



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

June 14, 2011

The Honorable Joseph R. Biden, Jr.
President of the Senate
United States Senate
Washington, D.C. 20510

Dear Mr. President:

The Prescription Drug User Fee Amendments of 2007 require the Food and Drug Administration (FDA or the Agency) to report annually on the financial aspects of its implementation of the Prescription Drug User Fee Act (PDUFA), as amended. Please find enclosed the Fiscal Year 2010 report which documents how the Food and Drug Administration (FDA) met each of the necessary conditions specified in PDUFA for continued collection of prescription drug user fees. Availability of these fees enables FDA to operate a more robust drug review process and meet the performance goals established for this program.

I look forward to continuing to work together with you to ensure that the Food and Drug Administration has appropriate funding to fulfill its important public health and consumer protection mandates.

Sincerely,

A handwritten signature in black ink that reads "Kathleen Sebelius". The signature is fluid and cursive, with the first name "Kathleen" and the last name "Sebelius" clearly legible.

Kathleen Sebelius

Enclosure

FY 2010 PDUFA FINANCIAL REPORT

REQUIRED BY THE

PRESCRIPTION DRUG USER FEE ACT

AS AMENDED

FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

EXECUTIVE SUMMARY

The Prescription Drug User Fee Amendments of 2007 requires the Food and Drug Administration (FDA or the Agency) to report annually on the financial aspects of its implementation of the Prescription Drug User Fee Act (PDUFA), as amended. This report covers fiscal year (FY) 2010.

PDUFA specifies that the following three conditions must be satisfied each year in order for FDA to collect and spend PDUFA fees:

1. FDA's overall Salaries and Expenses Appropriation, excluding fees, must exceed FDA's overall FY 1997 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 human drug applications as it spent in FY 1997, adjusted for inflation, within certain tolerances.

This report describes how FDA met those specific statutory conditions during FY 2010. The statements and tables included in this report also provide the user fee revenues and expenditures in FY 2010, the carryover balance, and comparative data for earlier periods.

In FY 2010, FDA collected \$551.7 million in fees, including fees collected for earlier periods. This is less than the \$569 million FDA projected at the beginning of the year when fees for FY 2010 were established. The lower revenue is attributable primarily to a lower number of fee paying applications received during FY 2010 than projected at the beginning of the year. The amount of revenue collected would have been much lower but it was offset by collections from earlier periods, including the additional FY 2009 product and establishment fees received in the first quarter of FY 2010.

In FY 2010, FDA obligated \$573 million from PDUFA fee revenues. This accounted for about 62 percent of all funds obligated by FDA from all sources in support of the process for the review of human drug applications. This \$573 million was about \$21 million more than net collections for the year, decreasing the balance of funds collected in previous years to slightly less than \$151 million at the end of FY 2010. Due to reserves for specific needs, only about \$49.4 million of this carryover balance is available for obligation. About 60 percent of funds obligated from all sources were for employee salaries and benefits, and the balance was for costs necessary to support and maintain those employees.

Challenges FDA faces in FY 2011 include pursuing development of standards for the electronic data included in regulatory submissions. Also, effective information management has become a critical element of FDA's strategy to address the challenges of new legislative mandates and industry shifts to multi-site worldwide operations. Additionally, FDA will need to continue work on the next reauthorization of PDUFA. Continued PDUFA funding is essential to the human drug review program.

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BACKGROUND

Enacted in 1992, PDUFA authorized FDA to collect fees from the pharmaceutical industry to be spent on drug review, in addition to minimum amounts that are required to be spent from appropriated funds exclusive of user fees. FDA used these additional resources to hire and support additional staff for the review of human drug applications, so that safe and effective drug products would reach the American public more quickly. PDUFA has been a very successful program. With the support of the pharmaceutical industry, other stakeholders, and the Administration, Congress amended and extended PDUFA in 1997 (PDUFA II), 2002 (PDUFA III) and 2007 (PDUFA IV).

Under PDUFA IV, application fees, establishment fees, and product fees each contribute one-third of the total fee revenues in a fiscal year. An application fee must be submitted when certain New Drug Applications (NDAs) or Biologic License Applications (BLAs) are submitted. Product and establishment fees are due annually on October 1. The total annual fee revenue amounts set in statute for PDUFA IV, after a base workload adjustment, must be adjusted for annual changes in drug review workload and for cumulative inflation since FY 2008. PDUFA IV authorizes FDA to set user fees in each fiscal year, so that the total revenue that FDA receives from each fee category (application fees, product fees, and establishment fees) approximates one-third of the estimated revenue amount after adjustments for workload and inflation.

PDUFA IV also requires FDA to submit two reports to Congress each fiscal year. A performance report is to be sent within 120 days after the end of a fiscal year, and a financial report is also to be sent within 120 days. The FY 2010 PDUFA Performance Report, which discusses FDA's progress in meeting the goals set for FDA in PDUFA IV, is being transmitted separately to Congress. This report is FDA's FY 2010 PDUFA Financial Report, covering the period from October 1, 2009 to September 30, 2010.

As required by the statute, this report presents the legal conditions that must be satisfied before FDA can collect and spend the fees, and the calculations on how these conditions were met in FY 2010. This report also presents summary statements of FY 2010 revenue by fee source and fee obligations by expense category. Finally, this report presents the total costs in FY 2010, from both fee revenues and appropriations, of the process for the review of human drug applications, as defined in PDUFA.

MEETING THE LEGAL CONDITIONS FOR USER FEES IN FY 2010

PDUFA imposes three legal conditions that FDA must satisfy each year before the Agency may collect and spend user fees. The calculations on how these conditions were met in FY 2010 are summarized below and are 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 1997 Salaries and Expenses appropriation (excluding user fees and adjusted for inflation). In FY 2010, FDA's overall Salaries and Expenses appropriation (excluding user fees and excluding rent to the U.S. General Services Administration (GSA), which was also not included in the FY 1997 appropriation amount) totaled \$2,200,634,000. FDA's FY 1997 total Salaries and Expenses appropriation (excluding user fees) multiplied by the FY 2010 adjustment factor as required by the statute, and rounded to the nearest thousand dollars, was \$1,121,816,000. Therefore, since the FY 2010 appropriated amount is greater, the first condition was met.

