Food and Drug Administration
Department of Health and Human Services

FY 2004 PERFORMANCE REPORT TO THE PRESIDENT AND THE CONGRESS

for the

Prescription Drug User Fee Act

Center for Biologics Evaluation and Research

Center for Drug Evaluation and Research
FDA

Commissioner's Report

I am pleased to present the Food and Drug Administration's (FDA's) fiscal year (FY) 2004 Performance Report to the President and the Congress for the Prescription Drug User Fee Act (PDUFA). This report marks the twelfth year of PDUFA, and completion of the second year of its most recent reauthorization (PDUFA III). Over the 12 years of PDUFA, the Agency has met or exceeded nearly all the PDUFA goals, drug approval time has been cut almost in half, and the Agency has maintained its traditionally high standards for safety and effectiveness.

PDUFA I challenged the Agency with goals to speed Agency review of new drug applications (NDAs) and biologics licensing applications (BLAs) without compromising safety. PDUFA II added goals to improve the speed of drug development before submission of the NDA or BLA.

PDUFA III expands on those efforts by adding new goals and initiatives to further improve the quality and efficiency of drug development, review, and risk management for newly approved products. The need for these improvements is significant. By some estimates, it costs more than $800 million and takes more than a decade to develop a new drug. After approval, it is important to ensure that drugs are used safely. Even with the best available data, drugs sometimes have side effects that were not predictable or detectable in studies conducted before their approval. Adverse drug events result in an estimated 770,000 injuries and deaths each year. Elderly patients, who take more medications and have greater drug sensitivity, are particularly vulnerable to these risks.

PDUFA III initiatives can have a public health impact beyond the earlier market access to safe and effective new drugs. By improving development efficiency and patient safety, these initiatives can also help in controlling health care costs.

The Agency has applied and extended many of the good ideas and process innovations pioneered in the PDUFA program to other FDA-regulated products. FDA's Strategic Plan goal for efficient risk management asserts that providing timely, high-quality, and cost-effective processes for the review of new technologies remains a high priority for the Agency.

Lester M. Crawford, D.V.M., Ph.D.
Acting Commissioner of Food and Drugs

Executive Summary

This report updates the Agency's review performance on the FY 2003 application submissions and presents preliminary performance in reviewing FY 2004 application submissions and meeting other PDUFA performance goals.

With all but two of the original applications submitted during FY 2003 having been reviewed and acted on by September 30, 2004, FDA can report that it exceeded all the review performance goals for FY 2003.

FDA's PDUFA workload increased substantially in FY 2004. This included an increase in review workload, such as applications, supplements, and resubmissions, as well as an increase in administrative workload, such as responding to meeting management activities and other review processes such as special protocol assessments.

- FDA received a total of 137 original NDAs and BLAs in FY 2004. This represented a 5-year high and an increase of 26 percent over FY 2003.
- FDA received 81 resubmitted NDAs and BLAs in FY 2004. This represented the first increase in this category in 5 years.
- The increased number of submissions and resubmissions in FY 2004 translated into a 20 percent overall increased workload for meeting management goals. The Agency received 2,287 meeting requests, scheduled 2,132 meetings, and prepared meeting minutes for 1,863 meetings during FY 2004.

Although only a preliminary performance assessment on applications submitted during FY 2004 is possible now, the Agency appears to be exceeding all the review performance goals for FY 2004 submissions. Even with an increased workload when compared to FY 2003, FDA improved its level of performance on two of the three meeting management goals. And, it met or exceeded two of the remaining three FY 2004 procedural and processing goals related to clinical holds, major dispute resolution, and special protocol question assessment and agreement.

FY 2004 was also the first year for the performance goal of issuing a discipline review letter to pre-submitted "reviewable units" of NDAs/BLAs under the Continuous Marketing Applications Pilot 1 study. It was the second year for the goal of notifying sponsors of substantive deficiencies (or the lack of same) in original NDAs, BLAs, and efficacy supplements identified during the initial filing review, within 14 days after the 60-day filing date. Although it is too early to make a final determination, performance is well over the targeted performance level for both goals for FY 2004.

FDA continued its progress on PDUFA III Management Initiatives and Electronic Applications and Submissions commitments to help improve the overall review process.

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Introduction

In 1992, Congress passed PDUFA, authorizing FDA to collect fees from companies that produce and submit applications for marketing for human drug and biological products. The original PDUFA had a five-year life; it ended in 1997, the same year Congress passed the FDA Modernization Act (FDAMA). FDAMA contained a five-year reauthorization of PDUFA (PDUFA II) that ended on September 30, 2002. When Congress passed the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), it extended the PDUFA program for five more years (PDUFA III). Information about PDUFA III, including the text of the amendments and the performance goals and procedures, can be found at http://www.fda.gov/oc/pdufa/PDUFA3.html.

PDUFA requires FDA to submit two annual reports to the President and the Congress for each fiscal year during which fees are collected: 1) a performance report due within 60 days of the end of the fiscal year, and 2) a financial report due within 120 days of the end of the fiscal year. This document fulfills the first of these requirements for FY 2004. This year's report covers FDA's progress in meeting the quantifiable PDUFA review goals for FYs 2003 and 2004 submissions and the FY 2004 processing and procedural goals. The report also describes FDA's progress in accomplishing new management initiatives and in meeting the information technology commitments of PDUFA III.

Overview of PDUFA

PDUFA provides FDA more revenue to hire additional reviewers and support staff and upgrade its information technology systems to speed up the application review process for new drugs and biological products without compromising FDA's traditionally high standards for approval. Under PDUFA, FDA agreed to meet certain performance goals that apply to the review of original and resubmitted new product applications and efficacy and manufacturing supplements to approved applications. FDA also agreed to meet certain procedural and processing goals aimed at speeding up drug development.

