PDUFA IV Five-Year Financial Plan— 2009 Update

Fiscal Years
2008 - 2009 - 2010 - 2011 - 2012

Department of Health and Human Services
FOOD AND DRUG ADMINISTRATION
Office of Administration
Office of Financial Operations

Update—September 2009

Executive Summary

The Prescription Drug User Fee Act (PDUFA) provides authority for the Food and Drug Administration (FDA) to collect additional resources (fees from industry) that enable FDA to accelerate its drug evaluation process without compromising review quality. The Prescription Drug User Fee Amendments of 2007 extended PDUFA through September 30, 2012 (PDUFA IV). Under PDUFA IV, FDA is committed to meeting the demanding performance goals documented in a September 7, 2007 letter from the Secretary of Health and Human Services to the Chairmen and Ranking Minority Members of the House Committee on Energy and Commerce and the Senate Committee on Health, Education, Labor and Pensions.

In July 1998, FDA completed the first PDUFA II Five-Year Plan. In July 2003, FDA completed the PDUFA III Five Year Plan. In September 2008 FDA completed the PDUFA IV Five-Year Financial Plan similarly sets out FDA's plans for investing the resources expected under PDUFA IV, by organization component and areas of PDUFA IV program increase. This FY 2009 Update to that plan revises the revenue FDA assumes that it will collect over the 5 years due to the workload adjustment in PDUFA IV. That change (Assumption 2 on page 7) causes an upward adjustment of planned revenue of about $130 million over the 5 years of the plan.

The planned fee collections and spending over the 5-year period from fiscal year (FY) 2008 through FY 2012 increase to a total of over $2.88 billion. This plan provides background information on PDUFA, documents the assumptions upon which the plan is based, and describes the efforts and anticipated costs to meet the performance goals associated with PDUFA IV.

By spending category, 60 percent of the fee revenues will be allocated for employee salary and benefit costs, 18 percent for operating expenses to support the staff, 8 percent for IT investments, 7 percent for rental payments to GSA and rent related costs, and 7 percent central accounts.

Spending at this level will sustain 1989 full time equivalent (FTE) staff years paid from fees in FY 2008. This is an increase of 472 more FTE paid from fees in FY 2008 than in FY 2007—290 FTE to sustain 2007 performance levels, plus 183 FTE for program enhancements. In addition, the agency will be able to add another 330 FTE by FY 2012. Planned increases over FY 2007 FTE levels, by component, are:

- CDER—a net increase of 381 staff years in 2008 and of 720 at the end of 5 years
- CBER—a net increase of 67 staff years in 2008 and of 127 at the end of 5 years
- ORA— a net increase of 1 staff year in 2008 and through the end of 5 years
- OC—a net increase of 23 staff years in 2008 and of 52 by the end of 5 years

Operating at these levels should enable the agency to meet PDUFA IV goals through FY 2012.

Contents

Purpose

This document updates the September 2008 PDFUA 5-Year Financial plan. The major change is an assumption regarding the workload adjustment under the recently reauthorized Prescription Drug User Fee Act, referred to as PDUFA IV (Assumption 2 on page 7). That change increases the estimated collection of PDUFA fees over the 5 years of PDUFA IV from $2.75 billion to $2.88 billion.

This document is a financial blueprint for investing the $2.88 billion the agency expects to collect over the 5 fiscal years (2008 through 2012) of PDUFA IV. It provides FDA's initial estimates of the revenues, allocations, and expenditures anticipated over the five-year period.

The plan seeks to ensure that fee revenues will be effectively used to meet the challenging goals associated with PDUFA IV. It proposes an initial allocation of the resources expected each year among the FDA components responsible for achieving PDUFA goals, to assure timely resource availability. The plan keeps faith with the agreements made prior to the recent reauthorization of PDUFA by planning expenditures in the same categories that were used during discussions that preceded reauthorization. Those categories are:

- PDUFA IV Fee Base –resources to continue to meet the challenging drug review timelines in effect at the end of FY 2007 over each of the next 5 years
- Increased Critical Path Efforts
- Increased Drug Safety Capacity
- Enhanced Information Technology Capabilities
- Additional Capabilities Added for Drug Safety by Congress

Resources for the PDUFA IV fee base are essential to assure the agency's ability to continue to meet the challenging PDUFA III review goals that FDA is committed to continue to meet over the 5 years of PDUFA IV. The additional bulleted items represent distinct enhancements added under PDUFA IV.

FDA may update the plan, if necessary, to reflect significant changes in workload and replace revenue and expenditure estimates with amounts actually received and spent. Updates, if made, will also reflect any unanticipated contingencies that may occur. As was done over the past five years, FDA will make the plan, and any subsequent updates, publicly available for anyone to review and comment on.

Background

PDUFA I

The Prescription Drug User Fee Act of 1992 provided FDA with increasing levels of resources for the review of human drug applications. Fees that FDA collected from drug and biologic firms from 1993 through 1997 were used to reduce the evaluation time for certain human drug applications without compromising review quality. Letters from the Secretary of Health and Human Services to Congressional Committee Chairmen detailed goals for the program**.** By 1997, fees provided FDA with an additional $87.5 million a year for the drug evaluation process.

FDA primarily spent these new resources to hire additional personnel to review human drug applications and to update the information technology (IT) infrastructure supporting the human drug review process. FDA staff dedicated to these reviews in the Center for Drug Evaluation and Research (CDER), the Center for Biologics Evaluation and Research (CBER), the Office of Regulatory Affairs (ORA), and the Office of the Commissioner (OC) increased 56 percent during this period--from 1,277 staff-years in 1992 before PDUFA was enacted to 1,990 staff-years by 1997.

FDA's success in making the drug approval process more predictable, accountable, and scientifically sound, while making safe and effective drugs available to the public more quickly, was recognized in late 1997 when FDA received the prestigious Innovations in American Government Award, jointly sponsored by the Ford Foundation and the Harvard University's John F. Kennedy School of Government.

PDUFA II

As a result of this success, PDUFA was reauthorized and extended through September 30, 2002 (PDUFA II). This extension authorized FDA to collect and spend fee revenue to accomplish increasingly challenging goals over this five-year span. These new goals were set forth in letters from the Secretary of Health and Human Services to Congressional Committee Chairmen on November 12, 1997. By 2002, PDUFA fees permitted FDA to spend an additional $161.8 million a year for the drug evaluation process.

FDA continued to spend these new resources primarily to hire additional personnel to review human drug applications and to update the IT infrastructure supporting the human drug review process. FDA staff dedicated to these reviews in the CDER, CBER, ORA, and OC increased over 85 percent during the 10 years since PDUFA was enacted--from 1,277 staff years in 1992 before PDUFA was enacted to 2,365 staff years by 2002.

PDUFA III

Because of the continued success of this program, PDUFA was reauthorized for another five years. This reauthorization covered FY 2003 through FY 2007, and is known as PDUFA III.

PDUFA III attempted to correct some of the flaws in PDUFA II to provide for more stable fee revenues over the next five years. It was expected to provide sufficient resources for FDA to continue to be able to meet the challenging PDUFA III goals and undertake pilot programs and new initiatives. Fee revenues were expected to be sufficient to sustain the 1,464 staff years supported by fees, in addition to the 1,277 supported from appropriations—for a total of 2741 staff years dedicated to the process for the review of human drug applications by FY 2007. These staff-year numbers were expected to further increase as workload adjustments were made under the provisions of PDUFA III. PDUFA III also permitted fee revenues to be used for some post-approval risk management activities for the first time.

In actuality, the financial stability expected in PDUFA III did not materialize for several reasons. The rate of growth in FDA's appropriated resources over this period did not keep up with the increases in costs of pay and benefits per paid staff year and increases in facility related costs. As a result, by FY 2007 the number of staff years dedicated to the process for the review of human drug applications which were funded by appropriations decreased from 1277 to1222 and the number of staff years funded from fees totaled 1516, for a total of 2738, about 400 more than at the end of PDUFA II, but still about 100 less than expectations when PDUFA III was initially enacted, and with no net increases resulting from workload adjustments.

PDUFA IV

PDUFA was again reauthorized for another five years on September 27, 2007 (Public Law 110-85). This reauthorization covers fiscal years 2008 through 2012, and is known as PDUFA IV. PDUFA IV contains several provisions aimed at correcting financial shortfalls that occurred in PDUFA III. These include a substantial initial increase in fee revenues at the outset to make up for the fact that total drug review resources in PDUFA III did not keep up with actual FDA cost increases, an annual fee revenue adjustment linked to actual FDA cost increases per paid staff year over the most recent 5 years, and a revised fee revenue adjustment for workload increases. With these increases in revenue, and appropriations that keep up with FDA's actual cost increases, it is expected that FDA will be able to continue to meet the PDUFA III goals that are incorporated into PDUFA IV, as well as the enhanced goals agreed to for PDUFA IV.

PDUFA Goals

The goals for PDUFA IV are challenging, diverse, and resource intensive. Many of the goals require the development of guidance documents and databases to track performance. The development of infrastructure and tools necessary to enhance electronic application receipt and review is also required. The following table provides an overview and comparison of the major goals by the end of PDUFA I, PDUFA II, PDUFA III, and PDUFA IV. Some of the goals are phased in gradually over time; for phased-in goals, only the goal for the final year of PDUFA IV, FY 2012, is reflected in this summary table. For more detail on the actual goals and FDA's performance, see FDA's latest Performance Report on the Internet at http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/UserFeeReports/PerformanceReports/default.htm. In addition to the summarized goals described below, over the five-year PDUFA IV period, FDA is also committed to the development and publication of 7 guidance documents, ongoing scientific collaboration, and improvements in performance management over the 5 years of PDUFA IV.

Summary Comparison of Goals at the End of PDUFA I, II, III, and IV

<table>
<tr><th>Goal</th><th>PDUFA I</th><th>PDUFA II</th><th>PDUFA III</th><th>PDUFA IV</th></tr>
<tr><td>Complete review of priority original new drug and biologic applications and efficacy supplements</td><td colspan="4">90% in 6 months</td></tr>
<tr><td>Complete review of standard original new drug and biologic applications and efficacy supplements</td><td>90% in 12 months</td><td colspan="3">90% in 10 months</td></tr>
<tr><td>Complete review of manufacturing supplements</td><td>90% in 6 months</td><td colspan="3">90% in 4 months if prior approval needed, otherwise 90% within 6 months</td></tr>
<tr><td>Complete review of resubmitted new drug and biologic applications</td><td>90% in 6 months</td><td colspan="3">90% of class 1 in 2 months and 90% of class 2 in 6 months</td></tr>
<tr><td>Complete review of resubmitted efficacy supplements</td><td>No Goal</td><td>90% in 6 months</td><td colspan="2">90% of class 1 in 2 months and 90% of class 2 in 6 months</td></tr>
<tr><td>Discipline review letters for pre-submitted "Reviewable Units" of new drug and biologic applications</td><td colspan="2">No Goal</td><td>90% in 6 months *</td><td>No Goal</td></tr>
</table>

Goal	PDUFA I	PDUFA II	PDUFA III	PDUFA IV
Report of substantive deficiencies (or lack thereof)	No Goal		90% within 14 days of filing date *	In new PDUFA IV First Cycle Review Goal
Respond to industry requests for meetings	No Goal	90% within 14 days		90% within 14 days (Type A) or 21 days (Type B or C)
Meet with industry within set times	No Goal	90% within: 30 days (Type A); 60 days (Type B); or 75 days (Type C)		
Provide industry with meeting minutes	No Goal	90% within 30 days		
Communicate results of review of complete industry responses to FDA clinical holds	No Goal	90% within 30 days		
Resolve major disputes appealed by industry	No Goal	90% within 30 days		
Complete review of special protocols	No Goal	90% within 45 days		
First Cycle Review—communicate substantive review issues and notification of review timeline	No Goal			90% of substantive review issues & planned review timeline within 14 calendar days after the 60 day filing date *
Electronic application receipt and review	No Goal	In place by the end of FY 2002	Enhanced by the end of FY 2007	Automated review environment by end of FY 2012

* Items noted with an asterisk are phased in gradually over time. Only the goal for the final year is shown here.

