PDUFA II
Five-Year Plan

FY 2000 Update

1998 - 1999 - 2000 - 2001 - 2002

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

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Executive Summary

The Prescription Drug User Fee Act of 1992 (PDUFA I) provided substantial additional resources and staffing that enabled FDA to accelerate its drug evaluation process without compromising review quality. The Food and Drug Administration Modernization Act (FDAMA) of 1997 amended PDUFA I and extended it through September 30, 2002 (PDUFA II). PDUFA II also commits FDA to faster review goals for some applications, new goals for meetings and dispute resolution, and the electronic receipt and review of applications by 2002.

In July 1998, FDA completed the original PDUFA II Five-Year Plan, which was FDA's blueprint for investing the resources expected under PDUFA II. It was based on the planning efforts of the three FDA components directly responsible for meeting these goals: (1) the Center for Drug Evaluation and Research (CDER), (2) the Center for Biologics Evaluation and Research (CBER), and (3) the Office of Regulatory Affairs (ORA). This is the second annual update of that plan.

In this update, total staffing increases by 313 FTE's for the centers and ORA by FY 2002. These are increases over FY 1997 staffing levels at the end of PDUFA I. All components believe these increases are essential to meet the PDUFA II goals that become increasingly difficult in the final 2 years of PDUFA II. The increases from 1997 staffing levels are spread as follows:

- CDER—an increase of 234 FTE's by the end of 5 years (compared with an increase of 240 FTE's in the original plan and an increase of 101 in last year's scaled-back update);
- CBER—an increase of 79 FTE's by the end of 5 years (compared with an increase of 57 FTE's in the original plan and an increase of 37 in last years update); and
- ORA—level staffing by the end of 5 years (compared with an increase of 28 FTE's in the original plan, and a decrease of 40 in last year's scaled-back update).

These spending increases are made possible by the following:

- Due to slight adjustments in inflation and workload assumptions, the estimate of revenue expected over the 5 years is increased from $681 million in last year's scaled-back plan to $690 million. This is still a reduction of $50 million from the original plan, however.
- Updated estimates of costs to maintain staffing levels at the end of PDUFA I have decreased by $19.8 million over 5 years, making funds available for staffing increases.
- The overhead estimate has decreased by $14 million from the original plan ($5 million less than last years update), freeing up funds for increased review and support staff.
- $33 million of carry-over balances will be spent over the final three years of PDUFA for increased staffing; spending in each of these final 3 years will exceed fees collected.

Of the total planned, 58 percent will be allocated for pay and benefits—up from 56 percent in last year's plan. Center and ORA operating funds will get 13% and IT funds 11%. Of the total, CDER will get 56% and CBER will get 20% (both the same percent as last year); ORA will get 6% (up from 4% last year). Overhead will get 8% of the funds (down from 9% last year); centrally funded items will get 5% (up from 4% last year), and rent to GSA will get 3% (same as last year). The contingency reserve has been reduced to 1% (compared to 2% last year).

Operating at these levels should enable the agency to meet PDUFA goals through FY 2002.

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Purpose

This plan sets out, in broad terms, an update to the five-year blueprint for investing the substantial resources FDA expects to collect under the Prescription Drug User Fee Act (PDUFA), as amended and extended by the Food and Drug Administration Modernization Act of 1997 (FDAMA). FDA must ensure that these resources are used to meet the challenging new goals associated with PDUFA. The plan helps to ensure that resources are used to achieve these goals. It allocates the resources expected each year among the FDA components responsible for achieving PDUFA goals, and the most recent update is the basis for the initial allocation of resources after the beginning of the next fiscal year. This enables quick allocation of funds after the beginning of each fiscal year. Adjustments may be made later in the fiscal year as the plan is updated again.

The plan was originally developed in Fiscal Year (FY) 1998 and made available in July 1998. Annual reviews are conducted and adjustments made as changes in workload and revenues replace original estimates, unanticipated contingencies occur, and new technologies develop. This FY 2000 revision is the second update of the original plan.

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 Commissioner of Food and Drugs 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 acquire 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), and the Office of Regulatory Affairs (ORA) increased over 57 percent during this period--from 1,147 staff-years in 1992 before PDUFA was enacted to 1,806 staff-years by 1997. Since 1994, FDA has submitted annual Performance and Financial Reports to Congress on progress in meeting performance goals and the use of fees.

The growing recognition of FDA's success in ensuring that these resources were well used culminated in late 1997 when FDA received the prestigious Innovations in American Government Award, jointly sponsored by the Ford Foundation and the Harvard University John F. Kennedy School of Government, in partnership with the Council for Excellence in Government. This award honored FDA's achievement in combining user fees and management principles to develop a new drug approval process that is predictable, accountable, and scientifically sound while making safe and effective drugs available to the public more quickly.

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 maintaining the review process improvements after that date.

PDUFA II

Congress worked with the regulated industry and the Administration to ensure PDUFA's continuation. As a result, President Clinton signed the FDAMA on November 21, 1997. Subtitle A of Title 1 of FDAMA amended PDUFA and extended it through September 30, 2002. This extension authorizes funds that will enable FDA 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, as amended and extended by FDAMA and with its new goals, is referred to as PDUFA II and its predecessor is now referred to as PDUFA I.

PDUFA II authorizes appropriations that will provide FDA with resources to sustain the larger

drug review staff developed in the last 5 years and to achieve the even more stringent new goals.

New Goals

The new goals of PDUFA II are enormously challenging, diverse, and resource intensive. Major components of the review process will be accelerated further. Many of the goals required the development and issuance of guidance documents and data bases to track and report performance. Goals were established in totally new areas, such as meetings with industry and dispute resolution. The development of infrastructure and tools necessary to move to electronic application receipt and review will also be essential. The following table provides an overview and comparison of the major goals by the end of PDUFA I and the end of PDUFA II. 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/ope/pdufa/report99/default.html.

Comparison of Goals at the End of PDUFA I and PDUFA II

Goal	PDUFA I	PDUFA II
Complete review of priority original new drug applications and efficacy supplements	90% in 6 months	90% in 6 months
Complete review of standard original new drug 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
Complete review of resubmitted new drug applications	90% in 6 months	90% of class 1 in 2 months and 90% of class 2 in 6 months
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 2002

FY 2000 Update

When the PDUFA II Five-Year Plan was originally published in July 1998, FDA committed to annual reviews and adjustments as actual changes in workload and revenues replace original estimates, unanticipated contingencies occur, and new technologies develop. This FY 2000 Update is the second update since the original plan was developed and published. Some of the assumptions in the next section have changed significantly in this revised plan as a result of our experience through the end of FY 1999.

Since 1998, FDA has used linear regression analysis to estimate the number of fee-paying applications and application fee revenues. Under PDUFA formulas, the estimate of revenue for fee-paying applications impacts product and establishment fees estimates, since each of them is set to generate the same level of revenue as application fees are expected to generate. Annual revenue forecasts and expenditure plans were reduced substantially in FY 1999, as discussed more fully in last year's plan update.

FDA's application workload forecasts and fee levels for FY 2000 were published in a *Federal Register* notice on December 28 (Attachment 1). Extending the same linear regression line depicted in that Federal Register notice, the forecast of fee-paying applications and revenues through FY 2002 is updated in this plan revision. Due to slight increases in both workload and inflation estimates, the revenues forecast for FY 2000 through FY 2002 have increased slightly from last year's projections. These workload and inflation estimates are discussed in the report (Assumption 2, page 6), and their cumulative impact is summarized in the PDUFA II Fee and Revenue Estimation Worksheet (Attachment 2).

Expenditure forecasts have increased substantially in this FY 2000 plan update, permitting FDA to hire sufficient staff to cope with the increasingly challenging PDUFA II goals in the final years of the plan. Such increased spending with only modest revenue increases is possible in large part because actual expenditures in FY 1998 and FY 1999 were below planned levels and the agency had substantial carry-over balances at the end of PDUFA I; these funds are available during the final 3 years of PDUFA II, and permit levels of spending in excess of planned fee collections over the final three years of PDUFA II.

This update retains the same basic format as the FY 1998 plan and FY 1999 plan update, with some minor modifications. Two format changes have been made in the tables for this update to the plan. First, actual amounts spent are provided in the FY 1998 and FY 1999 columns (rather than repeating the figures originally planned for these years). Second, the summary plans for CDER, CBER, and ORA have been revised to incorporate the fees spent for the PDUFA I Additive Base into the overall plan summary, rather than have that amount appended in a separate table as it was previously.