PDUFA I: Speeding Up Application Review

During the first few years of PDUFA I, FDA eliminated backlogs of original applications and supplements that had formed in earlier years when the program had fewer resources. Over the course of PDUFA I, the Agency agreed to review and act on a progressively increasing proportion of original NDAs, BLAs, and efficacy supplements within 12 months and resubmissions and manufacturing supplements within 6 months. The Agency also agreed to review and act on 90 percent of priority NDAs, BLAs, and efficacy supplements (i.e., submissions for products providing significant therapeutic gains) submitted in FY 1997 within 6 months. Over the course of PDUFA I, FDA exceeded all of these performance goals.

PDUFA II: Speeding Up Drug Development

In 1997, Congress passed the FDAMA and reauthorized PDUFA (PDUFA II) for five more years. Under PDUFA II, most review times were shortened and the Agency met or exceeded nearly all its review goals. PDUFA II also set new goals intended to improve communication between FDA and application sponsors during the drug development process. These goals specified time frames for scheduling meetings, responding to various sponsor submissions, such as special protocols and responses to clinical holds, and other activities.

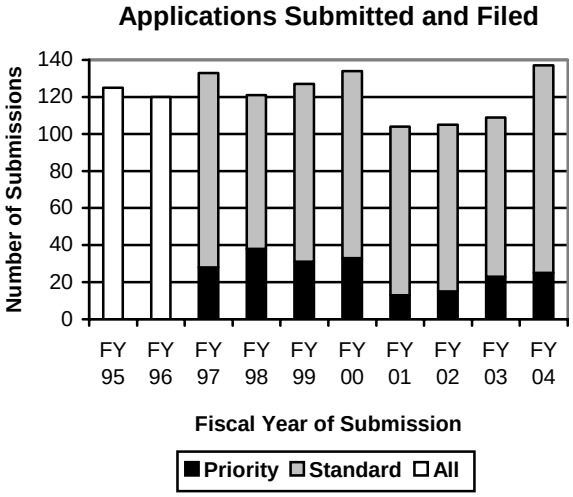
PDUFA III: Refining the Process - From Drug Development Through Application Review to Postmarket Surveillance

In 2002, Congress passed the Bioterrorism Act, which included an extension of PDUFA (PDUFA III) for five more years, FY 2003 through FY 2007. PDUFA III review performance goals and the procedural and processing goals are largely the same as the PDUFA II FY 2002 performance levels for these goals. PDUFA III establishes several new initiatives to improve application submissions and agency-sponsor interactions during drug development and application review. In addition, it authorizes FDA to spend user fee funds on certain aspects of postmarket risk management. Details about PDUFA III, including the text of the amendments and the performance goals and procedures can be found at http://www.fda.gov/oc/pdufa/PDUFA3.html.

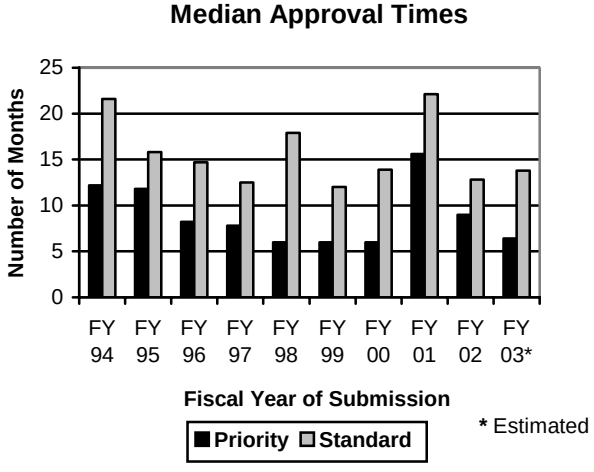
Trends in NDA/BLA Submissions and Approval Times

PDUFA-enabled improvements in review efficiency and application quality have had an impact on the overall time to marketing approval. FDA tracks a variety of metrics related to the process of human drug review. The time-to-approval statistics are affected by a number of factors, including the total number of NDA and BLA submissions and the number of newly submitted priority applications, as well as the overall quality of submitted applications and the number of review staff relative to the review workload. These factors can vary from year to year; the charts that follow provide an update on trends in submissions and overall approval times.

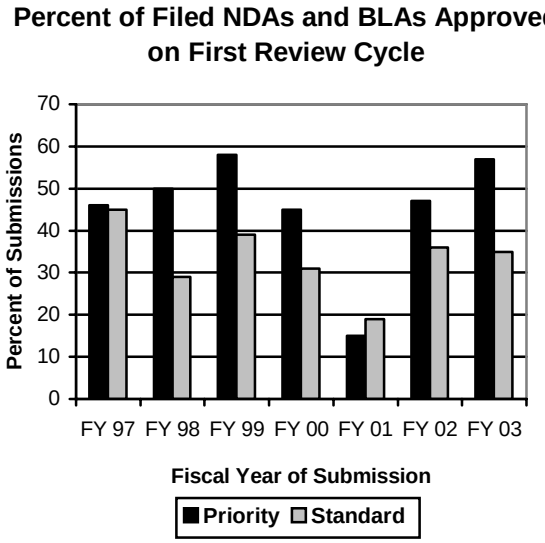
Number of Applications and Priority Applications Increased in FY 2004. The total number of submitted and filed applications increased from 109 in FY 2003 to 137 in FY 2004, and the number of priority applications increased from 23 in FY 2003 to 25 in FY 2004. Priority applications represent significant therapeutic gains, and in FY 2004 they accounted for over 18 percent of the total application pool. FDA began to measure performance by priority and standard under PDUFA in FY 1997.