Assumptions

Throughout this plan there are a number of tables. The numbers in the tables may not always add due to rounding.

The plan to utilize the PDUFA IV additional revenues to meet the challenging PDUFA IV goals is based on 14 major assumptions. A discussion of each of these assumptions follows.

1. Inflation and Inflation Adjustments

The statute provides for annual adjustment of revenues for the costs of inflation after FY 2008. The inflation adjustment is the greater of: (1) the total percentage change that occurred in the Consumer Price Index (CPI) for all urban consumers for the 12 month period ending June 30 preceding the beginning of the fiscal year for which fees are being established; (2) the total percentage change for the previous fiscal year in pay for Federal employees stationed in the Washington DC metropolitan area; or (3) the average annual change in the cost, per full-time equivalent position of the Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions, for the first 5 years of the preceding 6 fiscal years. The third condition above is new, and was added by PDUFA IV, because the previous adjustments did not keep pace with FDA's actual cost increases per paid staff year. It was expected, when this change was added, that this provision would result in a higher inflation adjustment than had been made in the past, when only the first 2 conditions were included in the law. The adjustment made each fiscal year by this subsection will be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 2008.

For FY 2009, the inflation adjustment factor was 5.64 percent, and for FY 2010 the inflation adjustment factor was 5.54 percent. Both of these were the average annual change in the cost, per full-time equivalent position of the Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions, for the first 5 years of the preceding 6 fiscal years. The specified amount for Federal pay was 4.49 percent and 4.78 percent respectively—the rate of increase for employees in the Washington DC area that took place in January 2008. Both of these are greater than the CPI change for the 12-month period ending June 30, 2008 and 2009—which was 5.05 percent and negative 1.43 percent respectively. For purposes of this plan 5.64 and 5.54 percent will be rounded to the nearest tenth of a percent (5.6 percent) and this plan will use that amount (5.6 percent) as the estimated inflation adjuster to apply to FY 2009 and to each subsequent year. This is unchanged from the amount used in the original plan of September 2008.

The table below uses these values, adding them on a compounded basis to each successive year, as the statute directs. The value on the last line of the table is the estimated amount by which statutory fee revenues will be increased each year by of the statutory inflation adjustment.

Inflation Adjustment Estimates

Fiscal Year	2008	2009	2010	2011	2012
Annual Inflation	***NA***	**5.6%**	**5.6%**	**5.6%**	**5.6%**
Cumulative Inflation	***NA***	**5.6%**	**11.51%**	**17.76%**	**24.35%**

2. Workload and Workload Adjustments (Major change from September 2008 Plan)

The statute also provides for annual adjustment of revenues each year beginning in FY 2009 for increases in workload for the process of the review of human drug applications. This adjustment has been modified with PDUFA IV and was implemented for the first time when fees for FY 2009 were set in August of 2008. It is updated now based on 2 years of experience with this workload adjustment.

The workload adjuster will use as its base the average number of various types of applications received for the five-year period ending on June 30, 2007. The number of human drug applications will be adjusted for changes in review activities (number of meetings per IND/BLA, annual reports per NDA/BLA/ and labeling supplements per NDA/BLA). For each fiscal year after FY 2009, FDA will compare base workload numbers for each type of application to the average number of applications of each type for the most recent five-year period, and assign a weighting factor to represent the portion of drug review workload represented by each type of application. If the workload for the most recent five years is higher than the five-year average for the base period, then revenues will be increased proportionately. The statute directs that the adjustment may not result in fee revenues for a fiscal year that are less than the inflation adjusted fee revenues for the fiscal year, and that the adjustment made in FY 2009 may not increase revenues by more than 2 percent.

The workload adjuster that was calculated for FY 2009 and published in the Federal Register on August 1, 2008 was 2.98 percent. The workload adjuster that was calculated for FY 2010 and published in the Federal Register on August 3, 2009 was 6.82 percent. The average yearly increase over the first 2 years (6.82 percent divided by 2) was 3.41 percent. FDA is adding 3.4 percent to the FY 2010 adjustment for each of the remaining two years, and the resultant workload adjustment estimates are shown in the table below. Only the FY 2009 value is the same as it was in the plan as originally published. This is a significant change form the initial PDUFA IV 5-Year plan of September 2008.

Workload Adjustment Estimates

Fiscal Year	2008	2009	2010	2011	2012
Workload Adjustment	***NA***	**3.00%**	**6.82%**	**10.23%**	**13.64%**

3. Revenue Levels and Adjustments

PDUFA IV specifies that the fee revenue amount for FY 2008 for all fees is $392,783,000 specified in 21 U.S.C. 379h(b)(1)(A). The statute specifies that $354,893,000 of this base amount is to be adjusted for workload in accordance with the workload adjustment provisions that were in effect for FY 2007, except that the adjustment for investigational new drug workload is based on the number of INDs with a submission in the previous 12 months rather than on the number of new commercial INDs submitted in the same 12 month period (see 21 U.S.C. 379h(b)(1) and (3)). FDA published that adjustment and the calculations and data that support it in the Federal Register on October 12, 2007 beginning at page 58103. This resulted in an increase of 11.73 percent, or $41,629,000, rounded to the nearest thousand dollars, for a total adjusted base amount of $434,412,000. The statute also specifies that an additional amount for drug safety (see 21 U.S.C. 379h(b)(4)) be added each year.

The table below shows the statutorily specified amounts for each year, including the drug safety addition, before inflation and workload adjustments are made.

PDUFA IV Statutory Revenue Levels Before Inflation & Workload Adjustments

Fiscal Year	2008	2009	2010	2011	2012
Statutory Base Amount	$392,783,000	$392,783,000	$392,783,000	$392,783,000	$392,783,000
Base Adjustment	$41,629,000	$41,629,000	$41,629,000	$41,629,000	$41,629,000
SUBTOTAL	$434,412,000	$434,412,000	$434,412,000	$434,412,000	$434,412,000
Drug Safety Addition	$25,000,000	$35,000,000	$45,000,000	$55,000,000	$65,000,000
Total	**$459,412,000**	**$469,412,000**	**$479,412,000**	**$489,412,000**	**$499,412,000**

These statutory revenue levels are to be adjusted for inflation after FY 2008. When the inflation assumptions described in Assumption 1 are applied to the statutory revenue levels above, the inflation adjusted revenue levels that result, adjusted to the nearest thousand dollars, are set forth in the table below:

PDUFA IV Inflation Adjusted Revenue Levels Each Year

Fiscal Year	2008	2009	2010	2011	2012
Base Amount	**$459,412,000**	**$469,412,000**	**$479,412,000**	**$489,412,000**	**$499,412,000**
Inflation Adj.	0.00%	5.60%	11.51%	17.76%	24.35%
Total	**$ 459,412,000**	**$ 495,699,000**	**$ 534,592,000**	**$ 576,332,000**	**$ 621,019,000**

The inflation adjusted revenue levels are to be adjusted again for workload (21 U.S.C. 379h(c)(2)). As stated in Assumption 2, above, the workload adjustment is being made as 3.0 percent for FY 2009, 6.82 percent for FY 2010 (as stated in the Federal register notice of FY 2010 fee amounts published on August 3, 2009), and increased each subsequent year by 3.41 percent (the average annual workload adjustment during the first 2 years of PDUFA IV). The total dollar amounts in the table below are rounded to the nearest thousand dollars.

PDUFA IV Workload and Inflation Adjusted Revenue Levels Each Year

Fiscal Year	2008	2009	2010	2011	2012
Inflation Adj. Amt	**$459,412,000**	**$495,699,000**	**$534,592,000**	**$576,332,000**	**$621,019,000**
Workload Adj.	*NA*	3.0%	6.82%	10.23%	13.64%
Total	**$459,412,000**	**$510,570,000**	**$ 571,051,000**	**$ 635,291,000**	**$ 705,726,000**

The statute specifies that one-third of the revenue is to come from application fees, one-third from annual establishment fees, and one-third from annual product fees (21 U.S.C. 379h(b)(2)). The table below takes the total amount of fee revenue planned for each year and divides that number by 3, so that one-third of the revenue amount is estimated to come from application fees, one-third from establishment fees and one-third from product fees.

PDUFA IV Inflation and Workload Adjusted Revenue Levels Each Year and Fee Source

Fiscal Year	2008	2009	2010	2011	2012
Total Amount	**$459,412,000**	**$ 510,570,000**	**$ 571,051,000**	**$ 635,291,000**	**$ 705,726,000**
Applications	$153,137,333	$ 170,190,000	$ 190,350,333	$ 210,763,667	$ 235,242,000
Establishments	$153,137,333	$ 170,190,000	$ 190,350,333	$ 210,763,667	$ 235,242,000
Products	$153,137,333	$ 170,190,000	$ 190,350,333	$ 210,763,667	$ 235,242,000

Some numbers in the table may not add due to rounding.

4. Anticipated Collections

The two-thirds of PDUFA fee revenues that come from establishment fees and product fees are relatively stable, and can be counted on each year. However, the one-third of fee revenues that comes from application fees has proven fairly volatile and can fluctuate widely from year to year. In two of the five years of PDUFA II, fee revenues fell below anticipated collections. Because of this volatility, FDA only allocated 80% of the anticipated application fee revenues each year during PDUFA III.

The table below shows the difference in allocations over the 5 years of PDUFA IV if FDA allocates 100% of the anticipated application fee collections and if FDA allocates only 80% of the anticipated application fee collections.

Difference between Allocating 100% and 80% of Planned Application Fees

Fiscal Year	2008	2009	2010	2011	2012	5-Year Total
100% Allocation	$153,137,333	$170,190,000	$190,350,333	$211,763,667	$ 235,242,000	**$960,683,333**
80% Allocation	$122,509,867	$136,152,000	$152,280,267	$169,410,933	$188,193,600	**$768,546,667**
Difference	**$ 30,627,467**	**$34,038,000**	**$38,070,067**	**$42,352,733**	**$47,048,400**	**$192,136,666**

Some numbers in the table may not add due to rounding.

If FDA only allocated 80% of the anticipated application fee revenues each year for the 5 years of PDUFA IV, it would allocate a total of $192.1 million less than FDA hopes to collect.

However, FDA experience indicates that it is very unlikely that FDA collections will fall short of anticipated collections in more than 2 or 3 of the 5 years of PDUFA IV. In addition, FDA is began PDUFA IV with over $130 million in carryover balances on hand. Therefore, in developing plans for the 5 years of PDUFA IV, FDA will routinely count on receiving and spending 100% of the establishment, product, and application fee revenues each year. If experience over the initial years of PDUFA IV proves this to be an imprudent assumption, future updates of the plan may alter this assumption. Anticipated total annual collections, and amounts available for allocation, are shown in the table below:

Anticipated PDUFA IV Collections

Fiscal Year	2008	2009	2010	2011	2012
Product Fees	$153,137,333	$170,190,000	$190,350,333	$211,763,667	$ 235,242,000
Establishment Fees	$153,137,333	$170,190,000	$190,350,333	$211,763,667	$ 235,242,000
Application Fees	$153,137,333	$170,190,000	$190,350,333	$211,763,667	$ 235,242,000
Total	$ 459,412,000	$ 510,570,000	$ 571,051,000	$ 635,291,000	$ 705,726,000

Some numbers in the table may not add due to rounding.

Revenues at this level will be planned and allocated. If less than 100% of the application fee revenues are collected, the agency will utilize the PDUFA carryover balances to cover any shortfalls. This plan results in minimal carryover balances each year.

