



OCT - 8 2003

PDUFA III Five-Year Plan

2003 - 2004 - 2005 - 2006 - 2007

Department of Health and Human Services
FOOD AND DRUG ADMINISTRATION
Office of Management and Systems

July 2003

2003N-0429

RPT 1

Executive Summary

The Prescription Drug User Fee Act (PDUFA) provides authority for 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 2002 extended PDUFA through September 30, 2007 (PDUFA III).

Under PDUFA III, FDA is committed to meeting demanding performance goals documented in a June 4, 2002 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. It was FDA's blueprint for investing the resources expected under PDUFA II. That plan was revised and updated periodically. Following that tradition, this initial PDUFA III Five-Year Plan similarly sets out FDA's plans for investing the resources expected under PDUFA III, by organization component and major performance goals.

The planned fee collections and spending over the 5-year period from FY 2003 through FY 2007 total a little over \$1.25 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 III.

By spending category, 64 percent of the fee revenues will be allocated for employee salary and benefit costs, 15 percent for center and ORA operating funds, 11 percent for IT investments, 4 percent for rental payments to GSA, and 5 percent central accounts. By organization, CDER will spend 58 percent, CBER will spend 11 percent, ORA will spend 2 percent, and OC overhead will spend 8 percent, centrally funded items will use 5%, and rent payments to GSA will use 4%.

Spending at this level will not only sustain the 1088 staff years paid from fees by the end of FY 2002, but will also enable the agency to add an additional 376 staff years for the drug review process by FY 2007. Planned increases from 2002 staffing levels by component are:

- CDER—a net increase of 293 staff years by the end of 5 years
- CBER—a net increase of 59 staff years by the end of 5 years
- ORA—level staffing by the end of 5 years
- OC—a net increase of 24 staff years by the end of 5 years

Operating at these levels should enable the agency to meet PDUFA III goals through FY 2007.

Contents

Purpose	1
Background.....	2
PDUFA I.....	2
PDUFA II.....	2
PDUFA III	3
PDUFA Goals.....	3
Assumptions	5
1. Inflation and Inflation Adjustments.....	5
2. Workload and Workload Adjustments	6
3. Revenue Levels and Adjustments.....	6
4. Anticipated Collections	7
5. Support of PDUFA II Fee Base Levels.....	8
6. All Statutory Triggers Will Be Met.....	9
7. Human Resources May Be Acquired By Either Hiring Or Contracting.....	11
8. Resources For The Human Drug Application Review Process Will Increase By About 16 Percent By The End Of PDUFA III	11
9. The Resources Are Allocated To Assure That The Performance Goals Are Met	11
10. The Plan Will Be Reassessed And Updated Annually	12
Planning Process.....	13
CDER Plan Summary.....	14
CDER Plan Summary Tables	16
CDER Plan Summary	17
CDER Plan Summary Tables	19
ORA Plan Summary	20
ORA Plan Summary Tables	21
OC Plan Summary	22
OC Plan Summary Tables	25
Information Technology, Rent and Central Accounts.....	26
Information Technology, Rent and Central Account Summary Tables.....	29
FDA Plan Summary.....	30
FDA Plan Summary Tables.....	32
Annual Reassessments.....	34
PDUFA III Information Technology Five-Year Plan	Appendix A

Purpose

This document is a blueprint for investing the substantial resources the agency expects to collect under the recently reauthorized Prescription Drug User Fee Act, referred to as PDUFA III. It provides FDA's initial estimates of the revenues and expenditures anticipated over the five-year period of the most recent PDUFA reauthorization, fiscal years 2003 through 2007.

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

- Meeting PDUFA II goals –the PDUFA II Additive Base
- Enhanced Training and Staffing
- Risk Management
- Electronic Submissions
- Continuous Marketing Applications
- Efficacy Supplement Resubmissions
- First Cycle Reviews
- Expert Outside Consultants
- Performance Management

In the discussions that preceded the enactment of PDUFA III, the first two bulleted items above were collectively referred to as “Sound Financial Footing” for the drug review program. FDA stressed that resources for these items were necessary to assure the agency's ability to continue to meet the old PDUFA II goals in future years. The remaining bulleted items represent distinct new or enhanced goals under PDUFA III.

FDA will update the plan annually to reflect changes in workload and replace revenue and expenditure estimates with amounts actually received and spent. Updates will also respond to any unanticipated contingencies that may occur. As was done over the past five years, FDA will make the plan, and 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 contained a "sunset" provision for automatic expiration on September 30, 1997. Without further legislation, FDA would have been unable to continue to collect and spend PDUFA fees essential to maintain review process improvements.

PDUFA II

As a result of this success, PDUFA was reauthorized and extended through September 30, 2002. 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. PDUFA, amended and extended and with its new goals, was referred to as PDUFA II, and its predecessor as PDUFA I. 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 again reauthorized for another five years. That reauthorization was contained in the Prescription Drug User Fee Amendments of 2002 (Title 5 of the Public Health and Security and Bioterrorism Preparedness and Response Act of 2002), signed by the President on June 12, 2002. This reauthorization covers fiscal years 2003 through 2007, and is known as PDUFA III.

PDUFA III corrects some of the flaws in PDUFA II and should provide for more stable fee revenues over the next five years. It should 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 should be sufficient to sustain the 1,088 staff years supported by fees in FY 2002, and to add at least an additional 376 staff years. PDUFA III also permits fee revenues to be used for some post-approval risk management activities for the first time. The goals for PDUFA III were set forth in letters from the Secretary of Health and Human Services to Congressional Committee Chairmen on June 4, 2002.

PDUFA Goals

The goals for PDUFA III 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, and PDUFA III. Some of the goals are phased in gradually over time, but only the goal for the final year, FY 2007, 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/oc/pdufa/reports.html>. In addition to the summarized goals described below, over the five-year PDUFA III period, FDA is to also undertake a pilot project in a new type of application review process designated "continuous marketing application," to study ways to complete more reviews in the first review cycle, and to undertake some initiatives aimed at improving review performance.

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

Goal	PDUFA I	PDUFA II	PDUFA III
Complete review of priority original new drug and biologic applications and efficacy supplements			90% in 6 months

Goal	PDUFA I	PDUFA II	PDUFA III
Complete review of standard original new drug and biologic applications and efficacy supplements	90% in 12 months	90% in 10 months	
Complete review of manufacturing supplements	90% in 6 months	90% in 4 months if prior approval needed, 6 months otherwise	
Complete review of resubmitted new drug and biologic applications	90% in 6 months	90% of class 1 in 2 months and 90% of class 2 in 6 months	
Complete review of resubmitted efficacy supplements	No Goal	90% in 6 months	90% of class 1 in 2 months and 90% of class 2 in 6 months *
Discipline review letters for pre-submitted "Reviewable Units" of new drug and biologic applications	No Goal		90% in 6 months *
Report of substantive deficiencies (or lack thereof)	No Goal		90% within 14 days of filing date *
Respond to industry requests for meetings	No Goal	90% within 14 days	
Meet with industry within set times	No Goal	90% within 30, 60, or 75 days, depending on type of meeting	
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	
Electronic application receipt and review	No Goal	In place by the end of FY 2002	Enhanced by the end of FY 2007

* Items noted with an asterisk are phased in gradually over time. Only the goal for the final year, FY 2007, 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 III additional revenues to meet the challenging PDUFA III goals is based on ten 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 2003. This is identical to the inflation adjustments that have been in place since 1998. The inflation adjustment is the greater of the total percentage change that occurred in either 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, or the total percentage change for the previous fiscal year in pay for Federal employees stationed in the Washington DC metropolitan area. 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 2003.

For FY 2004, the adjustment factor specified for Federal pay is 4.27 percent—the rate of increase for employees in the Washington DC area that took place in January 2003. This was greater than the CPI change for the 12-month period ending June 30, 2003—which was 2.225 percent. As a result this plan will use 4.27 percent as the estimated inflation adjuster to apply to FY 2004. For this unique workload adjuster defined in PDUFA, the plan will use the average annual increase in pay for Federal employees in the Washington DC area for the past five years as the basis for estimating future inflation adjustments. That average for the most recent five-year period is 4.08 percent. Future plans will replace this estimate with the actual inflation adjustment as it becomes available.

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 of the plan as a result of the statutory inflation adjustment.

Inflation Adjustment Estimates

Inflation Adjustment	2003 Plan	2004 Plan	2005 Plan	2006 Plan	2007 Plan
Inflation Adjustment Estimate					
Annual Inflation Estimate		4.27%	4.08%	4.08%	4.08%
Cummulative Inflation Estimate		4.27%	8.52%	12.95%	17.56%
Estimated Inflation Adjustor		4.27%	8.52%	12.95%	17.56%

2. Workload and Workload Adjustments

The statute also provides for annual adjustment of revenues each year after FY 2003 for increases in workload for the process of the review of human drug applications. This adjustment is new with PDUFA III and will be implemented for the first time when fees for FY 2004 are set in August of 2003.

The workload adjuster will use as its base the average number of various types of applications received for the five-year period from FY 1998 through FY 2002. It will compare those 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.

For the purpose of this initial five-year plan, FDA is assuming that workload over the course of PDUFA III will be stable. This assumption will change in future plans if, over time, our analyses reflect an increase in workload that causes us to adjust fee revenues.

3. Revenue Levels and Adjustments

The statute sets revenue levels for the five years of PDUFA III. They are:

	2003	2004	2005	2006	2007
Product Fees	\$ 74,300,000	\$ 77,000,000	\$ 84,000,000	\$ 86,434,000	\$ 86,434,000
Establishment Fees	\$ 74,300,000	\$ 77,000,000	\$ 84,000,000	\$ 86,433,000	\$ 86,433,000
Application Fees	\$ 74,300,000	\$ 77,000,000	\$ 84,000,000	\$ 86,433,000	\$ 86,433,000
Total	\$ 222,900,000	\$ 231,000,000	\$ 252,000,000	\$ 259,300,000	\$ 259,300,000

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

	2003	2004	2005	2006	2007
Product Fees	\$ 74,300,000	\$ 80,287,900	\$ 91,160,341	\$ 97,628,935	\$ 101,612,196
Establishment Fees	\$ 74,300,000	\$ 80,287,900	\$ 91,160,341	\$ 97,627,806	\$ 101,611,020
Application Fees	\$ 74,300,000	\$ 80,287,900	\$ 91,160,341	\$ 97,627,806	\$ 101,611,020
Total	\$ 222,900,000	\$ 240,863,700	\$ 273,481,024	\$ 292,884,546	\$ 304,834,236

The inflation adjusted revenue levels are to be adjusted again for workload. As stated in

Assumption 2, above, no workload adjustment is being made in the initial PDUFA III Five-year Plan. However, in future years there may be a further adjustment to these revenue levels for workload in future revisions of this plan.

4. Anticipated Collections

Experience has taught FDA that the two-thirds of PDUFA fee revenues that come from establishment and product fees are relatively stable, and can be counted on each year. However, the remaining one-third of revenues that comes from applications 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, it is not prudent for FDA to plan for the allocation of 100% of the application fees each year.

Therefore, in developing plans for the future, FDA will routinely count on getting 100% of the establishment and product fee revenues each year, but only 80% of the application fee revenues, as depicted in the table below:

Fiscal Year	2003	2004	2005	2006	2007
Product Fees	\$ 74,300,000	\$ 83,716,193	\$ 98,931,046	\$ 97,628,935	\$ 101,612,196
Establishment Fees	\$ 74,300,000	\$ 83,716,193	\$ 98,931,046	\$ 97,627,806	\$ 101,611,020
Application Fees	\$ 59,440,000	\$ 66,972,955	\$ 79,144,837	\$ 78,102,245	\$ 81,288,816
Total	\$ 208,040,000	\$ 234,405,341	\$ 277,006,928	\$ 273,358,985	\$ 284,512,032

Revenues at this reduced level will be planned and allocated. If more than 80% of the application fee revenues are collected, and the agency assumes that will be increasingly the case in future years, the revenues will increase FDA's carryover balances, and may support increased levels of planned expenditures in future years. This plan results in minimal carryover balances each year.

It should be noted that at the time of agreement on the substantive provisions of PDUFA III FDA envisioned sufficient resources to add about 450 additional staff years of effort over the five years of PDUFA III. However, the assumption above (that we may prudently plan on only 80% of application fee revenues each year) reduces the level of resources we may plan on, making this current plan reduce expectations to 376 additional staff years.

This strategy of planning and allocating only 80 percent of the anticipated application fee revenues each year replaces the strategy of planning a contingency reserve for each year that was used in the previous PDUFA II five-year plans.

5. Support of PDUFA II Fee Base Levels

The fees collected during PDUFA II funded activities that became an integral part of FDA's resources for reviewing human drug applications are referred to as the **PDUFA II Fee Base**. In FY 2002, over two-thirds of these funds were spent on pay and benefits for an additional 1088 staff years in CDER, CBER, ORA, and OC. These were above the staffing level FDA had been devoting to the review of human drug and biologic applications in FY 1992, the year before PDUFA was enacted. The remaining one-third of the funds was used to provide operating support, IT support, centrally funded support (for indirect costs such as utilities and telecommunications), rent, and overhead costs. The continuation of these 1088 staff years of effort each year is crucial to FDA's ability to review drug and biologic applications efficiently and effectively. These resources are the foundation upon which the improvements mandated by PDUFA III are built.

The PDUFA II Fee Base staff years are allocated as follows:

PDUFA II Fee Base Staff Year Levels with Adjustments for Therapeutics Transfer

Fiscal Year	CDER	CBER	ORA	OC	Total
2003	678	246	41	123	1088
2004 and Beyond	762	162	41	123	1088

The difference of 84 staff years from CBER to CDER in FY 2004 and later years reflects the reorganization of the therapeutics products from CBER to CDER in FY 2004. In addition to these PDUFA fee-funded resources, appropriated funds and staff years were also reassigned from CBER to CDER as part of this reorganization.

The five-year estimated costs associated with the PDUFA II Fee Base are detailed in the table below and reflect:

- Annual pay and benefit cost increases of these 1088 staff years
- Operating and support costs for these staff years
- Office of the Commissioner overhead costs is calculated as a percent of center/ORA pay and benefits. (Overhead calculations are discussed beginning on page 22.)
- Information Technology, Central Account and Rent estimates are based on base year costs. (Information Technology, Central Account and Rent estimates are discussed beginning on page 26.)

PDUFA II Additive Base Fund Estimates (\$000) ¹

Item\Year	2003 Estimate	2004 Estimate	2005 Estimate	2006 Estimate	2007 Estimate	Five-Year Total
Pay and Benefits for Centers/ORA	\$107,696	\$112,295	\$116,877	\$121,645	\$126,608	\$585,121
Base Operating Funds--Centers/ORA	\$22,598	\$23,563	\$24,524	\$25,525	\$26,566	\$122,776
OC--Salaries and Operating/Contract \$	\$13,445	\$14,019	\$14,591	\$15,186	\$15,805	\$73,045
Information Technology	\$18,750	\$19,551	\$20,348	\$21,179	\$22,043	\$101,870
Rent	\$7,813	\$8,147	\$8,479	\$8,825	\$9,185	\$42,451
Central Accounts	\$9,197	\$9,590	\$9,981	\$10,388	\$10,812	\$49,969
Total--PDUFA II Additive Base	\$179,499	\$187,164	\$194,800	\$202,748	\$211,020	\$975,232

¹ Numbers may not add due to rounding.