Median Time to Approval Decreased in FY 2003 for Priority Applications. Median approval times for original NDA and BLA priority applications decreased in FY 2002 to 9.0 months and preliminary estimates indicate that median approval times for FY 2003 priority applications have continued to decrease. Based on applications approved by September 30, 2004, and under the theory that 80 percent of all filed applications will eventually be approved, the estimated median approval time is 6.4 months for FY 2003. The median approval time for standard applications was 12.8 months in FY 2002 and is estimated to be 13.8 months in FY 2003.



Percentage of First Cycle Approvals for Priority Applications Increased in FY 2003. The percentage of priority applications that were approved on the first cycle increased in FY 2003. FDA approved 57 percent of priority applications as compared to 47 percent in FY 2002. The percentage of first cycle approvals for standard applications was 36 percent in FY 2002 and 35 percent in FY 2003. Longer times to marketing approval can usually be attributed to applications that require more than one review cycle. PDUFA III includes an initiative to identify the causes of multiple review cycles and to provide earlier feedback on major deficiencies to application sponsors.



Report on FY 2003 and 2004 PDUFA Goals

This report updates the Agency's review performance on the FY 2003 application submissions and evaluates its performance in reviewing FY 2004 application submissions and meeting other PDUFA performance goals. The following information refers to FDA performance presented in this report.

- FDA has reviewed and acted on all but two of the original applications submitted during FY 2003, and final performance can now be compared against the goals and reported.

- Only a preliminary performance assessment on applications submitted during FY 2004 is possible now. For submission categories with a 10-month review goal, it is too early to measure review performance. For those submission categories with a review goal that is shorter than 10 months, performance on submissions received early in the fiscal year provides an early indicator of final review performance.

- FDA completed a Center for Biologics Evaluation and Research (CBER) and Center for Drug Evaluation and Research (CDER) product consolidation on October 1, 2003. The product consolidation was conducted to achieve a more efficient, effective, and consistent review program for human drugs and biologics. As a result of this change, workloads between CBER and CDER have shifted and are not comparable to previous years. In addition, the previous association of BLA reviews only with CBER is no longer valid. BLAs are now received by both CBER and CDER.

- The following terminology is used throughout this document: "application" means new, original application; "supplement" means supplement to an approved application; "resubmission" means resubmitted application or supplement; and "new molecular entity" or "NME" refers only to NMEs that are NDAs. (For FDAMA purposes, all BLAs are equivalent to NMEs; however, workload and performance statistics for BLAs are reported separately.)

- The counts of NMEs in workload tables are of 'discrete,' filed NMEs. FDA often receives multiple submissions for the same NME, for different dosage forms for example. All are initially designated as NMEs, but, when the FDA approves the first of the multiple submissions, the Agency redesignates the others as non-NMEs.

- Unless otherwise noted, all performance data are as of September 30, 2004.

Original Applications

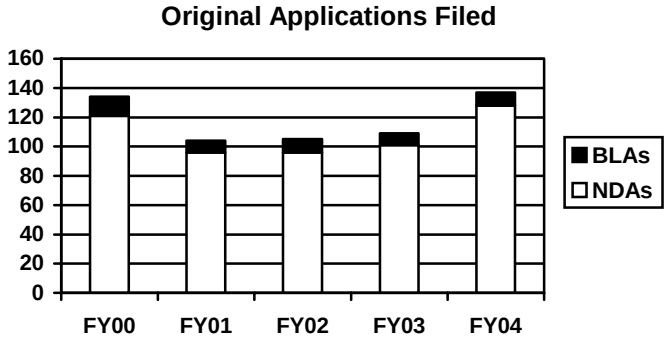
Goal - Review and act on complete original NDAs and BLAs

The table below summarizes the review time goals for original NDAs and BLAs. Over the five-year period defined by PDUFA III, the goal of reviewing 90 percent of priority applications in 6 months and standard applications in 10 months remains constant.

Original Application Type	Review Time Goal	Performance Goal FY 2002 – FY 2007 Submissions
Priority	6 months	90% on time
Standard	10 months	

Workload

The number of original applications filed increased by 26 percent in FY 2004 when compared to FY 2003 and was at a five-year high. Most of the increase was with NDAs. The number of NME applications filed increased by 20 percent.



Original Applications Filed *(Priority / Standard)*					
Type	FY 00	FY 01	FY 02	FY 03	FY 04[1]
NDAs	**121** *(29/92)*	**96** *(10/86)*	**96** *(12/84)*	**101** *(19/82)*	**128** *(22/106)*
BLAs	**13** *(4/9)*	**8** *(3/5)*	**9** *(3/6)*	**8** *(4/4)*	**9** *(3/6)*
PDUFA Total	**134** *(33/101)*	**104** *(13/91)*	**105** *(15/90)*	**109** *(23/86)*	**137** *(25/112)*
NMEs[2]	**30** *(16/14)*	**32** *(8/24)*	**22** *(8/14)*	**25** *(8/17)*	**30** *(14/16)*

[1] The count of FY 2004 submissions assumes that all submissions received in the last two months of FY 2004 are filed. When FDA files a submission, it is deemed "complete" by PDUFA definition. FDA makes a filing decision within 60 days of an original application's receipt. All PDUFA review times are calculated from the original receipt date of the filed application.

[2] In FY 2004, CDER designated 41 filings as NMEs initially (17 priority, 24 standard). However, only 30 of these are 'discrete' (14 priority, 16 standard).

