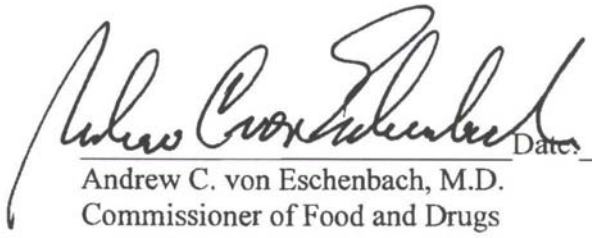
FY 2007 ADUFA
FINANCIAL REPORT

REQUIRED BY THE

ANIMAL DRUG USER FEE ACT OF 2003

FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES



Date: 6/16/08

Andrew C. von Eschenbach, M.D.
Commissioner of Food and Drugs

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

OCT 16 2008

The Honorable Richard Cheney
President of the Senate
United States Senate
Washington, DC 20510

Dear Mr. President:

Enclosed for your consideration is the fourth annual financial report to Congress required by the Animal Drug User Fee Act (ADUFA) of 2003. This report covers fiscal year (FY) 2007, 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 2007, 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 2007, FDA had net collections of $13.5 million and spent $12.3 million in animal drug user fees. Approximately 54 percent of the fees were spent on personnel compensation and benefits for staff. The remaining 46 percent was spent for other operational expenses including support and infrastructure for the animal drug review process.

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

Sincerely,

Michael O. Leavitt

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 fourth financial report that covers activities for fiscal year (FY) 2007.

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.

This report explains how FDA met the three legal conditions in FY 2007. The statements and tables in the report provide data on animal drug fee collections and expenditures for the animal drug review process in FY 2007. In FY 2007, FDA collected $13.5 million in animal drug user fees, spent $12.3 million in user fees for the review process, and carried a cash balance of $6.1 million forward for future fiscal years.

ADUFA implementation strategies facilitated the recruitment of 18 new review staff in FY 2007. The animal drug user fees spent in FY 2007 supported 55 full-time equivalent staff years and in addition, other operational expenses such as computers, furniture, supplies, rent, and other infrastructure needs. In FY 2008, 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 2008.

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BACKGROUND

ADUFA, Public Law 108-130, authorizes 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 reach the American public more quickly.

ADUFA was patterned in part after the Prescription Drug User Fee Act. Under ADUFA, approximately one fourth of the revenues are derived from animal drug applications and supplemental animal drug applications (for which safety or effectiveness data are required), approximately one fourth of the revenues are derived from annual animal drug product fees, approximately one fourth of the revenues are derived from annual animal drug establishment fees, and approximately one fourth of the fees are derived from annual animal drug sponsor fees. The aggregate fee revenue amount, and amounts for each type of fee, are set in statute, and after FY 2004 are adjusted in each fiscal year for both cumulative inflation and changes in drug review workload. FY 2007 is the fourth year of the ADUFA program. FDA set fees for FY 2007 with a 12.97 percent adjustment for cumulative inflation. Changes in workload in FY 2005 to FY 2007 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 is estimated to equal 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 2007 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 2007 ADUFA Financial Report that addresses the implementation and use of animal drug user fees by FDA during the period of October 1, 2006 through September 30, 2007.

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. In addition, this report presents summary statements of FY 2007 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 2007

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 2007 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 2007, FDA's budget authority appropriation for salaries and expenses was $1,569,244,000, excluding user fees. FDA's FY 2003 salaries and expenses appropriation, excluding user fees and then adjusted for inflation, was $1,506,003,107. Because $1,569,244,000 is greater than $1,506,003,107, 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 2007, FDA's Appropriation Act specified that $11,604,000 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 2007 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 2007 after the adjustment for inflation is $35,901,632. In FY 2007, FDA obligated $37,318,801 from appropriations for the reviews of animal drug applications. Because FDA spent more than the specified minimum amount from appropriations in FY 2007, 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 upon their submission, and annual fees shall be collected for certain products, establishments, and sponsors. The statute also specifies the amount FDA is allowed to collect for each of these categories, and how the fee rates should be adjusted in each fiscal year for 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 receivable by fee source during each of the past 2 fiscal years.

FOOD AND DRUG ADMINISTRATION
STATEMENT OF ANIMAL DRUG USER FEE COLLECTIONS
AND RECEIVABLES BY FEE SOURCES
AS OF SEPTEMBER 30, 2007

FEES COLLECTED	FY 2006	FY 2007
Application Fees	$1,973,400	$4,552,200
Product Fees	$3,061,520	$2,921,650
Establishment Fees	$2,952,000	$2,721,550
Sponsor Fees	$2,958,946	$2,751,115
TOTAL COLLECTIONS	**$10,945,866**	**$12,946,515**
FEES RECEIVABLE		
Product Fees	$0	$0
Establishment Fees	$49,200	$0
Sponsor Fees	$149,029	$179,400
TOTAL RECEIVABLES	**$198,229**	**$179,400**

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 2006, even if it is received in FY 2007, is attributed to FY 2006 collections. In FY 2007, FDA received $493,196 that was attributed to FY 2006 collections. Therefore, FDA increased its FY 2006 fee collections of $10,452,670 reported from last year to $10,945,866.