6. All Statutory Triggers Will Be Met

The law allows FDA to collect and spend PDUFA III 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, adjusted for inflation at the rate of change in the Consumer Price index since FY 1997. For FY 2005 and later, the chart below assumes that this will be a change of 2.5 percent each year. The assumed rates will be updated in future revisions of this plan. The estimates are as follows:

Fiscal Year	1997 Amount (\$ Millions) Less Rent and User Fees	Est. Adjustment Factor (Actual factors through FY 2004, estimated for later years)	Minimum Appropriation (\$ Millions)	Actual Appropriation (\$Millions) Less Rent and Fees
2003	\$820	1.1224	\$920	\$1,275
2004	\$820	1.1473	\$941	
2005	\$820	1.1760	\$964	
2006	\$820	1.2054	\$988	
2007	\$820	1.2355	\$1,013	

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, tobacco, counter-terrorism).

- 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 at the rate of change in the Consumer Price index since FY 1997. For FY 2005 and later, the chart below assumes that this will be a change of 2.5 percent each year. The assumed rates will be updated in future revisions of this plan. The estimates are in the table below:

Fiscal Year	1997 Amount Spent on Drug Review from Appropriations (\$ Millions)	Adjustment Factor <small>(Actual factors through FY 2004, and estimated for later years)</small>	Minimum Drug Review Spending from Appropriations (\$ Millions)	Actual Drug Review Spending from Appropriations (\$Millions)
2003	\$148	1.1224	\$166	
2004	\$148	1.1473	\$170	
2005	\$148	1.1760	\$174	
2006	\$148	1.2054	\$178	
2007	\$148	1.2355	\$183	

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 year when final accounting reports are prepared. 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 further 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 exceed appropriations, the surplus can be kept by FDA and used to reduce anticipated collections in a future year.

Fiscal Year	PDUFA Fees Provided in Appropriations (\$Millions) ¹	PDUFA Fees Actually Collected (\$Millions) as of 9/30/2002	Overage, if Any (\$Millions)
2003	\$222.9		
2004			
2005			
2006			
2007			

¹ Actual amount shown for 2003. In updates of the plan, amounts appropriated in subsequent years and amounts actually collected each year will be added to this table.

7. Human Resources May Be Acquired By Either Hiring Or 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.

8. Resources For The Human Drug Application Review Process Will Increase By About 16 Percent By The End Of PDUFA III

Over the five years covered by PDUFA III, spending on the process for the review of human drug applications is expected to increase to about \$467 million, as reflected in the table below. This is an increase of about 34 percent, or \$119 million, compared with \$348 million spent in FY 2002, the last year of PDUFA II. This increase by itself may seem large. However, the impact of pay increases over the five years is about 18 percent—or a little over half of the increase. This means that, after accounting for inflation, and excluding the impact of any workload changes, the total resources available for drug review will increase by 16 percent by the end of PDUFA III—an increase of about \$50 million. This is expected to add at least 376 more staff years to the drug review process than were spent by the end of PDUFA II—an increase of about 15 percent over the human resources available in FY 2002.

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

Source of Funds	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate
S&E Appropriations	\$166,062	\$169,756	\$174,000	\$178,350	\$182,809
Fees from Industry	\$208,040	\$224,806	\$255,249	\$273,359	\$284,512
Total Funds	\$374,102	\$394,562	\$429,249	\$451,709	\$467,321

9. The Resources Are Allocated To Assure That The 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 III. The resources are being allocated in performance goal categories, with the expectation that all of the performance goals that were agreed to when PDUFA III was reauthorized will be met.

10. The Plan Will Be Reassessed And Updated Annually

All allocations in the plan are subject to review and reassessment each fiscal year as figures for workload and revenue for the previous year are available and better estimates for the next year's revenues are made. 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. This annual reassessment process is discussed further on page 34.

Planning Process

The planning process for meeting new PDUFA III goals began during discussions with stakeholders in the last year of PDUFA II. The ability to continue to meet PDUFA II goals was contingent on getting enough resources to maintain the PDUFA II additive base and the resources needed to enhance training and staffing. As new goals were proposed, resource implications were also estimated and discussed. These ongoing discussions over many months resulted in the PDUFA III goal letters of June 4, 2002. The PDUFA III resource levels and adjusters to achieve these goals were enacted in the PDUFA III statute.

This PDUFA III Five-Year Plan is patterned after the five-year plan for PDUFA II and its annual updates. The plan reflects the resources anticipated and FDA plans for investing those resources. The plan is intended to be a living and dynamic document, and will be updated annually.

In developing this plan, the Office of Management and Systems (OMS) worked with CDER, CBER, and ORA to integrate their plans into an overall FDA plan. The primary focus of this effort was to ensure sound plans supporting PDUFA III goals. CDER, CBER and ORA were each asked to reassess essential needs in order to ensure that they meet the PDUFA III goals.

The complete PDUFA III Information Technology (IT) Five-Year Plan is included in this plan (Appendix A). It is summarized in the following pages as a single overall plan for FDA, rather than in the narratives and estimates of each component, as was the case in the PDUFA II IT plans.

The overall PDUFA III Five-Year Plan resulting from this process provides a sound blueprint for the investments needed to ensure FDA success with PDUFA III. The following pages summarize the planned distribution of PDUFA III 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 III 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 2003 and the subsequent fiscal years authorized in PDUFA III are summarized below, using the PDUFA III goal categories.

Enhanced Staffing & Training

In FY 2003, CDER plans to increase review staffing in support of the Sound Financial Footing initiative. An additional 34 FTEs are planned for this category. The estimated increase is \$4.5 million with 83%, \$3.7 million, of the total for pay and benefits. The goal of this increase is to achieve a sufficient level of staffing to allow reviewers time to maintain their review workloads and engage in professional development and training opportunities. Under PDUFA II staffing levels did not keep up with increases in workload and therefore reviewers were required to forego some training and professional development activities. This precluded reviewers from pursuing development activities (e.g., training in new technology) that are considered to be essential to support the attainment of PDUFA III goals.

Additional funds will be used to provide training related to PDUFA III activities, including the implementation of new guidance (e.g., Good Review Management Principles and Continuous Marketing Application Pilot Programs). Other training will cover topics such as counter-terrorism efforts, current good manufacturing initiatives, and pediatric labeling information.

Risk Management

The Commissioner has established Efficient Risk Management as one of FDA's five strategic goals. The goal includes both the new drug review process and oversight after approval. When a drug product is approved, it is impossible to know everything about its safety. Therefore, it is important that we increase the surveillance of the safety of medicines during their first two years on the market (or first three years for drugs with potentially serious safety concerns identified at the time of approval). This increased focus on detection of adverse events and monitoring of risk management programs during the peri-approval period will allow improved safe use of newly approved drugs.

The FY 2003 estimated increase for Risk Management is \$5.7 million. CDER plans to hire and support an additional 10 FTEs, an increase of \$1.2 million for pay and benefits. The personnel will enforce regulations on postmarketing adverse event reporting to ensure that submitted reports are accurate, timely and complete. Plans also include the development of regulatory strategies and final guidance documents; and inspections to ensure industry compliance with the regulations. The largest portion of the increase, \$4.5 million will be utilized for the Adverse Event Reporting System (AERS). Upgrading the reporting format from paper to electronic will expedite the reporting process as well as reduce the cost of receiving and processing a report (\$31 per report) by at least half for those submitted electronically.

Efficacy Supplement Resubmissions

CDER plans to hire an additional five FTEs in FY 2003 for Resubmitted Efficacy Supplements. The total estimated increase is \$590,000. The additional personnel will be used to achieve the Center's expedited performance goals.

Continuous Marketing Application

FDA recognizes the importance of providing safe, effective, and high quality drugs to the American public that treat serious and life-threatening diseases as soon as possible. The Continuous Marketing Application (CMA) goal is a new performance goal comprised of two pilot programs that will test whether early review of selected applications and additional feedback and advice to sponsors during drug development will further shorten drug development and review times.

CDER is in the process of developing guidance with CBER on how the pilot program will be implemented. The Center estimates \$982,000 will be required to fund the salaries and support of 8 additional Staff years. Personnel will complete the initial phase of the guidance development by the end of FY 2003. The guidance will describe the principles, processes, and procedures of the pilot program as well as other required technical and scientific information.

Independent Expert Consultants

CDER plans to retain independent expert consultants to assist in review of clinical protocols expected to serve as the basis for approval for new biotechnology drugs. CDER will engage these consultants on an ad hoc basis in response to requests from applicants. CDER has developed draft guidance on how this program will be implemented and will work to finalize the guidance. The estimate for FY 2003 is \$56,000.

First Cycle Review Performance

FDA plans to develop a joint CDER/CBER guidance on Good Review Management Principles (GRMPs) and publish a guidance by the end of FY 2003 that will address critical principles for the efficient management of the review of new marketing applications. The plan also includes the development and implementation of a training program for all review personnel on the GRMPs. An independent expert consultant will subsequently evaluate issues that pertain to the first cycle reviews. The study will evaluate current performance and changes that occur after the GRMPs guidance is published; an assessment of the first cycle review history of all NDA's for NME's during PDUFA III; and the effectiveness of the training program. CDER plans to hire an additional 2 FTEs in FY 2003, a total increase of \$295,000.

FY 2003 Five-Year Plan
CDER Plan Summary Tables--PDUFA III
Plan for Funds from PDUFA Fee Revenues (\$000)

Note: Numbers Are Rounded and May Not Add

Category	2003 Plan	2004 Plan ²	2005 Plan	2006 Plan	2007 Plan	5-Year Total
Inflation Adjustment Estimate						
Annual Inflation Estimate		4.27%	4.08%	4.08%	4.08%	
Cumulative Inflation Estimate		4.27%	8.52%	12.95%	17.56%	
Estimated Inflation Adjustor		104.27%	108.52%	112.95%	117.56%	
PDUFA II Additive Base						
PDUFA II Additive Base Staff Years	678	762	762	762	762	
Payroll for PDUFA II Staff Years	\$78,239	\$90,717	\$94,418	\$98,271	\$102,280	\$463,925
Operating Support for PDUFA II Base	\$18,330	\$20,212	\$21,036	\$21,895	\$22,788	\$104,261
Subtotal--To Maintain PDUFA II Levels	\$96,569	\$110,929	\$115,455	\$120,165	\$125,068	\$568,186
PDUFA III Enhancements Over PDUFA II						
Enhanced Training and Staffing	\$4,466	\$11,593	\$19,573	\$23,965	\$26,410	\$85,996
Additional Staff Years	34	85	138	162	172	
Payroll for Additional Staff Years	\$3,723	\$9,720	\$16,425	\$20,115	\$22,168	\$72,151
Operating Support	\$742	\$1,863	\$3,147	\$3,849	\$4,242	\$13,844
Risk Management	\$5,767	\$8,122	\$12,020	\$13,967	\$16,281	\$56,137
Additional Staff Years	10	23	43	68	78	
Payroll for Additional Staff Years	\$1,152	\$2,659	\$5,182	\$8,429	\$10,101	\$27,523
Operating Support	\$125	\$291	\$565	\$919	\$1,102	\$3,002
Contract Support ¹	\$4,480	\$5,172	\$6,273	\$4,608	\$5,079	\$25,612
Continuous Marketing Applications	\$982	\$1,830	\$2,809	\$3,314	\$3,652	\$12,588
Additional Staff Years	8	14	21	24	26	
Payroll for Additional Staff Years	\$886	\$1,650	\$2,532	\$2,987	\$3,292	\$11,347
Operating Support	\$96	\$181	\$277	\$327	\$361	\$1,241
Efficacy Supplement Resubmissions	\$589	\$1,152	\$1,536	\$1,716	\$1,891	\$6,884
Additional Staff Years	5	9	12	12	13	
Payroll for Additional Staff Years	\$532	\$1,038	\$1,384	\$1,547	\$1,705	\$6,205
Operating Support	\$58	\$114	\$152	\$169	\$187	\$679
First Cycle Reviews	\$295	\$339	\$375	\$390	\$430	\$1,830
Additional FTE's	2	3	3	3	3	
Payroll for Additional FTE's	\$266	\$306	\$338	\$352	\$388	\$1,649
Operating Support	\$29	\$33	\$37	\$38	\$42	\$180
Expert Outside Consultants	\$56	\$95	\$107	\$112	\$122	\$492
Additional Staff Years	0	1	1	1	1	
Payroll for Additional Staff Years	\$44	\$75	\$83	\$86	\$95	\$382
Operating Support	\$12	\$20	\$25	\$26	\$27	\$110
Subtotal of PDUFA III Additional Staff Years	60	135	218	270	293	
Subtotal PDUFA III Enhancements	\$12,145	\$23,121	\$36,420	\$43,454	\$48,787	\$163,927
Total PDUFA Additive Funds--CDER	\$108,715	\$134,050	\$151,875	\$163,619	\$173,855	\$732,113
Total PDUFA Additive Staff Years--CDER	738	897	980	1,032	1,054	

¹ Risk Management Contract support includes funds for both CDER and CBER, but funds for both centers are being managed by CDER.

² Estimates for 2004 and beyond include transfer of 34% of CBER's PDUFA resources along with the transfer of CBER therapeutic product review functions to CDER.

CBER Plan Summary

CBER's overall plan for the five years of PDUFA III totals \$139.3 million. A year-by-year resource summary of CBER's plan is on page 19. It has 6 principal components (1) enhanced training and staffing (2) risk management (3) continuous marketing applications (4) efficacy supplement resubmissions (5) first cycle reviews (6) expert outside consultants.

CBER's plan shows a total increase of 59 FTEs. This number is offset by the reductions as a result of the transfer of the CBER therapeutic product review functions to CDER in FY 2004. CBER actually transferred 84 PDUFA additive positions and 82 appropriated base positions dedicated to the drug review process, and 42 positions not part of the drug review process. CBER's appropriated base for human drug review is now reduced to 210 and PDUFA additive staff year number increases to 221, for a total of 414 PDUFA staff years by FY 2007.

In CBER's plan the additional FTEs needed each year were arrayed with the specific PDUFA III goals.

Enhanced Training and Staffing

The largest portion of the CBER plan, \$16.2 million over five years, will be dedicated to keeping the staff abreast of the latest advances in technology. The staff will be trained in new processes intended to facilitate the drug development process. It will be necessary to increase the current staff to handle new tracking and review requirements stemming from CMA and first cycle review commitments.

Risk Management

Risk Management is an important part of the goals under PDUFA III. CBER plans \$4.7 million over five years for this purpose. These resources will be used to develop guidance on appropriate risk management programs for new products, evaluate industry risk management programs, and carry out specific peri-approval surveillance activities.

Continuous Marketing Applications

Additional resources are included under Continuous Marketing Applications (CMA) to develop guidance documents on the fundamentals of the two CMA pilot programs. The funding will enable the Center to revise the Managed Review process and tracking systems to accommodate the CMA. In addition the Center will be able to provide more intensive interactions with Industry.

Efficacy Supplement Resubmissions

The Center will use increased funding to revise tracking systems to accommodate the revisions in processes dealing with Efficacy Supplements.

First Cycle Reviews

CBER will work with CDER to develop guidance on Good Review Management Practices (GRMP). Additional staffing and funding will be used to revise review processes to enhance interactions with industry. CBER will also develop and implement training for staff on GRMPs.

Expert Outside Consultants

The final component of CBER's plan is funding for expert outside consultants. CBER plans to use this increase to enhance staff to deal with requests for engagement of expert independent consultants, identify and clear consultants as special government employees and provide background and other necessary information to consultants.