Original Applications

Performance

FY 2003 Submissions

FDA reviewed and acted on all 23 priority applications within 6 months, exceeding the 90 percent on-time PDUFA review goal. FDA reviewed and acted on all but two (84 of 86) standard applications within 10 months. With the remaining two standard applications pending and not overdue as of September 30, 2004, FDA will also exceed the on-time PDUFA review goal for standard applications.[3]

FY 2003 Submissions						
Original Application Type	**Review Within**	**Type**	**Reviewed and Acted On**	**Number on Time**	**PDUFA Performance Goal**	**Percent on Time**
Priority	6 months	All Applications	23	23	90%	100%
		NMEs & BLAs	12	12	90%	100%
Standard	10 months	All Applications	84	84	90%	100%[4]
		NMEs & BLAs	21	21	90%	100%

FY 2004 Submissions

As of September 30, 2004, 44 percent (11 of 25) of the priority applications received in FY 2004 had been reviewed and acted on; and all had met the 6-month review goal. Twenty percent (22 of 112) of the standard applications received had been reviewed and acted on, and all had met the 10-month review goal. With submissions still pending and not overdue, it is too early to make a final performance determination.

FY 2004 Submissions						
Original Application Type	**Review Within**	**Type**	**Reviewed and Acted On**	**Number on Time**	**PDUFA Performance Goal**	**Percent on Time**
Priority	6 months	All Applications	11	11	90%	100%
		NMEs & BLAs	10	10	90%	100%
Standard	10 months	All Applications	22	22	90%	100%
		NMEs & BLAs	1	1	90%	100%

[3] The statute allows three additional months for review of original NDA and BLA submissions that receive a major amendment within the last three months prior to their goal date.

[4] The final on-time statistic will range from 98 percent to 100 percent depending on the final disposition of the two applications that had not been reviewed as of September 30, 2004.

Resubmitted Applications

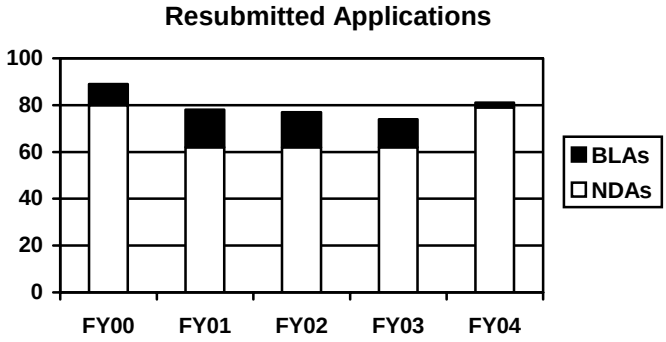
Goal - Review and act on resubmitted NDAs and BLAs

A resubmission is a firm's response after an FDA action of "approvable", "not approvable," or "complete response" on an application. The applicable performance goal for a resubmission is determined by the year in which the resubmission itself is received, rather than the year in which the original application was submitted. The definitions of Class 1 and Class 2 resubmissions can be found in Appendix A. Over the 5-year period defined by PDUFA III, the goal of reviewing 90 percent of Class 1 resubmitted new applications in 2 months and Class 2 resubmitted new applications in 6 months remains constant.

Resubmitted Application Type	Review Time Goal	Performance Goal FY 2002 – FY 2007 Submissions
Class 1	2 months	90% on time
Class 2	6 months	

Workload

The total number of resubmitted NDAs and BLAs received increased for the first time in five years in FY 2004. The total increase was a result of a 27 percent increase in resubmitted NDAs in FY 2004. BLA resubmissions decreased substantially.



Resubmitted Applications *(Class 1 / Class 2)*					
Type	FY 00	FY 01	FY 02	FY 03	FY 04
NDAs	**80** *(25/55)*	**62** *(25/37)*	**62** *(20/42)*	**62** *(24/38)*	**79** *(24/55)*
BLAs	**9** *(1/8)*	**16** *(6/10)*	**15** *(2/13)*	**12** *(1/11)*	**2** *(1/1)*
PDUFA Total	**89** *(26/63)*	**78** *(31/47)*	**77** *(22/55)*	**74** *(25/49)*	**81** *(25/56)*

Resubmitted Applications

Performance

FY 2003 Resubmissions

FDA reviewed and acted on 24 of 25 Class 1 resubmissions within 2 months. Additionally, FDA reviewed and acted on all 49 Class 2 resubmissions within 6 months. The PDUFA review time goal of 90 percent was exceeded in both classes of resubmissions.

FY 2003 Submissions					
Resubmitted Application Type	**Review Within**	**Reviewed and Acted On**	**Number on Time**	**PDUFA Performance Goal**	**Percent on Time**
Class 1	2 months	25	24	90%	96%
Class 2	6 months	49	49	90%	100%

FY 2004 Resubmissions

As of September 30, 2004, 84 percent (21 of 25) of the Class 1 resubmissions received in FY 2004 had been reviewed and acted on; and all had met the 2-month review goal. Sixty-one percent (34 of 56) of the Class 2 resubmissions had been reviewed and acted on, and all had met the 6-month review goal. With resubmissions still pending and not overdue, it is too early to make a final performance determination.

FY 2004 Submissions					
Resubmitted Application Type	**Review Within**	**Reviewed and Acted On**	**Number on Time**	**PDUFA Performance Goal**	**Percent on Time**
Class 1	2 months	21	21	90%	100%
Class 2	6 months	34	34	90%	100%

Efficacy Supplements

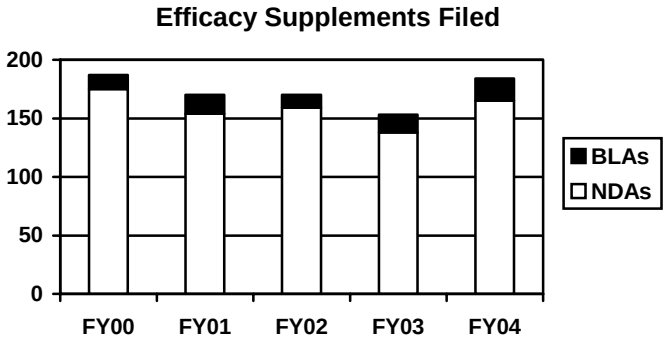
Goal - Review and act on complete efficacy supplements to NDAs and BLAs

The table below presents the annual review time goals for original efficacy supplements to NDAs and BLAs. Under PDUFA III, the goals remain steady for both reviewing 90 percent of priority supplements within 6 months and for reviewing 90 percent of standard supplements within 10 months.