The receivables for FY 2006 and FY 2007 are from uncollected 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 described in Appendix D.

In FY 2007, FDA obligated $12,270,000 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, 2007

Expense Category	FY 2006	FY 2007
Personnel Compensation and Benefits	$6,725,480	$6,656,238
Travel and Transportation	$158,106	$167,641
Rent	$627,500	$675,400
Communications	$218,917	$52,065
Contract Services	$1,732,132	$4,456,947
Equipment and Supplies	$179,293	$196,415
Other [1]	$34,251	$65,294
Total Obligations	**$9,675,679**	**$12,270,000**

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

The overall ADUFA process spending from user fees increased 27 percent in FY 2007. The largest increase is in the contract services category, which reflects investments in efforts to gain further efficiencies in the review process. 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 2007, FDA dedicated a total of 255 full time equivalent (FTE) positions to the process for the review of animal drug applications, of which 55 were funded by animal drug user fees. In addition to funding 55 FTEs in FY 2007, animal drug user fees

supported other operational expenses such as computers, furniture, supplies, rent, and other infrastructure needs. During FY 2008, 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 2008.

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 2007 resulted in a net carryover balance of $6,139,736.

FOOD AND DRUG ADMINISTRATION
STATEMENT OF ANIMAL DRUG USER FEE COLLECTIONS, OBLIGATIONS, AND CARRYOVER BALANCES BY FISCAL YEAR
AS OF SEPTEMBER 30, 2007

Fiscal Year	Beginning Carryover	Net Collection	Obligation	Year-End Carryover
2004	-	$4,866,475	$1,083,300	$3,783,175
2005	$3,783,175	$8,301,551	$8,489,000	$3,595,726
2006	$3,595,726	$11,017,828	$9,675,678	$4,937,876
2007	$4,937,876	$13,471,861	$12,270,000	$6,139,736
2008	$6,139,736			

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 accounts receivable.

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 2007 fee collections realized[2], collection ceilings specified in the Appropriation Act, and amounts that must be set aside to be used to offset future collections.

[2] Collections Realized in the table on page 8 are the same as the Total Collections in the 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, 2007

Fiscal Year	Collections Realized	Collection Ceiling	Amount to Offset Future Collections
2004	$5,154,700	$5,000,000	$154,700
2005	$8,519,101	$8,354,000	$165,101
2006	$10,945,866	$11,318,000	$0
2007	$12,946,515	$11,604,000	$1,342,515
		Total:	**$1,662,316**
Amount Offset When Fees for FY 2008 Were Determined:			$320,000
Balance to be Offset in a Subsequent Fiscal Year			**$1,342,316**

As discussed earlier on page 3, FY 2005 and FY 2006 collections realized have been updated from last year's report. The update reflects net collections through September 30, 2007. Additional FY 2007 cohort year fees collected subsequent to September 30, 2007 will be reported in the FY 2008 financial report.

RESERVES AND BALANCE AVAILABLE FOR ALLOCATION

The table below provides a summary of carryover balances as of September 30, 2007, and anticipated claims on those balances.

The first anticipated claim is the reserve for future offsets of $1,342,316 shown above. In addition, prudent operations require that a reserve be kept aside for other potential refunds. For that purpose a total of $500,000 is being set aside. That leaves a total of $4,297,420 available for allocation in FY 2008. This is enough to fund estimated FY 2008 operations dependent upon user fee revenue for approximately 4 months.

FOOD AND DRUG ADMINISTRATION
SUMMARY STATEMENT OF CARRYOVER BALANCE
As of September 30, 2007

Status of Carryover Funds	Amount
Reserve for Future Collection Offset	$1,342,316
Reserve for Refunds	$500,000
Available for Allocation	$4,297,420
TOTAL Carryover Balance	**$6,139,736**

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 2007.

FOOD AND DRUG ADMINISTRATION
PROCESS FOR THE REVIEW OF ANIMAL DRUG APPLICATIONS – TOTAL COST
AS OF SEPTEMBER 30, 2007

FDA Component	FY 2006	FY 2007
Center for Veterinary Medicine (CVM)	$40,975,359	$43,622,984
Field Inspection and Investigation	$2,298,089	$2,520,695
Agency General and Administrative Costs	$3,039,062	$3,445,122
Total Process Costs	**$46,312,510**	**$49,588,801**
Obligations from Appropriations	$36,636,831	$37,318,801
Obligations from Animal Drug User Fees	$9,675,678	$12,270,000

In FY 2007, 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 2007 and beyond.