5. PDUFA IV Fee Base

The fees collected during PDUFA III funded activities that became an integral part of FDA's resources for reviewing human drug applications are referred to as the PDUFA III Fee Base. Before enactment of PDUFA IV, FDA estimated that in FY 2007, the last year of PDUFA III, before considering the funds added for the PDUFA III workload adjustment, FDA would spend a total of $305,455,400 from PDUFA fees to fund a total of 1,464 FTE, over and above the FTE level funded from appropriations. This was considered the PDUFA III Fee Base, and was the starting point for estimating the PDUFA IV base levels.

This funding and FTE level was substantially less than FDA needed to do the work that FDA had agreed to in the PDUFA III performance goals. The fact that the FTE levels were lower than the levels FDA needed were due to several factors that the PDUFA IV statute remedied in setting the PDUFA IV Fee Base. They included:

- The need for a cost increase going into FY 2008 to cover the increased FDA pay and benefit costs, which had increased at an average rate of 5.8% each year for the previous 5 years. $17,716,413 was added to the PDUFA IV fee base for these costs
- FDA had allocated funds each year of PDUFA III that supported 75 fewer FTE than originally planned for PDUFA III, out of caution that application fee revenues fluctuated substantially from year to year, and could not be counted on to pay for all of the planned FTE. It was agreed that carryover balances were sufficient at the end

of PDUFA III (the beginning of PDUFA IV) to cover shortfalls in application fees that might occur for up to 3 or 4 years of PDUFA IV, so FDA should fully allocate the FTE needed in PDUFA IV.

- The workload adjustment for PDUFA III was conservatively calculated comparing the latest 5 years with the 5 years of PDUFA II. The adjustment would be the greatest only after the end of FY 2007 because for the first time it would not contain any of the base years in the most recent 5 years. Rather than specifying a number for this adjustment, the PDUFA IV statute called for calculating this number after the end of FY 2007 based on actual data, and embedded the methodology for determining the PDUFA IV Fee base in the statute. Based on the data and this methodology, a total of $41,629,000 was added to the PDUFA fee base when FDA published the PDUFA IV fees for FY 2008 in the *Federal Register* on October 12, 2007. That amount should fund a total of 180 more FTE for the drug review process each year of PDUFA IV.
- The PDUFA III workload adjuster had flaws in that it did not adequately increase to cover FDA's increase in workload associated with the increased number and complexity of meetings associated with the drug review process over the course of PDUFA III. To address this, a total of $20 million was added to the PDUFA IV fee base to fund a total of 87 additional FTE for work in the review process. In addition, a modification was made to the workload adjustment to remedy this situation in PDUFA IV.
- Finally, the mechanisms of PDUFA III did not provide increased funding to FDA for rent and rent related costs to keep pace with increasing rent and building security costs. To compensate for this, $11,721,000 was added to the PDUFA IV fee base.

The table below summarizes the FY 2008 PDUFA IV fee base before program increases:

PDUFA IV Fee Base before Program Increases

Fiscal Year	**2008**	
	Dollars	**FTE**
PDUFA III in 2007 Before Workload Adjustment	$305,455,400	1,464 [1]
Inflation Adjustment for 2008 (5.8%)	$17,716,413	
FTE Increase (Planning on full Application Fee receipts)		75
Adjustment for PDUFA III Workload Adjustment	$41,629,000	180
Adjustment for Increased Meeting Workload	$20,000,000	87
Adjustment for Rent costs	$11,721,000	
PDUFA IV Fee Base before Program Increases	**$396,521,813**	**1,806**

1 The actual number of FTE paid from fees in FY 2007 was 1516, but that number included those paid from funds generated by the workload adjustment. In making these estimates, the FTE paid from workload adjustment revenues were not counted, because the workload adjustment was separately calculated.

6. PDUFA IV Program Increases

There are 4 specific sets of program increases for PDUFA IV. In the discussion below these increases are described with the FY 2008 level of funding. The first 3 areas are to increase each year by the inflation and workload adjustment discussed in the assumption 1 and 2 above. The 4th area is to increase by an additional $10 million each year, and then is to be increased by the inflation and workload adjustment. These increases are:

- $4,600,000 and 20 FTE for Critical Path projects.
- $29,290,000 and 82 FTE for enhanced drug safety and risk management.
- $4,000,000 for IT Enhancements.
- $25,000,000 and 81 FTE for an additional drug safety increase directed by Congress. This is the only program area that has specific increases each year. The specific additional increase each subsequent year is $10 million, plus inflation since 2008. The plan assumes that 75 percent of the funds for this increase go for allocated for additional staff and operating support each year, and 25 percent of the funds are allocated for contract support. This assumption is subject to modification over time, allowing more or less funds to go for contract support, with a corresponding adjustment in FTE levels for any modification that may be made.

The table below summarizes these initiatives and the dollars and FTE associated with them, including the additional $10 million for Drug Safety activities each year, inflation increases, and workload adjustment increases over the 5 years of PDUFA IV. The only change from the September 2008 plan is the increase in dollars and FTE related to the workload adjustment in FY 2010, 2011, and 2012.

PDUFA IV Fee Revenue Estimates-Including Program Increases, Inflation, & Workload Increases
Dollars in Thousands

Fiscal Year	2008		2009		2010		2011		2012	
	Dollars	FTE	Dollars	FTE	Dollars	FTE	Dollars	FTE	Dollars	FTE
PDUFA III Base in 2007	$ 305,455	1464								
Inflation Asjustment for 2008 (5.8%)	$ 17,716	0								
FTE Increase		75								
Increase for Meeting Workload	$ 20,000	87								
Adjustment for Rent Costs	$ 11,721	0								
PDUFA IV Base Workload Adjustment	$ 41,629	180								
PDUFA IV Base Before Increases	**$ 396,522**	**1806**	**$ 418,727**	**1806**	**$ 442,161**	**1806**	**$ 466,944**	**1806**	**$ 493,075**	**1806**
PDUFA IV Increases										
Critical Path	$ 4,600	20	$ 4,858	20	$ 5,129	20	$ 5,417	20	$ 5,720	20
Increase Drug Safety	$ 29,290	82	$ 30,930	82	$ 32,661	82	$ 34,492	82	$ 36,422	82
IT Enhancements	$ 4,000		$ 4,224	0	$ 4,460	0	$ 4,710	0	$ 4,974	0
Congressional Drug Safety Addition	$ 25,000	81	$ 36,960	113	$ 50,180	145	$ 64,768	177	$ 80,828	209
Workload Adjuster			$ 14,871	62	$ 36,459	144	$ 58,959	220	$ 84,707	300
PDUFA IV Increases	**$ 62,890**	**183**	**$ 91,843**	**277**	**$ 128,890**	**391**	**$ 168,346**	**499**	**$ 212,651**	**611**
PDUFA IV Total--Rounded to $1000	**$ 459,412**	**1,989**	**$ 510,570**	**2,083**	**$ 571,051**	**2,197**	**$ 635,290**	**2,305**	**$ 705,726**	**2,417**
								5-Year Total	**$ 2,882,048**	

Numbers may not add due to Rounding

7. All Statutory Triggers Will Be Met

The law allows FDA to collect and spend PDUFA IV revenues each year only if three specific

conditions are met. This plan assumes that each of the three statutory conditions will be met each year:

- Total FDA appropriations each year (exclusive of user fees and rent payments to GSA) must total at least as much as FDA received in FY 1997, $820 million, adjusted for inflation at the rate of change in the Consumer Price index between October 1996 and October of the year prior to the beginning of the fiscal year. For FY 2009 and later, the chart below estimates that this will be a change of 4 percent each year. The assumed rates may be revised in future updates of this plan based on more recent actual rates of change. The estimates are as follows:

Fiscal Year	1997 Amount ($ Millions) Less Rent and User Fees	Est. Adjustment Factor (Actual factor for FY 2008, estimated for later years at 4% increase)	Minimum Appropriation ($ Millions)	Actual Appropriation ($Millions) Less Rent and Fees
2008	$820	1.3199	$1,082	$1,761.6
2009	$820	*1.4276*	$1,082	$1,883.5
2010	$820	*1.4847*	$1,082	
2011	$820	*1.5441*	$1,082	
2012	$820	*1.6058*	$1,082	

FDA meets this trigger consistently, even though for most years since FY 1997 FDA did not receive increases to cover the cost of pay increases and inflation for its core programs—which was the original intent of this trigger. FDA meets this trigger primarily because FDA has received appropriation increases earmarked for specific initiatives since FY 1997 (e.g., food safety, counter-terrorism, etc.).

- Each year FDA must actually spend at least as much from appropriations on the human drug review process as it spent from appropriations on this process in FY 1997, adjusted for inflation. For FY 2009 and later, the chart below assumes that this will be a change of 4.0 percent each year. The assumed rates may be revised in future updates of this plan based on more recent actual rates of change. The estimates are as follows:

Fiscal Year	1997 Amount Spent on Drug Review from Appropriations	Adjustment Factor (Actual factor for FY 2008, and est. at	Minimum Drug Review Spending from Appropriations	Actual Drug Review Spending from Appropriations

	($ Millions)	4% each later year)	($ Millions)	($Millions)
2008	$148	1.3199	$195	$263
2009	$148	*1.4276*	$211	
2010	$148	*1.4847*	$220	
2011	$148	*1.5441*	$228	
2012	$148	*1.6058*	$238	

If FDA spending from appropriations on the drug review process is less than 5 percent of the specified minimum above, no fees may legally be collected or spent for the year. FDA will not know exactly how much it has spent from appropriations until after the end of the fiscal year when final accounting reports are prepared and process costs can be calculated. FDA plans to spend this minimum from appropriations each year. In years when FDA programs do not receive appropriations to cover costs of inflation and mandatory pay increases, core FDA programs other than drug review may have to be reduced to assure that appropriated spending for drug review meets the requirements of this trigger.

PDUFA fee revenues may be collected and spent only to the extent provided each year in FDA's appropriation. If collections in aggregate for the first 4 years of PDUFA IV exceed appropriations in aggregate over the same period, the surplus can be kept by FDA but must be used to reduce anticipated collections in the final year of PDUFA IV, FY 2012.

Appropriations, Collections, and Overages as of September 30, 2008

Fiscal Year	PDUFA Fees Provided in Appropriations ($Millions) [1]	PDUFA Fees Actually Collected ($Millions)	Overage, if Any ($Millions)
2008	$459.4	$472.5	$13.1
2009			
2010			
2011			
2012			

[1] Updates of the plan, if any, will add amounts appropriated in subsequent years and amounts actually collected each year will be added to this table.

8. Human Resources May Be Acquired By Contracting

To develop cost estimates, it was assumed that human resources would be acquired by hiring additional employees. The centers and ORA are not constrained in how necessary additional human resources are acquired. They are encouraged to utilize contract support any time it is more practical or cost effective than hiring.

9. Estimated FTE Resources from Appropriations

In 1992, before PDUFA was enacted, appropriations funded a total of 1,277 FTE dedicated to the process of human drug review, as defined in PDUFA. Over the course of PDUFA III, appropriated resources did not fund as many FTE as they did in FY 1992, before PDUFA was enacted, primarily because appropriations increases did not keep pace with the rate of increase in FDA's cost for salary and benefits per FTE—which increased at an average cost of 5.6 percent per year over the 5 years of PDUFA III. As a result, by the last year of PDUFA III, appropriations funded a total of 1,222 FTE, while fees funded a total of 1,516 FTE.