The **second condition** is that the amount of user fees collected in each year must be specified in Appropriation Acts. The President signed the Agriculture, Rural Development, Food And Drug Administration, And Related Agencies Appropriations Act, 2010 (Public Law 111-80) specifying amounts collectable from fees during FY 2010 on October 21, 2009. It provided for \$578,162,000 from prescription drug user fees. The Appropriation Act specified that the fees collected could remain available until expended. Thus, the second condition was met.

The **third condition** is that FDA may collect and spend user fees only in years when FDA also uses a specified minimum amount of appropriated funds for the review of human drug applications. The specified minimum is the amount FDA spent on the review of human drug applications from appropriations (exclusive of user fees) in FY 1997, adjusted for inflation. That amount, adjusted for inflation for FY 2010 and rounded to the nearest thousand dollars, is \$202,426,000. In FY 2010, FDA obligated \$358,587,181 from appropriated funds for the process for the review of human drug applications. Since this amount exceeds the specified minimum amount, the third condition has been met.

Appendix A provides more detailed calculations and explanations of how FDA met each of these three statutory conditions.

USER FEE REVENUES

PDUFA IV specifies that FDA shall collect fee revenues from establishment, product, and application fees. The statute specifies revenue amounts for each of these categories and specifies that the statutory amounts are to be adjusted in each fiscal year for inflation, workload, and statutory drug safety increases. FDA then establishes fees at the beginning of each fiscal year so that the total revenue collected approximates the adjusted statutory total fee amount.

Under PDUFA, 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 over from year to year are described in the section on carryover balances beginning on page 7.

The following table provides a breakout of user fees collected by fee category during the past two fiscal years, and also reflects estimates of receivables.

TABLE 1
STATEMENT OF PDUFA USER FEE REVENUES BY FEE SOURCE
As of September 30, 2010

Fiscal Year	FY 2009	FY 2010
Fees Collected:		
Application Fees	\$176,347,662	\$172,238,150
Establishment Fees	\$183,913,904	\$183,328,513
Product Fees	\$173,343,808	\$173,709,880
TOTAL FEES COLLECTED:	\$533,605,374	\$529,276,543
Fee Receivables:		
Application Fees	\$34,600	\$957,400
Establishment Fees	\$1,064,000	\$929,488
Product Fees	\$1,001,280	\$956,640
TOTAL FEES RECEIVABLE:	\$2,099,880	\$2,843,528

Note that user fee revenues are reported in the year the fee was originally due—referred to as cohort years. Collections in a cohort year include all fees for applications filed in that 12 month period, from October 1 through September 30, regardless of when the cash was actually received. For example, a fee due in FY 2009, even if it is received in FY 2010, is attributed to FY 2009 revenues. Totals reported are net of any refunds for that year. FDA bills the uncollected fees twice a year – in August for fees due on October 1, and in November after the close of the fiscal year for product and establishments that were not billed and paid for in the earlier billing for the fiscal year. In order to ensure the quality of the information provided in this financial report, FDA updates prior year numbers each year.

OBLIGATION OF USER FEE REVENUES

User fee revenues are expended only for costs necessary to support the process for the review of human drug applications, as defined in PDUFA. Allowable and excludable costs for the process of the review of human drug applications are defined in Appendix C. In FY 2010, FDA obligated \$573,258,400 from user fee revenues.

TABLE 2
STATEMENT OF PDUFA FEE OBLIGATIONS BY EXPENSE CATEGORY
As of September 30, 2009 and 2010

Expense Category	FY 2009	FY 2010
Personnel Compensation and Benefits	\$317,836,710	\$361,264,217
Travel and Transportation	\$4,903,162	\$6,993,109
Rent	\$20,893,636	\$26,801,316
Communications	\$13,477,913	\$3,988,179
Contract Services	\$132,439,531	\$144,029,238
Equipment and Supplies	\$21,891,912	\$29,062,386
Other	\$608,536	\$1,119,955
TOTAL OBLIGATIONS:	\$512,051,400	\$573,258,400

FDA dedicated 1,277 staff years to the review of human drug applications in FY 1992, before PDUFA was enacted. (In this report the time worked by one full time person for one year is referred to as either a “staff year” or as a “full-time-equivalent” (FTE).) FDA conducted a time reporting study in 1993 to determine the percentage of time each organizational component devoted to user fee-related activities. The data from this study allowed FDA to calculate the personnel-related costs of the drug review process. The percentages are updated regularly through additional time surveys, which are consistent with the method used by independent consultants in FY 1993. More detailed information about the development of the costs associated with the review of human drug applications can be found in Appendix D.

In FY 2010, PDUFA fees and appropriations paid for a total of 3,760 staff years, 2,483 more staff years than were used in FY 1992 for the review process of human drug applications, before user fees were authorized. Employee salary and benefits paid from user fees in FY 2010 totaled over 60 percent of the obligations from fees. This includes all pay and benefits for the additional personnel. The FY 2010 PDUFA Performance Report, which discusses FDA’s progress in meeting the goals set for FDA in PDUFA IV, and overall FDA application review performance, is being transmitted separately to Congress.

In FY 2010, FDA completed significant steps in migrating most of the software systems to the new data centers and established processes and procedures for the development and deployment of applications in the new data centers. The following were the most significant: The Information and Computer Technologies for the 21st Century (ICT21) project was initiated by FDA to provide an Agency-wide computing platform for the 21st Century that is scalable, flexible, and reliable and effectively meets business requirements. The Office of Information Management (OIM) implemented two new state of the art electronic data centers under the ICT21 initiatives. The target technologies and application architecture were defined for the new data centers which resulted in a more secure environment and standardized system development. FDA was actively involved throughout the year in the immense task of analyzing, documenting, and migrating hundreds of applications to the new data centers in different environments such as Development, Test, Pre-Production, and Production. Substantial efforts were made to use shared environments to achieve efficiency and common technical architecture across centers. FDA successfully migrated most of the software systems to the new data centers. OIM also refined standard operating procedures for effectively developing and deploying systems in the new data center environments.