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

The field inspection and investigation are pre-approval inspections of manufacturing facilities, investigations of clinical studies, and analytical testing of samples that are counted for the review process for animal drug applications. FDA's Office of Regulatory Affairs (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 2008

FDA's first 4 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; developing staff; and, developing and disseminating 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 the progressive and more demanding review time goals established under ADUFA in FY 2008, FDA plans to:

- Continue progress on management initiatives that include development of standard operating procedures for review processes, scientific policies for review staff, and implementation of a quality business system.

- Maintain staffing necessary to help FDA meet ADUFA review time goals.

- Develop and 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. We are dedicated to exploring new approaches and technologies that offer high quality and cost-effective improvements in FDA's review of new animal drug applications (NADA) and submissions. FDA looks forward to the continued success and significant improvements in the animal drug review process that ADUFA will help make achievable.

Most importantly, FDA is committed to working with the Department and the Administration to provide whatever assistance may be requested by Congress to assure that this crucial legislation, which will otherwise sunset on September 30, 2008, is reauthorized for another 5 years.

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. This appendix provides detailed descriptions of these conditions and explanations of how FDA met these conditions in FY 2007.

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 2006, the fiscal year preceding FY 2007, was 201.5. 201.5 divided by 183.8 equals to 1.0963 (rounded to fourth decimal place). That is the adjustment factor for FY 2007.

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 2007 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 1.0963 (rounded to fourth decimal place) equals to $1,506,002,658.

In FY 2007, Congress appropriated $1,569,244,000 to FDA for salaries and expenses, excluding user fees, after a 1 percent rescission. Because the FY 2007 salaries and expenses appropriation is greater than the adjusted FY 2003 Salaries and Expenses appropriation the first legal condition was met.

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 February 15, 2007, the President signed the FY 2007 Appropriation Act, Public Law 110-5, which specified the collectable user fees amount for ADUFA. That provision approved FDA to collect $11,604,000 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 the amount that FDA spent on the process for the review of animal drug applications in FY 2003, adjusted for inflation. FDA must spend at or above this minimum spending level from appropriations.

In FY 2003, the amount spent from appropriations for the process for the review of animal drug applications was $32,748,000 (rounded to thousand). After applying the adjustment factor of 1.0963 (rounded to fourth decimal place), the minimum appropriation spending level for the process for the review of animal drug applications for FY 2007, excluding user fees, is $35,901,632.

In FY 2007, FDA obligated $37,318,801 from appropriations for the process for the review of animal drug applications, which exceeds the specified minimum appropriation spending level. Therefore, FDA met the third condition.

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 2006 and FY 2007.

FOOD AND DRUG ADMINISTRATION
OBLIGATIONS FOR THE PROCESS FOR THE REVIEW OF
ANIMAL DRUG APPLICATIONS
AS OF SEPTEMBER 30, 2007

	FY 2006	FY 2007
From Appropriations	$36,636,831	$37,318,801
From Fee Revenues	$9,675,678	$12,270,000
Total Obligations	**$46,312,509**	**$49,588,801**

NUMBER OF APPLICATIONS PAID BY FEES IN FY 2007

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 2007 fee rates for all categories in August 2006[1]. In FY 2007, the highest fee was for an animal drug application – $168,600. 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 $84,300. 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 $4,115, $51,350, and $44,850, respectively.

The table below summarizes the number and type of fees actually received in FY 2007 for cohort year 2007 in comparison to what the FDA estimated it would receive in FY 2007 when ADUFA fees for FY 2007 were established in August 2006.

FOOD AND DRUG ADMINISTRATION
NUMBERS OF ANIMAL DRUG USER FEES COLLECTED AND ANTICIPATED IN FY 2007
AS OF SEPTEMBER 30, 2007

User Fee Category	# of Fees Actually Collected in FY 2007	# of Fees Anticipated to Establish FY 2007 Fees
Animal Drug Applications		
Applications	19	10
Supplemental Applications	16	13
Products	711	686
Establishments	53	55
Sponsors	61	63

[1] FDA published FY 2007 animal drug user fee rates in the federal register notice – August 2, 2006 (71 FR 43776, http://www.fda.gov/OHRMS/DOCKETS/98fr/E6-12396.pdf).

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 2007, 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 2007 only.

