32,748,388**	**$32,857,167**
Amount from Appropriations	$32,748,388	$31,773,867
Amount from Fees	0	$1,083,300

In FY 2004, all costs were slightly increased for FDA Components. In FY 2004, appropriations for the Animal Drugs and Feeds program, exclusive of user fees, were $84.2 million—down from $87.7 million in FY 2003. As a result, spending from appropriations on the animal drug review process was still slightly lower than in FY 2003. We are encouraged that, in part as a result of ADUFA, appropriated budget authority for Animal Drugs and Feeds in FY 2005 is $90.5 million, assuring adequate resources for this program in FY 2005.

MANAGEMENT CHALLENGES FOR FY 2005

As part of ADUFA implementation in this initial year, the Agency 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. The Agency, 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 year under ADUFA was highly productive and successful, many challenges and much work remain to complete the building process begun in FY 2004. In FY 2005, FDA plans to do the following:

- Continue hiring additional staff necessary to achieve ADUFA performance goals for FY 2005 and subsequent years.

- Continue work already begun on management initiatives (including quality business systems and new information technology systems and solutions).

- Develop improved standard operating procedures for review processes and improved scientific policies for review staff.

- Issue guidance to the industry to clarify current Agency thinking.

- Direct and target training and educational opportunities for staff and management to improve the knowledge base of the review organization.

- Sustain the infrastructure supporting the review program.

The Agency is committed to improving the efficiency, quality, and predictability of the new animal drug application 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 will make possible in the coming years.

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 each year before the animal drug user fees can be collected and spent. A summary of these conditions and how they were met was provided earlier on page 2. A description of each of these conditions is provided below with an explanation of how the condition was met in FY 2004.

For making the comparisons to determine whether the statutory conditions are met, an adjustment factor, which is defined in section 739(10) of the Act, must be calculated in each year. 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, the base year is 2003 rather than 1997. The consumer price index for April 2003, the fiscal year preceding FY 2004, is 183.8. Since this number, 183.8, is both the numerator and denominator of the adjustment factor for FY 2004, the first year of the program, the applicable adjustment factor is 1.0000.

The **first 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 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 $1,382,702,000. Multiplying this amount by the adjustment factor of 1 results in an adjusted FY 2003 Salaries and Expenses appropriation of $1,382,702,000.

For FY 2004, FDA's total Salaries and Expenses appropriation, excluding user fees, was $1,386,962,000. Since FY 2004 amount is greater than FY 2003 by $4,260,000, the first condition was met.

The **second 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 specifying amounts collectable from user fees for FY 2004 on January 23, 2004 (Public Law 108-199). It provided $5,000,000 to come from ADUFA fees. Therefore, the second condition was met.

The **third 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, in section 740(g)(2)(B) of the Act, it 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 obligations from appropriation for the process for the review of animal drug applications were $32,748,388. The adjustment factor for FY 2003 was 1.0000. Thus, FDA's 2003 adjusted minimum spending for the process for the review of animal drug applications from appropriations in FY 2004, excluding user fees, must be $32,748,388.

The FDA obligations from appropriation for the process for the review of animal drug applications for FY 2004 were $31,773,867. This amount is 2.97 percent less than $32,748,388. However, the Act provides that FDA shall be considered to have met the requirements of this provision if its obligations from appropriations are not more than 3

percent below the FY 2003 costs multiplied by the adjustment factor. The third condition was met.

The table below shows the amounts FDA spent on the process for the review of animal drug applications in FY 2003 and FY 2004. 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, 2004

	FY 2003	FY 2004
From Appropriations	$32,748,388	$31,773,867
From User Fee Revenues	0	$1,083,300
Total Obligations	$32,748,388	$32,857,167

Appendix B

SUMMARY OF NUMBER OF APPLICATION FEES PAID IN FY 2004

ADUFA established four fee categories and sets fee revenue amounts for each. Based on those statutory revenue amounts, and estimated numbers of fees that would be paid in each category, FDA established fees for FY 2004 in April 2004. The highest fee rate was for an animal drug application – $61,000. The fee rate for a supplemental animal drug application for which safety or effectiveness data are required is set to be 50 percent of an animal drug application fee, which is $30,500. 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. For FY 2004, the product fee was the lowest among all, $1,750. The establishment fee was $23,950, and the sponsor fee was $15,450.

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

NUMBERS OF FEES COLLECTED AND ANTICIPATED IN FY 2004
As of September 30, 2004

User Fee Category	Number of Fees Actually Collected in FY 2004 [1]	Number of Fees Anticipated when FY 2004 Fee Rates were Established
Application Fee	12	16.3
Supplemental Application Fee	15	8.3
Product Fee	766	714
Establishment Fee	55	52
Sponsor Fee	66	81

[1] The number of fees collected does not include those that were assessed but that were not paid, were waived, or were refunded in full.