In conjunction with the implementation of the new data centers, OIM has also defined and implemented a centralized security program, allowing for better oversight of both the networks and environments which resulted in robust and secured environments.

The Enterprise Architecture (EA) team continued to refine the IT Investment Management (ITIM) process to govern all of the FDA IT investments so that they advance towards the target architecture. The governance framework enables the standardized evaluation, prioritization, and processing of requests for IT investments, products and services. The ITIM process aligns related Federal and the Department of Health and Human Services (HHS) defined processes such as the Capital Planning and Investment Control (CPIC), the Federal Enterprise Architecture (FEA), and the HHS Enterprise Architecture Repository (HEAR). The baseline data for the target (current state analysis and data collection) has been captured and modeled in HEAR. In addition, the IT Strategic Plan (ITSP) has been reviewed and, together with the investment portfolio gap analysis, the data will serve as a foundation for target architecture planning. The EA staff has established FDA compliance with HHS mandates and demonstrated effective oversight through rationalization, accounting, and reduction of FDA's portfolio and technical footprint.

The EA work provides comprehensive enterprise architecture, a defined target state, and a governance process for ensuring that IT investments match business needs and the strategic goals of the organization.

OIM established different divisions to support Agency-wide IT requirements and continued to support current centers and office IT systems. In FY 2010, OIM's Division of Systems (DOS) continued to evolve and formulate a new organization structure to support system development efforts and deliver coordinated and efficient systems in support of increasingly complicated business requirements. DOS established vertical and horizontal task groups to support system development across Centers while leveraging common system development life cycle components. Vertical task groups support system development across Centers based on business functionality and product lines. Horizontal task groups support common components across system development, such as project management support, testing support, quality management, data management, and configuration management. System development efforts leverage services of horizontal task groups to minimize redundancy, resulting in a structured approach to system development. DOS has centralized project management tools for software delivery and continues to implement the Enterprise Performance Lifecycle (EPLC) methodology across projects. This consistency will allow for improved monitoring and control techniques to track issues and quality throughout the lifecycle of a project.

The Document Archiving Reporting and Regulatory Tracking System (DARRTS) is a flexible, integrated, fully electronic workflow tracking and information management system to receive, log, track, assign, process, manage, and report official submissions with internal stakeholders. The system maintains the official submission records and manages and tracks all communications, documentation, meetings, and deadlines concerning submissions. The earlier release of DARRTS integrated multiple legacy applications and implemented a web-based secured application. The two releases in FY2010 addressed multiple enhancements such as IND, NDA Volume Accountability System (INVAS) maintenance screens, mass assignments, Tracked Safety Issues (TSI) modifications, etc. Additionally, DARRTS was successfully migrated to the new Data Center.

CARRYOVER BALANCES

Under PDUFA, 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. The net result of operations in FY 2010 decreased the carryover balances by \$21,524,140. This decrease was largely the result of receiving about 17 fewer full-fee-paying applications in FY 2010 than anticipated when fees were set before the beginning of the year (118 received, compared with 135 expected). Additional FY 2009 fees for products and establishments collected in the first quarter of FY 2010 reduced the impact of this application fee shortfall.

Table 3 captures the changes in carryover balances from FY 1993.

TABLE 3
STATEMENT OF COLLECTIONS, OBLIGATIONS, AND CARRYOVER BALANCES BY FISCAL YEAR
As of the end of each fiscal year shown and not including payments for next fiscal year

Fiscal Year	Beginning Carryover	Net Collections	Fee Revenue Obligations	Year-End Carryover
1993	-	\$28,531,996	\$8,949,000	\$19,582,996
1994	\$19,582,996	\$53,730,244	\$39,951,020	\$33,362,220
1995	\$33,362,220	\$70,953,500	\$74,064,015	\$30,251,705
1996	\$30,251,705	\$82,318,400	\$85,053,030	\$27,517,075
1997	\$27,517,075	\$93,234,125	\$84,289,046	\$36,462,154
1998	\$36,462,154	\$132,671,143	\$101,615,000	\$67,518,297
1999	\$67,518,297	\$126,580,456	\$122,515,000	\$71,583,753
2000	\$71,583,753	\$133,060,339	\$147,276,000	\$57,368,092
2001	\$57,368,092	\$138,761,294	\$160,713,000	\$35,416,386
2002	\$35,416,386	\$149,078,939	\$161,812,100	\$22,683,225
2003	\$22,683,224	\$209,667,051	\$200,154,500	\$32,159,776
2004	\$32,195,776	\$251,617,821	\$232,081,500	\$51,732,097
2005	\$51,732,097	\$283,491,495	\$269,433,800	\$65,789,792
2006	\$65,789,792	\$315,502,786	\$305,644,137	\$75,648,440
2007	\$75,648,440	\$375,597,273	\$320,429,620	\$130,816,093
2008	\$130,816,093	\$485,165,229	\$450,786,835	\$165,194,487
2009	\$165,194,487	\$518,992,651	\$512,051,400	\$172,135,738
2010	\$172,135,738	\$551,734,260	\$573,258,400	\$150,611,598
2011	\$150,611,598			

The balances above reflect cumulative cash at the beginning/end of each fiscal year, and the net cash collected during each fiscal year. The figures do not include accounts receivable. The net collections balance shown above for FY 2010 of \$551,734,260 is greater than the FY 2010 cohort year collections balance in Table 1 on page 3 (\$529,276,543) because the FY 2010 net collections figure above also includes some FY 2009 product and establishment fees that were counted in the FY 2009 cohort year revenue in the chart on page 3, but are reflected in Table 3 as part of the total collections that occurred in FY 2010. There are also a number of restrictions on the use of these carryover funds, as explained below.