For this plan, FDA is assuming that its appropriations, exclusive of user fees, will increase at an annual rate of 4 percent, compounded—although this figure is greater than the appropriated increases for inflationary costs over the past 5 years. As stated in assumption 1, FDA is also assuming that costs per FTE continue to increase at a rate of 5.6 percent compounded per year—the average for the most recent 5 years. Based on these 2 assumptions, FDA assumes that there will still be a small but steady erosion of the number of FTE funded from appropriations each year, as shown in the table below:

Estimate of FTE for Drug Review to be Funded from Appropriations rather than Fees

Assumption \ Fiscal Year	2008	2009	2010	2111	2012
Appropriations Increase at 4%, compounded	4.0%	8.2%	12.5%	17.0%	21.7%
Cost per FTE Increase at 5/6%, compounded	5.6%	11.5%	17.8%	24.4%	31.3%
Difference	-1.6%	-3.4%	-5.3%	-7.4%	-9.7%
Impact on 1,222 Appropriation-Funded FTE	-20	-41	-64	-90	-118
Estimated number of Appropriated FTE	**1202**	**1181**	**1158**	**1132**	**1104**

These estimates are the number of FTE that FDA anticipates will be funded from its Salary and Expenses Appropriation, exclusive of user fees, for each year over the 5 years of PDUFA IV. The estimates are subject to revision in future plan updates, depending on FDA's actual experience with appropriations increases to offset the impact of cost increases.

10. Estimated Total FTE Available for the Drug Review Process

The table below uses the FTE's funded from appropriations (Assumption 9) and the FTE's to be funded from Fees (Assumption 6) to estimate the total FTE level FDA anticipates using each year of the PDUFA IV program.

Projection of Total FTE to be Expended for the Human Drug Review Process ($000)

Source of Funds	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
S&E Appropriations	1,202	1,181	1,158	1,132	1,104
Fees from Industry	1,989	2,083	2,197	2,305	2,417
Total FTE	3,191	3,264	3,355	3,437	3,521

11. Estimated Total Dollars Available for the Drug Review Process

FDA is assuming that amounts spent from appropriations will increase at 4 percent per year, to keep up with most but not all cost increases. Adding this amount to the amount FDA expects to spend from PDUFA fees (Assumption 4), by the final year of PDUFA IV, spending on the process for the review of human drug applications is expected to increase to about $949 million, as reflected in the table below. This is an increase of about 65 percent, or $374 million, compared with the $575 million FDA spent on the process for the review of human drug applications in FY 2007, the last year of PDUFA III.

Projection of Total Spending for the Human Drug Review Process ($000)

Source of Funds	FY 2007 Actuals	FY 2008 Estimate	FY 2009 Estimate	FY 2010 Estimate	FY 2011 Estimate	FY 2012 Estimate
S&E Appropriations	$254,576	$264,759	$275,349	$286,363	$297,818	$309,731
Fees from Industry	$320,430	$459,412	$510,570	$571,051	$635,290	$705,725
Total Funds	**$575,006**	**$724,171**	**$785,919**	**$857,414**	**$933,108**	**$1,015,456**

12. Resources Are Allocated To Assure Performance Goals Are Met

These resources are available to FDA to assure that the agency has the additional resources it needs to meet the performance goals negotiated for PDUFA IV. The resources are being allocated with the expectation that all of the performance goals that were agreed to when PDUFA IV was reauthorized will be met. This plan provides the framework for fund allocations each year, to assure that funds are made available on a timely basis to all components involved in the process for the review of human drug applications at the beginning of each fiscal year.

13. Plan Will Be Reassessed Annually

All estimates in the plan are subject to review and reassessment each fiscal year as actual amounts for appropriations, workload, and revenue for the previous year are available and better estimates for the next year's revenues are possible. Of course, adjustments will have to be made based on these assessments. The plan will continue to have value as the baseline from which future changes will be made. Depending on the magnitude of the adjustments, FDA may decide to publish additional updates of this plan during PDUFA IV.

14. Fee Revenue Annual Appropriations Amounts

The amount appropriated to FDA from PDUFA fee revenue each year serves two purposes. First, it permits FDA to spend fee revenues that year. Second, the appropriated amount sets an upper limit on the amount that FDA may collect and spend for that fiscal year.

The fee revenue that FDA receives form establishment and product fees is fairly stable form year to year, but the amount that FDA collects from application fees is quite variable from year to year. The mechanism that FDA uses to estimate number of full application equivalents (FAEs) that will pay a fee for each fiscal year is based on the average number of FAEs that FDA actually received in the most recent 5-year period. The table below shows the projections at the beginning of the fiscal year, and the actual number collected for each fiscal year from FY 2001.

Estimated Full Application Equivalents When Fees Were Set before the Fiscal Year and Actual FAE Receipts at the End of the Fiscal Year

Fiscal Year	2001	2002	2003	2004	2005	2006	2007	2008
Actual Fee-Paying FAEs Received	126.6	132.1	119.5	145.1	121.5	136.7	134.4	141.0
Estimated FAEs When Fees were Set based on 5-Year Avg.	163.5	158.3	139.3	140.0	138.1	129.0	131.0	130.0
Difference	-36.9	-26.2	-19.8	5.1	-16.6	7.7	3.4	11.0
Percent Difference	-22.6%	-16.6%	-14.2%	3.6%	-12.0%	6.0%	2.6%	8.5%

As this table shows, FDA actual FAE receipts have varied from 22.6 percent below FDA's estimate to 8.5% above FDA's estimate. It is not possible to exactly predict the number of FAEs that FDA will receive each year.

Since the amount appropriated to FDA from PDUFA fee revenue sets an upper limit on the amount of fee revenue that FDA may keep and spend each year, FDA's appropriation each year should be slightly higher than its fee revenue estimate made before the beginning of the fiscal year. If FDA collects less than the fee estimate at the beginning of the year and less than the fee appropriation, collections rather than appropriations set the upper limit on how much FDA may actually keep and spend. If FDA collects more than fee estimates at the beginning of the year, however, a slightly higher fee appropriation will permit FDA to keep and spend the higher collections in order to respond to a very real surge in review workload that caused the increased collections—a unexpected increase in the number of applications that FDA must review in accord with PDUFA goals.

The PDUFA workload adjuster is a lagging adjustment dampened by averages over 5 years and will not help with the sudden increases in the number of applications to be reviewed in the current fiscal year. For this reason, over most of the history of PDUFA since 1993, actual appropriations have slightly exceeded PDUFA fee revenue estimates made each year. This plan continues the assumption of slightly higher appropriations. Appropriated amounts for PDUFA fee revenue each year are estimated in the table below at 5 percent higher than estimated fee revenues for each year, to provide FDA with the ability to cope with surges in application review workload should that occur. The following table shows FDA's PDUFA fee revenue estimates for the 5 years of the plan, and projects the appropriated amounts for PDUFA fee revenue each year at 5 percent higher that the estimated fee revenue.

Estimated PDUFA Fee Revenue and Appropriations from PDUFA Fee Revenue ($000)

Fiscal Year	2008	2009	2010	2011	2012
Planned Fee Revenue	$459,412	$510,570	$570,051	$635,291	$705,726
Estimated Appropriations		**$536,099**	**$599,604**	**$667,056**	**$741,012**

These calculations were made after the FY 2010 fee revenues were published in the Federal Register in August of 2009. Both the planned revenue amounts and the estimated appropriation amounts will need to be recalculated each year in August after the fees for the next fiscal year have been published. These revised amounts will reflect updated actual calculations for both inflation and workload adjustments as reflected in the August Federal Notice publication of fees.

Planning Process

The planning process for meeting new PDUFA IV goals began during discussions with stakeholders in the last year of PDUFA III. The ability to continue to meet PDUFA III goals was contingent on receiving enough resources to maintain the PDUFA III fee base plus the resources described in Assumption 5, PDUFA IV Fee Base. As new goals were proposed, resource implications were also estimated and discussed. These ongoing discussions over many months resulted in the PDUFA IV goals sent to Congress on March 16, 2007. The PDUFA IV resource levels and adjusters to achieve these goals were enacted in the PDUFA IV statute.

This PDUFA IV Five-Year Financial Plan is patterned after the five-year plan for PDUFA III. The plan reflects the resources anticipated and FDA plans for investing those resources. The plan is intended to be a dynamic document, and will be updated if necessary for significant changes in circumstances.

In developing this plan, the Office of Management (OM) worked with the Center for Drug Evaluation and Research (CDER), the Center for Biologics Evaluation and Research (CBER), and the Office of Regulatory Affairs (ORA) to integrate their plans into an overall FDA plan. The primary focus of this effort was to ensure sound plans supporting PDUFA IV goals. CDER, CBER and ORA were each asked to reassess essential needs in order to ensure that they meet the PDUFA IV goals.

The complete PDUFA IV Information Technology (IT) Five-Year Plan has been developed and made available separately.

The overall PDUFA IV Five-Year Financial Plan resulting from this process provides a sound blueprint for the investments needed to ensure FDA success with PDUFA IV. The following pages summarize the planned distribution of PDUFA IV funds to each component (CDER, CBER, and ORA, and OC) over the five years of the plan and a summary section on IT, Rent and Central Accounts. At the end there are FDA Plan Summary Tables. The two largest demands continue to be: (1) additional human resources to meet the PDUFA IV goals and (2) IT investments both to enhance paperless application receipt and review and to consolidate IT resources to assure their efficient use.

CDER Plan Summary

CDER plans for FY 2008 and the subsequent fiscal years authorized in PDUFA IV are summarized below, using the PDUFA IV funding base and increase categories.

Increases to the PDUFA IV Funding Base

In FY 2008, CDER plans to increase review staffing by about 220 FTE, just to sustain the work necessary to continue to meet PDUFA III performance goals that are incorporated into PDUFA IV. Under PDUFA III, funding levels did not keep up with increases in workload and therefore CDER employed fewer review staff than needed to meet goals. This led to CDER's inability to meet some goals and to insufficient staffing levels to be able to provide necessary staff development opportunities.

The additional PDUFA IV base funds will be used to hire needed drug review staff and to provide training opportunities to existing staff to sustain performance toward the PDUFA review goals. The additional staff are also necessary to ensure that CDER can address the growing workload associated with increased Investigational New Drug submissions, special protocol assessments, and meeting requests. In addition, the new fee resources allow CDER to ensure that scientists and medical officers have opportunities to participate in and attend professional development and training activities so that they can remain current in scientific and medical technology.

Critical Path

CDER will hire an additional 19 staff in 2008 to work on critical path objectives, and these staff will be supported through FY 2012.

FDA will use the funds to support specific projects to modernize FDA regulatory standards and strategies. Most projects will extensively leverage other Federal, private sector and philanthropic resources to complete the tasks.

To update the regulatory standards and review for new human drugs, FDA will:

- Continue development of public private partnerships to advance biomarker development, understanding of the genetic basis of serious adverse events, predictive safety, and opportunities to improve the conduct of clinical trials.
- Broaden projects with NIH and various other stakeholders to evaluate the effectiveness of individualized dosing using pharmacogenomic information.
- Collaborate on developing new biomarkers for acute cardiovascular risks (i.e., stroke, MI) that can be used to identify and study people at high risk.
- Study additional biomarkers for individualizing cancer treatment, to avoid patient exposure to ineffective therapy, and to increase chances for beneficial response to treatment.

- Develop a pilot process for qualification of biomarkers in CDER.
- Develop guidance on trial design, clinical endpoints, and acceptable claims for several serious rheumatic diseases.
- Develop guidance on advanced clinical trial designs including use of multiple endpoints, adaptive trial and enrichment designs, non-inferiority trial designs and handling of missing data.
- Launch the Sentinel Initiative to provide a national, integrated, electronic mechanism by which FDA will be able to query multiple exiting data sources.
- Modernize the Agency's bioresearch monitoring programs.
- Continue critical efforts on the bioinformatics initiative, including modeling and simulation.
- Promote use of quality systems drug development, regulation, and manufacturing, including developing new methods technologies and standards to improve manufacturing quality.
- Develop risk-based approaches to guide the prioritization of inspections.