WAIVERS AND REDUCTIONS GRANTED AND USED BY FEE CATEGORY IN FY 2007 AS OF SEPTEMBER 30, 2007

Reason	Application & Supplement	Product	Establishment	Sponsor	Total
Significant Barrier to Innovation	0	0	0	18	**18**
Fees Exceed Costs	0	0	0	0	**0**
Free Choice Feeds	0	0	0	2	**2**
Minor Use or Minor Species	2	11	2	42	**57**
Small Business	0	0	0	0	**0**
Total	**2**	**11**	**2**	**62**	**77**

VALUE OF WAIVERS AND REDUCTIONS GRANTED AND USED IN FY 2007
AS OF SEPTEMBER 30, 2007

Fee Category	Fee Rate	Number	Value
Applications	$168,600	1	$168,600
Supplemental Applications	$84,300	1	$84,300
Products	$4,115	11	$45,265
Establishments	$51,350	2	$102,700
Sponsors	$44,850	62	$2,780,700
Total		**77**	**$3,181,565**

The waivers and the reductions presented in the table above were fees that were otherwise due and payable in FY 2007, 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, 2007 (and therefore the waiver was not used), or the waivers were for FY 2007 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 be collected in FY 2008, and their impact will be reflected in the FY 2008 ADUFA Financial Report.

In addition to the waivers and reductions shown above, on September 30, 2007, there were three waiver requests pending relating to fees payable in FY 2007 that were requested on the basis that fees assessed exceed FDA's costs.

For FY 2006 FDA granted an additional 10 waivers after September 30, 2006, that therefore were not reported in the FY 2006 Financial Report.

In FY 2007 FDA denied 10 applications for waivers and reductions. All 10 requests that were denied were for sponsor 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 2 years, obligations represent an accurate measure of costs.

ADUFA RELATED COSTS

INCLUDED ACTIVITIES

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

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

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

- with respect to NADAs - original applications, pre- and post-market supplements, chemistry reports, reactivations, Veterinary Master Files, Public Master Files, and application-related correspondence;
- with respect to 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 CVM, ORA, and Office of the Commissioner (OC). These organizations correspond to the cost categories presented 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 Pre-approval 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 ADUFA, as expanded in the discussion in Appendix D, the cost categories within each organization listed above were identified as parts of the animal drug review process.

CENTER COSTS

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

CVM'S ATR

CVM developed and implemented a total time reporting system as part of a multi-year Activity Based Costing initiative. The ATR has a robust Activity Dictionary developed

by CVM employees, describing the work "activities" of the Center employees. The system was implemented center-wide in October 2003. All CVM employees report their time in ATR.

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

FDA's budget is very payroll intensive - 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 each individual cost center for the fiscal year.

CENTER TIME REPORTING RESULTS FOR FY 2007

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

AGENCY-WIDE EXPENSES

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

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

Prior to FY 2004, many of the Office of Shared Services Full Time Equivalent employees and resources were performed in CVM, ORA, and OC. In FY 2007, resources expended by the Office of Shared Services in supporting the animal drug review process are reported as if they were incurred in CVM, ORA, or OC, for comparability to the FY 2003 base year.

FIELD INSPECTION AND INVESTIGATION COSTS

ORA 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, multiplies the total number of staff-years used in the process for the review of animal drug applications by the average salary cost in ORA to arrive at ORA salary costs for work that is a part of the process for the review of animal drug applications as defined in ADUFA. The final step is to allocate ORA obligations for operations and rent to the animal drug review process based upon the ratio of user fee related staff-years to total ORA staff-years. The following table summarizes the calculation of ORA costs for the review of animal drug applications for FY 2006 and FY 2007.

FOOD AND DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS
COSTS OF THE REVIEW PROCESS FOR ANIMAL DRUG APPLICATIONS
AS OF SEPTEMBER 30, 2007

Cost Component	FY 2006	FY 2007
Staff Years Utilized	14	14
ORA Average Salary and Benefits	$99,675	$104,700
Salary and Benefits (Staff Years times ORA Average Salary and Benefits)	$1,395,453	$1,465,800
Operating and Other Costs [1/]	$902,636	$1,054,895
Grand Total (salary/benefits and operating/other costs)	**$2,298,089**	**$2,520,695**

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

AGENCY GENERAL AND ADMINISTRATIVE COSTS

The agency general and administrative costs are incurred in the FDA's OC. At the end of FY 2007, OC was comprised of the following offices:

- Immediate Office of the Commissioner
- Office of the Chief Counsel
- Office of the Chief of Staff
- Office of the Administrative Law Judge
- Office of Equal Employment and Diversity Management
- Office of International and Special Programs
- Office of Operations
- Office of Policy, Planning and Preparedness
- Office of Scientific and Medical Programs

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 $3,445,122 in general and administrative costs to the animal drug review process in FY 2007. The costs are total costs obligated from appropriations and user fees. FDA strives to maintain a low overhead cost for the review process of the animal drug applications. General and administrative costs are approximately 6.9 percent of FY 2007 total animal drug review process costs.