Appendix C

WAIVED OR REDUCED FEES

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 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 supplemental animal drug application is intended solely to provide for a minor use or minor species indication;
- the sponsor involved is a small business submitting its first animal drug application to FDA for review.

The tables below summarize the waiver actions taken by FDA for fees payable in FY 2004, as well as the value of the waivers and reductions granted.

WAIVERS AND REDUCTIONS GRANTED BY FEE CATEGORY IN FY 2004
As of September 30, 2004

Fee Category	Applications & Supplements	Products	Establishments	Sponsors	Total
Significant Barrier to Innovation	-	-	-	10	10
Fees Exceed Costs	-	-	-	-	-
Free Choice Feeds	1	-	-	2	3
Minor Use or Minor Species	1	2	-	29	32
Small Business	1	-	-		1
TOTAL - Exemptions Granted	**3**	2	**0**	**41**	**46**

VALUE OF FY 2004 WAIVERS AND REDUCTIONS GRANTED IN FY 2004
As of September 30, 2004

Fee Category	Fee Amount	Number Granted	Value
Application	$61,000	1	$61,000
Supplemental Application	$30,500	2	$61,000
Product	$1,750	2	$3,500
Establishment	$23,950	0	0
Sponsor	$15,450	41	$633,450
Total	**NA**	**46**	**$758,950**

The waivers reflected in the tables above were all for fees that were otherwise due and payable in FY 2004, 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, 2004, or the waivers were for FY 2004 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 2005, and their impact will be reflected in the FY 2005 ADUFA Financial Report.

In addition to the waivers and reductions shown above, on September 30, 2004, there were two waiver requests pending relating to fees payable in FY 2004 that were requested on the basis that fees assessed exceed FDA's costs. To evaluate them, FDA must establish the standard costs for major types of review action. After those standard costs are developed, then FDA will make decisions on these requests received in FY 2004.

In FY 2004 FDA also denied 18 applications for waivers. The following is a summary of the waiver requests that were denied:

- 4 for application or supplement fees
- 4 product fees
- 7 sponsor fees
- 3 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 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 animal drug applications, supplemental animal drug applications, and investigational animal drug submissions includes, among other activities:

- Agency initiated action related to these applications and submissions
- General NADA and INAD activities that do not directly relate to a pending submission, such as staff training and administrative support
- Administrative processing of these applications and submissions
- Maintenance and support of automated systems that track these applications and submissions
- 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, Supplements, Products, and Sponsors	CVM
Costs for Field Inspection and Investigation	ORA
Costs for Agency General and Administrative	OC

The costs were accumulated using 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 development of review process guidance to industry and infrastructure support; and 3) center-wide expenses. CVM's Activity Time Reporting (ATR) System supports the allocation of costs 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 employee. The system was implemented center-wide on October 6, 2003. All employees participated in the implementation process.

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, part of 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 is 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 (OSS) in FY 2004. It combined the support responsibilities and resources previously located both in the center 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 OSS FTE and resources were part of the CVM organization. In FY 2004, the OSS expenses related to the review of the animal drug process costs are reported as if they were incurred in CVM or in the Office of the Commissioner, to keep them consistent with the way these costs were reported in the FY 2003 base year.

Center Time Reporting Results for FY 2004

The time reporting system operated by CVM indicated 48 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 and investigation costs. ORA costs are incurred in both district offices (the "field") and headquarters support offices. In FY 2002, the Agency began to track the accumulated ORA costs through a new system, called the Field Accomplishment 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 2003 and 2004.

FOOD AND DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS
COSTS OF THE REVIEW PROCESS FOR ANIMAL DRUG APPLICATIONS
As of September 30, 2004

Cost Component	FY 2002	FY 2003
Staff Years Utilized	14	14
ORA Average Salary & Benefits	$79,696	$86,376
Salary and Benefits	$1,115,739	$1,209,263
Operations, Rent, and Shared Services	$705,183	$664,481
Total	**$1,820,921**	**$1,873,743**

AGENCY GENERAL AND ADMINISTRATIVE COSTS

The Agency general and administrative costs are incurred in the FDA's Office of the Commissioner (OC). During most of FY 2004, 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 process, $2,243,755 and $2,275,763 in general and administrative obligations were dedicated to the animal drug review process in FY 2003 and FY 2004, respectively. These are total costs, including funds obligated both from appropriations and from fees. The Agency general and administrative obligations in FY 2003 and FY 2004, similarly, accounted for about 6.9 percent of the total costs in each fiscal year for the review process of the animal drug applications.