Drug Safety /Risk Management

The center will hire an additional 73 staff and $6 million in contract funds in 2008 to work on drug safety/risk management objectives, and these staff and contract funds will be supported through FY 2012.

With these funds, CDER will be able to increase the number of employees dedicated to safety evaluation of marketed medications. CDER will also be able to add resources for adopting new scientific approaches to drug safety, reducing the risk of medication errors, improving the utility of existing tools for detection and prevention of adverse events, and incorporating the new approaches into the Agency's drug safety program.

With these new resources CDER will:

- Develop and periodically update a 5-year plan describing activities that will lead to enhancing and modernizing FDA's drug safety activities/system;
- Assess current and new methodologies to collect adverse event information at various points during the product lifecycle;
- Identify epidemiology best practices and develop guidance(s) describing these practices;
- Expand database acquisition to be used for targeted post-marketing surveillance and epidemiology;
- Develop and validate risk management and risk communication tools; and
- Improve post-market information technology systems.

Further CDER will work to meet its commitments to increase the timely and consistent review

of new drug trade names to prevent name confusion, including:

- Increasing consistency and scientific validity resulting in reduced medication errors associated with name confusion;
- Developing two new guidance documents to industry regarding: 1) contents of a complete submission package; and 2) best practices for naming, labeling and packaging;
- Establishing review goals and timelines;
- Conducting a pilot program to evaluate new Proprietary Name review paradigm; and
- Providing the public the full source code for the Agency's Phonetic and Orthographic Computer Analysis (POCA) tool (used by FDA to assess potential name confusion).

Additional Drug Safety Increase

The center will hire an additional 68 staff in 2008 to work on additional drug safety objectives. Additional staff for this purpose will increase steadily each year, as shown in the table below.

Additional CDER FTE for Additional Drug Safety Increases by Year

Fiscal Year	2008	2009	2010	2011	2012
CDER FTE	68	95	122	149	176

In addition, CDER will have about $5 million available for Congressional drug safety contract initiatives in FY 2008, growing steadily to a total of almost $22 million in FY 2012.

CDER will use these additional resources to increase the Center's capacity for handling new authorities and requirements of the FDA Amendments Act of 2007, including (as examples) efforts associated with implementing Risk Evaluation and Mitigation Strategies (REMS), Post-Market Study/Trial Requirements, Safety Labeling Changes, Active Postmarket Risk Identification, and other provisions.

Workload Adjustment Increases

The September 2008 PDUFA 5-Year Financial Plan reflected a workload adjustment that was made in 2009 (3 percent) and then increased only for inflation each subsequent year. That adjustment funded a total of 46 FTE for CDER in FY 2009, and maintained that same FTE level for the remaining 3 years. This FY 2009 Update to the plan reflects the increase of 6.82 percent in FY 2010, and annual increases at the rate of 3.41 percent for each subsequent year. With these revised assumptions, the workload adjustment funds an additional 65 FTE in FY 2010, for a total of 111 FTE that year. It funds an additional 59 FTE in FY 2011, for a total of 170 FTE in FY 2011. It funds an additional 62 FTE in FT 2012 for a total of 232 FTE in FY 2012 funded from the workload adjustment increases. These additional FTE will help assure that CDER is better able to meet its performance goals.

PDUFA IV Five-Year Financial Plan--2009 Update

CDER Plan Summary Tables--PDUFA IV

Plan for Funds from PDUFA Fee Revenues ($000)

Note: Numbers Are Rounded and May Not Add

Category	2008 Plan	2009 Plan	2010 Plan	2011 Plan	2012 Plan	5-Year Total
Inflation Adjustment Estimate						
Annual Inflation Estimate		5.60%	5.60%	5.60%	5.60%	
Cummulative Inflation Estimate		5.60%	11.51%	17.76%	24.35%	
Estimated Inflation Adjustor		105.60%	111.51%	117.76%	124.35%	
PDUFA III Additive Base						
PDUFA III Additive Base Staff Years	1,065	1065	1065	1065	1065	
Share of unallocated FTE	17	17	17	17	17	
Share of Increase for Meeting Workload (87 total)	66	66	66	66	66	
Share of Increase for Workload Adjustment (180)	137	137	137	137	137	
Total PDUFA IV Base FTE	**1285**	**1285**	**1285**	**1285**	**1285**	
Payroll for PDUFA III Staff Years	$154,299	$162,939	$172,064	$181,700	$191,875	
Operating Support for PDUFA III Base	$27,762	$29,316	$30,958	$32,692	$34,522	
Risk Management Contracts [1]	$5,374	$5,675	$5,992	$6,328	$6,682	
Subtotal	$187,434	$197,930	$209,014	$220,719	$233,079	
Base Additions for PDUFA IV						
Share of Unallocated FTE	$3,007	$3,176	$3,354	$3,541	$3,740	
Share of Increase for Meeting Workload	$11,675	$12,329	$13,020	$13,749	$14,519	
Share of Increase for Workload Adjustment	$24,235	$25,592	$27,026	$28,539	$30,137	
Subtotal	$38,918	$41,097	$43,399	$45,829	$48,396	
Subtotal--PFUFA IV Base	**$226,352**	**$239,027**	**$252,405**	**$266,552**	**$281,469**	**$1,265,805**
PDUFA IV Enhancements Over PDUFA III						
Critical Path Increase	**$3,753**	**$3,964**	**$4,185**	**$4,420**	**$4,667**	**$20,990**
Additional Staff Years	19	19	19	19	19	
Payroll for Additional Staff Years	$2,761	$2,915	$3,078	$3,251	$3,433	$15,438
Operating Support	$993	$1,048	$1,107	$1,169	$1,234	$5,551
Drug Safety/Risk Management Increase	**$20,384**	**$21,525**	**$22,730**	**$24,004**	**$25,348**	**$113,991**
Additional Staff Years	73	73	73	73	73	
Payroll for Additional Staff Years	$11,378	$12,015	$12,688	$13,399	$14,149	$63,630
Operating Support	$3,056	$3,227	$3,407	$3,598	$3,800	$17,087
Contract Support	$5,950	$6,283	$6,635	$7,007	$7,399	$33,274
IT Increase	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
Additional Staff Years						
Payroll for Additional Staff Years						$0
Operating Support						$0
Contract Support						$0
Additional Drug Safety Increase	**$17,720**	**$26,974**	**$37,231**	**$48,577**	**$61,094**	**$191,595**
Additional Staff Years	68	95	122	149	176	
Payroll for Additional Staff Years	$9,890	$14,566	$19,735	$25,438	$31,717	$101,346
Operating Support	$2,749	$3,800	$4,959	$6,237	$7,642	$25,387
Contract Support	$5,081	$8,608	$12,537	$16,901	$21,735	
Workload Adjustment Addition	**$0**	**$9,052**	**$22,900**	**$37,080**	**$53,215**	**$122,246**
Additional Staff Years		46	111	170	232	
Payroll for Additional Staff Years		$7,374	$18,789	$30,389	$43,793	$100,345
Operating Support		$1,678	$4,110	$6,690	$9,422	$21,900
Contract Support						
Subtotal of PDUFA III Additional Staff Years	161	233	325	411	500	
Subtotal PDUFA IV Enhancements	**$41,857**	**$61,515**	**$87,046**	**$114,080**	**$144,324**	**$448,821**
Total PDUFA Additive Funds--CDER	**$268,209**	**$300,542**	**$339,451**	**$380,633**	**$425,792**	**$1,714,626**
Total PDUFA Additive Staff Years--CDER	**1,446**	**1,519**	**1,611**	**1,696**	**1,785**	

[1] Risk Management Contract support for both CDER and CBER is included in the CDER plan.CDER is managing these funds for both centers.

CBER Plan Summary

CBER plans for FY 2008 and the subsequent fiscal years authorized in PDUFA IV are summarized below, using the PDUFA IV funding base and increase categories.

Increases to the PDUFA IV Funding Base

In FY 2008, CBER plans to increase review staffing by about 53 FTE, just to sustain the work necessary to continue to meet PDUFA III performance goals that are incorporated into PDUFA IV. Under PDUFA III, funding levels did not keep up with increases in workload and therefore CBER employed fewer review staff than needed to meet goals. This led to CBER's inability to meet some goals and to insufficient staffing levels to be able to provide necessary staff development opportunities.

The additional PDUFA IV base funds will be used to hire and train needed drug review staff and continue professional development to existing staff. CBER will continue to focus resources on enhancement of the application evaluation process and related performance commitments as well as in PDUFA IV significant expansion of the post-market safety activities.

Drug Safety /Risk Management

The center will hire an additional 4 FTE and utilize $1 million in contract support in 2008 to work on negotiated drug safety objectives, and these staff and contract funds will be supported through FY 2012. The resources will focus on assessing current and new methodologies to collect adverse event information during the product lifecycle and expand database acquisition for targeted post-marketing surveillance

Additional Drug Safety Increase

The center will hire an additional 10 FTE and utilize $378,000 in contract funds in 2008 to work on additional drug safety objectives. Additional staff for this purpose will increase steadily each year, as shown in the table below.

Additional CBER FTE for Additional Drug Safety Increases by Year

Fiscal Year	2008	2009	2010	2011	2012
CBER FTE	10	14	18	22	26

In addition, CBER, will utilize $378,000 in contract funds for this effort in FY 2008, and contract funds will grow steadily to a total of almost $1.3 million in FY 2012.

The work that will be accomplished under this initiative includes taking steps to support and

strengthen its post-market safety activities. CBER is increasing the staff in the Office of Biostatistics and Epidemiology for safety activities. In addition, CBER will continue to include members of the Division of Epidemiology on all new vaccine BLA committees to review pharmacovigilance plans for post-marketing safety studies submitted by manufacturers. CBER has also put in place interdisciplinary product safety teams and will be expanding resources and FTE's to access and analyze health care databases.

Workload Adjustment Increases

The September 2008 PDUFA 5-Year Financial Plan reflected a workload adjustment that was made in 2009 (3 percent) and then increased only for inflation each subsequent year. That adjustment funded a total of 10 FTE for CBER in FY 2009, and maintained that same FTE level for the remaining 3 years. This FY 2009 Update to the plan reflects the increase of 6.82 percent in FY 2010, and annual increases at the rate of 3.41 percent for each subsequent year. With these revised assumptions, the workload adjustment funds an additional 11 FTE in FY 2010, for a total of 21 FTE that year. It funds an additional 11 FTE in FY 2011, for a total of 32 FTE in FY 2011. It funds an additional 12 FTE in FY 2012 for a total of 44 FTE in FY 2012 funded from the workload adjustment increases. These additional FTE will help assure that CBER is better able to meet its performance goals.