Efficacy Supplement Type	Review Time Goal	Performance Goal FY 2002 – FY 2007 Submissions
Priority	6 months	90% on time
Standard	10 months	

Workload

The total number of efficacy supplements filed increased by 20 percent from FY 2003 to FY 2004, reversing a four-year trend downward. This increase occurred due to increases in the numbers of supplements to both NDAs and BLAs.



Efficacy Supplements Filed *(Priority / Standard)*					
Type	FY 00	FY 01	FY 02	FY 03	FY 04
NDAs	**175** *(18/157)*	**154** *(7/147)*	**159** *(31/128)*	**138** *(35/103)*	**165** *(38/127)*
BLAs	**12** *(2/10)*	**16** *(2/14)*	**11** *(4/7)*	**15** *(2/13)*	**19** *(2/17)*
PDUFA Total	**187** *(20/167)*	**170** *(9/161)*	**170** *(35/135)*	**153** (37/116)	**184** (40/144)

Efficacy Supplements

Performance

FY 2003 Submissions

FDA reviewed and acted on all 37 priority efficacy supplements within 6 months. FDA reviewed and acted on 97 percent (113 of 116) of the standard efficacy supplements within 10 months. Review performance on both priority and standard efficacy supplements exceeded the 90 percent on-time PDUFA review goals.

FY 2003 Submissions					
Efficacy Supplement Type	**Review Within**	**Reviewed and Acted On**	**Number on Time**	**PDUFA Performance Goal**	**Percent on Time**
Priority	6 months	37	37	90%	100%
Standard	10 months	116	113	90%	97%

FY 2004 Submissions

As of September 30, 2004, 70 percent (28 of 40) of the priority efficacy supplements submitted in FY 2004 have been reviewed and acted on; and all have met the 6-month review goal. Twenty-two percent (31 of 144) of the standard efficacy supplements have been reviewed and acted on, and all have met the 10-month review goal. With submissions still pending and not overdue, it is too early to make a final performance determination.

FY 2004 Submissions					
Efficacy Supplement Type	**Review Within**	**Reviewed and Acted On**	**Number on Time**	**PDUFA Performance Goal**	**Percent on Time**
Priority	6 months	28	28	90%	100%
Standard	10 months	31	31	90%	100%

Resubmitted Efficacy Supplements

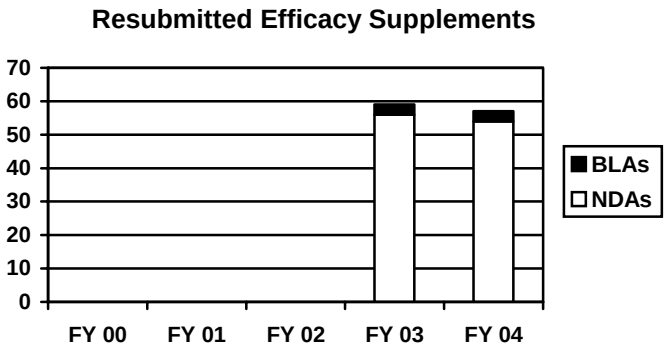
Goal - Review and act on resubmitted efficacy supplements to NDAs and BLAs

This goal is new under PDUFA III starting with FY 2003. For Class 1 resubmissions, the goal progresses from reviewing 90 percent of FY 2004 resubmissions in 4 months and 50 percent in 2 months to reviewing 90 percent of FY 2007 resubmissions in 2 months. For Class 2 resubmissions, the goal of reviewing 90 percent in 6 months remains constant over the five-year period.

Resubmitted Efficacy Supplement Type	Review Time Goal	Performance Goal				
		FY 03	FY 04	FY 05	FY 06	FY 07
Class 1	2 months	30%	50%	70%	80%	90%
	4 months	--	90%			--
	6 months	90%	--			
Class 2	6 months	90%				

Workload

The total number of resubmitted efficacy supplements received was relatively stable in FY 2003 and FY 2004. Approximately 95 percent of the resubmitted efficacy supplements were to NDAs. The number of Class 1 resubmitted supplements received doubled from FY 2003 to FY 2004.



Resubmitted Efficacy Supplements *(Class 1 / Class 2)*					
Type	FY 00	FY 01	FY 02	FY 03	FY 04
NDAs	n/a	n/a	n/a	**56** *(16/40)*	**54** *(32/22)*
BLAs	n/a	n/a	n/a	**3** *(1/2)*	**3** *(3/0)*
PDUFA Total	--	--	--	**59** *(17/42)*	**57** *(35/22)*

Resubmitted Efficacy Supplements

Performance

FY 2003 Resubmissions

FDA reviewed and acted on 94 percent (16 of 17) of Class 1 efficacy supplement resubmissions within 2 months and all 17 within 6 months. FDA reviewed and acted on all 42 Class 2 efficacy supplement resubmissions within 6 months. Review performance on both classes of efficacy supplement resubmissions exceeded the respective PDUFA review goals.

FY 2003 Submissions					
Resubmitted Efficacy Supplement Type	**Review Within**	**Reviewed and Acted On**	**Number on Time**	**PDUFA Performance Goal**	**Percent on Time**
Class 1	2 months	17	16	30%	94%
	6 months		17	90%	100%
Class 2	6 months	42	42	90%	100%

FY 2004 Resubmissions

As of September 30, 2004, 97 percent (34 of 35) of the Class 1 efficacy supplement resubmissions received in FY 2004 had been reviewed and acted on; and 91 percent had met the 2-month review goal and all had met the 4-month review goal. Fifty-five percent (12 of 22) of the Class 2 resubmissions had been reviewed and acted on, and all had met the 6-month review goal. With resubmissions still pending and not overdue, it is too early to make a final performance determination.