The table on the following page summarizes CBER's revised plans to invest the additional funds made available under PDUFA III.

FY 2003 Five-Year Plan
CBER Plan Summary Tables--PDUFA III
Plan for Funds from PDUFA Fee Revenues (\$000)

Note: Numbers Are Rounded and May Not Add

Category	2003 Plan	2004 Plan ²	2005 Plan	2006 Plan	2007 Plan	5-Year Total
Inflation Adjustment Estimate						
Annual Inflation Estimate		4.27%	4.08%	4.08%	4.08%	
Cumulative Inflation Estimate		4.27%	8.52%	12.95%	17.56%	
Estimated Inflation Adjustor		104.27%	108.52%	112.95%	117.56%	
PDUFA II Additive Base						
PDUFA II Additive Base Staff Years	246	162	162	162	162	
Payroll for PDUFA II Staff Years	\$25,774	\$17,737	\$18,461	\$19,214	\$19,998	\$101,183
Operating Support for PDUFA II Base	\$3,100	\$2,133	\$2,220	\$2,311	\$2,405	\$12,168
Subtotal--To Maintain PDUFA II Levels	\$28,873	\$19,870	\$20,681	\$21,525	\$22,403	\$113,352
PDUFA III Enhancements Over PDUFA II						
Enhanced Training and Staffing	\$1,348	\$2,040	\$3,487	\$4,412	\$4,862	\$16,150
Additional Staff Years	12	17	29	35	37	
Payroll for Additional Staff Years	\$1,204	\$1,822	\$3,115	\$3,941	\$4,343	\$14,424
Operating Support	\$144	\$218	\$373	\$471	\$520	\$1,726
Risk Management	\$539	\$556	\$820	\$1,210	\$1,568	\$4,694
Additional Staff Years	5	5	7	10	12	
Payroll for Additional Staff Years	\$481	\$497	\$733	\$1,081	\$1,401	\$4,193
Operating Support	\$58	\$59	\$88	\$129	\$168	\$502
Contract Support ¹	\$0	\$0	\$0	\$0	\$0	\$0
Continuous Marketing Applications	\$359	\$371	\$615	\$712	\$784	\$2,842
Additional Staff Years	3	3	5	6	6	
Payroll for Additional Staff Years	\$321	\$331	\$550	\$636	\$700	\$2,538
Operating Support	\$38	\$40	\$66	\$76	\$84	\$304
Efficacy Supplement Resubmissions	\$180	\$247	\$342	\$356	\$392	\$1,517
Additional Staff Years	2	2	3	3	3	
Payroll for Additional Staff Years	\$160	\$221	\$305	\$318	\$350	\$1,355
Operating Support	\$19	\$26	\$37	\$38	\$42	\$162
First Cycle Reviews	\$90	\$62	\$88	\$71	\$78	\$370
Additional Staff Years	1	1	1	1	1	
Payroll for Additional Staff Years	\$80	\$55	\$61	\$64	\$70	\$330
Operating Support	\$10	\$7	\$7	\$8	\$8	\$39
Expert Outside Consultants	\$103	\$71	\$80	\$83	\$91	\$428
Additional Staff Years	0.8	0.528	0.561	0.561	0.594	
Payroll for Additional Staff Years	\$80	\$55	\$61	\$64	\$70	\$330
Operating Support	\$23	\$16	\$19	\$20	\$21	\$98
Subtotal of PDUFA III Additional Staff Years	23	29	44	54	59	
Subtotal PDUFA III Enhancements	\$2,619	\$3,348	\$5,413	\$6,844	\$7,777	\$26,000
Total PDUFA Additive Funds--CBER	\$31,492	\$23,218	\$26,094	\$28,368	\$30,179	\$139,352
Total PDUFA Additive Staff Years--CBER	269	191	207	216	221	

¹ Risk Management Contract support includes funds for both CDER and CBER, but funds for both centers are being managed by CDER.

² Estimates for 2004 and beyond include transfer of 34% of CBER's PDUFA resources along with the transfer of CBER therapeutic product review functions to CDER.

ORA Plan Summary

At this time ORA has no increases planned as a part of implementing PDUFA III. ORA expects to expend a total of 147 staff years on the drug review process in each year of the plan (41 staff years paid from PDUFA fees and 106 Staff years paid from appropriations). This is 33 fewer staff years paid from fees than were spent in most of the PDUFA II years.

This reduction in staff years reflects the fact that fewer pre-approval inspections are being ordered each year. This is occurring because, if recent inspections have been performed and reflect that the production facility is in compliance, then a pre-approval inspection is waived as part of the application approval process. It is also due to the fact that fewer applications were submitted over the past two years. The table on the next page reflects the cost of the 41 ORA staff years to be paid from fees for each of the next five years.

FY 2003 Five-Year Plan
ORA Plan Summary Tables--PDUFA III
Plan for Funds from PDUFA Fee Revenues (\$000)

Note: Numbers Are Rounded and May Not Add

Category	2003 Plan	2004 Plan	2005 Plan	2006 Plan	2007 Plan	5-Year Total
Inflation Adjustment Estimate						
Annual Inflation Estimate		4.27%	4.08%	4.08%	4.08%	
Cumulative Inflation Estimate		4.27%	8.52%	12.95%	17.56%	
Estimated Inflation Adjustor		104.27%	108.52%	112.95%	117.56%	
PDUFA II Additive Base						
PDUFA II Additive Base Staff Years	41	41	41	41	41	
Payroll for PDUFA II Staff Years	\$3,683	\$3,841	\$3,997	\$4,161	\$4,330	\$20,012
Operating Support for PDUFA II Base	\$1,168	\$1,218	\$1,268	\$1,320	\$1,373	\$6,347
Subtotal--To Maintain PDUFA II Levels	\$4,852	\$5,059	\$5,265	\$5,480	\$5,704	\$26,359
PDUFA III Enhancements Over PDUFA II						
Enhanced Training and Staffing	\$0	\$0	\$0	\$0	\$0	\$0
Additional Staff Years	0	0	0	0	0	
Payroll for Additional Staff Years	\$0	\$0	\$0	\$0	\$0	\$0
Operating Support	\$0	\$0	\$0	\$0	\$0	\$0
Risk Management	\$0	\$0	\$0	\$0	\$0	\$0
Additional Staff Years	0	0	0	0	0	
Payroll for Additional Staff Years	\$0	\$0	\$0	\$0	\$0	\$0
Operating Support	\$0	\$0	\$0	\$0	\$0	\$0
Contract Support *	\$0	\$0	\$0	\$0	\$0	\$0
Continuous Marketing Applications	\$0	\$0	\$0	\$0	\$0	\$0
Additional Staff Years	0	0	0	0	0	
Payroll for Additional Staff Years	\$0	\$0	\$0	\$0	\$0	\$0
Operating Support	\$0	\$0	\$0	\$0	\$0	\$0
Efficacy Supplement Resubmissions	\$0	\$0	\$0	\$0	\$0	\$0
Additional Staff Years	0	0	0	0	0	
Payroll for Additional Staff Years	\$0	\$0	\$0	\$0	\$0	\$0
Operating Support	\$0	\$0	\$0	\$0	\$0	\$0
First Cycle Reviews	\$0	\$0	\$0	\$0	\$0	\$0
Additional Staff Years	0	0	0	0	0	
Payroll for Additional Staff Years	\$0	\$0	\$0	\$0	\$0	\$0
Operating Support	\$0	\$0	\$0	\$0	\$0	\$0
Expert Outside Consultants	\$0	\$0	\$0	\$0	\$0	\$0
Additional Staff Years	0	0	0	0	0	
Payroll for Additional Staff Years	\$0	\$0	\$0	\$0	\$0	\$0
Operating Support	\$0	\$0	\$0	\$0	\$0	\$0
Subtotal of PDUFA III Additional Staff Years	-	-	-	-	-	
Subtotal PDUFA III Enhancements	\$0	\$0	\$0	\$0	\$0	\$0
Total PDUFA Additive Funds--ORA	\$4,852	\$5,059	\$5,265	\$5,480	\$5,704	\$26,359
Total PDUFA Additive Staff Years--ORA	41	41	41	41	41	

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, hires additional staff, coordinates the acquisition and management of the additional space, 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 including the PDUFA III goal for improved Performance Management and the various contracts associated with this goal.

OC personnel necessary to support the drug review process are paid for under the overhead calculation described below. The management of contract funds necessary for the Performance Management goals is then discussed.

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:

$$\text{Total Costs of OC} \div (\text{Salary Costs of All of FDA} - \text{OC Salary Costs}) = \text{Overhead Rate}$$

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. In FY 2002, FDA spent a total of \$347.6 million on the drug review process as defined in PDUFA, and the FY 2002 PDUFA overhead costs were \$28.6 million, or about 8.2 percent. This is down from 10.4 percent in 1998 and 11.1 percent in 1993, due in large part to the reorganizations and reductions in the Office of the Commissioner. This plan assumes a continuation of the 2002 rate—8.2 percent of total PDUFA spending for each year of PDUFA III. The FY 2003 overhead for the drug review process is estimated to be about \$30.6 million.

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. Under PDUFA I, the portion that must be paid from appropriations was the overhead amount FDA actually spent on this process in 1992, adjusted for cost increases since then. Under PDUFA II, the portion that must be paid from appropriations was the overhead amount FDA actually spent on this process in 1997, adjusted for cost increases since then. The adjusted amount that must

come from appropriations in FY 2003 is \$14.1 million.

The difference between the total estimated overhead costs of \$30.6 million in FY 2003 and the \$14.1 million that must be paid from appropriated funds is \$16.5 million. This \$16.5 million is the amount of FDA's estimated overhead costs to be paid from fees in FY 2003. Estimates of overhead costs by fund source over the five years of PDUFA III are provided in the chart that follows.

Projected Drug Review Process Overhead Costs and Source (\$000)

Source	2003 Estimate	2004 Estimate	2005 Estimate	2006 Estimate	2007 Estimate
S&E Appropriations	\$14,084	\$14,822	\$16,747	\$17,836	\$18,087
PDUFA Fees ¹	\$16,593	\$17,532	\$18,451	\$19,204	\$20,233
Total Overhead	\$30,676	\$32,354	\$35,198	\$37,040	\$38,320

¹ The amount on this line is the same as the amount in the last line of the tables on page 25. This amount does not include the cost of the performance management contracts discussed below, since they are a separate and unique requirement of PDUFA—an expense that otherwise would not be incurred.

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. For FY 2003, approximately \$16,593,000 in fees from PDUFA will pay for about 13 percent of total OC overhead costs. Since OC will utilize about 800 Staff years in FY 2003, PDUFA fees will pay for 13 percent of these FTE, or about 150 FTE. This is an increase of 22 staff years over the level spend from fees in FY 2002. The OC Summary plan table on page 24 estimates the allocation of these additional staff years by PDUFA III goals.

Performance Management Contracts

The PDUFA III goals letter includes a new area of goals for improved Performance Management, and specifies that resources for this purpose are to be managed by the Office of the Commissioner. These resources in the Office of the Commissioner are in addition to estimated overhead costs.

PDUFA III performance management resources are to be used to enhance the new drug review process by improving the efficiency and effectiveness of the review process, improving communications between FDA and applicants, and improving harmonization and consistency of the review process. The first two initiatives under performance management are an evaluation of first cycle review performance and a process review and analysis of the drug review process focused on implementing a quality management system. FDA plans to award a contract in early FY 2004 to a firm with the expertise to conduct evaluations and analyses of the new drug review

process. The first task will include a retrospective evaluation of the first cycle review process and an evaluation of the first cycle initiatives under PDUFA III. FDA expects that this contract could also be used for the evaluation of the CMA pilots and other PDUFA related performance management initiatives.

The process review and analysis initiative will focus on implementing a continuous improvement/quality management system for new drug review. Review of new drugs is a challenging and constantly changing task: the relevant technologies are changing rapidly, new innovations are occurring in statistical methods and in data systems to support product evaluations, and in many respects the information surrounding effective use is becoming more complex. To help reviewers keep up with the latest relevant developments in biomedical, statistical, and risk assessment sciences, to continue to improve efficiency in its operations, and to attract and retain the best possible scientific talent, FDA is committed to implementing a continuous learning quality systems approach to new drug review. FDA plans to award one or more tasks in FY 2003 (e.g., under an existing contract or with a purchase order) for training about quality systems before developing a request and soliciting a contract for implementation of a quality system. The quality system implementation contract is expected to be awarded in FY 2004.

The OC Summary plan table on page 25 estimates the allocation of these additional contract funds in the Performance Management line near the bottom of the chart, and in the contract support line for CMA and first cycle reviews.

FY 2003 Five-Year Plan
OC Plan Summary Tables--PDUFA III
Plan for Funds from PDUFA Fee Revenues (\$000)

Note: Numbers Are Rounded and May Not Add

Category	2003 Plan	2004 Plan 104.27%	2005 Plan 108.52%	2006 Plan 112.95%	2007 Plan 117.56%	5-Year Total
Estimated Inflation Adjustor						
PDUFA II Additive Base						
PDUFA II Additive Base Staff Years	123	123	123	123	123	
Payroll for PDUFA II Staff Years	\$11,895	\$12,403	\$12,909	\$13,435	\$13,983	\$64,625
Operating Support for PDUFA II Base	\$1,550	\$1,616	\$1,682	\$1,751	\$1,822	\$8,420
Subtotal--To Maintain PDUFA II Levels	\$13,445	\$14,019	\$14,591	\$15,186	\$15,805	\$73,045
PDUFA III Enhancements Over PDUFA II						
Enhanced Training and Staffing	\$1,739	\$1,451	\$1,604	\$1,670	\$1,840	\$8,305
Additional Staff Years	16	12.8	13.6	13.6	14.4	
Payroll for Additional Staff Years	\$1,547	\$1,291	\$1,427	\$1,486	\$1,637	\$7,388
Operating Support	\$192	\$160	\$177	\$184	\$203	\$917
Risk Management	\$435	\$635	\$702	\$731	\$805	\$3,307
Additional Staff Years	4	5.6	5.95	5.95	6.3	
Payroll for Additional Staff Years	\$387	\$565	\$624	\$650	\$716	\$2,942
Operating Support	\$48	\$70	\$77	\$81	\$89	\$365
Contract Support ¹	\$0	\$0	\$0	\$0	\$0	\$0
Continuous Marketing Applications	\$574	\$898	\$993	\$1,033	\$1,139	\$4,636
Additional Staff Years	2	2.4	2.55	2.55	2.7	
Payroll for Additional Staff Years	\$155	\$242	\$268	\$279	\$307	\$1,250
Operating Support	\$19	\$30	\$33	\$35	\$38	
Contract (Study) Support	\$400	\$626	\$692	\$720	\$794	\$3,231
Efficacy Supplement Resubmissions	\$0	\$113	\$100	\$104	\$115	\$433
Additional Staff Years	0	1	0.85	0.85	0.9	
Payroll for Additional Staff Years	\$0	\$101	\$89	\$93	\$102	\$385
Operating Support	\$0	\$13	\$11	\$12	\$13	\$48
First Cycle Reviews	\$400	\$417	\$461	\$480	\$529	\$2,287
Additional Staff Years	0	0	0	0	0	
Payroll for Additional Staff Years	\$0	\$0	\$0	\$0	\$0	\$0
Operating Support	\$0	\$0	\$0	\$0	\$0	
Contract (Study) Support	\$400	\$417	\$461	\$480	\$529	\$2,287
Expert Outside Consultants	\$0	\$0	\$0	\$0	\$0	\$0
Additional Staff Years	0	0	0	0	0	
Payroll for Additional Staff Years	\$0	\$0	\$0	\$0	\$0	\$0
Operating Support	\$0	\$0	\$0	\$0	\$0	\$0
Performance Management	\$500	\$2,502	\$1,302	\$1,017	\$940	\$6,262
Contract (Study) Support	\$500	\$2,502	\$1,302	\$1,017	\$940	\$6,262
Subtotal of PDUFA III Additional Staff Years	22	22	23	23	24	
Subtotal PDUFA III Enhancements	\$3,648	\$6,016	\$5,163	\$5,035	\$5,368	\$25,230
Total PDUFA Additive Funds--OC	\$17,093	\$20,035	\$19,753	\$20,220	\$21,174	\$98,275
Total Without Perf. Mgmt. Contract	\$16,593	\$17,532	\$18,451	\$19,204	\$20,233	\$92,013
Total PDUFA Additive Staff Years--OC	145	145	146	146	147	

Information Technology, Rent and Central Accounts

The funds in three important areas are centrally managed in PDUFA III. 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 III Five Year Information Technology Plan is included as Appendix A to this document. Only a high level summary of that plan is included here.