PDUFA IV Five-Year Financial Plan--2009 Update

CBER Plan Summary Tables--PDUFA IV

Plan for Funds from PDUFA Fee Revenues ($000)

Note: Numbers Are Rounded and May Not Add

Category	2008 Plan	2009 Plan	2010 Plan	2011 Plan	2012 Plan	5-Year Total
Inflation Adjustment Estimate						
Annual Inflation Estimate		5.60%	5.60%	5.60%	5.60%	
Cummulative Inflation Estimate		5.60%	11.51%	17.76%	24.35%	
Estimated Inflation Adjustor		105.60%	111.51%	117.76%	124.35%	
PDUFA III Additive Base						
PDUFA III Additive Base Staff Years	214	214	214	214	214	
Share of unallocated FTE Increase	3	3	3	3	3	
Share of Increase for Meeting Workload (87 total)	16	16	16	16	16	
Share of Increase for Workload Adjustment (180)	34	34	34	34	34	
Total PDUFA IV Base FTE	**267**	**267**	**267**	**267**	**267**	
Payroll for PDUFA III Staff Years	$28,855	$30,471	$32,178	$33,980	$35,883	$161,367
Operating Support for PDUFA III Base	$3,730	$3,938	$4,159	$4,392	$4,638	$20,856
Subtotal	$32,585	$34,410	$36,337	$38,372	$40,520	
Base Additions for PDUFA IV						
Share of unallocated FTE	$527	$556	$587	$620	$655	
Share of Increase for Meeting Workload	$2,808	$2,965	$3,131	$3,307	$3,492	
Share of Increase for Workload Adjustment	$5,967	$6,301	$6,654	$7,027	$7,420	
Subtotal	$9,302	$9,822	$10,372	$10,953	$11,567	
Subtotal--PFUFA IV Base	**$41,886**	**$44,232**	**$46,708**	**$49,325**	**$52,087**	**$234,238**
PDUFA IV Enhancements Over PDUFA III						
Critical Path Increase	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
Additional Staff Years						
Payroll for Additional Staff Years						$0
Operating Support						$0
Drug Safety/Risk Management Increase	**$1,861**	**$1,965**	**$2,075**	**$2,191**	**$2,314**	**$10,407**
Additional Staff Years	4	4	4	4	4	
Payroll for Additional Staff Years	$646	$682	$720	$761	$803	$3,613
Operating Support	$215	$227	$240	$253	$267	$1,202
Contract Support	$1,000	$1,056	$1,115	$1,178	$1,244	$5,592
IT Increase	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
Additional Staff Years						
Payroll for Additional Staff Years						$0
Operating Support						$0
Contract Support						$0
Additional Drug Safety Increase	**$2,133**	**$3,184**	**$4,324**	**$5,559**	**$6,898**	**$22,098**
Additional Staff Years	10	14	18	22	26	
Payroll for Additional Staff Years	$1,372	$2,021	$2,738	$3,529	$4,400	$14,059
Operating Support	$383	$564	$764	$985	$1,228	$3,925
Contract Support	$378	$599	$822	$1,045	$1,270	
Workload Adjustment Addition		**$1,943**	**$4,450**	**$7,253**	**$10,557**	**$24,203**
Additional Staff Years		10	21	32	44	
Payroll for Additional Staff Years		$1,603	$3,555	$5,720	$8,306	$19,184
Operating Support		$340	$895	$1,533	$2,251	$5,019
Contract Support						
Subtotal of PDUFA III Additional Staff Years	14	28	43	58	74	
Subtotal PDUFA IV Enhancements	**$3,994**	**$7,092**	**$10,848**	**$15,004**	**$19,769**	**$56,707**
Total PDUFA Additive Funds--CBER	**$45,880**	**$51,324**	**$57,556**	**$64,329**	**$71,855**	**$290,945**
Total PDUFA Additive Staff Years--CBER	**281**	**295**	**310**	**325**	**341**	

Note: Some risk Management Contract support for both CDER and CBER is included in the CDER plan.CDER is managing these funds for both centers.

ORA Plan Summary

At this time ORA has no increases planned as a part of implementing PDUFA IV, other than the restoration of 1 FTE to ORA's PDUFA IV additive base—to restore it to the levels of previous years. This should be sufficient to assure that pre-approval inspections are completed in a timely manner.

ORA is able to keep abreast of the increasing workload because fewer pre-approval inspections are being ordered each year. This is occurring because, if a recent inspection has been performed and reflects that the production facility is in compliance, then a pre-approval inspection is waived as part of the application approval process. The table on the next page reflects the cost of the 40 ORA staff years to be paid from fees for each of the next five years.

PDUFA IV Five-Year Financial Plan--2009 Update

ORA Plan Summary Tables--PDUFA IV

Plan for Funds from PDUFA Fee Revenues ($000)

Note: Numbers Are Rounded and May Not Add

Category	2008 Plan	2009 Plan	2010 Plan	2011 Plan	2012 Plan	5-Year Total
Inflation Adjustment Estimate						
Annual Inflation Estimate		5.60%	5.60%	5.60%	5.60%	
Cummulative Inflation Estimate		5.60%	11.51%	17.76%	24.35%	
Estimated Inflation Adjustor		105.60%	111.51%	117.76%	124.35%	
PDUFA III Additive Base						
PDUFA III Additive Base Staff Years	39	39	39	39	39	
Share of unallocated FTE	1	1	1	1	1	
Share of Increase for Meeting Workload (87 total)						
Share of Increase for Workload Adjustment (180-?)						
Total PDUFA IV Base FTE	**40**	**40**	**40**	**40**	**40**	
Payroll for PDUFA III Staff Years	$4,255	$4,493	$4,745	$5,011	$5,291	$23,794
Operating Support for PDUFA III Base	$1,480	$1,563	$1,650	$1,743	$1,840	$8,276
IT Operating Contracts		$0	$0	$0	$0	
Subtotal	$5,735	$6,056	$6,395	$6,753	$7,131	
Base Additions for PDUFA IV		$0	$0	$0	$0	
Share of unallocated FTE	$144	$152	$160	$169	$178	
Share of Increase for Meeting Workload						
Share of Increase for Workload Adjustment						
Subtotal	$144	$152	$160	$169	$178	
Subtotal--PFUFA IV Base	**$5,878**	**$6,207**	**$6,554**	**$6,922**	**$7,310**	**$32,872**
PDUFA IV Enhancements Over PDUFA III						
Critical Path Increase	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
Additional Staff Years						
Payroll for Additional Staff Years						$0
Operating Support						$0
Drug Safety/Risk Management Increase	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
Additional Staff Years						
Payroll for Additional Staff Years						$0
Operating Support						$0
Contract Support						$0
IT Increase	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
Additional Staff Years						
Payroll for Additional Staff Years						$0
Operating Support						$0
Contract Support						$0
Additional Drug Safety Increase	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
Additional Staff Years						
Payroll for Additional Staff Years						$0
Operating Support						$0
Contract Support						$0
Workload Adjustment Addition		**$0**	**$0**	**$0**	**$0**	**$0**
Additional Staff Years						
Payroll for Additional Staff Years						$0
Operating Support						$0
Contract Support						$0
Subtotal of PDUFA III Additional Staff Years	-	-	-	-	-	
Subtotal PDUFA IV Enhancements	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
Total PDUFA Additive Funds--ORA	**$5,878**	**$6,207**	**$6,555**	**$6,922**	**$7,310**	**$32,873**
Total PDUFA Additive Staff Years--ORA	**40**	**40**	**40**	**40**	**40**	

OC Plan Summary

The Office of the Commissioner provides support to the process for the review of human drug applications in a variety of ways. It collects and manages the fee revenue, coordinates the acquisition and management of the additional space, provides contract and acquisition support to the centers, provides IT support, and reports to Congress on the financial aspects of the program each year. It is also responsible for the annual PDUFA performance report to Congress and for assisting with other management responsibilities. Funds for the management of contracts necessary for the continuation of Performance Management from PDUFA III funds ($2.495 million in FY 2008 and with annual inflation adjustments) are also included in the OC totals.

OC personnel necessary to support the drug review process are paid for under the overhead calculation described below.

Overhead Calculation

As FDA developed PDUFA baseline costs in 1993, the Office of the Assistant Secretary for Finance prescribed the formula FDA uses to determine OC overhead costs. For this discussion, OC is used in its larger sense to encompass the several management and staff offices that report to the Commissioner. That formula conforms with generally accepted accounting principles and was found reasonable by Arthur Andersen consultants in subsequent annual audits. The formula is:

Total Costs of OC ÷ (Salary Costs of All of FDA - OC Salary Costs) = Overhead Rate

The salary costs used in this formula do not include the costs of any benefits. At the end of each fiscal year, the Office of Financial Management recalculates this overhead rate. To determine overhead costs attributable to the drug review process activities, this rate is multiplied by the total drug review process salary costs (excluding benefits) for CDER, CBER, and ORA. This is the method used at the end of each year to report the actual costs of the process for the review of human drug applications that may be charged to overhead.

As with all drug review process costs, this overhead has two components: (1) a portion paid from traditional appropriations and (2) a portion paid from fees collected from industry. This plan assumes that OC costs paid from fees will total about 7.9% of the total FY 2008 costs, and this percent decreases steadily each year, to about 7.4 percent by FY 2012.

All overhead costs paid from PDUFA fees are now treated as indirect costs. The fees allocated to overhead are used to pay for the same percent of the costs of all components of the Office of the Commissioner. The table on the next page reflects the estimated cost of OC overhead to be paid from fees for each of the next five years.

Workload Adjustment Increases

The September 2008 PDUFA 5-Year Financial Plan reflected a workload adjustment that was made in 2009 (3 percent) and then increased only for inflation each subsequent year. That adjustment funded a total of 6 FTE for OC in FY 2009, and maintained that same FTE level for the remaining 3 years. This FY 2009 Update to the plan reflects the increase of 6.82 percent in FY 2010, and annual increases at the rate of 3.41 percent for each subsequent year. With these revised assumptions, the workload adjustment funds an additional 6 FTE in FY 2010, for a total of 12 FTE that year. It funds an additional 6 FTE in FY 2011, for a total of 18 FTE in FY 2011. It funds an additional 6 FTE in FY 2012 for a total of 24 FTE in FY 2012 funded from the workload adjustment increases. These additional FTE will help assure that OC is better able to support CDER and CBER in meeting their performance goals.

PDUFA IV Five-Year Financial Plan--2009 Update

OC Plan Summary Tables--PDUFA IV

Plan for Funds from PDUFA Fee Revenues ($000)

Note: Numbers Are Rounded and May Not Add

Category	2008 Plan	2009 Plan	2010 Plan	2011 Plan	2012 Plan	5-Year Total
Inflation Adjustment Estimate						
Annual Inflation Estimate		5.60%	5.60%	5.60%	5.60%	
Cummulative Inflation Estimate		5.60%	11.51%	17.76%	24.35%	
Estimated Inflation Adjustor		105.60%	111.51%	117.76%	124.35%	
PDUFA III Additive Base						
PDUFA III Additive Base Staff Years	199	199	199	199	199	
Share of unallocated FTE	2	2	2	2	2	
Share of Increase for Meeting Workload (87 total)	4	4	4	4	4	
Share of Increase for Workload Adjustment (180)	9	9	9	9	9	
Total PDUFA IV Base FTE	**214**	**214**	**214**	**214**	**214**	
Payroll for PDUFA III Staff Years	$24,293	$25,653	$27,090	$28,607	$30,209	$135,851
Operating Support for PDUFA III Base	$6,433	$6,793	$7,173	$7,576	$8,000	$35,974
Subtotal	$30,725	$32,446	$34,262	$36,182	$38,208	
Base Additions for PDUFA IV						
Share of unallocated FTE	$338	$357	$377	$398	$420	
Share of Increase for Meeting Workload	$676	$713	$753	$796	$840	
Share of Increase for Workload Adjustment	$1,520	$1,605	$1,695	$1,790	$1,890	
Subtotal	$2,534	$2,675	$2,825	$2,983	$3,150	
Subtotal--PFUFA IV Base	**$33,259**	**$35,122**	**$37,087**	**$39,166**	**$41,359**	**$185,992**
PDUFA IV Enhancements Over PDUFA III						
Critical Path Increase	**$169**	**$178**	**$188**	**$199**	**$210**	**$945**
Additional Staff Years	1	1	1	1	1	
Payroll for Additional Staff Years	$136	$143	$151	$160	$168	$758
Operating Support	$33	$35	$37	$39	$42	$187
Drug Safety/Risk Management Increase	**$773**	**$816**	**$861**	**$910**	**$961**	**$4,320**
Additional Staff Years	4	4	4	4	4	
Payroll for Additional Staff Years	$595	$628	$663	$700	$739	$3,325
Operating Support	$178	$188	$198	$209	$221	$995
Contract Support						$0
IT Increase	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
Additional Staff Years						
Payroll for Additional Staff Years						
Operating Support						
Contract Support						
Additional Drug Safety Increase	**$2,376**	**$2,721**	**$3,096**	**$3,505**	**$3,950**	**$15,648**
Additional Staff Years	3	4	5	7	8	
Payroll for Additional Staff Years	$407	$599	$811	$1,046	$1,304	$4,166
Operating Support	$100	$148	$200	$258	$321	$1,027
Contract Support	$1,870	$1,974	$2,085	$2,202	$2,325	
Workload Adjustment Addition		**$1,166**	**$2,462**	**$3,900**	**$5,491**	**$13,019**
Additional Staff Years		6	12	18	24	
Payroll for Additional Staff Years		$962	$2,031	$3,218	$4,530	$10,741
Operating Support		$204	$431	$683	$961	$2,278
Contract Support						
Subtotal of PDUFA III Additional Staff Years	8	15	22	30	37	
Subtotal PDUFA IV Enhancements	**$3,318**	**$4,881**	**$6,608**	**$8,514**	**$10,612**	**$33,932**
Total PDUFA Additive Funds--OC	**$36,576**	**$40,002**	**$43,695**	**$47,680**	**$51,970**	**$219,924**
Total PDUFA Additive Staff Years--OC	**222**	**229**	**237**	**244**	**251**	

Information Technology, Rent and Central Accounts

The funds in three important areas are centrally managed in PDUFA IV. These areas are Information Technology, Rent, and Central Accounts. This section provides a summary of each one, and ends with a chart summarizing the year by year planned spending in each area.