Assumptions

Taking advantage of experience gained during PDUFA I, this plan was originally based on ten major assumptions. Each of the assumptions was reassessed in FY 1999 and again for FY 2000. Half are unchanged or have minor revisions from last year's plan. Assumptions 1, 2, 3, 4, and 9 have been significantly revised since last year. A discussion of all ten assumptions follows.

1. As in the original plan, the increases funded by PDUFA I will be maintained over the course of PDUFA II.

The fees collected during PDUFA I funded activities that became an integral part of FDA's resources for reviewing human drug applications. In 1997, two-thirds of these funds were spent on pay and benefits for an additional 659 Full Time Equivalents (FTE's) in CDER, CBER and ORA—above the level of effort FDA was expending on the review of human drug and biologic applications in 1992. 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 659 work-years of effort each year is crucial to FDA's ability to review drug and biologic applications rapidly. These resources are the foundation upon which the improvements mandated by PDUFA II are built.

Further, in FY 2000 three additional FTE's were transferred to CDER from the Ombudsman's Office as part of the reorganization of the Office of the Commissioner. These were formerly paid from PDUFA overhead funds from the PDUFA I additive base, but are now considered as a center component of the PDUFA I additive base, bringing the total to 662. PDUFA II ensures that these 662 FTE's (referred to as the PDUFA I Additive Base FTE's) continue to be dedicated to the drug review process over the next 5 years. They are allocated as follows:

PDUFA I Additive Base FTE's by Component

Year	CDER	CBER	ORA	Total
1998	398	187	74	659
1999	418	167	74	659
2000 and Beyond	421	167	74	662

Further adjustments in these allocations may be made if warranted by workload or other changes.

The 5-year estimated costs associated with these PDUFA I additive base activities are detailed in the table on the next page and reflect:

- Future annual pay and benefit cost increases of 5 percent (based on past experience)

- Center support costs of $9,000 per FTE annually
- ORA's support costs of $16,000 annually per FTE (largely due to travel costs for pre-approval inspections)
- Center support cost estimates also include research support funds for CBER of $590,000 in 1998 and $295,000 in 1999. Research funding from fees was discontinued after 1999.
- Overhead is calculated as a percent of center/ORA pay and benefits (a formula prescribed by the Office of the Assistant Secretary for Finance and found reasonable by Arthur Andersen, a major accounting firm, and validated by Inspector General audits).
- Central account and rent estimates are based on previous actual costs and future estimates are inflated at 5 percent annually, based on past experience.

As a result of using actual costs for maintaining the PDUFA I Additive Base in FY 1998 and 1999, and revising out-year estimates based on these actual costs, the aggregate over five years to maintain the PDUFA I Additive Base is now estimated at about $20 million (4 percent) less than reflected in last year's plan update.

PDUFA I Additive Base Fund Estimates ($000)

Item	1998 Actual	1999 Actual	2000 Plan	2001 Plan	2002 Plan	Total [1]
Pay and Benefits for 662 Center/ORA FTE's	$56,993	$60,280	$64,553	$67,781	$71,170	**$320,778**
Center/ORA Support	$7,246	$6,749	$6,476	$6,476	$6,476	**$33,423**
Overhead	$10,753	$9,869	$8,787	$9,226	$9,688	**$48,323**
Central Accounts	$5,521	$4,687	$6,469	$6,792	$7,132	**$30,600**
Rent		$1,140	$1,197	$1,256	$1,319	**$4,912**
Total [1]	**$80,513**	**$82,725**	**$87,482**	**$91,532**	**$95,785**	**$438,036**

[1] Numbers may not add due to rounding.

2. Fee revenue estimates are based on annual increases of about 5 percent in fee-paying applications (rather than 7 percent as assumed in the original plan) and inflation increases for FY 2001 and 2002 of 3.7 percent. The total is still $50 million less than originally planned, over 5 years.

During discussions leading to the enactment of PDUFA II, both industry and FDA participants focused on the largely unanticipated increase in application review workload during PDUFA I and the need to ensure increasing revenues if this trend continues in PDUFA II. The following table, derived from the *Federal Register* Notices FDA published each year as a part of its fee-setting process, summarizes the increasing workload.

PDUFA Fee-Paying Full Application Equivalent Estimates by Year

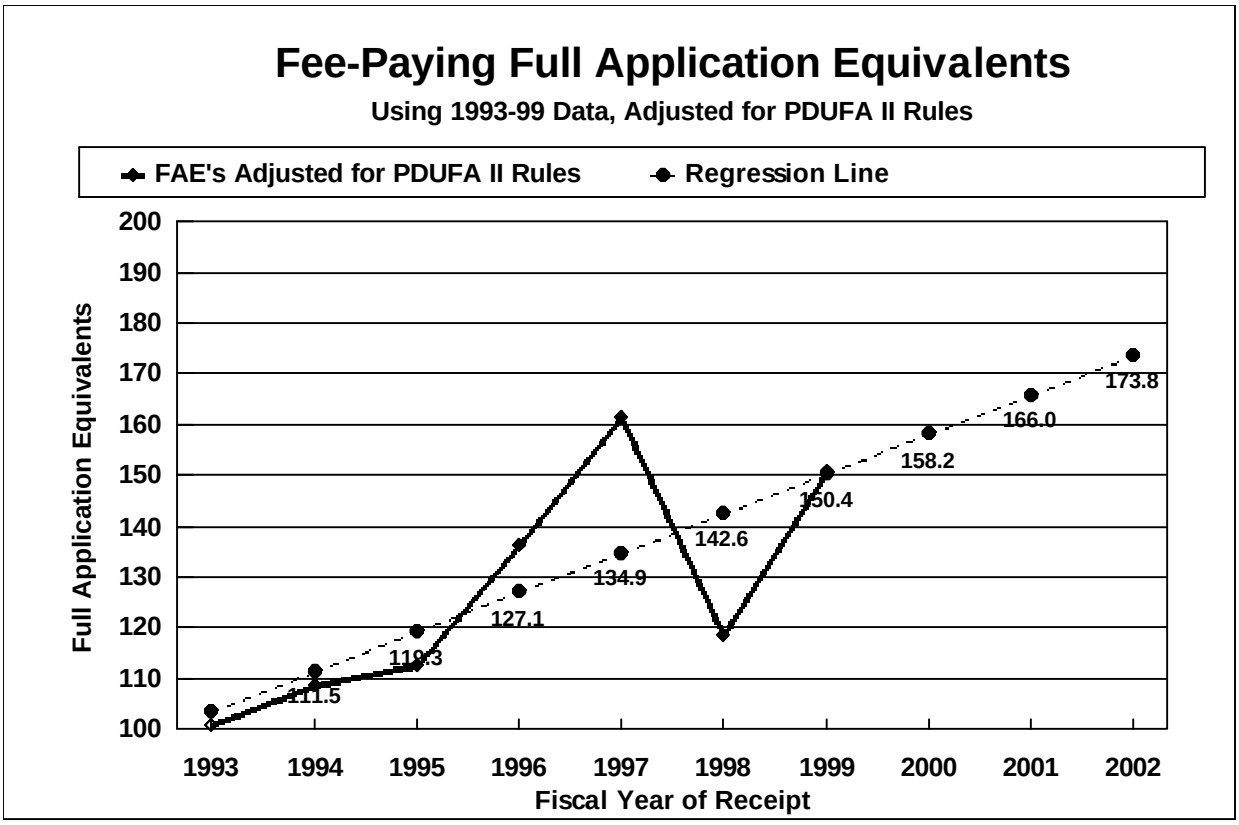
Fiscal Year	Full Application Equivalents	Percent Change from Previous Year	Allowance for Waivers or Reductions	Basis for Next Year's Fees	Percent Change from Previous Year
1993	116			116	
1994	129	11.2%	5	124	6.9%
1995	137	6.2%	6	131	5.6%
1996	157	14.6%	16	141	7.6%
1997	192	22.3%	40	152	7.8%

Using this information (excluding 1997 data which was unavailable during discussions that led to PDUFA II) negotiators agreed that it was reasonable to include a workload adjuster in PDUFA II. The adjuster would cause FDA resources to increase or decrease as the workload fluctuated. The statute was crafted so that FDA fee revenues would increase in any year FDA anticipated receiving more than 142 fee-paying full application equivalents (the number used to set the fee level each year in the statute). Conversely, fee revenues would decrease in any year FDA anticipated receiving less than 142 fee-paying full application equivalents.