COLLECTION CEILINGS, POTENTIAL REFUNDS AND OFFSETS

PDUFA I prohibited FDA from keeping fees in excess of the amount specified in appropriations (collection ceiling) each fiscal year through FY 1997. Amounts collected that exceeded collection ceilings through FY 1997 were required to be refunded. A total of \$6.3 million surplus collections from this period were refunded in FY 2000 and FY 2001. Under PDUFA II and III, collections in excess of fee amounts appropriated after FY 1997 may be kept and used to reduce fees that would otherwise be assessed in a later fiscal year. The first such offset (for excess collections in 1998 and 2004) was made when fees were set for FY 2007, as reflected in the table below. At the time fees were set for FY 2007 (August 2006), there were no excess collections for other years. Collections since then have resulted in additional excess collections. Under the provisions of PDUFA IV, if cumulative collections from FY 2008 through FY 2010 and estimated for FY 2011 exceed cumulative fee appropriations for the same period, FDA will reduce fees when fees are set for FY 2012 by the cumulative amount by which fees collected over this period exceed fees appropriated over the same period. The table below depicts the net collections, the collection amounts specified in appropriations, and the amounts that FDA may have to use to offset future collections.

TABLE 4
STATEMENT OF FEES COLLECTED, COLLECTION CEILINGS, AND POTENTIAL OFFSETS
As of September 30, 2010

Fiscal Year	Collections Realized	Collection Ceiling	Potential Offset to Future Collections
1998	\$117,849,016	\$117,122,000	\$727,016
1999	\$125,729,367	\$132,273,000	-
2000	\$141,134,682	\$145,434,000	-
2001	\$138,421,429	\$149,273,000	-
2002	\$141,408,975	\$161,716,000	-
2003	\$218,302,684	\$222,900,000	-
2004	\$258,333,700	\$249,825,000	\$8,508,700
2005	\$287,178,231	\$284,394,000	\$2,784,231
2006	\$313,541,278	\$305,332,000	\$8,209,278
2007	\$370,903,656	\$352,200,000	\$18,703,656
Collections Exceeding Appropriations through 2007			\$38,932,881
Excess Collections Offset under 736(g)(4) when fees for FY 2007 were set			\$7,957,922
Remaining Excess Collections to be Offset			\$30,974,959
2008	\$479,582,086	\$459,412,000	\$20,170,086
2009	\$533,605,375	\$510,665,000	\$22,940,375
2010	\$529,276,573	\$578,162,000	(\$48,885,457)
2008-2010	\$1,542,463,896	\$1,548,239,000	(\$5,774,997)
Collections FY 2008-2010 Compared to Appropriations			(\$5,774,997)
Net Balance to be Offset in a Subsequent Year			\$30,974,959

OTHER RESERVES AND BALANCE AVAILABLE FOR ALLOCATION

Table 5 provides a summary of reserves of carryover balances for potential claims on those balances. The first line sets forth the amount collected in excess of appropriations through PDUFA III, which FDA will offset against fees collected when fees are set in a subsequent fiscal year. The second line shows a reserve of \$2,500,000 for refunds of fees paid. The third line sets aside funds to be paid from PDUFA fees for the move of CBER components to White Oak in the future. The fourth line shows the cost through 2012 of additional FTEs allocated in 2009 to address increased PDUFA workload. The fifth line shows the amount of all claims/reserved amounts.

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

Limitations/Claims on Carryover Funds	Amount
Reserve for Future Offset	\$30,974,959
Reserve for Refunds	\$2,500,000
Reserve for CBER move to White Oak	\$37,896,000
Allocation of Additional 53 FTE, FY 2011-2012	\$29,771,000
TOTAL of all Claims on Carryover Balances	\$101,141,959
TOTAL Carryover Balance	\$150,611,598
Amount of Balances Available for Allocation	\$49,469,639

Total carryover balances exceed limitations and claims by a total of \$49,469,639. This amount is available for allocation, or for holding in reserve in FY 2011 against any revenue shortfalls in FY 2011 and FY 2012, or towards operating costs in FY 2013.

PDUFA IV authorizes FDA to have up to 3 months of available carryover balance at the end of FY 2012. FDA currently estimates that it will need a total of \$184.3 million in fee revenues (\$61.4 million per month) to cover PDUFA operations in the first 3 months of FY 2013. How much of that will have to be added to 2012 fee collections will be determined when fees are set for 2012 in August of 2011.

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

Table 6 presents the costs for the review of human drug applications for FY 2009 and FY 2010 by organizational components. It indicates the full cost of the process for the review of human drug applications, including costs paid both from appropriations and from user fee revenues. The amounts are based upon the obligations recorded at the end of each fiscal year. In the past, over 81 percent of amounts obligated are expended within one year, and 96 percent within two years. Thus, obligations represent an accurate measure of costs.

TABLE 6
PROCESS FOR THE REVIEW OF HUMAN DRUG APPLICATIONS – TOTAL COSTS
As of September 30, 2009 and 2010

FDA Component	FY 2009	FY 2010
Center for Drug Evaluation and Research (CDER)	\$585,414,578	\$640,509,784
Center for Biologics Evaluation and Research (CBER)	\$170,363,705	\$176,353,112
Field Inspection and Investigation Costs (ORA)	\$36,509,080	\$34,968,204
Agency General and Administrative Costs (OC)	\$63,138,931	\$80,014,481
Total Process Costs		
	\$855,426,294	\$931,845,581
Amount from Appropriations	\$343,374,894	\$358,587,181
Amount from Fees	\$512,051,400	\$573,258,400

Of the total of \$931,845,581 obligated in support of the process for the review of human drug applications as defined in PDUFA in FY 2010, about 62 percent came from PDUFA fees and about 38 percent came from appropriations. The costs for all components except ORA increased in FY 2010. The increases in expenditures primarily reflects the fact that in FY 2010 FDA used a total of 3,760 FTE for the process for the review of human drug applications, 234 more FTE than the 3,526 FTE utilized by FDA in FY 2009. Most of this increase reflected FDA's success in hiring or reassigning employees to work in support of the process of the review of human drug applications. A portion of the cost increase is also due to mandatory pay and benefit increases for all Federal employees.