Information Technology

The complete PDUFA IV Five Year Information Technology Plan has been separately made available.

The PDUFA IV agreement builds upon the progress made in PDUFA III and will commit the FDA to develop, implement, and maintain new information systems consistently across all organizational divisions participating in the process for human drug review throughout the product lifecycle. To help meet this goal, there is an ongoing effort to document the business processes in CBER and CDER, building upon the FDA Business Process Framework developed in 2004 and updated in 2006.

The FDA considers the first year of the PDUFA IV timeframe to be a period of considerable transition. The Agency must resolve many near-term planning activities and strategic investment decisions prior to committing resources to future, long-range systems development plans for the out years of PDUFA IV. For example, due to a variety of external pressures, the FDA is conducting studies to determine a strategy for modernizing IT infrastructure and services. Similarly, the FDA is working to shift its IT decision-making and governance to an Agency-wide, less de-centralized model. Further, FDA must resolve security issues with standard, Agency-wide solutions for secure submissions, secure e-mail, and electronic signatures. In the first 12 to 24 months of PDUFA IV, the FDA will focus on completing these plans to ensure that they are developed, published, and widely understood. Once these foundational plans are implemented, the FDA will be in a position to expand planning of specific systems development and infrastructure projects into the PDUFA IV out-years.

This plan represents only a portion of the overall IT work to be accomplished at FDA, but it is imperative that these PDUFA activities map clearly to overall Agency business and IT strategic planning. Several of the strategies must be accomplished not only to meet PDUFA IV IT goals, but also Agency and DHHS goals. The strategies outlined in the plan are presented to show their alignment with overall Department, Agency, and Program goals and objectives. Therefore, the strategies presented here must be applied consistently across the Agency to achieve the maximum benefit of the efforts.

The plan also provides a future-state vision for the FDA standards and technical infrastructure supporting the process for the review of human drugs throughout the product lifecycle. Specifically, this plan details how the FDA intends to:

- strengthen and improve information management within the new drug and biologic products review processes;

- strengthen the IT infrastructure to improve capacity for post market safety data management and analysis;

- improve the FDA's ability to communicate, share, and disseminate information more clearly within the Agency and with other government organizations, the regulated industry, and the American Public; and

- seek more efficient and effective means for supplying technology tools and services to the FDA user community.

The plan will help guide the direction and implementation of IT projects initiated to meet Agency program objectives and specific PDUFA IV IT goals. Among the principal IT planning documents to be developed by the Agency during the PDUFA IV timeframe, the plan will be the mechanism to communicate the steps the FDA plans to take to achieve its objectives to stakeholders, both internal and external to the Agency.

The summary IT/Rent/Central Plan Summary Tables reflect the five-year IT costs in three places. The first is in the top portion of the chart that reflects the PDUFA IV Additive Base Costs—starting with $33.145million in FY 2008. The second place is the Information Technology line, which reflects anticipated expenditures on IT enhancements each year. The last place is near the bottom of the chart where two IT subtotals are given. The IT subtotal for FY 2008 is $40.625 million, increasing to $50.517 million by FY 2012.

Rent and Rent Related Costs

The General Services Administration charges rent to FDA for the Federal buildings that FDA occupies. This rent is charged at different rates depending on the type and location of the space provided. Since rent is an essential support cost for the process for human drug review, part of those charges are paid from appropriations and part from PDUFA fees. Also included in this account are recurring costs that FDA pays directly to non-Federal sources under the delegation of direct lease and service authority. These services include rental of space, and all recurring services for building operations such as overtime utilities, janitorial, guard, and ground maintenance. The amount of rent and rent related costs FDA pays is directly related to the number of employees that must be housed. Under PDUFA III the funds available did not keep pace with the increasing costs of space—particularly with the transition of much of FDA to the

new White Oak campus, and with the substantial increases in facility security costs in the aftermath of September 11, 2001. An adjustment was made in the PDUFA IV Fee Base for rent and rent related costs to address these higher costs in PDUFA IV. In addition, the agency will be hiring additional employees, and the cost of acquiring and maintaining space for those additional employees is reflected in the rent and rent related estimates.

The summary IT/Rent/Central Plan Summary Tables reflect the five year Rent estimates in three places. The first is in the top portion of the chart that reflects the PDUFA IV Fee Base Costs—starting with $12.850 million for rent and $15.799 million for rent related costs in FY 2008. The second place is a separate rent line in each of the enhancement areas. In each enhancement area, the first line shows the cumulative additional staff years associated with the goal area for each year—additional staff years to be hired during PDUFA IV. The number of additional staff years that must be housed each year drives the amount of increased rent each year. The last place is near the bottom of the chart where rent and rent related subtotals are given. The rent subtotal for FY 2008 is $15.252 million, increasing to $22.596 million by FY 2012. The rent related total for FY 2008 is $16.515 million, increasing to $21.536 million by FY 2012. For purposes of this plan, amounts are shown increasing at a steady rate over 5 years. In fact actual amounts spent may be lower in earlier years, but may have spiked cost increases in later years as FDA moves components of the Center for Biologics Evaluation and Research to new facilities on the White Oak Campus.

Central Accounts

The Central Account pays for shared agency-wide services such as telecommunications, training, printing, mail and document management, IT systems including maintenance, employee health units, and other support and miscellaneous services. Like rent, the amount of central account support FDA pays is directly related to the number of employees that must be serviced. PDUFA provides the increased resources for these costs for the additional staff associated with the implementation of PDUFA.

The summary IT/Rent/Central Plan Summary Tables reflect the five-year Central Account estimates in three places. The first is in the top portion of the chart that reflects the PDUFA IV Fee Base Costs—starting with $27.372 million in FY 2008. The second place is a separate central account line in each of the enhancement areas. In each enhancement area, the first line shows the cumulative additional staff years associated with the enhancement area for each year—additional staff years hired during PDUFA IV. The number of additional staff years that must be supported each year drives the amount of increased central account costs each year. The last place is near the bottom of the chart where two central account subtotals are given. The central account subtotal for FY 2008 is $30.475 million, increasing to $41.897 million in FY 2012.

Workload Adjustment Increases

The September 2008 PDUFA 5-Year Financial Plan reflected a workload adjustment that was made in 2009 (3 percent) and then increased only for inflation each subsequent year. That adjustment funded a total of 62 FTE for all of FDA in FY 2009, and maintained that same FTE level for the remaining 3 years. This FY 2009 Update to the plan reflects the increase of 6.82 percent in FY 2010, and annual increases at the rate of 3.41 percent for each subsequent year. With these revised assumptions, the workload adjustment funds an additional 82 FTE in FY 2010, for a total of 144 FTE that year. It funds an additional 76 FTE in FY 2011, for an FDA total of 220 FTE in FY 2011. It funds an additional 80 FTE in FY 2012 for an FDA total of 300 FTE in FY 2012 funded from the workload adjustment increases. These additional FTE requires significant increases in centrally funded amounts that FDA will have to pay for rent, rent related, and central account costs for these additional FTE, which are reflected in the following table.

PDUFA IV Five-Year Financial Plan--2009 Update

IT/Rent/Central Plan Summary Tables--PDUFA IV

Plan for Funds from PDUFA Fee Revenues ($000)

Note: Numbers Are Rounded and May Not Add

Category Estimated Inflation Adjustor	2008 Plan	2009 Plan 105.60%	2010 Plan 111.51%	2011 Plan 117.76%	2012 Plan 124.35%	5-Year Total
PDUFA III Additive Base						
Total PDUFA III Additive Base Staff Years	1464	1464	1464	1464	1464	
Total Additions to PDUFA IV Fee Base	342	342	342	342	342	
	1806	**1806**	**1806**	**1806**	**1806**	
PDUFA III Fee Base						
IT	$33,145	$35,001	$36,961	$39,031	$41,217	
Rent	$9,206	$9,721	$10,266	$10,841	$11,448	
Rent Related	$2,876	$3,037	$3,208	$3,387	$3,577	
Central Accounts	$22,232	$23,477	$24,792	$26,180	$27,646	
PDUFA IV Fee Base Adjustments						
IT	$0	$0	$0	$0	$0	
Rent	$3,644	$3,848	$4,064	$4,291	$4,532	
Rent Related	$12,903	$13,625	$14,388	$15,194	$16,045	
Central Accounts	$5,140	$5,428	$5,732	$6,053	$6,391	
Total PDUFA IV Fee Base						
IT	$33,145	$35,001	$36,961	$39,031	$41,217	
Rent	$12,850	$13,570	$14,330	$15,132	$15,979	
Rent Related	$15,779	$16,663	$17,596	$18,581	$19,622	
Central Accounts	$27,372	$28,905	$30,523	$32,233	$34,038	
Subtotal--PDUFA IV Fee Base before Enhancements	**$89,146**	**$94,138**	**$99,410**	**$104,977**	**$110,856**	**$498,527**
PDUFA IV Enhancements Over PDUFA III						
Critical Path Increase	**$678**	**$716**	**$756**	**$798**	**$843**	**$3,790**
Additional Staff Years	20	20	20	20	20	
IT	$0	$0	$0	$0	$0	
Rent	$273	$288	$304	$321	$339	
Rent Related	$79	$84	$88	$93	$98	
Central Accounts	$326	$344	$363	$384	$405	
Drug Safety/Risk Management Increase	**$6,273**	**$6,624**	**$6,995**	**$7,387**	**$7,800**	**$35,079**
Additional Staff Years	82	82	82	82	82	
IT	$3,480	$3,675	$3,881	$4,098	$4,327	
Rent	$1,093	$1,154	$1,219	$1,287	$1,359	
Rent Relaed	$328	$346	$366	$386	$408	
Central Accounts	$1,372	$1,449	$1,530	$1,616	$1,706	
IT Increase	**$4,000**	**$4,224**	**$4,461**	**$4,710**	**$4,974**	**$22,369**
Additional Staff Years						
IT	$4,000	$4,224	$4,461	$4,710	$4,974	
Rent						
Rent Related						
Central Accounts						
Additional Drug Safety Increase	**$2,771**	**$4,081**	**$5,529**	**$7,127**	**$8,886**	**$28,394**
Additional Staff Years	81	113	145	177	209	
IT	$0	$0	$0	$0	$0	
Rent	$1,036	$1,526	$2,068	$2,666	$3,324	
Rent Related	$329	$484	$656	$846	$1,055	
Central Accounts	$1,406	$2,070	$2,805	$3,615	$4,508	
Workload Adjustment Addition		**$1,656**	**$4,063**	**$6,555**	**$9,438**	**$21,712**
Additional Staff Years		62	144	220	300	
IT		$0	$0	$0	$0	$0
Rent		$1,355	$3,324	$5,363	$7,722	$17,764
Rent Related		$301	$739	$1,192	$1,716	
Central Accounts		$1,054	$2,585	$4,171	$6,006	
Subtotal of PDUFA III Additional Staff Years	183	277	391	499	$611	
Subtotal PDUFA IV Enhancements	**$13,721**	**$17,301**	**$21,803**	**$26,577**	**$31,941**	**$111,343**
Enhancement Subtotal IT	$7,480	$7,899	$8,341	$8,808	$9,302	$41,830
Enhancement Subtotal Rent	$2,402	$4,324	$6,915	$9,636	$12,744	$36,020
Enhancement Subtotal Rent Related	$736	$1,215	$1,849	$2,517	$3,277	$9,594
Enhancement Subtotal Central Accounts	$3,104	$4,917	$7,284	$9,786	$12,625	$37,716
Subtotal IT	$40,625	$42,900	$45,302	$47,840	$50,517	$227,185
Subtotal Rent	$15,252	$17,893	$21,244	$24,768	$28,722	$107,880
Subtotal Rent Related	$16,515	$17,878	$19,445	$21,098	$22,898	$97,834
Subtotal Central Accounts	$30,475	$33,822	$37,807	$42,019	$46,662	$190,784
Total PDUFA Additive Funds--IT-Rent-Centrl	**$102,868**	**$111,439**	**$121,213**	**$131,554**	**$142,797**	**$609,870**
Total PDUFA IV Staff Years	**1,989**	**2,083**	**2,197**	**2,305**	**2,417**	