As part of these negotiations, FDA analyzed the effect of both increasing and decreasing workload levels and inflation. Industry and FDA negotiators agreed that the most reasonable planning scenario was a continued yearly increase in fee-paying application workload of 7 percent and inflation of 3 percent. These assumptions were the basis for projecting both revenues and workload in the original plan of July 1998.

In 1998, FDA received only 119 fee-paying full application equivalents, considerably below the 152 fee-paying full application equivalents estimated in the December 9, 1997 *Federal Register* notice. In light of this shortfall, the original projections above have been revised.

FDA published a *Federal Register* notice on December 22, 1998, using linear regression analysis to estimate the next year's number of fee paying applications and application fee revenues. That linear regression analysis was updated and published again in the *Federal Register* notice on December 28, 1999 (Attachment 1). Using that same data and method to estimate fee-paying applications and revenues through FY 2002 projects an increase of about 5 percent each year, as depicted in the graph that follows.



Based on the regression line shown above, and estimating the inflation adjustment for the next two years at 3.7 percent (based on federal salary increase proposed in the President's FY 2001 budget) rather than 3 percent, FDA updated its projection of fee revenues that is included in Attachment 2. The following table summarizes the revised projection and how it differs from the original projection in July 1998.

Planned PDUFA Fee Collections by Year--Original, Now, and Difference ($000)

Item	1998	1999	2000	2001	2002	Total
Fees--Original Plan	$117,122	$132,273	$145,435	$167,168	$177,915	$739,914
Fees—Current Plan	$117,122	$122,007	$135,441	$154,047	$161,716	$690,333
Difference		($10,266)	($9,994)	($13,121)	($16,199)	($49,581)

As a result of this reassessment of potential revenues through FY 2002, this revised five-year plan assumes that revenue collections will be $50 million less than originally planned—rather than $62 million less as envisioned in last year's plan update.

3. Each of the next 3 years, FDA will spend more than it collects in fees, maintaining an adequate carryover balance at the end of each year.

If FDA spends approximately as much as it collects each year, all of the PDUFA II revenues collected over the 5 years will be used. However, since FDA has spent less than it collected in each of the past two years, and because FDA began PDUFA II with a carryover balance, FDA can spend more than it collects in each of the last three years. (The PDUFA fees FDA collects but does not obligate by the end of the fiscal year are "carried over" for use in a future fiscal year.) At the end of FY 1999, the carryover cash amounted to about $71.5 million.

Each year, two-thirds of the PDUFA fees (product and establishment fees) are not paid to FDA until January 31--4 months after the fiscal year starts on October 1. The other one-third of PDUFA revenue (application fees) is spread out over the year. For estimating purposes, this portion is distributed evenly over 12 months. These application fees in aggregate would cover FDA costs for 1 1/3 months of the first 4 months of the fiscal year. At a bare minimum, FDA needs to carry forward into each new fiscal year enough fee revenue to cover costs for at least 2 2/3 months into each new fiscal year to cover expenses until the product and establishment fees are received at the end of January. In addition, because PDUFA contains provisions that could prevent FDA from being able to assess or collect fees (specified minimum levels that must be available from traditional appropriations, etc.—see Assumption5), FDA must maintain a substantial carryover balance to cope with possibility that the PDUFA program may terminate if triggers are not met. (Carryover balances are discussed further on page 27.)

4. About $252 million will be available over 5 years for PDUFA II increases, rather than the $284 million estimated in the original plan and $219 million estimated in last year's plan.

If the total amount needed to sustain the PDUFA I initiatives derived under Assumption 1 is subtracted from the total revenues FDA expects to have available each year under Assumption 2, the net available for allocation to meet the PDUFA II goals is derived. Net available is the increment available to FDA over and above the PDUFA I Additive Base resources already invested to support and maintain the 662 additional FTE's in the centers and ORA. This is the amount available for additional investments over the next 5 years to meet the PDUFA II goals.

Revenues Anticipated and Net New Resources Available for PDUFA II ($000)

Item	1998	1999	2000	2001	2002	Total
Fees Anticipated	$117,122	$122,007	$135,441	$154,047	$161,716	$690,333
PDUFA I Additive Base	$80,513	$82,725	$87,482	$91,532	$95,785	$438,036
Net New Resources	$36,609	$39,282	$47,959	$62,514	$65,932	$252,297

This is a substantial increase from last year's plan update, but still represents about a 13 percent reduction from the $290 million originally planned in 1998.

5. As in the original plan, it is assumed that all statutory conditions necessary for

PDUFA to operate will be met each year.

The law allows FDA access to PDUFA II revenues only if three conditions are met. This plan assumes the following statutory conditions will be met:

- Total FDA appropriations (exclusive of user fees and rent) in future years must total at least as much as FDA received in 1997, with some adjustments. Those amounts are:

Fiscal Year	1997 Amount ($ Millions) Less Rent and User Fees	Adjustment Factor (Actual factors through FY 2001, estimated for FY 2002)	Minimum Appropriation ($ Millions)	Actual Appropriation ($Millions) Less Rent and Fees
1998	$820	1.0000	$820	$858
1999	$820	1.0144	$832	$888
2000	$820	1.0375	$851	$938
2001	$820	1.0687	$876	
2002	$820	1.0932	$896	

Because FDA has gotten earmarked increases for specific initiatives since 1997 (e.g., Food Safety, Tobacco), this trigger is easily met, even though FDA has not received increases to cover the cost of pay increases and inflation for its core programs for seven years.

- 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 1997--with some adjustments.

Fiscal Year	1997 Amount Spent on Drug Review from Appropriations ($ Millions)	Adjustment Factor (Actual factors through FY 2001, and estimated for FY 2002)	Minimum Drug Review Spending from Appropriations ($ Millions)	Actual Drug Review Spending from Appropriations ($Millions)
1998	$148	1.0000	$148	$152
1999	$148	1.0144	$150	$160
2000	$148	1.0375	$154	
2001	$148	1.0687	$158	
2002	$148	1.0932	$162	

If this trigger is not met, even by one dollar, no fees may legally be collected or spent for the year. This is the most difficult of the triggers for FDA to meet. FDA will not know exactly how much it has spent from appropriations until the very end of the year when final spending is finished. FDA plans to spend this minimum from appropriations each year. Because of the unforgiving nature of this trigger, FDA must spend more than the minimum, just to be sure that the trigger is met when the final accounting is done. However, in times when appropriations for most FDA programs do not keep pace with costs of inflation and pay increases, those programs have to be cut even more in order to assure that the statutory

minimum (including an inflation increase) is spent on drug approval.

- 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 ($Millions)	PDUFA Fees Actually Collected ($Millions) *as of 9/30/1999*	Overage, if Any ($Millions)
1998	$117	$117	
1999	$132	$122	
2000	$145		
2001	*$154*[1]		
2002	*$162*		

[1] The President's FY 2001 Budget estimates $149 million, but data available after that budget was submitted indicate that about $154 million should be collected in FY 2001. Spending this larger amount would require a supplemental appropriation for the additional $5 million from fees.

6. As in the original plan, funds planned for acquiring human resources may be spent on 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.

7. As in the original plan, the amount FDA pays for rent for PDUFA and other programs is no longer capped beginning in FY 1999.

For a substantial period before FY 1992, and continuing through FY 1998, FDA's Appropriation Act maintained a cap on the amount of rent FDA could pay the General Services Administration (GSA). As a result, since there was no increase in rent costs from FY 1992 through FY 1998, PDUFA fees were not used to pay for GSA rent--the flat GSA rent payments were all a part of the PDUFA appropriated base.

Beginning in FY 1999, the Appropriation Act for FDA no longer contained that cap. Instead FDA's Appropriation Act requires FDA to pay full GSA rent charges just as all other government departments and agencies do. With the removal of the cap, the total amount of rent that FDA paid to GSA doubled in FY 1999--increasing from $46.3 million in FY 1998 to $88.3 million. This impacted all programs, including the human drug review process. The share of rent payable for the human drug review process from PDUFA revenue increased by $5.4 million in FY 1999, and will increase with inflation. In addition, small annual increases are anticipated each year, as the staff grows to cope with increasing workload.