FY 2004 Submissions					
Resubmitted Efficacy Supplement Type	**Review Within**	**Reviewed and Acted On**	**Number on Time**	**PDUFA Performance Goal**	**Percent on Time**
Class 1	2 months	34	31	50%	91%
	4 months		34	90%	100%
Class 2	6 months	12	12	90%	100%

Manufacturing Supplements

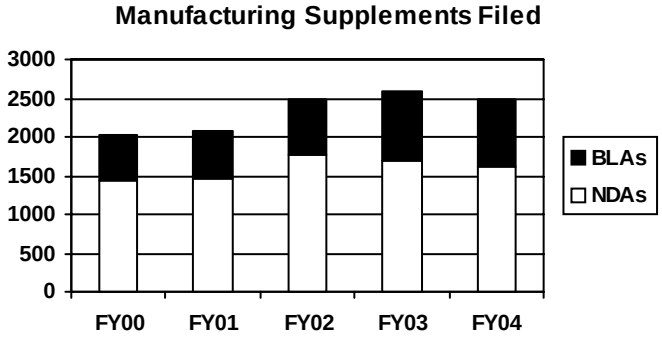
Goal - Review and act on complete manufacturing supplements to NDAs and BLAs

The table below summarizes the review time goals for manufacturing supplements to NDAs and BLAs. The PDUFA goal for manufacturing supplements that require FDA's approval before the changes can be enacted is 90 percent of supplements within 4 months of submission. The PDUFA goal for manufacturing supplements that do not require FDA's approval before the changes can be enacted is 90 percent of supplements within 6 months of submission.

Manufacturing Supplement Type	Review Time Goal	Performance Goal FY 2002 – FY 2007 Submissions
Prior approval Required	4 months	90% on time
Prior approval not required	6 months	

Workload

The total number of manufacturing supplements filed has been relatively steady over the past 3 years (FY 2002 through FY 2004). However, during the same period, the number of NDA manufacturing supplements filed has decreased while the number of BLA manufacturing supplements has increased.



Manufacturing Supplements Filed *(Prior Approval / No Prior Approval)*					
Type	FY 00	FY 01	FY 02	FY 03	FY 04[5]
NDAs	**1,438** *(684/754)*	**1,474** *(579/895)*	**1,759** *(602/1,157)*	**1,696** *(618/1,078)*	**1,616** *(539/1,077)*
BLAs	**587** *(239/348)*	**591** *(185/406)*	**717** *(228/489)*	**902** *(303/599)*	**865** *(304/561)*
PDUFA Total	**2,025** *(923/1,102)*	**2,065** *(764/1,301)*	**2,476** *(830/1,646)*	**2,598** *(921/1,677)*	**2,481** *(843/1,638)*

[5] The statute, under PDUFA III, allows 2 additional months for review of manufacturing supplement submissions that receive a major amendment within the last 2 months prior to their goal date.

Manufacturing Supplements

Performance

FY 2003 Submissions

FDA reviewed and acted on 98 percent (902 of 921) of manufacturing supplements, which required prior approval, within 4 months. FDA reviewed and acted on 99 percent (1,659 of 1,677) of manufacturing supplements, where no prior approval was required, within 6 months. Review performance on all manufacturing supplement reviews exceeded the 90 percent on-time PDUFA review goals.

FY 2003 Submissions					
Manufacturing Supplement Type	**Review Within**	**Reviewed and Acted On**	**Number on Time**	**PDUFA Performance Goal**	**Percent on Time**
Prior approval required	4 months	921	902	90%	98%
Prior approval not required	6 months	1,677	1,659	90%	99%

FY 2004 Submissions

As of September 30, 2004, more than 73 percent (612 of 843) of manufacturing supplements that require prior approval had been reviewed and acted on; and 97 percent were reviewed within the 4-month PDUFA goal. Sixty-three percent (1,035 of 1,638) of those that do not require prior approval had been reviewed and acted on, and 99 percent were reviewed within the 6-month PDUFA goal. With submissions still pending and not overdue, it is too early to make a final performance determination for FY 2004.

FY 2004 Submissions					
Manufacturing Supplement Type	**Review Within**	**Reviewed and Acted On**	**Number on Time**	**PDUFA Performance Goal**	**Percent on Time**
Prior approval Required	4 months	612	594	90%	97%
Prior approval not required	6 months	1,035	1,025	90%	99%

First Cycle Filing Review Notification

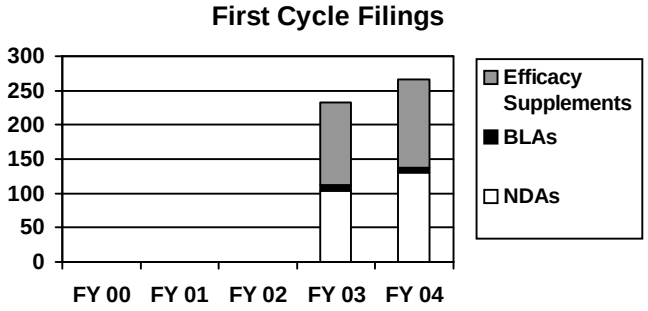
Goal - Report substantive deficiencies (or lack of same) within 14 days after the 60-day filing date for original BLAs, NDAs, and Efficacy Supplements

This is the second year for this goal. FDA is to report substantive deficiencies (or lack of same) identified during the initial filing review to the sponsor by letter, telephone conference, facsimile, secure e-mail, or other expedient means within 14 days after the 60-day filing date. Performance levels progress from 50 percent on time for FY 2003 submissions to 90 percent for FY 2005 to FY 2007 submissions.