FDA PDUFA IV Financial Plan Summary

The Agency plan for PDUFA IV is a composite of the plans developed by CDER, CBER, ORA, and OC components. Tables 1-6 on pages 32 and 33 summarize the overall FDA plan. The discussion below summarizes information in each of these tables.

- Table 1 (page 39) shows the total that FDA estimates it will spend from PDUFA fees over each of the next five years. The first six lines of the chart show how the PDUFA IV Fee Base will be allocated by major expense category. (The PDUFA IV Fee Base is the amount spent at the end of PDUFA III, plus the adjustments to that amount made by PDUFA IV as necessary to continue to support the goals of PDUFA III through the 5 years of PDUFA IV.) The chart shows on one line the total amount FDA estimates it will spend on PDUFA IV program enhancements each year—and charts 2 and 3 each give a more detailed breakout of this line. The final line gives the total PDUFA IV estimated costs each year. (Estimated costs each year equal total anticipated collections each year.)

- Table 2 (page 39) shows estimates of how the funds FDA plans to spend for PDUFA IV enhancements (next-to-last line of table 1) will be allocated in each of the next five years, by component, planned to meet PDUFA IV goals. The yearly amounts and totals for CDER, CBER, ORA, and OC on the first four lines are from their individual plans. The next three lines show the amounts for: (1) information technology, (2) rent and rent related, and (3) central accounts. These are necessary to meet PDUFA IV goals and to accommodate the additional staff hired by the centers. The total line allocates all the PDUFA IV enhancement funds FDA expects to spend through FY 2012.

- Table 3 (page 39) shows estimates of how the funds FDA plans to spend for PDUFA IV enhancements (next-to-last line of table 1) will be allocated in each of the next five years, by PDUFA IV enhancement category. About $26 million (4% of the increase) will be spent for critical path initiatives. About $164 million (25% of the increase) is planned for drug safety/risk management enhancements. About $22 million (3% of the increase) is planned for IT/electronic submission enhancements. About 258 million (39% of the increases) is planned for implementing the additional drug safety enhancements. About $195 million (29% of the increases) is planned for additional staff to keep up with workload increases.

- Table 4 and 5 (page 40) summarize the allocation of the total amount available from PDUFA IV fees each year (PDUFA IV Fee Base plus enhancements) will be spent over each of the next 5 years by component (table 4) and by major expense category (table 5). These are similar to table 2 and 3, but include all PDUFA IV fee funds available—not just enhancements. In table 4, by component, CDER will be allocated 59 percent, CBER 10 percent, ORA 1 percent, overhead 8 percent, information technology 8 percent, rent and

rent related costs 7 percent, and central accounts 7 percent. In table 5, by major expense categories, 60 percent of the total PDUFA IV revenues will be dedicated to pay and benefits for staff, 18 percent for operating costs, 8 percent for IT, 7 percent for rent and rent related costs, and 7 percent for central accounts.

- Table 6 (page 40) summarizes the total staff years planned each year for the process for the review of human drug applications, showing the number of staff years paid from the salary and expense appropriations, the number of staff years paid from fees and considered funded by the PDUFA IV fee base, and the number of staff years added over the course of PDUFA IV under this plan.

PDUFA IV Five-Year Financial Plan--2009 Update

FDA Plan Summary Tables--PDUFA IV ($000)

Note: Numbers Are Rounded and May Not Add

Table1: PDUFA IV Fee Base after PDUFA IV Adjustments

Item\Year	2008 Estimate	2009 Estimate	2010 Estimate	2011 Estimate	2012 Estimate	Five-Year Total	Five-Year Percent
Pay and Benefits for Centers/ORA	$226,758	$239,456	$252,857	$267,030	$281,973	$1,268,074	57%
Base Operating Funds--Centers/ORA	$47,359	$50,011	$52,810	$55,770	$58,891	$264,841	12%
OC--Salaries and Operating/Contract $	$33,259	$35,122	$37,087	$39,166	$41,358	$185,993	8%
Information Technology	$33,145	$35,001	$36,960	$39,032	$41,216	$185,353	8%
Rent & Rent Related	$28,629	$30,232	$31,924	$33,714	$35,600	$160,100	7%
Central Accounts	$27,372	$28,905	$30,522	$32,233	$34,037	$153,069	7%
Subtotal--PDUFA II Additive Base	$396,522	$418,727	$442,161	$466,945	$493,075	$2,217,431	100%
Subtotal--PDUFA IV Enhancements	$62,890	$91,843	$128,890	$168,345	$212,650	$664,618	
Total Estimated PDUFA Fees Expended	$459,412	$510,570	$571,051	$635,290	$705,726	$2,882,048	

Table 2: Funds Planned for Enhancements--by Organization or Cost Component

Component\Year	2008 Estimate	2009 Estimate	2010 Estimate	2011 Estimate	2012 Estimate	Five-Year Total	Five-Year Percent
CDER	$41,857	$61,515	$87,046	$114,080	$144,324	$448,821	68%
CBER	$3,994	$7,092	$10,848	$15,004	$19,769	$56,707	9%
ORA	$0	$0	$0	$0	$0	$0	0%
OC--Salaries and Operating/Contract $	$3,318	$4,881	$6,608	$8,514	$10,612	$33,932	5%
Information Technology	$7,480	$7,899	$8,341	$8,808	$9,302	$41,830	6%
Rent & Rent Related	$3,138	$5,539	$8,763	$12,153	$16,021	$45,614	7%
Central Accounts	$3,104	$4,917	$7,284	$9,786	$12,625	$37,716	6%
Total PDUFA IV Enhancements	$62,890	$91,843	$128,890	$168,344	$212,651	$664,617	100%

Table 3: Funds Planned for Enhancements--by Enhancement Category

Expense Category\Year	2008 Estimate	2009 Estimate	2010 Estimate	2011 Estimate	2012 Estimate	Five-Year Total	Five-Year Percent
Critical Path	$4,600	$4,858	$5,129	$5,417	$5,720	$25,724	4%
Drug Safety/Risk Management	*$25,810*	*$27,255*	*$28,781*	*$30,393*	*$32,095*	*$144,335*	
IT Amount for Drug Safety/Risk Mgmt.	*$3,480*	*$3,675*	*$3,881*	*$4,098*	*$4,327*	*$19,461*	
Drug Safety/Risk Management Total	$29,290	$30,930	$32,662	$34,491	$36,423	$163,796	25%
Information Technology	$4,000	$4,224	$4,461	$4,710	$4,974	$22,369	3%
Additional Drug Safety Increase	$25,000	$36,960	$50,179	$64,768	$80,827	$257,735	39%
Workload Adjustment	$0	$14,871	$36,459	$58,959	$84,707	$194,996	29%
Total PDUFA IV Enhancements	$62,890	$91,843	$128,890	$168,344	$212,651	$664,617	100%

PDUFA IV Five-Year Financial Plan--2009 Update

FDA Plan Summary Tables--PDUFA IV ($000)

Note: Numbers Are Rounded and May Not Add

Table 4: FDA Summary of all PDUFA Additive Resources--by Organization or Cost Component

Component\Year	2008 Estimate	2009 Estimate	2010 Estimate	2011 Estimate	2012 Estimate	Five-Year Total	Five-Year Percent
CDER	$268,209	$300,542	$332,871	$371,094	$412,759	$1,685,475	58%
CBER	$45,880	$51,324	$56,737	$63,029	$70,011	$286,981	10%
ORA	$5,878	$6,207	$14,358	$18,414	$22,869	$67,726	2%
Overhead	$36,576	$40,002	$43,286	$47,029	$51,285	$218,179	8%
Information Technology	$40,625	$42,900	$45,302	$47,839	$50,518	$227,185	8%
Rent & Rent Related	$31,767	$35,771	$40,689	$45,867	$51,622	$205,717	7%
Central Accounts	$30,475	$33,822	$37,807	$42,019	$46,663	$190,786	7%
Total	$459,412	$510,570	$571,051	$635,290	$705,726	$2,882,048	100%

Table 5: FDA Summary of all PDUFA Additive Resources--by Expense Category

Expense Category\Year	2008 Estimate	2009 Estimate	2010 Estimate	2011 Estimate	2012 Estimate	Five-Year Total	Five-Year Percent
Pay and Benefits	$280,266	$310,764	$347,183	$385,636	$428,060	$1,751,910	61%
Operating Expenses	$76,278	$87,313	$100,069	$113,930	$128,863	$506,452	18%
Information Technology	$40,625	$42,900	$45,302	$47,839	$50,518	$227,185	8%
Rent & Rent Related	$31,767	$35,771	$40,689	$45,866	$51,622	$205,715	7%
Central Accounts	$30,475	$33,822	$37,807	$42,018	$46,663	$190,785	7%
Total	$459,412	$510,570	$571,051	$635,290	$705,726	$2,882,048	100%

Table 6: FDA Summary of all Drug Review Staff Years by Funding Source

FTE Category\Year	2008 Estimate	2009 Estimate	2010 Estimate	2011 Estimate	2012 Estimate
Base Staff Years Paid from Appropriations	1,202	1,181	1,158	1,132	1,104
PDUFA IV Base Staff Years	1,806	1,806	1,806	1,806	1,806
Staff Years Added for PDUFA IV	183	277	391	499	611
Total	3,191	3,264	3,355	3,437	3,521

Annual Reassessments

This plan will be reassessed each year each year based on the latest information available. This information facilitates the resource allocation and planning for CDER, CBER, ORA and OC work required to meet the PDUFA IV goals. Actual workload and revenues will continue to be monitored closely.

If reassessments of CDER, CBER, ORA and OC drug-review related workload indicate that PDUFA workload is not in line with the distribution of resources in this plan, then adjustments may be made. If the adjustments are significant then the plan may be updated again.

Because FDA plans to spend all funds it expects to collect, adjustments needed by CDER, CBER, ORA and OC each year will generally be within the total amounts already planned for the fiscal year. For example, if an unplanned IT item becomes a high priority, then cutbacks will have to be made in other components of that organization's plan (such as other IT items, hiring, or operating support) in order to fund that need.