Estimated Rental Payments for Human Drug Review Process ($000)

Rent Paid to GSA	1998 Actual	1999 Actual	2000 Plan	2001 Plan	2002 Plan
Rent From Appropriation	$6,245	$7,817	$7,708	$7,993	$8,233
From PDUFA Fees	$0	$5,428	$5,643	$5,860	$6,240
Total Rent Paid to GSA	**$6,245**	**$13,245**	**$13,351**	**$13,853**	**$14,473**

8. A small amount will be held in a contingency reserve for FY 2002.

The likelihood of unanticipated events increases the further the plan tries to project into the future. No contingency reserve is set aside for next year, but a relatively modest amount ($6 million) is set aside in this update as a contingency reserve for FY 2002. This contingency reserve is being kept to a minimum so that as much of the planned revenue as possible is allocated to the centers and ORA to implement their plans.

Potential claims on this reserve will be assessed in FY 2002 and allocations will be made. Funds not required for contingencies will be allocated among CDER, CBER, and ORA for the needs of their drug review programs.

9. By the end of PDUFA II, total spending from all sources for the human drug application review process will have increased by about 44 percent, close to the 45 percent originally estimated.

The above assumptions permit a projection of revenues available for the review of human drug applications through 2002--shown in the chart below. The revenues resulting from PDUFA II will allow program funding to increase by about 44 percent over the 5 years of this program--from $232 million in 1997 to $333 million in 2002. At first this may appear large. Average salary and benefit costs alone, which account for well over half of all costs, are expected to increase by about 28 percent by the end of 5 years--the compounded result of an average increase of 5 percent each year. This leaves a rather modest increase for other costs--particularly in light of the very intense investment in information technology required to achieve the PDUFA II goal of electronic receipt and review of applications by the end of FY 2002.

Viewed from another perspective, this increase is less than the compounded increase in workload (5 percent) and inflation (3 percent) that forms the basis of the revenue projections. Workload and inflation increases alone, when compounded, exceed 47 percent over 5 years. And inflation at 3 percent really understates the costs of inflation that FDA expects to experience, since pay and benefit increases have historically been at substantially higher levels (5 percent).

This PDUFA II 5-year plan update is based on the total revenue stream shown in the table below.

Projection of Total Funds Spent for the Human Drug Application Review Process ($000)

Source of Funds	1997 Actual	1998 Actual	1999 Actual	2000 Estimate	2001 Estimate	2002 Estimate
S&E Appropriations[1]	$147,959	$151,836	$159,670	$153,501	$158,119	$161,756
Fees from Industry	$84,289	$101,615	$122,515	$148,998	$163,604	$171,319
Total Funds[2]	**$232,249**	**$253,452**	**$282,185**	**$302,499**	**$321,723**	**$333,075**

[1] Total includes Rent Appropriation in 1997 and 1998. Beginning in 1999 the Rent Appropriation was consolidated into the Salaries and Expenses Appropriation. Amounts for FY 2000 and beyond are current estimates of the minimum amounts that must be spent from appropriations on the process for the review of human drug applications in order to meet the statutory requirements of PDUFA II.

[2] Numbers may not add due to rounding.

10. The plan will be reassessed and updated annually.

All allocations in the plan are subject to review and reassessment early in 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 30.

Planning Process

The planning process for meeting new PDUFA II goals began during discussions with industry in the last year of PDUFA I. As new goals were proposed, resource implications were also estimated and discussed. These ongoing discussions over many months resulted in the PDUFA II goal letters of November 12, 1997 and the PDUFA II resource levels and adjusters to achieve those goals that were enacted in the statute.

The PDUFA II Five-Year Plan completed in July 1998 reflected the resources FDA initially anticipated and plans for investing those resources. Responding to the reduced resources FDA anticipated when the FY 1999 plan update was developed, last year FDA substantially reduced its expenditure forecast.

For this FY 2000 plan update, the Office of Management and Systems (OMS) again 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 II goals. CDER, CBER and ORA were each asked to reassess essential needs in order to ensure that they meet the PDUFA II goals, which become increasingly challenging in the final years. Substantial increases in staffing were deemed essential for all three components, and are reflected in this revised plan. Higher levels of spending have been planned for the final three years of PDUFA II to enable the centers and ORA to meet these goals. These higher levels of spending are possible because: (1) some funds originally planned for earlier years were not used, and remain available;
(2) costs of maintaining the PDUFA I additive base are less than originally forecast; and
(3) overhead costs have decreased.

The IT portions of each component's plan is provided in more detail in the PDUFA II Information Management Five-Year Plan (Attachment 3). This revised IT plan also identifies Electronic Regulatory Submission and Review (ERSR) accomplishments to date.

The overall PDUFA II Five-Year Plan update resulting from this process provides a sound framework for the investments needed to ensure FDA success with PDUFA II. The following pages summarize the planned distribution of PDUFA II funds to each component (CDER, CBER, and ORA) over the next 3 years and provide an Overhead Summary and an FDA Plan Summary. The two largest demands continue to be: (1) additional human resources to meet the more stringent application review times under PDUFA II goals and (2) IT investments to achieve paperless application receipt and review by the end of PDUFA II.

CDER Plan Summary

CDER has developed an amended, detailed overall plan for the 5 years of PDUFA II, reflecting the revised resource level estimates. The revised plan totals $165 million—about the level in the original plan. A year-by-year resource summary of CDER's plan is on page 17. It has the same three principal components as last year's plan: (1) personnel and support, (2) review process enhancements, and (3) information technology.

Personnel and Support

The largest portion of CDER's plan is for funds to hire and support additional staff for the drug evaluation process. This represents $85 million (51 percent) of CDER's total plan and will enable CDER to add 234 more FTE's to the drug review process since the beginning of PDUFA II in FY 1998.

This number is in addition to CDER's appropriated drug review base of 749 FTE's and the PDUFA I additive base of 421 FTE's paid from fees—for a total of 1,404 CDER FTE's dedicated to the drug review process by FY 2002.

The additional personnel will be used to achieve the Center's expedited new drug evaluation performance goals for NDA's, efficacy supplements, manufacturing supplements, and resubmissions of original NDA's as established under PDUFA II. Recognizing that it takes 12 to 24 months for new employees to become proficient reviewers, CDER has attempted to hire most of the new staff by the end of fiscal year 2000. This level of staffing will allow staff to be trained and to handle the increased workload associated with PDUFA II goals and increasing workload during the final 2 years of PDUFA II.

The Personnel and Support subtotal also includes funds to acquire more space for this additional staff--$1 million over the 5 years. This amount will be used to pay increased rental costs to GSA and will be held in reserve until arrangements are made for acquisition of this additional space.

Review Process Enhancements

The second component of CDER's plan is funding for a number of enhancements to the application review process. This has increased substantially from CDER's initial plan. CDER plans $34 million (21 percent of the total plan) for this purpose through FY 2002. These improvements span many offices that directly contribute to or support the attainment of PDUFA II goals. It includes funds to: standardize and improve review practices, enhance medical library resources for reviewers, expedite the validation of methods in new drug applications, train reviewers, increase clinical trial inspections, and improve PDUFA time

reporting systems, enhance support and services for the drug listing program, enhance document management and accountability, and support for additional advisory committee meetings essential to expedite review. Also included are estimated travel funds for International Conference on Harmonization (ICH) meetings that will promote accelerated drug development through agreements on shared standards for use in the United States, Japan, and European pharmaceutical authorities. The actual distribution of these funds will be decided each year by the Office of International and Constituent Relations which coordinates ICH activities.

Information Technology

The final component of CDER's plan is $48.1 million (29 percent of the total) for IT enhancements for the drug review process. This includes three parts: (1) funds to develop the capability for electronic application receipt and review by FY 2002 which account for $20.8 million, (2) funds for replacing CDER's management information system which account for $8 million, and (3) funds for many other IT enhancements that support the PDUFA II goals (such as replacement of one-third of the personal computers of the reviewers every 3 years and overall maintenance and upgrading of CDER's data systems and networks that support PDUFA) which account for $19.3 million over 5 years.

The IT goals for PDUFA remain fixed and this part of CDER's plan has changed the least from last year.