First Cycle Filing Review Notification Type	Review Time Goal	Performance Level				
		FY 03	FY 04	FY 05	FY 06	FY 07
Original NDAs	Within 14 days after 60-day filing date	50%	70%	90%		
Original BLAs						
Efficacy Supplements						

Workload

The total number of first cycle filings increased by 20 percent from FY 2003 to FY 2004.



First Cycle Filings					
Type	FY 00	FY 01	FY 02	FY 03	FY 04
NDAs	n/a	n/a	n/a	**104**	**128**
BLAs	n/a	n/a	n/a	**8**	**9**
Efficacy Supplements[6]	n/a	n/a	n/a	**121**	**130**
PDUFA Total	--	--	--	**233**	**267**

[6] The First Cycle Filing Review Notification goal applies to original NDAs, BLAs, and efficacy supplements only. It does not apply to labeling supplements that contain clinical data, even though these are counted as efficacy supplements for other PDUFA performance purposes. Therefore, the number of filing review notifications for efficacy supplements is less than the total number of efficacy supplements filed (as shown on p. 10).

First Cycle Filing Review Notification

Performance

FY 2003 Submissions

FDA completed initial filing reviews for 84 percent (87 of 104) of original NDAs and all 8 of original BLAs within 14 days after the 60-day filing date. FDA completed initial filing reviews for 87 percent (105 of 121) of efficacy supplements within 14 days after the 60-day filing date. Performance on all first cycle filing review notifications exceeded the 50 percent on-time PDUFA review goals.

FY 2003 Submissions					
First Cycle Filing Review Notification Type	**Review Within**	**Initial Filing Reviews**	**Number on Time**	**PDUFA Performance Goal**	**Percent on Time**
NDAs	Within 14 days after 60-day filing date	104	87	50%	84%
BLAs		8	8	50%	100%
Efficacy Supplements		121	105	50%	87%

FY 2004 Submissions

As of September 30, 2004, 85 percent (109 of 128) of NDAs, 78 percent (7 of 9) of BLAs and 81 percent (105 of 130) of efficacy supplements have received an initial filing review. Although it is too early to make a final determination, performance is well over the targeted performance levels for FY 2004.

FY 2004 Submissions					
First Cycle Filing Review Notification Type	**Review Within**	**Initial Filing Reviews**	**Number on Time**	**PDUFA Performance Goal**	**Percent on Time**
NDAs	Within 14 days after 60-day filing date	109	106	70%	97%
BLAs		7	7	70%	100%
Efficacy Supplements		105	101	70%	96%

Reviewable Unit Letter Notification

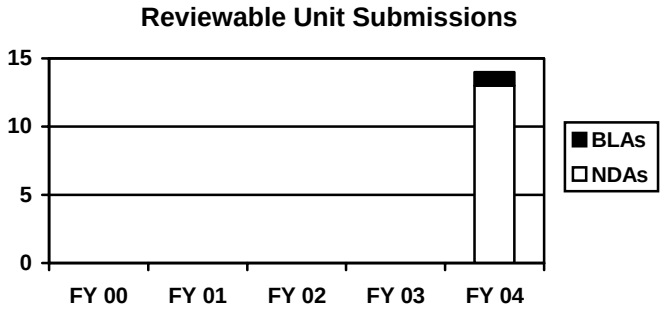
Goal – Issue discipline review letters for pre-submitted "Reviewable Units" of NDAs/BLAs

This is the first year for this goal. Under the Continuous Marketing Applications: Pilot 1 – Reviewable Units for Fast Track Products Under PDUFA, applicants may submit a portion of their marketing application, *reviewable unit* (RU), before submitting the complete application for Fast Track Original NDAs and BLAs, based on meeting specific criteria for inclusion in the Pilot. An NDA/BLA may have more than one RU. Each RU is tracked independently. Under this goal, FDA is to issue discipline review letters for pre-submitted RUs to NDAs/BLAs within 6 months of receipt of submission. Performance levels progress from 30 percent on time for FY 2004 submissions to 90 percent for FY 2007 submissions.

Reviewable Unit Type	Review Time Goal	Performance Level				
		FY 04	FY 04	FY 05	FY 06	FY 07
NDA	6 months	--	30%	50%	70%	90%
BLA						

Workload

The total number of reviewable units submitted in FY 2004 was 14.



Reviewable Unit Submissions					
Type	FY 00	FY 01	FY 02	FY 03	FY 04
NDAs	n/a	n/a	n/a	n/a	**13**
BLAs	n/a	n/a	n/a	n/a	**1**
PDUFA Total	--	--	--	--	**14**

Reviewable Unit Letter Notification

Performance

FY 2004 Submissions

As of September 30, 2004, 38 percent (5 of 13) of NDA RUs had been reviewed and acted on and all within the 6-month review goal. With the remaining eight RUs still pending and not overdue as of September 30, 2004, it is too early to make a final determination. Preliminary performance is well over the targeted performance levels for FY 2004.

FY 2004 Submissions					
Reviewable Unit Type	**Review Within**	**Reviewed and Acted On**	**Number on Time**	**PDUFA Performance Goal**	**Percent on Time**
NDAs	6 months	5	5	30%	100%
BLAs		0	0	30%	--

Procedural and Processing Goals

This section reports on a number of PDUFA goals related to the IND phase of drug development and some aspects of the infrastructure of drug review. A detailed description of the goals, the annual performance targets, and definitions of terms can be found in Appendix A. This section reports on actions on items that occurred in FY 2004.

Meeting Management

- **Meeting Requests:** Notify requestor of formal meeting in writing within 14 days of request.
- **Scheduling Meetings:** Schedule meetings within goal date (within 30 days of receipt of request for Type A meetings, 60 days for Type B meetings, and 75 days for Type C meetings). If the requested date for any of these types of meetings is greater than 30, 60, or 75 days, as appropriate, from the date the request is received by the Agency, the meeting date should be within 14 days of the requested date.
- **Meeting Minutes:** Agency-prepared minutes, clearly outlining agreements, disagreements, issues for further discussion, and action items will be available to the sponsor within 30-calendar days of meeting.