MANAGEMENT CHALLENGES FOR FY 2011

Since the implementation of PDUFA I, FDA has utilized PDUFA resources to significantly reduce the time it takes to evaluate new drugs and biologics without compromising the FDA's rigorous standards for safety and efficacy. This has allowed the American people to gain quicker access to valuable therapies and has increased the economic incentive for sponsors to develop innovative drug and biological products. Without the funds derived from PDUFA fees, the substantial progress FDA has achieved in improving and expediting the review of human drug applications would not have been possible.

PDUFA IV enters its fourth year in FY 2011. Re-authorized as Title I of the Food and Drug Administration Amendments Act of 2007 (FDAAA), PDUFA IV expanded user fee funding to cover post-market safety activities. FDAAA also expanded requirements under the re-authorized Pediatric Research Equity Act (Title IV) and the Best Pharmaceuticals for Children Act (Title V). In addition, FDAAA Title IX gave FDA substantially expanded responsibilities and authorities regarding the post-market safety of drugs.¹ For example, FDA can now require risk evaluation and mitigation strategies for approved drug products, require sponsors to conduct post-market studies and clinical trials, and require safety labeling changes to address new safety information for marketed drugs. FDA is also tasked with developing systems capable of performing active post-market risk identification and analysis. These new provisions greatly strengthen FDA's ability to perform its mission of ensuring the availability of safe and effective drugs and biologics, but they also place increasing workload demands on FDA. The added responsibilities of FDAAA Titles IV, V and IX pertaining to new drugs and biologics are now part of the process for the review of human drugs, and some of these additional technically challenging tasks must be conducted within the already existing review timeframes.

In addition to the statutory changes, the human drug review process is impacted by changes in industry operations that affect the content of NDA and BLA review. These include trends toward increasing numbers of distant, foreign-based clinical trials included in marketing applications, and similar trends in the drug manufacturing facilities named in marketing applications. FDA must plan for the time required to travel to these sites, as well as to conduct these inspections, within the same time frames that were established over a decade ago before manufacturing and clinical trials increasingly shifted to sites overseas.

To improve the efficiency of FDA review, the Agency is also pursuing development of standards for the electronic data included in regulatory submissions. This will help improve the quality and accessibility of drug safety and effectiveness data in submitted applications for FDA review and, hence, increase efficiencies in FDA's human drug review process. This effort includes development and testing of needed data standards, policy changes to require standardized data in drug sponsors' regulatory submissions, development of analytic tools for review, and the computational capacity to support electronic review.

Effective Information Management (IM) has become a critical element of FDA's strategy to address the challenges of new legislative mandates and industry shifts to multi-site

¹ FDAAA also expanded requirements (e.g., Clinical Trial Databases, Title VIII) that had less of an immediate impact on FDA resources

worldwide operations. This requires building a modern, stable, and secure Information Technology (IT) infrastructure. IT/IM costs represent a significant component of PDUFA spending. For example, system security costs have been increasing with the growing presence and sophistication of cyber threats. In general, successful IT/IM investment and operations will require continuing focused oversight and strong technical, business, and contract management throughout the entire IT/IM system lifecycle. IT/IM improvements are also needed to ensure that FDA can meet the timelines agreed to under PDUFA and implement drug safety requirements of FDAAA Title IX.

In addition, in FY 2011 FDA will complete many of the key steps required in FDAAA for the reauthorization of PDUFA, since the current authorization expires at the end of FY 2012.

PDUFA funding will continue to ensure that FDA rises to the challenge to meet the evolving demands of protecting the public health and the realities of the global situation.

CONDITIONS FOR ASSESSMENT AND USE OF FEES

The Federal Food, Drug, and Cosmetic Act (the FD&C Act) specifies three major conditions that must be met each year before prescription drug user fees may be collected and spent. A summary of these conditions and how FDA met them appears on page 2. A more detailed description of each of these conditions is provided below, with an explanation of how FDA met the conditions in FY 2010.

For making the calculations to determine if statutory conditions are met, an adjustment factor must be used. It is defined in Section 735(8) of the FD&C Act, as follows:

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

The consumer price index for October 2008, the October of the fiscal year preceding FY 2010, was 216.573. The consumer price index for October 1996 was 158.3. The result of dividing 216.573 by 158.3 is an adjustment factor of 1.368117 for FY 2010.

The **first condition** is based on Section 736(f)(1) of the FD&C Act. It states:

In general, fees under subsection (a) shall be refunded for a fiscal year beginning after FY 1997 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 1997 (excluding the amount of fees appropriated for such fiscal year) multiplied by the adjustment factor applicable to the fiscal year involved.

This provision does not allow FDA to collect or spend user fees unless FDA’s total Salaries and Expenses appropriation (excluding user fees) each year are greater than or equal to FDA’s FY 1997 Salaries and Expenses appropriation (excluding user fees) multiplied by the adjustment factor. FDA’s total FY 1997 Salaries and Expenses appropriation (excluding user fees) was \$819,971,000. Multiplying this amount by the adjustment factor of 1.368117, results in a minimum Salaries and Expenses appropriation for FY 2010 (excluding user fees, and rounded to the nearest thousand dollars) of \$1,121,816,000.

In FY 2010, FDA’s total Salaries and Expenses appropriation (excluding user fees and excluding rent to GSA, which was also not included in the FY 1997 appropriation amount) was \$2,200,634,000. Table 7 displays how this \$2,200,634,000 was calculated:

TABLE 7
FDA'S FY 2010 SALARY & EXPENSE (S&E) APPROPRIATION,
LESS FEES AND RENT TO GSA

Total FDA S&E Appropriation (PL 111-80)	\$3,237,218,000
Total for FDA in Supplemental Appropriations (PL 111-212)	\$2,000,000
Total FDA S&E Appropriation for FY 2010	\$3,239,218,000
Fee Amounts Specified in Appropriations	
PDUFA Fees	\$578,162,000
MDUFMA Fees	\$57,014,000
ADUFA Fees	\$17,280,000
AGDUFA Fees	\$5,106,000
Tobacco Fees	\$235,000,000
Subtotal—All Fee Amounts in Appropriations	\$892,562,000
Rent Payments to GSA (Not in 1997 S&E Appropriation)	
Amount of Rent to be paid from Fees	\$25,504,000
Rent Amount Appropriated Excluding Amounts from Fees	\$146,022,000
FY 2010 S&E Appropriation Less Fees and Rent	\$2,200,634,000

Because the FY 2010 appropriations, after deductions for fees and rent, exceeded the FY 1997 adjusted amount, the first condition was met.