The table on the following page summarizes CDER's revised plans to invest the additional funds made available as a part of PDUFA II. In the past the cost of maintaining the PDUFA I Additive Base was shown in a separate box below each component's plan. Beginning in the FY 2000 Revised Plan, the cost of maintaining the PDUFA I Additive Base is presented as a part of each plan, at the top of the table. This makes clearer the total amount PDUFA fee revenues planned for each component.

FY 2000 Five-Year Plan Update

CDER Plan Summary Tables--PDUFA II

Plan for Funds from PDUFA Fee Revenues ($000)

Note: Numbers Are Rounded and May Not Add

Category	1998 Actual	1999 Actual	2000 Plan	2001 Plan	2002 Plan	5-Year Total
PDUFA I Additive Base						
PDUFA I Additive Base FTE's [1]	398	418	421	421	421	
Payroll for PDUFA I FTE's	$36,847	$40,150	$43,090	$45,245	$47,507	$212,840
Operating Support for PDUFA I Base	$3,493	$3,805	$3,789	$3,789	$3,789	$18,665
Subtotal--To Maintain PDUFA I Levels	**$40,340**	**$43,955**	**$46,879**	**$49,034**	**$51,296**	**$231,505**
PDUFA II Enhancements Over PDUFA I						
Additional FTE's Planned	49	70	183	234	234	
(Increment Each Year)	49	21	116	51	0	
Total PDUFA Additive FTE's in This Plan [2]	447	488	604	655	655	
Payroll for Additional FTE's [3]	$4,162	$6,112	$17,005	$22,832	$23,973	$74,084
Operating Support for Additional FTE's [4]	$0	$1,108	$819	$2,106	$2,106	$6,139
Startup Costs for New FTE (One-time) [5]	$0	$861	$285	$0	$0	$1,146
Recruit/Relocation/Renos/Security	$752	$418	$590	$500	$500	$2,760
OMS Reserve for Additional Space			$370	$330	$350	$1,050
Subtotal--Personnel and Support	**$4,914**	**$8,499**	**$19,069**	**$25,768**	**$26,929**	**$85,179**
ICH Support [6]	$174	$96	$332	$420	$420	$1,442
Redesign of Sci. Review Process	$1,284	$6,658	$8,347	$8,234	$7,936	$32,459
Subtotal--Process Enhancements	**$1,458**	**$6,754**	**$8,679**	**$8,654**	**$8,356**	**$33,901**
Electronic Submissions	$2,934	$4,128	$5,376	$4,365	$3,955	$20,758
Document Management	$773	$2,660	$1,649	$1,726	$1,135	$7,943
Other Electronic Initiatives [7]	$3,811	$3,920	$4,223	$4,352	$3,050	$19,356
Subtotal--Information Technology	**$7,518**	**$10,708**	**$11,248**	**$10,443**	**$8,140**	**$48,057**
Subtotal PDUFA II Enhancements	**$13,890**	**$25,961**	**$38,996**	**$44,865**	**$43,425**	**$167,137**
Total PDUFA Additive Funds--CDER	**$54,230**	**$69,916**	**$85,876**	**$93,899**	**$94,722**	**$398,642**

[1] Payroll Base is for 398 FTE's in 1998, 418 in 1999 (20 FTE's Transferred from CBER); and 421 thereafter (3 from Ombudsman).

[2] PDUFA Additive FTE Base (top line) plus Additional FTE Planned amount shown above.

[3] Salary and benefits estimates based on $88,500 in 1999 and escalated at 5% annually thereafter. The 1998 and 1999 amounts are actual expenses.

[4] Operating Support per FTE is calculated at $9,000 per year.

[5] $9,500 per FTE is provided in first year only for start-up costs.

[6] Estimate only: Actual distribution of ICH funds will be decided each year by the Office of International and Constituent Relations.

[7] Includes $150,000 for enhancing eitherCDER or ORA automated system for tracking bioresearch monitoring inspections

CBER Plan Summary

CBER has developed an amended, detailed overall plan for the 5 years of PDUFA II, reflecting the revised resource level estimates. The revised plan totals $54.7 million--a reduction of $4.3 million below the level originally planned, but an increase of $6.3 million above the level planned in last year's revision. A year-by-year resource summary of CBER's plan is on page 20. It has the same three principal components as last year's plan: (1) personnel and support, (2) review process enhancements, and (3) information technology.

Personnel and Support

The largest portion of CBER's plan is for funds to hire and support additional staff for the drug evaluation process. This represents $21.4 million (39 percent) of CDER's total plan and will enable CBER to add 118 more FTE's to the drug review process by FY 2002.

This number is in addition to and CBER's appropriated drug review base of 292 FTE's and its PDUFA I additive base of 167 FTE's --for a total of 577 CBER FTE's dedicated to the drug review process by FY 2002.

In CBER's plan the additional FTE's needed each year were arrayed with the specific PDUFA II goals. The PDUFA II performance goals are much more demanding than the PDUFA I goals. Review times for standard applications are reduced gradually from 12 months to 10 months so that by FY 2002, 90% of the applications must be reviewed within 10 months after receipt. While the 6-month review performance goals for priority applications became effective in FY 1997 no additional resources were available to accomplish that commitment. Experience has shown that priority application review requires more resources than standard applications. Because of the intensity of application review effort required for priority applications, personnel are not available to perform other necessary tasks such as meeting with sponsors of pending applications, reviewing clinical hold responses, or providing special protocol assessments.

The CBER Managed Review Process must now be expanded to incorporate the IND sub-process. The rollout of the Managed Review Process to include the IND sub-process began in January 1998. There are FTE and dollar costs associated with the rollout of the Managed Review Process. The successful accomplishment of the PDUFA II commitments depends upon the expansion of this process.

Pre-IND and the first 30-days of IND review are now included in the new drug review process under PDUFA II. In addition to the application review workload, there are several other PDUFA II commitments which require resources. New tracking and reporting systems need to be set up and current systems need to be expanded. A system needs to be set up to track and report meeting-management performance.

Review Process Enhancements

The second component of CBER's plan is funding for enhancements to the application review process. CBER plans $4.7 million over 5 years (9 percent of the total plan) for this purpose. These improvements span several offices that contribute to attaining PDUFA II goals. Included are funds to train reviewers, increase pre-approval inspections, and cost increases for CBER's Document Control Center related to increasing application volume and the transition to electronic applications.

The Lot Release System for PDUFA products requires review and analysis to determine if the current database information can be integrated or new databases need to be developed. The ICH travel funds reflect projections based on FY 1998 and FY 1999 actual amounts. The actual distribution of these funds will be decided each year with the Office of International and Constituent Relations which coordinates ICH activities.

Information Technology

The Information Technology (IT) component remains the largest part of CBER's plan -- $ 28.6 million (52 percent of the total plan). It has three parts: (1) funds to develop the capability for electronic application receipt and review by FY 2002 account for $6.4 million; (2) funds for replacing CBER's document tracking system with state-of-the-art capabilities account for $15.9 million; and (3) funds for other IT enhancements that support the PDUFA II goals (such as overall maintenance and upgrading of CBER's data systems and networks that support PDUFA) account for $6.3 million over 5 years.

The funding for electronic submissions will enable CBER to comply with the Agency's initiative to develop and update its information management infrastructure to allow, by FY 2002, the paperless receipt and processing of IND's and human drug (including biologics) applications, as defined in PDUFA, and related submissions.

The table on the following page summarizes CBER's revised plans to invest the additional funds made available under PDUFA II. In the past the cost of maintaining the PDUFA I Additive Base was shown in a separate box below each component's plan. Beginning in the FY 2000 Revised Plan, the cost of maintaining the PDUFA I Additive Base is presented as a part of each plan, at the top of the table. This makes clearer the total amount PDUFA fee revenues planned for each component.