The first year of PDUFA III is a period of considerable transition. Many near-term fundamental activities and strategic issues must be resolved by the Agency as a foundation for long-range systems development plans for the out years of PDUFA III. For example FDA is conducting studies to determine a strategy for consolidating IT infrastructure and services. Similarly, FDA is working to shift its IT decision-making and governance to an Agency-wide, less decentralized model. Further, FDA must resolve security issues with standard, Agency-wide solutions for secure submissions, secure e-mail, and electronic signatures. In the first year to 18 months of PDUFA III, FDA will focus on completing these efforts to ensure that they are developed, published, and widely understood. Once this is done, FDA will be able to expand planning of specific systems development and infrastructure projects into the 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 III IT goals, but also Agency and DHHS goals. Therefore, the strategies presented here must be applied consistently across the Agency to achieve the maximum benefit of the efforts.

Many levels of planning efforts are underway within the Department of Health and Human Services, the FDA, the Centers and Offices, and within the PDUFA Program. The strategies outlined in the plan are presented to show their alignment with overall Department, Agency, and Program goals and objectives. One strategy that supports goals and objectives at all levels is the establishment of a formal IT governance process at FDA. Within this governance process, FDA will centralize accountability and funding for all PDUFA IT initiatives/activities for CBER, CDER, ORA and OC under the leadership of the Chief Information Officer (CIO). The FDA CIO is responsible for ensuring IT investments support the Agency's common IT goals, fit into a common computing environment, and follow IT industry standard management practices and capability maturity model principles. Establishing a formal PDUFA IT investment governance process that incorporates the oversight and approval by both the Agency CIO and Agency management is critical to the success of PDUFA IT investments.

The strategies FDA is pursuing within the PDUFA III IT Program are aligned and presented in

plan according to the CIO's PDUFA Program goals:

- Provide a governance framework, management, and oversight of IT decision-making
- Review the efforts within the Electronic Regulatory and Submission Review (ERSR) Program and move the Program forward; and
- Increase the efficiency of IT programs and services to better support all of its customers.

A table at the end of the Executive Summary in Appendix A summarizes the strategies the FDA will pursue in FY 2003-2004 and shows a mapping of those strategies to PDUFA III, Center/Office, Agency, and Departmental goals.

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 II Additive Base Costs—starting with \$18.8 million in FY 2003. The second place is the Electronic Submissions 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 2003 is \$23.7 million, increasing to \$30.3 million by FY 2007.

Rent

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. The amount of rent FDA pays is directly related to the number of employees that must be housed. Under PDUFA III the agency will be hiring additional employees, and the cost of acquiring and maintaining space for those additional employees is reflected in the rent 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 II Additive Base Costs—starting with \$7.8 million in FY 2003. The second place is a separate rent line in each of the goal areas. In each goal area, the first line shows of the cumulative additional staff years associated with the goal area for each year—additional staff years to be hired during PDUFA III. 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 two rent subtotals are given. The rent subtotal for FY 2003 is \$8.8 million, increasing to \$13.0 million by FY 2007.

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. 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. 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 II Additive Base Costs—starting with \$9.2 million in FY 2003. The second place is a separate central account line in each of the goal areas. In each goal area, the first line shows the cumulative additional staff years associated with the goal area for each year—additional staff years hired during PDUFA III. 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 2003 is \$10.5 million, increasing to \$16.4 million in FY 2007.

FY 2003 Five-Year Plan
IT/Rent/Central Plan Summary Tables—PDUFA III
Plan for Funds from PDUFA Fee Revenues (\$000)

Note: Numbers Are Rounded and May Not Add

Category	2003 Plan	2004 Plan 104.27%	2005 Plan 108.52%	2006 Plan 112.95%	2007 Plan 117.56%	5-Year Total
Estimated Inflation Adjustor						
PDUFA II Additive Base						
PDUFA II Additive Base Staff Years	1088	1088	1088	1088	1088	
IT	\$18,750	\$19,551	\$20,348	\$21,179	\$22,043	\$101,870
Rent	\$7,813	\$8,147	\$8,479	\$8,825	\$9,185	\$42,451
Central Accounts	\$9,197	\$9,590	\$9,981	\$10,388	\$10,812	\$49,969
Subtotal—To Maintain PDUFA II Levels	\$35,761	\$37,288	\$38,809	\$40,392	\$42,040	\$194,290
PDUFA III Enhancements Over PDUFA II						
Enhanced Training and Staffing	\$1,348	\$2,577	\$4,190	\$5,094	\$5,813	\$18,813
Additional Staff Years	62	115.2	180.2	210.8	223.2	
IT	\$0	\$0	\$0	\$0	\$0	\$0
Rent	\$611	\$1,083	\$1,720	\$2,075	\$2,287	\$7,776
Central Accounts	\$737	\$1,495	\$2,461	\$3,018	\$3,326	\$11,037
Risk Management	\$423	\$757	\$1,295	\$1,967	\$2,374	\$8,906
Additional Staff Years	19	33.6	56.1	83.3	96.3	
IT	\$0	\$0	\$0	\$0	\$0	\$0
Rent	\$183	\$328	\$551	\$835	\$998	\$2,895
Central Accounts	\$240	\$429	\$734	\$1,132	\$1,375	\$3,910
Electronic Submissions	\$4,906	\$5,465	\$6,870	\$7,518	\$8,286	\$33,045
IT	\$4,906	\$5,465	\$6,870	\$7,518	\$8,286	\$33,045
Continuous Marketing Applications	\$161	\$281	\$400	\$488	\$513	\$1,802
Additional Staff Years	13	20	28.9	32.3	34.2	
IT	\$0	\$0	\$0	\$0	\$0	\$0
Rent	\$116	\$189	\$277	\$320	\$353	\$1,245
Central Accounts	\$161	\$261	\$400	\$488	\$513	\$1,802
Efficacy Supplement Resubmissions	\$136	\$274	\$368	\$391	\$431	\$1,599
Additional Staff Years	6	12.2	15.3	16.15	17.1	
Rent	\$53	\$112	\$143	\$157	\$173	\$639
Central Accounts	\$82	\$162	\$215	\$234	\$257	\$949
First Cycle Reviews	\$68	\$70	\$78	\$81	\$89	\$396
Additional FTE's	3	3.2	3.4	3.4	3.6	
Rent	\$27	\$28	\$31	\$32	\$35	\$153
Central Accounts	\$41	\$43	\$47	\$49	\$54	\$234
Expert Outside Consultants	\$29	\$36	\$33	\$34	\$38	\$184
Additional Staff Years	1.2	1.2	1.275	1.275	1.35	
Rent	\$9	\$10	\$11	\$11	\$12	\$53
Central Accounts	\$19	\$20	\$22	\$23	\$26	\$111
Subtotal of PDUFA III Additional Staff Years	104	185	285	347	376	
Subtotal PDUFA III Enhancements	\$7,069	\$9,435	\$13,204	\$15,551	\$17,344	\$62,603
Enhancement Subtotal IT	\$4,906	\$5,465	\$6,870	\$7,518	\$8,286	\$33,045
Enhancement Subtotal Rent	\$1,000	\$1,749	\$2,733	\$3,431	\$3,859	\$12,771
Enhancement Subtotal Central Accounts	\$1,280	\$2,410	\$3,879	\$4,922	\$5,552	\$18,043
Subtotal IT	\$23,856	\$25,016	\$27,218	\$28,697	\$30,328	\$134,915
Subtotal Rent	\$8,813	\$9,896	\$11,212	\$12,256	\$13,045	\$55,221
Subtotal Central Accounts	\$10,477	\$12,000	\$13,861	\$15,310	\$16,365	\$68,013
Total PDUFA Additive Funds—IT-Rent-Centri	\$42,830	\$46,723	\$52,013	\$55,949	\$59,384	\$256,894
Total PDUFA Additive Staff Years—IT/Rent/Central	1,182	1,273	1,373	1,436	1,464	

FDA Plan Summary

The Agency plan for PDUFA III is a composite of the plans developed by CDER, CBER, ORA, and OC components. Tables 1-7 on pages 32 and 33 summarize the overall FDA plan. The discussion below summarizes information in each of these tables.

- Table 1 (page 32) shows the \$975 million set aside over five years to maintain and support the additional staff hired by the end of PDUFA II (referred to as the PDUFA II Additive Base) discussed in Assumption 5. It also shows the total fee revenues projected annually, the reserve set aside for application shortfalls, and the amounts still available for enhancements after the PDUFA II Additive Base funds have been subtracted from the total estimated fees available—a total of about \$271 million over the five years.
- Table 2 (page 32) shows the allocation of \$279 million over five years, by component, planned to meet PDUFA III 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 (3) central accounts. These are necessary to meet PDUFA III goals and to accommodate the additional staff hired by the centers. The total line allocates all the PDUFA funds, above the PDUFA II Additive Base, that FDA expects to spend through FY 2007.
- Table 3 (page 32) shows the allocation of this \$279 million by PDUFA III goal category. About \$129 million (46% of the increases) will be spent for enhanced training and staffing to meet the goals. About \$71 million (25% of the increases) is planned for risk management activities. About \$33 million (12% of the increases) is planned for IT/electronic submission enhancements. About 23 million (8% of the increases) is planned for implementing the pilot program for continuous marketing applications. The remaining \$23 million (8% of the increase) is planned for enhancements in the remaining 4 goal areas—efficacy supplement resubmissions, first cycle reviews, expert outside consultants, and performance management.
- A summary of the additional staff years planned each year, over and above the PDUFA II base levels shown on page 8, are shown below.

PDUFA III Program Staff Year Changes from the PDUFA II Additive Base

Organization	2003 Estimate	2004 Estimate	2005 Estimate	2006 Estimate	2007 Estimate
CDER	+60	+135	+218	+270	+293
CBER	+23	+29	+44	+54	+59
OC	+21	+21	+23	+23	+24
Total	+104	+185	+285	+347	+376

- Table 4 (page 33) shows the difference between the projected fee revenues and expenditures each year and the estimated PDUFA carryover balances at the beginning and end of each year. In FY 2003, FDA will spend about \$2.9 million less than it expects to collect and in FY 2004 about \$4.5 million more. FDA can do this because FY 2003 began with about \$22.7 million in PDUFA carryover funds. The plan shows that these carryover balances will be spent down to about \$14 million in the last year of the program. However, FDA's assumptions about application fee collections reflected in Table 1 may prove too pessimistic, and cause these carry over balances to be higher than the plan shows.
- Tables 5 and 6 (page 33) summarize the allocation of the \$1,254,248,000 total fee revenue that FDA plans to spend over the five years of PDUFA III (PDUFA II additive base plus PDUFA III increases) by component (Table 5) and by expense category (Table 6). The last column in both tables shows the percent of total PDUFA funds planned over the next five years. By component, CDER will be allocated 58 percent, CBER 11 percent, ORA 2 percent, overhead 8 percent, information technology 11 percent, central accounts 5 percent, and rental payments to GSA 4 percent. By other expense categories, 64 percent of the total PDUFA III revenues will be dedicated to pay and benefits for staff (same as in the original plan), 15 percent for operating costs, 11 percent for IT.
- Table 7 (page 33) summarizes the total PDUFA staff years planned each year, showing the number of staff years paid from the salary and expense appropriations, the number of staff years paid from fees and considered the PDUFA II additive base, and the number of staff years added over the course of PDUFA III under this plan.

**FY 2003 Five-Year Plan
FDA Plan Summary Tables--PDUFA III (\$000)**

Note: Numbers Are Rounded and May Not Add

Table 1: PDUFA II Additive Base, and Estimated Funds Available

Item\Year	2003 Estimate	2004 Estimate	2005 Estimate	2006 Estimate	2007 Estimate	Five-Year Total	Five-Year Percent
Pay and Benefits for Centers/ORA	\$107,696	\$112,295	\$116,877	\$121,645	\$126,608	\$585,121	60%
Base Operating Funds--Centers/ORA	\$22,598	\$23,563	\$24,524	\$25,525	\$26,566	\$122,776	13%
OC--Salaries and Operating/Contract \$	\$13,445	\$14,019	\$14,591	\$15,186	\$15,805	\$73,045	7%
Information Technology	\$18,750	\$19,551	\$20,348	\$21,179	\$22,043	\$101,870	10%
Rent	\$7,813	\$8,147	\$8,479	\$8,825	\$9,185	\$42,451	4%
Central Accounts	\$9,197	\$9,590	\$9,981	\$10,388	\$10,812	\$49,969	5%
Total--PDUFA II Additive Base	\$179,499	\$187,164	\$194,800	\$202,748	\$211,020	\$975,232	100%
Estimated Fee Receipts	\$222,900	\$240,864	\$273,481	\$292,885	\$304,834	\$1,334,964	
Reserve for Application Fee Shortfalls	\$14,860	\$16,058	\$18,232	\$19,526	\$20,322	\$88,998	
Available for Enhancements	\$28,541	\$37,642	\$60,449	\$70,611	\$73,492	\$270,734	

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

Component\Year	2003 Estimate	2004 Estimate	2005 Estimate	2006 Estimate	2007 Estimate	Five-Year Total	Five-Year Percent
CDER	\$12,145	\$23,121	\$36,420	\$43,454	\$48,787	\$163,927	59%
CBER	\$2,619	\$3,348	\$5,413	\$6,844	\$7,777	\$26,000	9%
ORA	\$0	\$0	\$0	\$0	\$0	\$0	0%
OC--Salaries and Operating/Contract \$	\$3,648	\$6,016	\$5,163	\$5,035	\$5,368	\$25,230	9%
Information Technology	\$4,906	\$5,465	\$6,870	\$7,518	\$8,286	\$33,045	12%
Rental Payments to GSA	\$1,000	\$1,749	\$2,733	\$3,431	\$3,859	\$12,771	5%
Central Accounts	\$1,280	\$2,410	\$3,879	\$4,922	\$5,552	\$18,043	6%
Total	\$25,597	\$42,109	\$60,477	\$71,204	\$79,629	\$279,015	100%