The **second condition** is stated in Section 736(g)(2)(A)(i): 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....”

The President signed Agriculture, Rural Development, Food And Drug Administration, And Related Agencies Appropriations Act, 2010 that specified the amounts from prescription drug user fees in FY 2010 (\$578,162,000) on October 21, 2009 (Public Law 111-80). Therefore, the second condition was met.

The **third condition** in Section 736(g)(2)(A)(ii), 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 human 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 1997 multiplied by the adjustment factor.

In FY 1997, FDA’s actual obligation for the process for the review of human drug applications (excluding obligations paid from user fees) was \$147,959,689, as reported in the FY 1997 Financial Report to Congress. Multiplying this amount by the FY 2010 adjustment

factor of 1.368117, FDA's adjusted minimum spending for the human drug applications review process from appropriations (exclusive of user fees) was \$202,426,000, rounded to the nearest thousand dollars, in FY 2010.

In FY 2010, FDA obligated \$358,587,181 from appropriations for the human drug applications review process. Because \$358,587,181 is greater than \$202,426,000, the third condition was met.

Table 8 provides the amounts that FDA spent on the review process of human drug applications in FY 2009 and FY 2010, and the adjusted FY 1997 amount that had to be spent from appropriations in FY 2010. It also provides the amounts of these costs derived from appropriations and from user fees in each fiscal year.

TABLE 8
OBLIGATIONS FOR THE PROCESS FOR THE REVIEW OF HUMAN DRUG APPLICATIONS
As of September 30, 2010

	FY 1997 Adjusted for FY 2010	FY 2009	FY 2010
From Appropriations	\$202,426,000	\$343,374,894	\$358,587,181
From User Fee Revenues		\$512,051,400	\$573,258,400
Total Obligations		\$855,426,294	\$931,845,581

EXEMPTIONS AND WAIVERS

Beginning in FY 1993, PDUFA directed FDA to waive or reduce fees in five different circumstances:

- when a waiver is necessary to protect the public health;
- when a fee is a significant barrier to innovation;
- when the fees paid exceed FDA's costs of reviewing a firm's human drug applications;
- when imposition of the fee creates an inequity between certain 505(b)(1) and 505(b)(2) human drug applications (this waiver provision was deleted in PDUFA III); and
- when a sponsor withdraws a pending human drug application after FDA has filed it, but before FDA has performed substantial work on the marketing application.

In addition, under PDUFA II, new exemptions from application fees were added beginning in FY 1998. These specific exemptions are automatic and do not require a waiver request. They include:

- human drug applications for designated orphan products (designated for rare diseases or conditions affecting fewer than 200,000 patients in the United States);
- supplemental applications for pediatric indications for use (statutorily repealed by section 5 of Public Law 107-109, effective January 4, 2002.)

Beginning in FY 1998, PDUFA II also provided a waiver, for certain small businesses, of the full application fee for the first application submitted. Before FY 1998, only half of the application fee was waived for small businesses.

The increased number of exemptions required by PDUFA II reduced the number of applications that require the payment of fees. Fees may be waived or reduced under the waiver provisions of the statute. Many of the application fee waiver requests FDA received through FY 1997 pertained to orphan products; since designated orphan products are now given automatic exemptions, the number of waiver requests for application fees has decreased substantially.

Additionally, beginning in FY 2008, PDUFA IV also provided exemptions for product fees and establishment fees for certain approved orphan products (See 21 USC 379h (k)).

Table 9 summarizes the exemption and waiver actions taken by FDA for fees payable in the five most recent fiscal years.

Table 9
EXEMPTIONS AND WAIVERS AS OF SEPTEMBER 30, 2010
Does not Include Data on FY 2011 Waivers Granted in FY 2010

FY 2006 FY 2007 FY 2008 FY 2009 FY 2010

Exempted Application Fees ¹

Orphan Product	23.8	21.3	27.8	23.8	19.8
Previously Submitted	6.0	4.5	4.0	7.5	4.0
Total Exemptions	29.8	25.8	31.8	31.3	23.8
TOTAL Value of Exemptions	\$22,830,150	\$23,077,150	\$37,401,500	\$38,975,000	\$33,380,625

Exempted Orphan Product and Establishment Fees (new in FY 2008)

Orphan Product Fee Exemptions	14	16	22
Value of Product Fee Exemptions	\$910,420	\$1,144,320	\$1,753,840
Orphan Establishment Fee Exemptions	5.24	7.45	8.99
Value of Establishment Fee Exemptions	\$2,056,963	\$3,169,869	\$4,109,314
Total Product and Establishment Fee Exemptions	\$2,967,383	\$4,314,189	\$5,863,154

Waived Fees

APPLICATIONS ²

Small Business Waivers	11.0	14.0	26.0	17.0	20.0
Miscellaneous Waivers (Includes PEPFAR) ³	13.0	14.0	21.0	10.0	13.0
Value of Waivers Approved	\$18,417,600	\$25,093,600	\$55,366,000	\$33,674,400	\$46,381,500

PRODUCTS

Waivers Approved	22.0	23.8	15.1	12.4	4.0
Value of Waivers Approved	\$926,860	\$1,184,344	\$982,070	\$883,613	\$318,880

ESTABLISHMENTS

Waivers Approved	12.2	12.1	6.8	3.8	4.0
Value of Waivers Approved	\$3,223,704	\$3,782,272	\$2,660,720	\$1,633,747	\$1,828,800

TOTAL Value of Waivers Granted	\$22,568,164	\$30,060,216	\$59,008,790	\$36,191,760	\$48,529,180
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GRAND TOTAL--Exemptions & Waivers	\$45,398,314	\$53,137,366	\$99,377,673	\$79,480,949	\$81,909,805
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Source: Periodic waiver reports and application counts compiled by the CDER Associate Director for Policy and Fee-Exceed-Cost Waivers Reported by the Office of Financial Management

¹ Actual number of Exempted Applications received in full fee equivalents.