FY 2000 Five-Year Plan Update

CBER Plan Summary Tables--PDUFA II

Plan for Funds from PDUFA Fee Revenues ($000)

Note: Numbers Are Rounded and May Not Add

Category	1998 Actual	1999 Actual	2000 Plan	2001 Plan	2002 Plan	5-Year Total
PDUFA I Additive Base						
PDUFA I Additive Base FTE's [1]	187	167	167	167	167	
Payroll for PDUFA I FTE's [1]	$15,097	$14,834	$15,816	$16,607	$17,437	$79,792
Operating Support for PDUFA I Base [2]	$2,519	$1,825	$1,503	$1,503	$1,503	$8,853
Subtotal--To Maintain PDUFA I Levels	**$17,616**	**$16,659**	**$17,319**	**$18,110**	**$18,940**	**$88,645**
PDUFA II Enhancement Levels Over PDUFA I						
Additional FTE's Planned	4	54	76	118	118	
Less FTE's Reprogrammed from Research	-13	-26	-39	-39	-39	
Net Additional FTE Requested	**-9**	**28**	**37**	**79**	**79**	
(Increment Each Year)	-9	37	9	42	0	
Total PDUFA Additive FTE's in This Plan [3]	178	195	204	246	246	
Payroll for Additional FTE's [4]		$1,135	$3,205	$7,186	$7,545	$19,072
Operating Support for Additional FTE's [5]	($297)	$0	$333	$711	$711	$1,458
Startup Costs for new FTE's (One-time)[6]	$0	$0	$29	$399	$0	$428
Moves and Renovations		$0	$428			$428
OMS Reserve for Additional Space						$0
Subtotal--Personnel and Support	**($297)**	**$1,135**	**$3,995**	**$8,296**	**$8,256**	**$21,386**
Review Process Improvements	$701	$958	$1,650	$540	$493	$4,342
International Conference on Harmonization [7]	$67	$45	$116	$50	$50	$328
Subtotal--Process Enhancements	**$768**	**$1,003**	**$1,766**	**$590**	**$543**	**$4,670**
Electronic Submissions	$457	$2,231	$1,604	$1,050	$1,050	$6,392
Document Management	$3,959	$3,409	$3,649	$2,559	$2,339	$15,915
Other Electronic Initiatives	$1,642	$1,863	$950	$927	$927	$6,309
Subtotal--Information Technology	**$6,058**	**$7,503**	**$6,203**	**$4,536**	**$4,316**	**$28,616**
Subtotal--PDUFA II Enhancements	**$6,529**	**$9,641**	**$11,964**	**$13,422**	**$13,115**	**$54,672**
Total PDUFA Additive Funds--CBER	**$24,145**	**$26,300**	**$29,284**	**$31,532**	**$32,056**	**$143,316**

[1] Payroll Base is for 187 FTE's in 1998 and 167 each year thereafter (20 FTE's were Transferred to CDER).
[2] Operating Base is reduced by $295,000 in FT 1999 and by another $295,000 in FY 2000 as PDUFA additive research is phased out.
[3] PDUFA I Additive FTE's Base (top line) plus Net Additional FTE Requested (bolded line above).
[4] Salary and benefits estimates are based on $82,505 in 1999 and escalated at 5% annually thereafter. The FY 1998 and FY 1999 amounts are actual expenses.
[5] Operating Support per FTE is calculated at $9,000 per year.
[6] $9,500 per FTE is added only in first year for start-up costs (desk, PC, etc,).
[7] Estimate only: Actual distribution of ICH funds will be decided each year by the Office of International and Constituent Relations.

ORA Plan Summary

ORA has revised the resource estimates for PDUFA II expenditures for the remaining 3 years of PDUFA II to reflect a 5-year total of $5.9 million. This reflects a more stable workload and eliminates the drastic reduction that was projected in last year's plan update. The table at the top of page 23 presents a year-by-year resource summary of ORA's plan. It has the same three principal components as the center plan: (1) personnel and support, (2) review process enhancements, and (3) information technology.

Personnel and Support

Most of the field PDUFA reimbursement formula depends on the time reported in the field information system. It is difficult to predict the precise amount of time that will be reported because both the reporting and use of field time are not spread evenly over the year. Both assignments and reporting ebb and flow during the year. In FY 1999 an unusually large proportion of PDUFA reimbursable time was reported not only late in the fiscal year, but also after the PDUFA time reporting deadline. This resulted in an apparent decline in PDUFA resource use and lower projections for the remaining years. However, after the end of the year when reports were finalized, ORA resource use did not decline, and lower out-year projections of ORA personnel requirements in last year's plan were understated.

ORA is monitoring PDUFA time use estimates in FY2000 so that last year's understated estimates of resource needs are not repeated. An in-depth analysis of field PDUFA time use has led to the current estimate of level resource use for the remaining portion of PDUFA II. This is the case although the number of field related PDUFA assignments may be increasing. ORA has identified several trends that are associated with this more efficient use of resources. Over the last 3 years an increasing number of PDUFA decisions were based on the ORA Profiles database on established inspections. CDER's Office of Compliance increasingly uses field data to make decisions in lieu of requesting pre-approval inspections. District offices are also able to make PDUFA recommendations to CDER using field records, decreasing the need for PDUFA inspections. The increase in use of alternatives to inspections is a real trend, which is offsetting the increased volume of PDUFA applications. Consequently, ORA's plan calls for a return to the additive 74 FTE in FY2000 and a stable level for the remaining years of PDUFA II.

ORA will be expending a total of about 180 FTE's each year on the drug review process in each of the last three years of the plan (74 FTE's paid from PDUFA fees and 106 FTE's paid from appropriations).

Review Process Enhancements

The second component of ORA's plan is $3.4 million over 5 years for enhancements to support pre-approval inspection work. These enhancements include equipment, training, and improved time accounting. Adequate laboratory equipment to analyze samples collected during pre-approval inspections will avoid delays in field completion of some pre-approval inspection work. In FY 2000 ORA plans $189,000 to purchase specific pieces of equipment required to analyze pre-approval inspection samples. ORA also plans $175,000 for PDUFA related training. ORA's training needs are exacerbated because the 180 staff-years devoted to PDUFA in FY 2000 represent time spent by about 600 different employees. Training and refresher courses for those that conduct PDUFA pre-approval inspections or analyze samples collected have to be provided to most of these 600 individuals who contribute to the 180 FTE's of PDUFA work. The amount planned for training will meet this need. ORA's process enhancement subtotal also includes $400,000 in FY 2000 to conduct a requirements analysis to upgrade the ability to track PDUFA resource use and accomplishments. Major enhancements including modifications to the Field Accomplishments and Compliance Tracking System (FACTS), ORA's new reporting system, and related data warehouse tools are scheduled for FY 2001. The data warehouse and FACTS enhancements will improve ORA's PDUFA time accounting system and reduce the impact of assignments occurring late in the fiscal year on resource accounting.

Information Technology

The final component of ORA's plan is $3.3 million over 5 years to enable the field offices to receive and review electronic applications and to enable field staff to prepare for pre-approval inspections. The requested funds will allow ORA to develop and update its information management infrastructure to allow paperless application processing.

In the past the cost of maintaining the PDUFA I Additive Base was shown in a separate box below each component's plan. Beginning in the FY 2000 Revised Plan, the cost of maintaining the PDUFA I Additive Base is presented as a part of each plan, at the top of the table. This makes clearer the total amount PDUFA fee revenues planned for each component.

FY 2000 Five-Year Plan Update

ORA Plan Summary Tables--PDUFA II

Plan for Funds from PDUFA Fee Revenues ($000)

Note: Numbers Are Rounded and May Not Add

Category	1998 Actual	1999 Actual	2000 Plan	2001 Plan	2002 Plan	5-Year Total
PDUFA Additive FTE Base	74	74	74	74	74	
Base Payroll for 74 FTE (5% Inflation)	$5,049	$5,296	$5,647	$5,929	$6,226	$28,146
Base Operating Funds (3% Inflation)	$1,234	$1,119	$1,184	$1,184	$1,184	$5,905
Subtotal--To Maintain PDUFA I Levels	**$6,283**	**$6,415**	**$6,831**	**$7,113**	**$7,410**	**$34,051**
PDUFA II Enhancements over PDUFA I						
Additional FTE Requested	0	-12	0	0	0	
(Increment Each Year)	0	-12	12	0	0	
Total PDUFA Additive FTE's in this Plan [1]	74	62	74	74	74	
Additional FTE Payroll [2]	$0	($739)	$0	$0	$0	($739)
Support Costs @ $9,000/FTE	$0	($108)	$0	$0	$0	($108)
FTE Start-up Costs [3]	$0	$0	$0	$0	$0	$0
Subtotal--Personnel and Support	**$0**	**($847)**	**$0**	**$0**	**$0**	**($847)**
ICH Travel	$9	$4	$12			$25
Equipment	$141	$378	$189	$203	$218	$1,129
Training	$21	$248	$175	$140	$184	$768
FACTS Upgrade to Monitor/Track Time		$37	$400	$1,100	$0	$1,537
Subtotal--Process Enhancements	**$171**	**$667**	**$776**	**$1,443**	**$402**	**$3,459**
Electronic Submissions	$165	$80	$426	$501	$551	$1,723
Document Management		$0	$22	$11	$21	$54
Other Electronic Initiatives	$347	$0	$538	$261	$399	$1,545
Information Technology [4]	**$512**	**$80**	**$986**	**$773**	**$971**	**$3,322**
Total PDUFA II Enhancements	**$683**	**($100)**	**$1,762**	**$2,216**	**$1,373**	**$5,934**
Total PDUFA Additive Funds--ORA	**$6,966**	**$6,315**	**$8,593**	**$9,329**	**$8,783**	**$39,985**

[1] PDUFA Additive FTE Base (preceeding line) plus additional FTE's included in this plan.