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

Expense Category\Year	2003 Estimate	2004 Estimate	2005 Estimate	2006 Estimate	2007 Estimate	Five-Year Total	Five-Year Percent
Enhanced Training and Staffing	\$8,900	\$17,652	\$28,845	\$35,140	\$38,726	\$129,263	46%
Risk Management	\$7,154	\$10,070	\$14,827	\$17,864	\$21,029	\$70,943	25%
Electronic Submissions	\$4,906	\$5,465	\$6,870	\$7,518	\$8,286	\$33,045	12%
Continuous Marketing Applications	\$2,193	\$3,549	\$5,095	\$5,845	\$6,441	\$23,123	8%
Efficacy Supplement Resubmissions	\$904	\$1,787	\$2,335	\$2,567	\$2,829	\$10,423	4%
First Cycle Reviews	\$852	\$889	\$983	\$1,023	\$1,127	\$4,873	2%
Expert Outside Consultants	\$188	\$196	\$221	\$230	\$251	\$1,085	0%
Performance Management	\$500	\$2,502	\$1,302	\$1,017	\$940	\$6,262	2%
Total	\$25,597	\$42,109	\$60,477	\$71,204	\$79,629	\$279,015	100%

FY 2003 Five-Year Plan Update
FDA Plan Summary Tables--PDUFA III (\$000)

Note: Numbers Are Rounded and May Not Add

Table 4: Difference Between Plans & Available Funds, with Year-end Carry-Over Balances

Category\Year	2003 Estimate	2004 Estimate	2005 Estimate	2006 Estimate	2007 Estimate	Five-Year Total
Difference Between Plan & Available	\$2,944	(\$4,467)	(\$29)	(\$593)	(\$6,137)	
Est. Carry-Over Balance-Year Beginning	\$22,683	\$25,627	\$21,160	\$21,131	\$20,539	
Est. Carry-Over Balance-Year End	\$25,627	\$21,160	\$21,131	\$20,539	\$14,401	

Table 5: FDA Summary of all PDUFA Additive Resources--by Organization or Cost Component

Component\Year	2003 Estimate	2004 Estimate	2005 Estimate	2006 Estimate	2007 Estimate	Five-Year Total	Five-Year Percent
CDER	\$108,715	\$134,050	\$151,875	\$163,619	\$173,855	\$732,113	58%
CBER	\$31,492	\$23,218	\$26,094	\$28,368	\$30,179	\$139,352	11%
ORA	\$4,852	\$5,059	\$5,265	\$5,480	\$5,704	\$26,359	2%
Overhead	\$17,093	\$20,035	\$19,753	\$20,220	\$21,174	\$98,275	8%
Information Technology	\$23,656	\$25,016	\$27,218	\$28,697	\$30,328	\$134,915	11%
Rental Payments to GSA	\$8,813	\$9,896	\$11,212	\$12,256	\$13,045	\$55,221	4%
Central Accounts	\$10,477	\$12,000	\$13,861	\$15,310	\$16,365	\$68,013	5%
Total	\$205,096	\$229,273	\$255,278	\$273,952	\$290,649	\$1,254,248	100%

Table 6: FDA Summary of all PDUFA Additive Resources--by Expense Category

Expense Category\Year	2003 Estimate	2004 Estimate	2005 Estimate	2006 Estimate	2007 Estimate	Five-Year Total	Five-Year Percent
Pay and Benefits	\$130,611	\$145,325	\$162,962	\$177,205	\$188,036	\$804,139	64%
Operating Expenses	\$31,540	\$37,037	\$40,026	\$40,483	\$42,876	\$191,961	15%
Information Technology	\$23,656	\$25,016	\$27,218	\$28,697	\$30,328	\$134,915	11%
Rental Payments to GSA	\$8,813	\$9,896	\$11,212	\$12,256	\$13,045	\$55,221	4%
Central Accounts	\$10,477	\$12,000	\$13,861	\$15,310	\$16,365	\$68,013	5%
Total	\$205,096	\$229,273	\$255,278	\$273,952	\$290,649	\$1,254,248	100%

Table 7: FDA Summary of all PDUFA Staff Years for CDER, CBER, ORA, and OC

FTE Category\Year	2003 Estimate	2004 Estimate	2005 Estimate	2006 Estimate	2007 Estimate
Base Staff Years Paid from Appropriations	1,277	1,277	1,277	1,277	1,277
PDUFA II Base Staff Years	1,088	1,088	1,088	1,088	1,088
Staff Years Added for PDUFA III	104	185	285	347	376
Total	2,469	2,550	2,650	2,712	2,741

Annual Reassessments

This plan will be revised each year based on the latest information available. This information facilitates the resource allocation and planning for center work required to meet the PDUFA III goals. Actual workload and revenues will continue to be monitored closely.

The plan is a dynamic framework for the investments FDA must make. It will be updated again in the second quarter of FY 2004. That update will take into account the actual accomplishments, workload, revenues, and expenses of the previous fiscal years and the planned accomplishments, workload, revenues and fees to be charged over the remaining period of PDUFA III. Workload and revenue estimates are always based on the information set forth in the latest *Federal Register* notice setting fees, published in August of each year.

If reassessments of center/ORAs PDUFA workload indicate that PDUFA workload is not in line with the distribution of resources in this plan, then adjustments may be made.

Because FDA plans to spend all funds it expects to collect, adjustments needed by the centers and ORAs 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.



U.S. Department of Health and Human Services

Food and Drug Administration

**Prescription Drug User Fee Act
(PDUFA) III
Information Technology
Five-Year Plan**

FY 2003 Publication

June 2003

EXECUTIVE SUMMARY

As a part of the Department of Health and Human Services (DHHS), the Food and Drug Administration's (FDA's) mission is to promote and protect the public health by ensuring that safe and effective products reach the market in a timely way, and to monitor products for continued safety after they are in use. Decisions made by FDA affect every single American every day. In 2001, consumers spent nearly \$1.5 trillion, or more than 20 percent of all consumer expenditures, on FDA regulated products. Operating as a modern, scientifically up-to-date, responsive, and efficient agency, FDA can provide better protection for consumers and more effectively promote their health.

In the last decade, FDA has achieved great success in reforming and modernizing its regulatory processes and responsibilities as a result of drastic changes and improvements driven by the requirements of the Prescription Drug User Fee Act (PDUFA), the 1997 FDA Modernization Act (FDAMA), and other legislation. The additional resources provided by user fees, when combined with appropriations, have enabled FDA to modernize its information technology infrastructure and begin a monumental transformation from a paper-based to an electronic work environment. Much work remains to be done and, with the recent renewal of user fees for the fiscal year 2003-2007 timeframe ("PDUFA III") under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, FDA plans to make even greater progress, building on the foundation established in previous years.

The additional resources provided by user fees, when combined with appropriations, have enabled FDA to modernize its IT infrastructure and begin a monumental transformation from a paper-based to an electronic work environment.

This document is the first publication of the FDA's PDUFA III Information Technology Five-Year Plan. This Plan will show how FDA will apply PDUFA III IT funds toward building on the success of the last several years, while focusing on moving the medical drug and biologic products review processes toward a strong, homogeneous electronic work environment.

This plan will guide the direction and implementation of IT projects initiated to meet Agency program objectives and specific PDUFA III IT goals. We believe it communicates clearly to stakeholders, internal and external to the Agency, the steps FDA plans to take to achieve its objectives.

FDA considers the first year of the PDUFA III timeframe to be a period of considerable transition. Many near-term fundamental activities and strategic issues must be resolved by the Agency prior to committing resources to future, long-range systems development plans for the out years of PDUFA III. For example, due to a variety of external pressures, FDA is conducting studies to determine a strategy for consolidating IT infrastructure and services. Similarly, 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 year to 18 months of PDUFA III, FDA will focus on completing these efforts to ensure that they are developed, published, and widely understood. Once these plans are implemented, FDA will be in a position to expand planning of specific systems development and infrastructure projects into the PDUFA III out-years.

The scope of information management and information technology efforts required for FDA to realize its vision is much greater than the efforts undertaken within the PDUFA III program alone. This plan, therefore, represents only a portion of the 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 within this section must be accomplished not only to meet PDUFA III IT goals, but also Agency and DHHS goals. Therefore, the strategies presented here must be applied consistently across the Agency to achieve the maximum benefit of the efforts. PDUFA funding for these strategies, however, will be applied only in a manner that is commensurate to the proportion of PDUFA organizations to Agency-wide organizations.

FDA is developing this plan within an environment of significant challenges such as consolidation of administrative services, including information technology services. Given the dynamic nature of the current environment, FDA determined it would publish this first version of the PDUFA III IT Five-Year Plan and provide a near-term outlook. Subsequent versions of this plan will detail strategies and activities farther out into the 5-year timeframe.

Many levels of planning efforts are underway within the Department of Health and Human Services, the FDA, the Centers and Offices, and within the PDUFA Program. The strategies outlined in this plan are presented to show their alignment with overall Department, Agency, and Program goals and objectives. One strategy that supports goals and objectives at all levels is the establishment of a formal IT Governance process at FDA. Within this governance process, FDA will centralize accountability and funding for all PDUFA IT initiatives/activities for CBER, CDER, ORA and OC under the leadership of the CIO. The FDA CIO is responsible for ensuring IT investments support the Agency's common IT goals, fit into a common computing environment, and follow IT industry standard management practices and CMM principles. Establishing a formal PDUFA IT investment governance process that incorporates the oversight and approval by both the Agency CIO and Agency management is critical to the success of PDUFA IT investments.

The strategies outlined in this plan are presented to show their alignment with overall Department, Agency, and Program Goals.

The strategies FDA is pursuing within the PDUFA III IT Program are aligned and presented in this plan according to the CIO's PDUFA Program goals:

- Provide a governance framework, management, and oversight of IT decision-making;
- Review the efforts within the Electronic Regulatory and Submission Review (ERSR) Program and move the Program forward; and
- Increase the efficiency of IT programs and services to better support all of its customers.

The following table summarizes the strategies the FDA will pursue in FY 2003-2004 and shows a mapping of those strategies to PDUFA III, Center/Office, Agency, and Departmental goals.

FDA IT STRATEGIES	PDUFA III IT (See Appendix A for Mapping)	Center/Office					Agency					DHHS			
		Information Dissemination	Standards Development	Pre-Market Decision-Making	Post-Market Surveillance	Field Processes	Strong FDA	Risk Management	BioDefense	Consumer Information	Adverse Events and Medical Errors	BioTerrorism	Nation's Health Science Research Enterprise	Quality of Health Care Services	Achieve Excellence in Management Practices
<i>Provide a governance framework, management, and oversight of IT decision-making</i>															
Establish an IT Governance Process	A, B, I	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
<i>Review the efforts within the ERSR Program and move the Program forward</i>															
Collaborate with standards organizations to define document and data standards	C, D, E, F, I	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Develop and publish guidance to industry	E, I		✓	✓				✓						✓	
Evaluate ERSR Program and develop a target ERSR Architecture	C, D, E, F, H, I		✓	✓		✓	✓	✓						✓	
Define a path forward to meet electronic submissions requirements	C, D, E, H, I	✓		✓		✓	✓	✓				✓	✓		
Comply with ICH eCTD submission standards	E, I			✓			✓	✓						✓	
Provide Training for Reviewers on using Electronic Submissions and new tools	E, I			✓		✓	✓	✓						✓	
Continue the operation and maintenance of existing systems and services	A, I	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
<i>Increase the efficiency of IT programs and services</i>															
Implement IT Consolidation	A, C, F, I			✓		✓	✓	✓					✓	✓	
Transfer Therapeutics Review from CBER to CDER	A, F, I			✓			✓	✓					✓	✓	
Standardize and improve project management techniques; advance software development maturity	A, F, G, I		✓			✓	✓	✓					✓	✓	✓
Develop an Enterprise Architecture	A, C, F, H, I	✓	✓			✓	✓	✓		✓		✓	✓		

TABLE OF CONTENTS

1.0 INTRODUCTION 1

2.0 PURPOSE 1

3.0 VISION 2

4.0 CHALLENGES 3

5.0 ORGANIZATION 4

6.0 GOALS AND OBJECTIVES 4

6.1 Department Goals 5

6.2 FDA Goals 6

 6.2.1 Agency Strategic Plan 6

 6.2.2 Information Management/Information Technology Goals and Objectives 6

 6.2.2.1 Agency PDUFA IT Objectives 6

 6.2.2.2 CBER and CDER IM/IT Goals and Objectives 7

6.3 PDUFA III Goals 9

 6.3.1 Business Goals 9

 6.3.2 PDUFA III IT Goals 9

7.0 PDUFA III IT Strategy 11

7.1 IT Governance 11

7.2 ERSR Program 11

 7.2.1 Standards 12

 7.2.2 Guidance 13

 7.2.3 Systems 14

 7.2.4 Technical and Non-technical Infrastructure 16

7.3 Efficiency 18

 7.3.1 IT Consolidation 18

 7.3.2 Transfer of CBER/OTRR to CDER 19

 7.3.3 Project Management/Capability Maturity Model (CMM) 20

 7.3.4 FDA Enterprise Architecture (EA) 20

7.4 Summary 22

ATTACHMENT A: PDUFA III ELECTRONIC APPLICATIONS AND SUBMISSION – GOALS 23

1.0 INTRODUCTION

As a part of the Department of Health and Human Services (DHHS), the Food and Drug Administration's (FDA's) mission is to promote and protect the public health by ensuring that safe and effective products reach the market in a timely way, and to monitor products for continued safety after they are in use. Decisions made by FDA affect every single American every day. In 2001, consumers spent nearly \$1.5 trillion, or more than 20 percent of all consumer expenditures, on FDA regulated products. Operating as a modern, scientifically up-to-date, responsive, and efficient agency, FDA can provide better protection for consumers and more effectively promote their health.

In the last decade, FDA has achieved great success in reforming and modernizing its regulatory processes and responsibilities as a result of drastic changes and improvements driven by the requirements of the Prescription Drug User Fee Act (PDUFA), the 1997 FDA Modernization Act (FDAMA), and other legislation. The additional resources provided by user fees, when combined with appropriations, have enabled FDA to modernize its information technology infrastructure and begin a monumental transformation from a paper-based to an electronic work environment. Much work remains to be done and, with the recent renewal of user fees for the fiscal year 2003-2007 timeframe ("PDUFA III") under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, FDA plans to make even greater progress, building on the foundation established in previous years.

This document is the first publication of the FDA's PDUFA III Information Technology Five-Year Plan. This Plan will show how FDA will apply PDUFA III IT funds toward building on the success of the last several years, while focusing on moving the medical drug and biologic products review processes toward a strong, homogeneous electronic work environment. Specifically, this Plan will show how FDA intends to:

- strengthen and improve information management within the new drug and biologic products review processes by facilitating faster, more-informed decision-making;
- improve 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.

2.0 PURPOSE

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

The Center for Drug Evaluation and Research (CDER), the Center for Biologics Evaluation and Research (CBER) and the Office of Regulatory Affairs (ORA) have collaborated with the Office of the Chief Information Officer (CIO) in the Office of the Commissioner (OC) to develop this FDA PDUFA III Information Technology Five-year Plan. Together, these offices will address their paramount concern: applying technology to the FDA regulatory review process in the most efficient and effective way possible to ensure reviewers have the information and tools that will allow them to make more informed and timely decisions.