² Actual Number of Application Fee Waivers Granted--number of waived applications actually received may vary slightly

³ PEPFAR refers to applications for drugs to treat HIV/AIDS excluded from fees under the President's Emergency Plan for AIDS Relief

ALLOWABLE AND EXCLUDED COSTS FOR THE PROCESS FOR THE REVIEW OF HUMAN DRUG APPLICATIONS

Over 96 percent of amounts FDA obligates (contractually promises to pay) each year are expended within two years. Therefore, obligations represent an accurate measure of costs and are the basis of the costs reported in this document.

PDUFA, as amended, and the related House of Representatives Reports, define the process for the review of human drug applications and the costs that may be included in that process. Using these definitions, the further refinements described below, and the methodologies described in this report, FDA identified those activities that were applicable to the process for the review of human drug applications.

User Fee Related Costs

Section 735(6) of the FD&C Act defines in general terms the activities necessary for the review of human drug applications (the “human drug review process”). In summary, costs related to the following process activities have been attributed to the process for the review of human drug applications:

- All investigational new drug (IND) review activities, including amendments;
- All review activities for NDAs, BLAs, including supplements and amendments;
- Regulation and policy development activities related to the review of human drug applications;
- Development of product standards for products subject to review and evaluation;
- Meetings between FDA and the sponsor of a covered application or supplement;
- Review of labeling prior to approval of a covered application or supplement and the review of the initial pre-launch advertising;
- Review of post-marketing studies and clinical trials that have been agreed to by sponsors as a condition for approval;
- Inspections of facilities undertaken as part of the review of pending applications or supplements;
- Lot release activities for covered biological products;
- Assay development and validation to ensure batch-to-batch consistency and reliability for covered biological products;
- Monitoring of clinical and other research conducted in connection with the review of human drug applications;
- User Fee Act implementation activities;
- Research related to the human drug review process; and
- Postmarket safety activities with respect to drugs approved under human drug applications or supplements, including the following activities: collecting,

developing, and reviewing safety information on approved drugs, including adverse event reports; developing and using improved adverse event data-collection systems, including information technology systems; developing and using improved analytical tools to assess potential safety problems, including access to external data bases; implementing and enforcing Section 505(o) (relating to postapproval studies and clinical trials and labeling changes) and Section 505(p) (relating to risk evaluation and mitigation strategies); and carrying out section 505(k)(5) (relating to adverse event reports and postmarket safety activities).

All user fee related costs represented by the above activities are collectively referred to in this report as costs for the process for the review of human drug applications.

Section 735(7) of the FD&C Act defines the “costs of resources allocated for the process for the review of human drug applications” as the expenses incurred in connection with this process for:

- (A) officers and employees of the FDA, contractors of the FDA, advisory committees, and costs related to such officers, employees, committees and contracts;
- (B) management of information, and the acquisition, maintenance, and repair of computer resources;
- (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
- (D) collecting user fees under Section 736 of the FD&C Act and accounting for resources allocated for the review of human drug applications and supplements.

User Fee Excluded Costs

The FD&C Act excludes costs related to the following:

Excluded Products

- Generic drugs
- Over-the-counter drugs not associated with an NDA or NDA supplement
- Large volume parenteral drug products approved before September 1, 1992
- Allergenic extract products
- Whole blood or a blood component for transfusion
- In vitro diagnostic biologic products
- Certain drugs derived from bovine blood

Excluded Process Activities

- Enforcement policy development not related to Sections 505(o) and (p) of the FD&C Act
- Post-approval compliance activities not related to the enforcement of Sections 505(o) and (p) of the FD&C Act
- Advertising review activities once marketing of the product has begun
- Inspections unrelated to the review of covered applications, unless undertaken for the enforcement of Sections 505(o) and (p) of the FD&C Act
- Research unrelated to the human drug review process

These inclusions and exclusions required accounting for a newly created subset of FDA activities after the fact. It was necessary to develop and implement a methodology that would allow the Agency retrospectively to capture the FY 1992 costs for the newly defined “process for the review of human drug applications,” and apply that same methodology for future years. In 1995, Arthur Andersen & Company independently reviewed FDA procedures for doing this and found the methodologies reasonable.

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

GENERAL METHODOLOGY

The costs associated with the process for the review of human drug applications are based on obligations recorded within FDA’s CDER, CBER), ORA, and the OC. These organizations correspond to the cost categories presented on the Statement of Costs for the Process for the Review of Human Drug Applications as follows:

<u>Cost Category</u>	<u>FDA Organization</u>
Costs for the Review of New Drug Applications (NDAs), Biologic License Applications (BLAs), and Supplements	CDER
Costs for the Review of BLAs and Supplements	CBER
Field Inspection and Investigation Costs	ORA
Agency General and Administrative Costs	OC

The costs were accumulated using time-reporting systems in CDER, CBER, and ORA, and were extrapolated for OC. Using the definitions of costs and activities included in the “process for the review of human drug applications” in the FD&C Act , a portion of the costs within each of the four organizations listed above was identified as part of the human drug review process.

CENTER COSTS

Costs are accumulated in CDER and CBER in cost centers corresponding to the organizational components (usually divisions) within the Centers. Most FDA components involved in the human drug review process perform a mixture of activities--some included in the definition of the process for the review of human drug applications, and some not included. These components fall into three categories: 1) direct review and laboratory components; 2) indirect review and support components; and 3) Center-wide expenses. The allocation of costs for the three categories is discussed below.

Direct Review and Laboratory Components

Employees in all components of CDER and CBER, other than those noted below as Center indirect review and support components, reported their time for eight weeks during FY 2010 in activities that could be used to differentiate between time spent on the process for the review of human drug applications and all other time.