[2] ORA pay and benefits estimates based on 1999 costs of $67,000 per FTE increasing at 5% annually.

[3] $9,500 per FTE is provided only in first year an FTE is added to cover one-time start-up costs.

[4] This line does not include $150,000 in CDER plan for enhancing either CDER or ORA automated tracking system for clinical trials inspections.

Overhead Summary

After the plans for CDER, CBER, and ORA were developed, the Office of Management and Systems estimated the overhead costs for PDUFA II. This section provides background information on how overhead is calculated.

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 Office of the Commissioner (OC) overhead costs. For this discussion, OC is used in its larger sense to encompass the several management and staff offices that report to the Commissioner. That formula conforms with generally accepted accounting principles and was found reasonable by Arthur Andersen consultants in subsequent annual audits. The formula is:

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

The salary costs used in this formula do not include any benefit costs. At the end of each fiscal year, the Office of Financial Management recalculates this overhead rate. To determine overhead costs attributable to the PDUFA activities, this rate is multiplied by the total PDUFA salary costs (excluding benefits) for CDER, CBER, and ORA. In 1999, FDA spent a total of $282.2 million on the drug review process as defined in PDUFA, and the 1999 PDUFA overhead costs were $24.5 million, or about 8.7 percent. This is down from 10 1/4 percent in 1998, due in large part to the Commissioner's reorganization and reduction of the Office of the Commissioner late in FY 1999. This revised plan assumes a lower rate—less than 8 percent of total PDUFA spending from FY 2000 through FY 2002. This further reduction is due to the reduction of the Office of the Commissioner for the entire year in FY 2000 and beyond. The FY 2000 overhead for the drug review process is estimated to be about $23.5 million--down substantially from the $28.4 million estimate in the original plan. Over the five year period, this plan reflects about $13.6 million less for PDUFA overhead than the original plan.

As with all PDUFA 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 overhead amount that must come from appropriations in FY 2000 is $11.9 million.

The difference between the total estimated overhead costs of $23.5 million in FY 2000 and the $11.9 million that must be paid from appropriated funds is $11.5 million. This $11.5 million is the amount of FDA's overhead costs to be paid from fees. Estimates of overhead costs by fund source over the 5 years of PDUFA II are provided in the chart that follows.

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

Source	1998 Actual	1999 Actual	2000 Estimate	2001 Estimate	2002 Estimate
S&E Appropriations[1]	$15,291	$14,683	$11,941	$12,290	$12,566
PDUFA Fees	$10,753	$9,869	$11,548	$13,327	$13,994
Total Overhead	**$26,044**	**$24,552**	**$23,489**	**$25,617**	**$26,560**

[1] The estimates for FY 2000 through FY 2002 represent the minimum that must be spent form Salary and Expense Appropriations for FDA to meet the second of the triggers discussed under Assumption 5 on Page 10. In FY's 1998 and 1999 FDA spent more than this minimum.

The aggregate result of these revised estimates is a reduction in fee revenue spent on overhead. The five-year overhead total in this FY 2000 plan update is $59.5 million—compared to $73.1 million estimated in the original plan and $64.2 million estimated in last year's plan update. Most of this saving comes from the Commissioner's reorganization and streamlining of the Office of the Commissioner. The result is about $13.6 million less spent on overhead, and therefore available for increased review and support staff in the centers and ORA.

Use of Overhead Funds

In the past, the industry fees supporting overhead were used in two ways: (1) direct PDUFA support, and (2) indirect support. The direct support funds paid for specific increases to support the growth of the drug review process. The remainder was indirect support, which paid for a portion of the OC offices that provide agency-level managerial direction and support services for all FDA programs, including PDUFA.

Beginning in FY 2000, all overhead costs paid from PDUFA fees are now treated as indirect costs. The fees allocated to PDUFA overhead are used to pay for the same percent of the costs of all components of the Office of the Commissioner. For FY 2000, approximately $11,548,000 in fees from PDUFA will pay for about 15 percent of total OC overhead costs. Since OC will utilize about 782 FTE's (total from both appropriations and fees) in FY 2000, PDUFA fees will pay for 15 percent of these FTE, or about 117 FTE.

FDA Plan Summary

The Agency plan for PDUFA II is a composite of plans developed by CDER, CBER, and ORA. Tables 1-7 on pages 28 and 29 summarize the overall FDA plan. The discussion below summarizes information in each of these tables.

- Table 1 (page 28) shows the $438 million set aside over 5 years to maintain and support the additional staff hired under PDUFA I (referred to as the PDUFA I additive base) discussed in Assumption 1. It also shows the total fee revenues expected annually and the amounts still available for enhancements after the PDUFA I additive base funds have been subtracted from the total estimated fees available--a total of about $252 million over the 5 years.

- Table 2 (page 28) shows the allocation of $269 million over 5 years, by component, planned to meet PDUFA II goals. (This is down from $290 million reflected in the original plan.) The yearly amounts and totals for CDER, CBER, and ORA on the first three lines are from their individual plans. The next three lines show the amounts for: (1) overhead, (2) central accounts, and (3) rental payments to GSA. These are necessary to accommodate the additional staff hired by the centers. The next to last line shows the contingency reserve in the last year of the plan (Assumption 8). The total line allocates all the PDUFA funds, above the PDUFA I Additive Base, that FDA expects to spend through FY 2002.

- Table 3 (page 28) shows the allocation of this $269 million by expense category. About $92 million will be spent for pay and benefits for a net of 313 additional staff (compared to $95.2 million for 325 additional staff in the original plan). About $80 million is planned for IT enhancements (compared to about $98 million in the original plan). The remainder is planned for other enhancements, operating expenses, overhead, rent, and contingencies. A summary of the change in FTE's planned each year from the PDUFA additive base levels on page 5 are shown below.

PDUFA II Program FTE Changes from the PDUFA I Additive Base

Organization	1998 Actual	1999 Actual	2000 Estimate	2001 Estimate	2002 Estimate
CDER	+49	+70	+183	+234	+234
CBER	-9	+28	+37	+79	+79
ORA		-12			
Total	**+40**	**+86**	**+220**	**+313**	**+313**

- Table 4 (page 29) 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 2000, FDA will spend about $13.6 million more than it expects to collect; in FY 2001 about $9 million more; and in FY 2002 about $9.6 million more. FDA can do this because FY 2000 began with about $71.6 million in PDUFA carryover funds. These carryover balances will be spent down in the last three years of the program so that FDA can hire the additional personnel necessary to continue to meet PDUFA goals.

FDA must have sufficient carryover funds at the end of each fiscal year in order to begin the following year with no less than 2 2/3 months of operating funds, or about 22.25 percent of the total planned for the year (Assumption 3). The table below compares those bare-minimum amounts with planned carryover balances.

Minimum Carryover Balance at the End of Each Fiscal Year and Planned ($000)

Item	2000	2001	2002
Plan Fee Spending in the Following Year	$163,604	$171,319	$177,658 [1]
Bare Minimum Carryover	$36,402	$38,118	$39,529
Carryover Balance in Plan	$58,027	$49,010	$39,407
Difference -- Minimum vs. Plan	$21,625	$10,892	($122)

[1] Estimate for the year following FY 2002 is a 3.7% increase above the FY 2002 planned amount. This is the amount for Federal Pay increase in the President's Budget estimates.