FDA considers the first year of the PDUFA III timeframe to be a period of considerable transition. Many near-term fundamental activities and strategic issues must be resolved by the Agency prior to committing resources to future, long-range systems development plans for the out years of PDUFA III. For example, due to a variety of external pressures, FDA is conducting studies to determine a strategy for consolidating IT infrastructure and services. Similarly, 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-mail, and electronic signatures. In the first year to 18 months of PDUFA III, FDA will focus its efforts on completing these efforts to ensure that they are developed, published, and widely understood. Once these plans are implemented, FDA will be in a position to expand planning of specific systems development and infrastructure projects into the PDUFA III out-years.

Therefore, the purpose of this document is to communicate FDA's long-range goals under PDUFA III, and it will present tactical strategies for accomplishing near-term objectives toward those goals. The intent of this plan is to:

- communicate the link between IT efforts and the expected business outcomes and benefits;
- communicate vision and strategies FDA will follow for using PDUFA III IT funds;
- ensure our ability to baseline our plans and measure our future progress;
- provide a framework to govern PDUFA III IT decision-making;
- supply Agency IT governing bodies with an understanding of PDUFA III IT planned activities to ensure compatibility and harmonization with other Agency strategic technology initiatives; and
- provide an understanding for how this plan links to other Agency and Departmental planning documents.

This Plan will be revised periodically and re-published at least annually as strategies and approaches are defined and clarified.

3.0 VISION

The FDA vision is one in which our advances in information technology will help provide the American public with even more timely, well-informed decisions about regulated drug and biologic products. FDA depends on the application of advanced information technologies to ensure this vision is realized, and therefore, IT planning and decision-making will be a much more corporate collaboration than in previous years.

IT planning and decision-making will be a much more corporate collaboration than in previous years.

The scope of information management and information technology efforts required for FDA to realize its vision is much greater than the efforts undertaken exclusively within the PDUFA III program. This plan, therefore, represents only a portion of the work to be accomplished at FDA. In addition, PDUFA activities must be aligned with the overall Agency business and IT strategic planning.

This Plan reflects that intent. The FDA views the PDUFA III goals as steps that would be taken by the Agency to reach the CIO's Office long-term vision of effective knowledge management capability. The long-term vision is not only to provide a seamless electronic submission process

for industry applications, but more importantly, to develop a fully integrated information management system across all FDA Centers and Offices with links to industry, the public and other government agencies for the sharing and processing of information.

4.0 CHALLENGES

During the last year or more, several major initiatives or external forces have converged, creating a particularly complex set of challenges for FDA. These challenges have a common theme in that they all have an information technology component, focus, or impact.

Early in FY 2003, FDA's new Commissioner identified a core set of strategic priorities for the Agency. These priorities focus on risk management, maintaining a strong-science-based organization, assisting in countering terrorist threats, providing information to constituents, and contributing to the reduction of adverse events and medical errors. The FDA strategic plan, structured around those five goals, highlights many very complex, advanced, and aggressive technical solutions and systems that will be required to achieve Agency goals.

One of those five priorities focuses on the critical role FDA plays in the country's efforts to counter terrorism. Among other responsibilities, FDA must take steps to ensure that regulated drugs and biologics are not used as vehicles of terrorism and to keep medically important products available to the American people despite any terrorist actions. These activities must be given an extremely high priority, and often demand immediate attention.

With the start of this Presidential Administration, DHHS Secretary Thompson instituted a "One Department" philosophy to govern management decisions. The Secretary stated that Information Technology (IT) is the key to providing better government services at reduced costs and that it is the foundation for efforts to re-engineer HHS. On May 31, 2001, the Secretary called for the development of the HHS Information Technology Strategic Five Year Plan. One of the goals articulated in the resulting Strategic Plan is the "aggregation and standardization of IT systems and services, resulting in significant consolidation within agencies and across the Department."

In line with the "One Department" philosophy, plans are underway to consolidate several other administrative functions in FDA. Until these plans are implemented, FDA must continue to operate during a very transitional period. Additionally, in this time of change, FDA must ensure an IT staffing capability that meets these changing needs. The Agency must also work to ensure that its staff is well trained and equipped with the skills necessary to deliver and maintain quality IT products.

Many other factors will influence FDA's strategy for accomplishing its IT goals. Financial and human resources, the number and types of product submissions, scientific advances, shifts in public expectations, changes in agency or industry priorities, major medical threats or breakthroughs, and other discontinuous changes might require FDA to reconsider its strategies in favor of unplanned but necessary adjustments.

FDA is developing this plan within this environment of significant challenges. Given the dynamic nature of current activities, FDA determined it would publish this first version of the PDUFA III IT Five-Year Plan and provide a near-term outlook. Subsequent versions of this plan will detail strategies and activities farther out into the 5-year timeframe.

5.0 ORGANIZATION

Players within the PDUFA III IT Program include the Office of the Chief Information Officer (OCIO), the Center for Biologics Evaluation and Research (CBER), the Center for Drug Evaluation and Research (CDER), and the Office of Regulatory Affairs (ORA). CBER and CDER have direct responsibility for reviewing and approving biologic and drug product applications, respectively, as well as monitoring those products once they are on the market. ORA inspects the full range of FDA-regulated products—both before and after marketing.

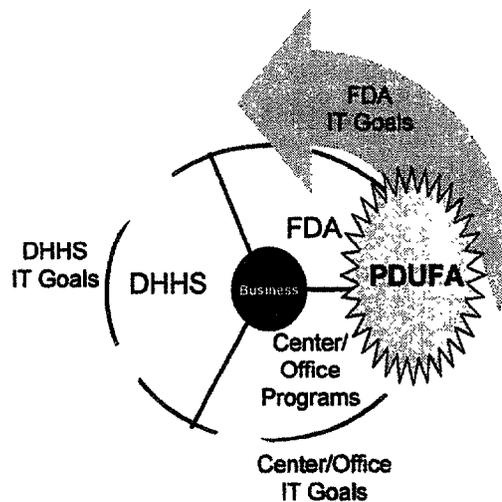
The OCIO provides Agency-wide information technology policy, guidance, support, and oversight to CBER, CDER, ORA and other FDA Centers. The OCIO is in the Office of the Commissioner's Office of Management and Systems and is responsible for managing the overall success of the IT portion of the PDUFA legislation. This office is also responsible for providing leadership in the provision of IT services across the Agency.

6.0 GOALS AND OBJECTIVES

This section presents the goals and objectives of the various governing layers within which FDA operates. First, it presents the goals, objectives, and strategic planning progress of the Department of Health and Human Services. FDA Agency level goals, objectives, and planning progress under the leadership of the new FDA Commissioner are then presented.

Next, specific information management/information technology goals and objectives for the FDA PDUFA Programs (CBER, CDER, ORA, OC) are presented. Accomplishment of these goals will be critical to the success of the Agency and Departmental goals.

Finally, the PDUFA business and information technology goals are presented.



6.1 Department Goals

DHHS has published a Strategic Plan for FY 2003-2008. It established eight strategic goals for accomplishing the DHHS mission to protect and improve the health and well being of the American public. These goals and accompanying objectives provide the focus for HHS investments of effort and resources over the next five years. Four of those eight goals relate directly to FDA's mission:

- *Goal 2: Enhance the ability of the Nation's Health Care System to Effectively Respond to Bioterrorism and Other Public Health Challenges.* To achieve this goal DHHS will focus efforts on:
 - ◆ Building the capacity of the health care system to prepare for and respond to public health threats, especially Bioterrorism; and
 - ◆ Initiating steps to ensure the safety of food, drugs, biological products, and medical devices

- *Goal 4: Enhance the Capacity and Productivity of the Nation's Health Science Research Enterprise.* To achieve this goal, DHHS will concentrate on:
 - ◆ Making investments that advance the understanding of basic biomedical and behavioral science and how to prevent, diagnose, and treat disease and disability; and
 - ◆ Accelerating the development of new drugs, medical technology, and biologic therapies.

- *Goal 5: Improve the Quality of Health Care Services.* DHHS will especially focus on:
 - ◆ Steps to reduce medical errors and improve consumer and patient protections; and
 - ◆ Accelerating the development and use of an electronic health information infrastructure.

- *Goal 8: Achieve Excellence in Management Practices.* To help us achieve the other goals and program objectives, DHHS will institute a multi-pronged approach to improve management practices and achieve excellence by focusing on key areas in the President's Management Agenda. For example, management reforms will center on:
 - ◆ Creating a unified "One HHS"
 - ◆ Improving workforce planning and financial management
 - ◆ Enhancing the efficiency and effectiveness of competitive sourcing; and
 - ◆ Enhancing the use of electronic commerce.

In addition, the DHHS Assistant Secretary for Budget, Technology, and Finance (ASBTF), Office of Information Resources Management (OIRM) is in the process of developing a Department-wide information technology strategic plan with the following goals:

- Provide a secure and trusted information technology environment
- Enable and improve the integration of health and human services information
- Enhance the quality, availability, and delivery of HHS information and services to citizens, employees, business, and governments
- Implement enterprise approach to IT infrastructure and common administrative systems that will foster innovation and collaboration
- Achieve excellence in IT management practices

6.2 FDA Goals

6.2.1 Agency Strategic Plan

FDA's Strategic Plan highlights the following five strategic priorities. There are significant information management and information technology components involved in the activities associated with these five strategic priorities:

Strong FDA – FDA will maintain a strong science-based organization to support its risk management responsibilities by: attracting and retaining the most talented scientists; operating a streamlined and cost-effective agency that is optimally organized to support mission-critical activities; and implementing the President's Management Agenda to deliver value to our constituents.

Risk Management – FDA will continue to effectively manage product risks throughout their life cycle— from research and development through consumption. Risk management decisions will be supported by rigorous scientific analysis that weighs the risk versus risk and risk-benefit associated with Agency actions.

BioDefense – FDA will assist in countering the terrorist threat by: 1) preparing for the possibility of attacks on the U.S. population through a strengthened product monitoring infrastructure and emergency preparedness plans; and 2) responding rapidly and appropriately in the event of an actual attack with effective medical countermeasures.

Consumer Information – FDA will provide information to consumers, health professionals, and other constituencies that will enable them to make prudent decisions regarding the use of FDA-regulated products. A well-informed constituency will raise the likelihood that product risks will be reduced and improved health outcomes will be realized.

Adverse Events and Medical Errors – FDA will contribute to the reduction of adverse events and medical errors through enhanced reporting capability, strengthened problem analysis, and appropriate risk management strategies to address the problems.

6.2.2 Information Management/Information Technology Goals and Objectives

6.2.2.1 Agency PDUFA IT Objectives

The Office of the CIO has identified three major objectives or courses of action to guide Agency PDUFA IT initiatives and efforts.

- *Provide a strong governance framework, management, and oversight of IT decision-making*

The CIO is responsible for the overall coordination and success of the PDUFA IT Program and will conduct quarterly reviews on the progress of projects and initiatives and take corrective action as appropriate. As outlined in the PDUFA IT goals, an annual assessment of the program's progress will be developed for the Commissioner of the FDA, with allowable information shared with the public.

- *Review the efforts within the Electronic Regulatory and Submission Review (ERSR) Program and move the Program forward.*

The ERSR program is comprised of many projects and activities. ERSR covers projects involved in applying IT solutions for the electronic receipt of submissions and for how data is submitted, tracked, managed and responded to throughout the review and approval processes for new drugs and biologic products. The ERSR program will be reevaluated to determine the best course to build upon its successful initiation in PDUFA II and continue advancing projects to fully achieve PDUFA III goals. Study results will influence future plans and the priority of resource allocation.

- *Increase the efficiency of IT programs and services to better support all of its customers*

There are many initiatives that will be led and directed by the Office of the CIO in collaboration with the FDA Centers and Offices. The FDA CIO's office has embarked on a number of crosscutting initiatives designed to increase the efficiency of IT programs and services to better support all of its customers. PDUFA efforts will be enhanced by these initiatives. The initiatives include consolidation planning and implementation (closely coordinated with the Agency's Shared Services initiative), the development of an Agency-wide enterprise architecture that includes PDUFA program needs, increased attention to IT portfolio management, and assessment, training and mentoring in the application of CMM best management practices for project managers.

6.2.2.2 CBER and CDER IM/IT Goals and Objectives

The PDUFA Centers are in the process of developing comprehensive information management/information technology strategic plans that will lay out the goals and objectives over the next five years. In addition, it will tie the work to be done to the overall Agency strategic plan. ORA requirements for communication with and access to Center information systems will be identified and incorporated within the strategies for accomplishing the Center goals.

Specific information management objectives that require IT solutions are being identified for the IM/IT goals that have been identified as follows:

- *Disseminate real-time drug information to healthcare providers, patients, and consumers in an easily usable and widely accessible format*

Directly supporting the FDA goal for providing information to consumers, health professionals, and other constituents, objectives for this goal include developing a structured format, repository, and review tools for the drug label and revitalizing the internet and intranet sites by expanding the comprehensiveness, quality, effectiveness, and delivery of information posted.

- *Identify or develop and maintain data standards and data transport standards for the drug development and clinical trials processes and for drug safety surveillance*

Underlying all the information management and information technology goals and objectives is the critical need for standard terminologies, formats, and other data. This goal encompasses efforts to define those standards, maintain them, and publish detailed guidance for using them.

- *Apply modern technology to enhance scientific decision-making and productivity during drug regulatory responsibilities prior to drugs reaching the market*

Significant time and resources will be devoted to providing better tools and systems to drug and biologic product reviewers. With powerful processing, storage, and analytical capability, reviewers will be able to leverage more existing information and make more-informed decisions. Objectives within this goal include provisions for addressing requirements for field investigator access of these tools and systems.

- *Apply modern technologies to enhance scientific decision-making and productivity during regulatory responsibilities after drugs reach the market*

Objectives for accomplishing this goal include increasing FDA's technological capability to perform drug safety surveillance, leveraging existing and potential Center and Agency information to support drug product compliance activities, and improving drug product quality monitoring. Other objectives involve updating and modernizing the Agency's capability to receive, process and query information about all manufacturers, repackers, and distributors and developing new tools to enhance evidence-based decision-making during drug surveillance activities.

- *Improve cost-effectiveness, efficiency, and security measures across the Center.*

To accomplish their goals and objectives, the Centers must create a solid foundation of management practices and infrastructure. The Centers will play active roles in supporting Agency initiatives such as establishing an Enterprise Architecture, improving project management tools, techniques, and skills, and establishing IT governance processes. Further, the Centers will work to enhance and maintain a reliable, robust, and secure computing infrastructure. With a firm foundation, the Centers hope to be able to provide their reviewers with high quality, cost-efficient, timely, and secure systems development and maintenance services.

6.3 PDUFA III Goals

6.3.1 Business Goals

Over the past 10 years, PDUFA has provided FDA with revenues essential for speeding up the application review process for new drugs and biological products. Hiring more professional staff and upgrading information technologies resulted from this influx of resources. FDA's performance met or exceeded expectations, and the benefits to consumers can be seen in the faster arrival of important new products to the market.

Generally regarded as an unqualified success, PDUFA I (FY 1992-97) sought and achieved quicker review of drug and biological product applications, and the elimination of backlogs at FDA. During PDUFA I, for example, FDA implemented performance tracking, project management methods, and standards for computer-assisted applications.

PDUFA II (FY 1998-2002) called upon FDA to shorten review times further, but more importantly, to speed up the entire drug development process. New performance goals were added that specified timeframes for activities such as scheduling meetings with product sponsors and responding to various sponsor submissions. Even though approval times for some applications began to increase toward the end of PDUFA II, FDA met the increasingly stringent performance goals.