Both CDER and CBER time-reporting systems were modified after the enactment of each PDUFA reauthorization, so that time could be reported in activities that could be separated into allowable and excluded activities with respect to the process for the review of human drug applications, as defined in PDUFA and as further explained in Appendix C. This method for determining allowable and excluded costs for PDUFA direct review and laboratory costs has been used consistently, with only minor modifications, since 1993, when costs were initially measured by Arthur Andersen & Company. The CBER time reporting system collects on-line time reports for all employees, other than management and administrative support personnel, for a 2-week period each quarter of the fiscal year. The enhanced system reports time for 58 possible functional activities, by seven product classes.

CDER also conducts an on-line time-reporting survey. It captures the expenditure of time by all employees, other than management and administrative support personnel, on activities that are part of the process for the review of human drug applications and all CDER mission-oriented activities of each employee within the Center for two 4-week periods—one in each half of the fiscal year.

FDA Centers are payroll-intensive organizations – about 60 percent of all FDA funds pay for employee salaries and benefits, and almost all other costs are directly supporting these employees. Thus the average percentage of time reported each year during this 8-week period (two weeks each quarter for CBER, and four weeks semiannually for CDER) as having been expended on drug review process activities for each cost center is then applied to all costs incurred for that cost center for the entire fiscal year. This provides an estimate of the costs for each cost center that were part of the process for the review of human drug applications.

Center Indirect Review and Support Components

Indirect review and support components provide the infrastructure for the review process. In CDER, these components include portions of the Office of the Center Director, the Office of Planning and Informatics, the Office of Management, the Office of Communications and the Office of Executive Programs. In CBER, these components include portions of the Office of the Center Director, Office of Management, Office of Information Technology, and the Office of Communications, Outreach, and Development. Most employees of these components do not report their time.

The time of the management and administrative support personnel supporting the process for the review of human drug applications is assumed to be the average percentage time of all Center employees in direct review and laboratory components who reported their time. Thus the total average percentage of time reported each year during this 8-week period as having

been expended on drug review process activities for all direct review and laboratory components was then applied to all costs incurred for the entire fiscal year by the indirect review and support components.

Center-Wide Expenses

A number of Center-wide expenses are paid from central FDA accounts rather than charged directly to a specific Center. These costs include rent for facilities that house drug review staff, telecommunications and utility costs, some computer equipment and support costs, facilities repair and maintenance, and some extramural and service contracts. Many of these costs were traced back to the specific division that generated the cost and were assigned the user fee percentage calculated for the division to which the expenditure related. For the costs that benefited the Center as a whole and could not be traced to a specific division, a weighted average user fee percentage was calculated based on the level of time-reporting component costs for the process for the review of human drug applications divided by the total costs of these components.

In support of the President's Management Agenda and Secretarial Goal of "One-HHS," FDA consolidated administrative functions from the Centers and the Office of Management (including facilities, procurement, finance, EEO, and IT services) into the Office of Shared Services in FY 2004. The goal of implementing the Office of Shared Services is to keep the administrative functions related to the review costs more efficient.

In the FY 2010 financial report, the resources that were previously provided by the Centers, but are now provided by the Office of Shared Services, are reported as if they were still performed by the Centers, in order to make the FY 2010 report comparable with the reports of previous years.

CENTER TIME REPORTING RESULTS FOR FY 2010

The time reporting systems operated by CBER and CDER indicated that 68 percent of all time spent in CBER and 81 percent of all time spent in CDER in FY 2010 was dedicated to the process for the review of human drug applications as defined in PDUFA.

FIELD INSPECTION AND INVESTIGATION COSTS

ORA incurs all field inspection and investigation costs. ORA costs are incurred in both district offices (the "field") and headquarters support offices and are tracked through the use of the Field Accomplishment and Compliance Tracking System (FACTS). FACTS is a time and activity tracking system which captures time in a variety of categories, including pre-approval inspections of manufacturing facilities, investigations of clinical studies, and analytical testing of samples--which are included in the process for the review of human 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 human drug review process based upon the ratio of user fee-related staff years to total ORA staff years. Table 10 summarizes the calculation of ORA costs for the review of human drug applications for FY 2009 and FY 2010.

TABLE 10
OFFICE OF REGULATORY AFFAIRS
COSTS OF THE PROCESS FOR THE REVIEW OF HUMAN DRUG APPLICATIONS
As of September 30, 2009 and 2010

Cost Component	FY 2009	FY 2010
Staff Years Utilized	194	174
ORA Average Salary and Benefits	\$107,401	\$108,065
Salary and Benefits	\$20,835,794	\$18,803,310
Operations, Rent, and Shared Services	\$15,673,286	\$16,164,894
TOTAL	\$36,509,080	\$34,968,204

ORA costs for the process for the review of human drug applications described above include total process costs, including costs paid from appropriations and costs paid from fee revenues. The number of FTEs is lower than in FY 2010 because of decreased assignments of drug review process work from the centers.

AGENCY GENERAL AND ADMINISTRATIVE COSTS

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

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

OC costs applicable to the process for the review of human drug applications were calculated using a method prescribed by the Division of Cost Determination Management, Office of Finance, Office of the Assistant Secretary for Resources and Technology, and Office of the Secretary, HHS. The method uses the percentage derived by dividing total OC costs by the total salary obligations of the Agency, excluding the OC. That percentage is then multiplied by the total salaries (excluding benefits) applicable to the process for the review of human drug applications in CDER, CBER, and ORA to arrive at the total General and Administrative Costs.

Using this process, \$63,138,931 and \$80,014,481 in general and administrative obligations were dedicated to the human drug review process in FY 2009 and FY 2010, respectively. They are the total costs, including the funds obligated both from appropriations and user fees. The Agency general and administrative obligations in FY 2010 accounted for about 8.6 percent of the total costs of the human drug application review process. This is up from the 7.4 percent reported for FY 2009. This percentage is still below the high point of 10.4 percent reported for general and administrative obligations in the FY 1998 PDUFA Financial Report.