Carryover balances at these levels assure adequate funds to begin operations each year and also provide minimal security. Actual carry-over balances may be higher if spending falls short of planned levels.

- Tables 5 and 6 (page 29) summarize the allocation of the total $708 million in total fee revenue that FDA plans to spend over the 5 years of PDUFA II (PDUFA I additive base plus PDUFA II increases) by component (Table 5) and by expense category (Table 6). The last column in both tables sho2ws the percent of total PDUFA funds planned over the next 5 years. By component, CDER will be allocated 56 percent, CBER 20 percent, ORA 6 percent, overhead 8 percent, central accounts 5 percent, rental payments to GSA 3 percent, and contingency reserve 1 percent. By other expense categories, 58 percent of the total PDUFA II revenues will be dedicated to pay and benefits for staff (same as in the original plan), 13 percent for center/ORA operating costs, 11 percent for IT.

- Table 7 (page 29) summarizes the total PDUFA FTE's planned each year, showing the number of FTE's paid from the salary and expense appropriations, the number of FTE's paid from fees and considered the PDUFA I additive base, and the number of FTE's added over the course of PDUFA II under this plan.

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

Note: Numbers Are Rounded and May Not Add

Table1: PDUFA I Additive Base, and Estimated Funds Available

Item\Year	1998 Actuals	1999 Actuals	2000 Estimate	2001 Estimate	2002 Estimate	Five-Year Total	Five-Year Percent
Pay and Benefits for Centers/ORA	$56,993	$60,280	$64,553	$67,781	$71,170	$320,778	73%
Base Operating Funds--Centers/ORA	$7,246	$6,749	$6,476	$6,476	$6,476	$33,423	8%
Overhead	$10,753	$9,869	$8,787	$9,226	$9,688	$48,323	11%
Central Accounts	$5,521	$4,687	$6,469	$6,792	$7,132	$30,600	7%
Rent		$1,140	$1,197	$1,256	$1,319	$4,912	
Total--PDUFA I Additive Base	$80,513	$82,725	$87,482	$91,532	$95,785	$438,036	100%
Estimated Fee Receipts	$117,122	$122,007	$135,441	$154,047	$161,716	$690,333	
Available for Enhancements	$36,609	$39,282	$47,959	$62,514	$65,932	$252,297	

Table 2: Funds Planned for Enhancements--by Component

Component\Year	1998 Actuals	1999 Actuals	2000 Estimate	2001 Estimate	2002 Estimate	Five-Year Total	Five-Year Percent
CDER	$13,890	$25,961	$38,996	$44,865	$43,425	$167,137	62%
CBER	$6,529	$9,641	$11,964	$13,422	$13,115	$54,672	20%
ORA	$683	($100)	$1,762	$2,216	$1,373	$5,934	2%
Overhead	$0	$0	$2,761	$4,101	$4,306	$11,168	4%
Central Accounts	$0	$0	$1,586	$2,324	$2,394	$6,305	2%
Rental Payments to GSA	$0	$4,288	$4,446	$4,604	$4,921	$18,259	7%
Contingency Reserve	$0	$0	$0	$0	$6,000	$6,000	2%
Total	$21,102	$39,790	$61,516	$71,532	$75,534	$269,475	100%

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

Expense Category\Year	1998 Actuals	1999 Actuals	2000 Estimate	2001 Estimate	2002 Estimate	Five-Year Total	Five-Year Percent
Pay and Benefits for Centers/ORA	$4,162	$6,508	$20,211	$30,018	$31,519	$92,417	34%
Support Costs for Personnel	$455	$2,279	$2,854	$4,046	$3,667	$13,301	5%
Process Enhancements	$2,397	$8,424	$11,221	$10,687	$9,301	$42,030	16%
IT	$14,088	$18,291	$18,437	$15,752	$13,427	$79,995	30%
Subtotal to Centers	$21,102	$35,502	$52,723	$60,503	$57,914	$227,743	85%
Overhead	$0	$0	$2,761	$4,101	$4,306	$11,168	4%
Central Accounts	$0	$0	$1,586	$2,324	$2,394	$6,305	2%
Rental Payments to GSA	$0	$4,288	$4,446	$4,604	$4,921	$18,259	7%
Contingency Reserve	$0	$0	$0	$0	$6,000	$6,000	2%
Total	$21,102	$39,790	$61,516	$71,532	$75,534	$269,475	100%

FY 2000 Five-Year Plan Update

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

Note: Numbers Are Rounded and May Not Add

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

Category\Year	1998 Actuals	1999 Actuals	2000 Estimate	2001 Estimate	2002 Estimate
Difference Between Plan & Available			($13,557)	($9,017)	($9,603)
Est. Carry-Over Balance-Year Beginning			$71,584	$58,027	$49,010
Est. Carry-Over Balance-Year End	$67,518	$71,584	$58,027	$49,010	$39,407

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

Component\Year	1998 Actuals	1999 Actuals	2000 Estimate	2001 Estimate	2002 Estimate	Five-Year Total	Five-Year Percent
CDER	$54,230	$69,916	$85,876	$93,899	$94,722	$398,642	56%
CBER	$24,145	$26,300	$29,284	$31,532	$32,056	$143,316	20%
ORA	$6,966	$6,315	$8,593	$9,329	$8,783	$39,985	6%
Overhead	$10,753	$9,869	$11,548	$13,327	$13,994	$59,491	8%
Central Accounts	$5,521	$4,687	$8,055	$9,116	$9,526	$36,905	5%
Rental Payments to GSA	$0	$5,428	$5,643	$5,860	$6,240	$23,171	3%
Contingency Reserve	$0	$0	$0	$0	$6,000	$6,000	1%
Total	$101,615	$122,515	$148,998	$163,064	$171,319	$707,511	100%

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

Expense Category\Year	1998 Actuals	1999 Actuals	2000 Estimate	2001 Estimate	2002 Estimate	Five-Year Total	Five-Year Percent
Pay and Benefits for Centers/ORA	$61,153	$66,788	$84,764	$97,799	$102,689	$413,193	58%
Operating Funds--Excluding IT	$10,100	$17,452	$20,551	$21,209	$19,444	$88,756	13%
Information Technology	$14,088	$18,291	$18,437	$15,752	$13,427	$79,995	11%
Overhead	$10,753	$9,869	$11,548	$13,327	$13,994	$59,491	8%
Central Accounts	$5,521	$4,687	$8,055	$9,116	$9,526	$36,905	5%
Rental Payments to GSA	$0	$5,428	$5,643	$5,860	$6,240	$23,171	3%
Contingency Reserve	$0	$0	$0	$0	$6,000	$6,000	1%
Total	$101,615	$122,515	$148,998	$163,064	$171,319	$707,511	100%

Table 7: FDA Summary of all PDUFA FTE's for CDER, CBER, and ORA

FTE Category\Year	1998 Actuals	1999 Actuals	2000 Estimate	2001 Estimate	2002 Estimate
Base FTE's Paid from Appropriations	1,147	1,147	1,147	1,147	1,147
PDUFA I Additive Base FTE's	659	659	662	662	662
FTE's Added for PDUFA II	40	86	220	313	313
Total	1,846	1,892	2,029	2,122	2,122

Annual Reassessments

As originally envisioned, this plan will continue to be revised each year based on the latest information available. This third annual plan update is intended to let the centers and ORA know the amounts to expect in FY 2000 and in each of the next two years. This information facilitates the resource acquisition and planning for center work required to meet the PDUFA II 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 continue to be updated in the second quarter of each fiscal year. 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 in the current year and remaining years. Workload and revenue estimates are always based on the information set forth in the latest *Federal Register* notice setting fees.

If revenues are expected to be at levels lower than the assumptions of this plan then cutbacks in hiring and other expenses will be required, as was the case in the 1999 revision. On the other hand, if available PDUFA revenues exceed planned amounts because of carry-over balances available, increased workload estimates, and/or higher inflation adjustments, the additional revenues will be allocated, as is the case in this FY 2000 update. Also, contingency reserves for the current year will continue to be allocated in the course of each current fiscal year update, and reserves for out-years will be reduced. Also, if reassessments of center/ORA PDUFA workload indicate that PDUFA workload is out of kilter with the distribution of resources in this plan, then adjustments may be made.

Because all funds FDA expects to collect have been planned, adjustments made by the centers and ORA each year will generally be within the total amounts already planned for each 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.