In PDUFA III (FY 2003-2007), Congress authorized higher fees for product sponsors and some new goals and approaches for FDA. PDUFA III retains the performance goals of PDUFA II, and it adds some new goals dealing with the exchange of information between FDA and product sponsors. Application submission processes, risk management practices, and information technology enhancements are examples of new goal areas.

PDUFA has seen a progression of performance commitments designed to speed drug development and approval while preserving and even raising FDA's high standards for safety, effectiveness, and product quality. The role of information technologies over the course of PDUFA is the topic of the next section.

6.3.2 PDUFA III IT Goals

As a result of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, in Section XII of a transmittal letter from the Department Secretary to Congress, goals for PDUFA III IT activities were presented. The text for these goals is presented in its entirety in Attachment A, but is summarized here:

- a) Centralize accountability of funds under the Agency Chief Information Officer (CIO);
- b) Hold quarterly briefings with Industry and provide annual progress reports to FDA Commissioner;
- c) Ensure common solutions for secure exchange and submission of application components;
- d) Provide a single point of entry for all electronic submissions within a highly secure environment;
- e) Implement the eCTD and provide format specification for electronic submissions of eCTDs;

- f) Conduct an objective analysis for consolidation of PDUFA III IT infrastructure and desktop management services;
- g) Implement a software development process improvement initiative consistent with the concepts and requirements for provided by the Capability Maturity Model (CMM) framework;
- h) Ensure that PDUFA organizations use the same software applications (e-CTD, COTS) for common business needs where appropriate; and
- i) Publish a PDUFA III 5-year Plan within 6 months of authorization.

These PDUFA III goals constitute an important subset of FDA's overall IT goals and objectives. FDA will address each and every PDUFA III IT goal in action and principle, reporting annually on progress made. To improve communications with our external partners, we have provided a broader picture of FDA's IT future in this IT 5-year plan, a view that goes beyond PDUFA.

7.0 PDUFA III IT STRATEGY

This section provides a summary of the programs, projects, and efforts FDA will pursue within the scope of "PDUFA III IT". In addition to providing the Agency strategy for accomplishing the PDUFA III IT goals (included in Attachment A), this section highlights how these activities will support Center/Office, Agency, and Departmental business goals.

The PDUFA III IT activities will be presented within the framework provided by the CIO's major goals:

- Provide a governance framework, management, and oversight of IT decision-making;
- Review the efforts within the Electronic Regulatory and Submission Review (ERSR) Program and move the Program forward; and
- Increase the efficiency of IT programs and services to better support all of its customers.

7.1 IT Governance

FDA will centralize accountability and funding for all PDUFA IT initiatives/activities for CBER, CDER, ORA and OC under the leadership of the CIO. The FDA CIO is responsible for ensuring IT investments support the Agency's common IT goals, fit into a common computing environment, and follow IT industry standard management practices and CMM principles.

FDA leadership will require IT projects or initiatives to have made a clear and compelling business case prior to committing resources. The governance process will include steps for monitoring and evaluating progress of IT projects by requiring in-process reviews of project schedule, cost, risk, and performance information.

STRATEGY
Establish an IT Governance Process

FY 2003-2004 Targets

- Publish standard operating procedures for governance process
- Hold quarterly reviews and meetings
- Formally assess all new projects
- Develop annual report
- Acquisition and implementation of an IT Portfolio Management tool

The governance process objectives are to:

- Review, prioritize and fund new PDUFA investments
- Review and authorize adjustment to existing PDUFA investments
- Review and authorize PDUFA maintenance and operations funding, and
- Maintain and update the PDUFA III IT 5-Year Plan to ensure linkage to Agency strategic goals.

FDA is in the process of acquiring and setting up an IT Portfolio Management process and repository. This Portfolio Management tool will help simplify the budget process and will facilitate prioritizing, approving, and monitoring IT investments.

7.2 ERSR Program

The ERSR initiative began under PDUFA II, and both CBER and CDER have made significant progress in establishing an electronic submission and review environment. The Agency has gained experience in receiving marketing applications in CBER and CDER and Investigational New Drug (IND) applications in CBER. In addition, FDA has gained experience in receiving files electronically using a central gateway and secure email. Currently, FDA also receives abbreviated new drug applications (ANDAs), Biologics Licensing Applications (BLAs), NDAs,

Investigational New Drugs (INDs) advertising material and post-marketing safety report submissions in electronic format.

The ERSR program objectives are to:

- Establish standards for the format, content, and technical specifications for electronic submissions;
- Provide guidance for industry to follow in preparing electronic submissions;
- Design and implement systems to provide the capability and capacity for the receipt, review, and tracking of electronic submissions; and
- Update and maintain the technical and non-technical infrastructure to support the electronic review environment

FDA management now believes that the ERSR program needs to be reviewed in its entirety to use its recently-gained experience and ensure that its direction and outcomes use the best and most cost effective technology over the next 5 to 10 years.

Further, with the many fundamental management and organizational changes taking place in FDA, the Agency considers this an opportune time to assess the ERSR Program both in the context of PDUFA III IT goals and overall business goals. FDA already has made significant progress toward accomplishing the PDUFA III IT goals by making the decision to transfer the review of biologic therapeutic products from CBER to CDER (discussed further in section 7.3.2). FDA must re-assess its ERSR project plans to determine the best path for system development in light of this decision.

The goal is to enhance the electronic submission and review environment by identifying opportunities to standardize the receipt and processing of electronic submissions, and to develop review tools with the objective of integration and collaboration.

Specific strategies for accomplishing ERSR program objectives are highlighted in the following paragraphs.

7.2.1 Standards

The Agency plans on developing and implementing an overall electronic submission strategy based on standards for document information developed by the International Conference on Harmonisation (ICH) for the electronic common technical document (eCTD) and working with other standards organizations, such as HL7 and CDISC, for establishing data submission standards. This strategy will also include a consolidated guidance process for providing human pharmaceutical applications and related submissions in electronic format including New Drug Applications (NDA), Biologics Licensing Applications (BLAs), Abbreviated NDAs (ANDAs), Investigational New Drugs (INDs), Drug Master Files (DMFs), annual report and advertising material.

STRATEGY

Collaborate with standards organizations to define document and data standards

FY 2003-2004 Targets

- Complete ICH eCTD specifications
- Develop standards for clinical and non-clinical study data

7.2.2 Guidance

FDA has found that reviewing applications provided in electronic format is more efficient than reviewing applications provided in paper. However, we have also discovered problems with electronic submissions that interfere with the review efficiency. For example, electronic submissions that do not follow our guidance can be worse than paper. In addition, lack of consistency with the organization of data delays the processing and evaluation of submissions.

FDA believes that improving the quality and quantity of electronic submissions will increase our review efficiency. To assist industry in providing quality submissions, we are working to improve our guidance to industry by consolidating the existing multiple electronic submissions guidance documents into a single guidance document.

Improved consistency in guidance should be helpful to industry in preparing submissions. In addition, we are considering various methods to assist companies in answering questions on preparing electronic submissions, including the concept of review technologist co-located in each review division. We feel that this will also improve consistency between review divisions on electronic submission advice.

We will continue to provide external training and tutorial sessions on preparing and using electronic submissions. We will work with vendors who are developing tools for preparing and reviewing electronic submissions.

We will work with Industry to increase the number of submissions sent to the Agency electronically. We will develop guidance and regulations to improve the consistency of data organization to improve submission processing, access to documents and data, and evaluation of submission information.

In FY2003, we will publish a draft consolidated guidance document and continue external training sessions. We will begin establishing the review technology staff.

In FY2004, we will publish final consolidated guidance document and have review technologists in each review unit. We will publish guidance and develop regulations to improve consistency with submission data.

STRATEGY
Develop and publish guidance to Industry

- FY 2003-2004 Targets**
- Publish consolidated electronic submissions guidance document
 - Continue external training sessions
 - Develop review technology staff
 - Publish guidance and develop regulations to improve consistency with submission data

7.2.3. Systems

The objective within the ERSR Program that requires the most resources is the objective to design, develop, and implement information systems. Various systems are required to perform end-to-end processing of an electronic submission. More are required to develop, manage, approve, and store internally developed documents. Where business requirements dictate, these systems must be integrated.

Design and development of many of these systems began during the PDUFA II timeframe. Some were implemented and are in production now. As mentioned earlier, FDA considers now the time to assess its plans for developing new and enhancing existing systems within the ERSR Program. To that end, FDA plans to develop and document the following:

- A target architecture for systems within the ERSR Program that will maximize use of existing ERSR systems, but will provide for a future homogeneous review environment, where feasible and appropriate;
- A gap analysis between existing systems and the target architecture; and
- A development and/or migration strategy for achieving the target architecture.

The following paragraphs describe the functional areas within the ERSR program that would be considered within the scope of this assessment.

A. Electronic Submissions

The scope of "electronic submissions" includes all systems necessary to receive and view information and applications submitted to FDA. It also includes any IT solutions necessary to ensure the security and validity of electronic submissions.

The FDA intends to review the electronic submission process within FDA and industry. As a part of this review, FDA will assess the implications of existing FDA and industry electronic submissions initiatives such as the concept of a trusted third party proposed by the Pharmaceutical Research and Manufacturers of America (PhRMA).

A gap analysis will be performed between the target business needs in this area and the available and planned technology. This will serve as input to define the e-submission component of the FDA target architecture described further in section 7.3.4, "Enterprise Architecture". The target architecture will provide the foundation to develop a transition strategy from the current architecture to the target architecture meeting all PDUFA III business requirements.

FDA will continue its progress with developing an eCTD Viewer System, a system already developed as a collaborative effort between CBER and CDER. FDA has worked diligently with their partners in the International Conference on Harmonisation (ICH) on the Common Technical Document (CTD). The CTD provides the harmonized format and content for new product applications in the US, the European Union (EU), and Japan. While the CTD is based on a paper paradigm, the FDA has also worked with their partners in ICH to develop the Electronic Common Technical Document (eCTD) to provide the electronic transmission of CTD applications from

STRATEGY
*Evaluate the ERSR Program
and Develop a Target
Architecture*

FY 2003-2004 Targets

- Define Target ERSR Architecture
- Conduct Gap Analysis from existing to target
- Develop migration strategy for achieving target architecture

STRATEGY
*Define a path forward to meet
electronic submissions
requirements*

FY 2003-2004 Targets

- Define Target E-Submissions Architecture
- Develop plan to achieve target architecture

applicant to regulator. The eCTD specification is ready for implementation, as it has reached Step 4 in the ICH process. For FDA, the eCTD format will replace many of the current electronic submission formats and will allow the electronic transmission of applications that currently do not have an electronic solution. Leveraging a common technology across submission types will enhance the review process by allowing the FDA to build a common infrastructure and user interfaces for multiple submission types.

STRATEGY
Comply with ICH eCTD
submission standards

To start receiving new product applications in the eCTD format, FDA has developed an internal prototype of the eCTD Viewer System (EVS). Version 1.0 of the software is scheduled for release to the review communities in CDER and CBER in the third quarter of FY03. This version will allow the reviewers to view, navigate, and download eCTDs that are submitted to the Agency. The EVS interface is built to reviewer requirements by utilizing the XML data associated with the content files and defined in the ICH Step 4 eCTD and Study Report proposal specifications.

FY 2003-2004 Targets

- Release eCTD viewer System v1.0 to production to CBER/CDER review community
- Integrate EVS into Agency architecture for e-submissions

B. Electronic Document Storage

The Electronic Document Room (EDR) functions as an electronic library for storing electronic submissions and regulatory correspondence. The EDR provides FDA a capability to receive, view, and store electronic submissions, allowing access to information from any desktop, automating analytical and administrative processes.

The EDR is integrated with the FDA regulatory databases to allow for advanced searches based on data in the FDA databases. The EDR automates processing of submissions and automatically sends notifications to reviewers. The EDR also serves as a repository for FDA generated final documents. FDA is planning enhancements to its EDR to create an automated document management system improving the efficiency of processing and accessing information.

C. Regulatory Project Management and Submission Tracking Systems

FDA is working on improving current project management tools and submission tracking systems. These systems facilitate management of applications and reporting of regulatory progress. The design includes an interface with several other systems to improve the efficiency of processing and accessing information. Submission tracking systems will improve the receipt, processing and routing of submissions and improve the ability of reviewers to retrieve documents.

D. Internal document Generation and Storage

Systems are being developed or improved to better manage the creation, storage and access to internal documents. Templates are used to assist reviewers in generating letters, memos and other types of review documents in a standardized electronic format. Functions such as automated routing, electronic signatures and integration with external document management systems improve the agency's ability for knowledge management

E. Improved, integrated user interface

Improvements to the interface to systems will improve user acceptance and their ability to work effectively. Development of Graphical User Interface (GUI) or IT Portal applications will provide the review community easy to use access to IT services and an organized structured approach for information display, retrieval, and manipulation of information while presenting the information in a clear, concise fashion.

F. Medical Information Dissemination

This significant area within ERSR is in a stage of conceptual discussion and proof of concept and involves the processing and dissemination of medical information contained in a drug label. CDER receives thousands of submissions for changes in labeling for drug products annually. These "Labeling submissions" are in addition to the tens of thousands of other application submissions (e.g., IND and NDAs) which CDER receives on an annual basis. Facilitating the processing, review and update of labeling, should improve the timeliness of disseminating medication information to the public.

The "DailyMed" initiative -- a collaborative effort between manufacturers, FDA, the National Library of Medicine (NLM), and healthcare information suppliers -- is an initiative that will improve the access to up-to-date medication information from the product labeling which is jointly created by manufacturers and FDA. Up-to-date labeling would be sent to NLM for dissemination to the healthcare information suppliers who would then make it available to the public. For the DailyMed to function properly, FDA needs to receive, process, and review labeling and then export it to the NLM in a timely fashion.

To help in the process, FDA is working on a proof of concept for an Electronic Labeling Information Processing System (ELIPs). This system will automate the receipt, validation and routing of labeling changes. It will also encompass the review, and approval process including editing, versioning, and sign-off. Finally, the system will export the up to date labeling for transmission to NLM for dissemination.

7.2.4 Technical and Non-technical Infrastructure

This objective within the ERSR program includes all support functions, including reviewer training and maintenance activities required to keep systems operating.

Training

As we strive to improve our efficiency using technology, reviewers are challenged to keep up with the skills necessary to do their work. From using email software to using sophisticated statistical software, reviewers must have the necessary proficiency to use these tools to do their job. We have found that training classes are not sufficient to maintain the high level of expertise needed. For some reviewers, it may be weeks or even months before they are required to use the skills taught in the sessions. For other reviewers, training classes are not the best environment for learning.

We are developing new training methods to improve reviewer efficiency in using technology tools. We are developing "core competencies" that detail what skills reviewers should have and "learning pathways" that list classes that should be taken for each discipline. In addition to existing training programs, we are considering developing a support staff of review technologists to personally assist reviewers in using software tools. The review technologists will be co located with the reviewers and provide "over the shoulder" training and assistance. The review technologists also provide "just in time" training so that new FDA reviewers and reviewers new to the electronic submission process have lessons right before they begin working on electronic submissions. We are also planning on providing training sessions on tape or online for easier access.

In FY 2003, we will update our training manuals to include new technologies and begin to develop the review technology staff. We also plan to implement the "core competencies and learning pathways. In FY 2004, we are targeting to have review technologist in each review unit.

Operations and Maintenance

Most infrastructure systems, applications, and services support a large number if not all of the FDA end users. Therefore, with such a broad dependency on these systems and services, it is critical to ensure reliable and thorough operations and maintenance resources are committed.

Operations and maintenance activities and costs include:

STRATEGY
*Provide Training for Reviewers
on using Electronic Submissions
and new tools*

FY 2003-2004 Targets

- Update training manuals to include new technologies
- Begin to develop review technology staff
- Implement "core competencies" and learning pathways

- FDA IT Security Program – includes planning and execution for the Federal Information Security Management Act and Critical Infrastructure Protection activities. These activities also include security audits and remediation and any other expenses related to IT Security such as antivirus software licensing, disaster recovery, and off-site storage;
- FDA Internet/ Intranet/Web Services – includes Agency Internet/Intranet services involving development, operations, and support;
- FDA Customer Service - includes customer service Support for personal computers (PCs) and software on the desktop;
- Desktop Management -- includes desktop and laptop receiving and distribution, purchases of desktop PCs and peripherals, software such as Enterprise Policy Orchestrator and desktop test equipment;
- Network Support – includes leases for dark fiber, network storage, connections between the Center buildings and the Agency Network Control Center (NCC). Also includes building cabling, routers, switches, remote access server (RAS) software, hardware, and other set-up costs.
- Applications Software Licensing - includes applications software licensing for e-mail, desktop operating systems, standard desktop software, external computing services, Oracle, Documentum, SAS, and other licensing agreements;
- Server Support (VMS/UNIX/NT) – includes network and application server support, network operating systems, service and equipment for file and print servers, and equipment and supplies for server support; and
- Existing Application Operations and Maintenance – includes activities required to keep existing applications operating. Also includes query and reporting support for end users.

STRATEGY

Continue the operation and maintenance of existing systems and services

FY 2003-2004 Targets

- Maintain technical infrastructure and applications
- Seek opportunities to reduce O&M costs

The FDA CIO's office is committed to ensuring high quality operations and maintenance resources to ensure superior reliability and availability of these services. With that in mind, the CIO will also be seeking opportunities to reduce the current high costs of system maintenance – costs that seem to grow higher each year.

7.3 Efficiency

This section highlights major efforts that will increase the efficiency of IT programs and services to better support all IT customers.

Several of the strategies within this section must be accomplished not only to meet PDUFA III IT goals, but also Agency and DHHS goals. Therefore, the strategies presented here must be applied consistently across the Agency to achieve the maximum benefit of the efforts. PDUFA funding for these strategies, however, will be applied only in a manner that is commensurate to the proportion of PDUFA organizations to Agency-wide organizations.

7.3.1 IT Consolidation

FDA will implement an IT consolidation strategy that focuses on outcomes in three areas: organization, infrastructure services and processes.

IT Organization

The first priority of the consolidation effort is to build an IT organization that will ensure the right services are consolidated and that the requisite personnel are available at the right organizational level to manage and provide the services.

FDA will consolidate certain IT services following a "Shared Services" concept. IT services that will be in the IT Shared Services portfolio include functions such as customer service call center and e-mail administration. These services will be consolidated and managed at the Agency-level, and services will be provided to Agency sub-organizations following the requirements of the customers as stipulated in service level agreements.

Success of this shared service model will be measured by attainment of certain service performance targets and agreed-upon levels of customer satisfaction, also stipulated in service level agreements.

Infrastructure Services

Within the framework of Shared Services, the Agency will meet the Department's goal of "Consolidation of the infrastructure organization to a single organization that administers and operates servers and supporting functions such as web, database, file, print, application, e-mail, network authentication, and remote access servers". This will be accomplished by first establishing a precise definition of the services, followed by the development and phased implementation of migration plans that minimize disruption to current services and ensure "manageable and achievable milestones". Eventually, consolidation will facilitate the Agency's ability to analyze and refine its infrastructure services for greater efficiencies, as well as provide smoother adoption of new technologies.

STRATEGY
Implement IT Consolidation

- FY 2003-2004 Targets**
- Establish IT Shared Services Organization
 - Develop Service Level Agreements
 - Implement consolidated call center

Supporting Processes

FDA must establish processes for introducing and managing the application of new technologies into the Agency. While FDA has some of those processes currently, they were configured for a decentralized IT organization and technology infrastructure. As a result, FDA will now create processes to ensure:

- The right projects are selected that most effectively support the Agency's mission and business needs;
- Technologies will be deployed that are consistent with the business needs of the Agency; and are managed to ensure standardization and technical success;
- Projects will be managed in a consistent, measurable manner that will increase the chance for successful implementation of IT projects, provide management with reliable progress reports, and enable more accurate cost estimates;
- Existing processes, where necessary and feasible, will be used in order to reduce costs and time; and
- Integration with the FDA Continuity of Operations Plan (COOP) will be a normal requirement of the planning process, with special emphasis on Data Backup and Recovery.

Infrastructure/organizational consolidation efforts are underway, most notably the consolidation of the FDA call center for CDER, CBER, OC and ORA/HQ, which is anticipated to be activated by the 4th quarter of FY 2003.

7.3.2 Transfer of CBER/OTRR to CDER

A major element of the FDA's consolidation efforts is organizational alignment to improve efficiency. The Agency plans to transfer the therapeutic biologic review functions from CBER to CDER. This decision was made after a lengthy process of fact finding and deliberation.

The transfer of these therapeutic review functions to CDER is a major undertaking that will take careful planning to implement. Slightly more than 200 positions will be moving from the CBER organization to CDER. This number equates to approximately one third of the PDUFA supported staffing and resources under CBER. The challenge is to make this transition as smooth as possible as these business functions and processes are integrated.

From an IT perspective, a smooth transition is best implemented gradually. Within the first year, the transition plan includes placing staff physically and organizationally. Network and email accounts will be set up within CDER, but review staff will still use CBER software applications and data for the review process. Access to CDER software applications and data will be set up for each person, as well as access to CBER/OTRR systems for CDER personnel. FY04 targets and beyond include the analysis and eventual migration of data into CDER's central database and the elimination of duplicate tracking systems and applications. Additional resources needed to support these additional systems, whether personnel or hardware, need to be established within the guidelines of the CIO's Shared Services model.

STRATEGY
*Transfer Therapeutics Review
from CBER to CDER*

FY 2003-2004 Targets

- Place staff physically and organizationally
- Ensure access to servers, systems, and applications
- Analyze data migration requirements
- Perform requisite data migration

The efficiency of reporting and the dissemination of information across the two databases will rely not only on the success of IT and data integration, but on the development of common reporting standards, common business practices, and common definitions of terms and codes. The initial target is for annual compilation of reports across the databases. Subsequent analysis and development of these common standards, practices, and definitions will help facilitate the migration of data into CDER's database.

The creation of an entire new Office of Drug Evaluation for the additional reviewers presents an obvious need for additional document room services. While a new document room is an obvious but expensive solution, it undermines the initiative of a central point of entry for all submissions. The targeted interim solution is to use an existing document room and establish courier service between the buildings. Analysis on the efficiency of this solution, whether it can work in other areas, and other alternative solutions will then be performed.

The difference in business practices between the two groups is the final hurdle in this transfer and affects each of the other areas above. Though parallel in the paths taken, adjustments are necessary in processes such as the tracking applications and submission status, calculating goal dates, time reporting, and user fees billing. These practices, in some cases, will require social change among the review community as much as process change will need to happen over time. The success of this consolidation, by all accounts, will make great strides toward an efficient and unified Center.

7.3.3 Project Management/Capability Maturity Model (CMM)

The FDA is pursuing a standardized approach to its IT project management to achieve full compliance with government capital planning investment control requirements and to expand sound project management (PM) practices within the Agency. At the current time, Centers and Offices are using a wide variety of project management techniques. CDER has had success in instituting a CMM program over the last two years, achieving near CMM Level II results. The Agency-wide effort will build on CDER's success and expand the application of best management practices to projects in CBER, ORA, OC and other FDA Centers. As part of the re-structuring of the CIO's office, a Project Management Office will be formed to serve as a center of excellence for the Agency.

STRATEGY
Standardize and improve project management techniques; advance software development maturity

At the beginning of FY2003, FDA acquired expert training and consulting services to assess FDA progress and train and mentor FDA IT staff. The consultant and FDA staff have performed an assessment of current Agency project management practices across centers and offices which concluded in the second quarter of FY 2003. This assessment examined two projects each from the eight Centers and Offices to form an Agency baseline of practices. From this, best management practices recommendations are expected to be developed in the late March/April time period. By the summer of 2003, training of staff will be underway. Training and mentoring of best management practices will be ongoing for the next 12 to 18 months as needed. At the same time, periodic measurement of results will be taken to assess Agency progress toward more standardized, repeatable project management results.

FY 2003-2004 Targets

- Establish an Agency-level Project Management Office
- Complete Assessment
- Develop Action Plan
- Begin training and mentoring
- Adjust training and mentoring as needs define

7.3.4 FDA Enterprise Architecture (EA)

Over the last few years, the Agency has proceeded aggressively with its Information Systems Architecture (ISA) initiative to standardize its infrastructure. FDA has established a common computing environment through the implementation of ISA by standardizing desktop and

network operating systems, desktop "office" processing software, and e-mail and calendar systems across the Agency.

FDA plans to progress further by building a common architecture for all of FDA that addresses mission/business needs. This Enterprise Architecture (EA) initiative is a collaborative effort that will include participation and cooperation of the FDA centers and the guidance of DHHS.

The architecture initiative will evaluate the business needs of the Agency, define a baseline, map a path to the desired target architecture, and provide guidance for capital expenditures. This project aligns with the Federal Enterprise Architecture published by the Office of Management and Budget (OMB) in that FDA will use the business reference model of the Federal Enterprise Architecture to identify and address areas of service to its customers.

STRATEGY
Develop an Enterprise Architecture

The EA study is underway at the writing of this Plan. In FY 2003, FDA will establish the baseline architecture. The first assessment of the "As Is" environment has been developed and will be reviewed in the spring of 2003. The first version of the "Target" architecture is expected in the summer of 2003.

FY 2003-2004 Targets

- Complete first "As-Is" Assessment
- Conduct first "Target" Assessment
- Complete second "Target" Assessment
- Implement CM practices

In FY 2004, FDA will establish Agency architecture configuration management (CM) procedures. The second versions of the "As Is" and "Target" architectures will be completed in early 2004. Establishment of the configuration management repository is expected in mid 2004. Full implementation of the "Target" architecture is anticipated in FY 2005.

7.4 Summary

The following table summarizes the strategies the FDA will pursue in FY 2003-2004 and shows a mapping of those strategies to PDUFA III, Center/Office, Agency, and Departmental goals.

FDA IT STRATEGIES	PDUFA III IT (See Appendix A for Mapping)	Center/Office					Agency					DHHS			
		Information Dissemination	Standards Development	Pre-Market Decision-Making	Post-Market Surveillance	Field Processes	Strong FDA	Risk Management	BioDefense	Consumer Information	Adverse Events and Medical Errors	BioTerrorism	Nation's Health Science Research Enterprise	Quality of Health Care Services	Achieve Excellence in Management Practices
<i>Provide a governance framework, management, and oversight of IT decision-making</i>															
Establish an IT Governance Process	A, B, I	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
<i>Review the efforts within the ERSR Program and move the Program forward</i>															
Collaborate with standards organizations to define document and data standards	C, D, E, F, I	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Develop and publish guidance to industry	E, I		✓	✓				✓						✓	
Evaluate ERSR Program and develop a target ERSR Architecture	C, D, E, F, H, I		✓	✓		✓	✓	✓						✓	
Define a path forward to meet electronic submissions requirements	C, D, E, H, I	✓		✓		✓	✓	✓				✓	✓		
Comply with ICH eCTD submission standards	E, I			✓				✓	✓					✓	
Provide Training for Reviewers on using Electronic Submissions and new tools	E, I			✓		✓	✓	✓						✓	
Continue the operation and maintenance of existing systems and services	A, I	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
<i>Increase the efficiency of IT programs and services</i>															
Implement IT Consolidation	A, C, F, I			✓		✓	✓	✓						✓	✓
Transfer Therapeutics Review from CBER to CDER	A, F, I			✓				✓	✓					✓	✓
Standardize and improve project management techniques; advance software development maturity	A, F, G, I		✓			✓	✓	✓						✓	✓
Develop an Enterprise Architecture	A, C, F, H, I	✓	✓			✓	✓	✓		✓		✓	✓		

ATTACHMENT A: PDUFA III ELECTRONIC APPLICATIONS AND SUBMISSION – GOALS

- A. The Agency will centralize the accountability and funding for all PDUFA Information Technology initiatives/activities for CBER, CDER, ORA and OC under the leadership of the FDA CIO. The July 2001 HHS IT 5-year plan states that infrastructure consolidation across the department should be achieved, including standardization. The Agency CIO will be responsible for ensuring that all PDUFA III IT infrastructure and IT investments support the Agency's common IT goals, fit into a common computing environment, and follow good IT management practices.
- B. The Agency CIO will chair quarterly briefings on PDUFA IT issues to periodically review and evaluate the progress of IT initiatives against project milestones, discuss alternatives when projects are not progressing, and review proposals for new initiatives. On an annual basis, an assessment will be conducted of progress against PDUFA III IT goals and, established program milestones, including appropriate changes to plans. A documented summary of the assessment will be drafted and forwarded to the Commissioner. A version of the study report redacted to remove confidential commercial or security information, or other information exempt from disclosure, will be made available to the public. The project milestones, assessment and changes will be part of the annual PDUFA III report.
- C. FDA will implement a common solution in CBER, CDER, ORA and OC for the secure exchange of content including secure e-mail, electronic signatures, and secure submission of, and access to application components.
- D. FDA will deliver a single point of entry for the receipt and processing of all electronic submissions in a highly secure environment. This will support CBER, CDER, OC and ORA. The system should automate the current electronic submission processes such as checking the content of electronic submissions for completeness and electronically acknowledging submissions.
- E. FDA will provide a specification format for the electronic submission of the Common Technical Document (e-CTD), and provide an electronic review system for this new format that will be used by CBER, CDER and ORA reviewers. Implementation should include training to ensure successful deployment. This project will serve as the foundation for automation of other types of electronic submissions. The review software will be made available to the public.
- F. Within the first 12 months, FDA will conduct an objective analysis and develop a plan for consolidation of PDUFA III IT infrastructure and desktop management services activities that will access and prioritize the consolidation possibilities among CBER, CDER, ORA and OC to achieve technical efficiencies, target potential savings and realize cost efficiencies. Based upon the results of this analysis, to the extent appropriate, establish common IT infrastructure and architecture components according to specific milestones and dates. A documented summary of analysis will be forwarded to the Commissioner. A version of the study report redacted to remove confidential commercial or security information, or other information exempt from disclosure, will be made available to the public.
- G. FDA will implement Capability Maturity Model (CMM) in CBER, CDER, ORA and OC for PDUFA IT infrastructure and investments, and include other industry best practices to ensure that PDUFA III IT products and projects are of high quality and produced with optimal efficiency and cost effectiveness. This includes the development of project plans and schedules, goals, estimates of required resources, issues and risks/mitigation plans for each PDUFA III IT initiative.
- H. Where common business needs exist, CBER, CDER, ORA and OC will use the same software applications, such as eCTD software, and COTS solutions.
- I. Within six months of authorization, a PDUFA III IT 5-year plan will be developed. Progress will be measured against the milestones described in the plan.