			Total	Met Goal	Missed Goal[7]	Pending Within Goal	PDUFA Performance Goal	Percent On Time[8]
Meeting Requests		CBER	269	262	6	1		
		CDER	2,018	1,669	307	42		
		Combined	**2,287**	**1,931**	**313**	**43**	**90 %**	**86%**
Scheduling Meetings	**Type A**	CBER	9	8	0	1		
		CDER	245	127	64	54		
	Type B	CBER	158	127	3	28		
		CDER	1,042	902	111	29		
	Type C	CBER	83	69	0	14		
		CDER	595	543	34	18		
	All	CBER	250	204	3	43		
		CDER	1,882	1,572	209	101		
		Combined	**2,132**	**1,776**	**212**	**144**	**90%**	**89%**
Meeting Minutes		CBER	181	152	5	24		
		CDER	1,682	1,081	219	382		
		Combined	**1,863**	**1,233**	**224**	**406**	**90%**	**85%**

[7] Includes those with late actions and those still pending whose goal date has passed and which have not had actions.

[8] Calculation based only on actions identified as being met or missed. Actions pending within goal were excluded from the calculation.

Procedural and Processing Goals

Clinical Holds: Respond to sponsor's complete response to a clinical hold within 30 days of receipt.[9]

	Total	Met Goal	Missed Goal[7]	Pending Within Goal	PDUFA Performance Goal	Percent On Time[8]
CBER	54	53	1	0		
CDER	81	65	13	3		
Combined	**135**	**118**	**14**	**3**	**90 %**	**89%**

Major Dispute Resolution: Respond to sponsor's appeal of decision within 30 days of receipt.[9]

	Total	Met Goal	Missed Goal[7]	Pending Within Goal	PDUFA Performance Goal	Percent On Time[8]
CBER	0	0	0	0		
CDER	10	9	1	0		
Combined	**10**	**9**	**1**	**0**	**90 %**	**90%**

Special Protocol Question Assessment and Agreement: Respond to sponsor's request for evaluation of protocol design within 45 days of receipt.[9]

	Total	Met Goal	Missed Goal[7]	Pending Within Goal	PDUFA Performance Goal	Percent On Time[8]
CBER	10	10	0	0		
CDER	336	296	24	16		
Combined	**346**	**306**	**24**	**16**	**90 %**	**93%**

[9] Actions in FY 2004 updated on October 31, 2004.

PDUFA III Management Initiatives

This section reports on management initiatives detailed in sections VII through XI of the PDUFA III commitment letter. A full description of the goals, the annual performance targets, and definitions of terms can be found in Appendix A. This section reports on accomplishments in FY 2004.

Continuous Marketing Application Pilots: The first Continuous Marketing Application (CMA) pilot (Pilot 1) applies to fast track products that have demonstrated significant promise as a therapeutic advance in clinical trials, and will provide an early discipline review of the RUs of the sponsor's NDA/BLA submitted in advance of the complete application. The second CMA pilot (Pilot 2) applies to fast track products and provides for FDA-sponsor agreement to engage in frequent scientific feedback and interactions during the clinical trial phase of product development.

> ***FY 2004 Accomplishments*:** Final guidances were published on October 6, 2003, and the pilot programs became effective as of that date. As of September 30, 2004, eight products had been identified for inclusion in Pilot 1. The RUs for seven of these products have been received. As of September 30, 2004, 38 percent (5 of 13) of RUs received had been reviewed and acted on and all within the goal time. Additionally, seven products were included in the Pilot 2 program as of September 30, 2004.

First Cycle Review Performance: Approvals that take more than one review cycle to complete are generally not in the best interest of the public, the agency, or the company submitting the product application. Although sometimes additional review cycles are necessary to resolve important issues regarding safety, quality, or efficacy, in most cases, the extra cycles could be avoided, saving time and effort. For applications that are ultimately approved, the causes of multiple review cycles can include deficiencies in sponsors' applications, communication problems during the review process, or difficulty finishing final negotiations on such topics as labeling. Sometimes additional review cycles are necessary to resolve important issues regarding safety, quality, or efficacy; but in other cases, the extra cycles could be avoided, saving time and effort. Efforts to improve the first cycle review process include an initiative for notification of substantive deficiencies identified during the initial filing review for original NDAs and BLAs and an initiative to develop and publish Good Review Management Principles (GRMP) with provisions for both FDA reviewers and industry sponsors.

> ***FY 2004 Accomplishments*:** As of September 30, 2004, 85 percent (109 of 128) of NDAs, 78 percent (7 of 9) of BLAs, and 81 percent (105 of 130) of efficacy supplements have received an initial filing review. Although it is too early to make a final determination, performance is well over the targeted performance levels for FY 2004. Additionally, FDA is implementing the PDUFA III First Cycle initiative to develop and publish the GRMP. The draft GRMP guidance was published on July 28, 2003, and the comment period ended on September 11, 2003. FDA received

extensive comments on the draft guidance and has been evaluating the comments and revising the guidance through FY 2004.

Improving FDA Performance Management: Under the PDUFA III performance management goal, FDA will conduct initiatives that are targeted to improve the new drug review process. FDA will award a task order contract to a contractor with the expertise to conduct evaluations and analyses of the new drug review process. The first tasks will include a retrospective evaluation of the first cycle review process, an evaluation of the first cycle initiatives under PDUFA III, and an evaluation of the continuous marketing application pilots. FDA will also contract for outside expert consultants for analysis, training, and technical assistance to help implement a quality systems approach to the new drug review process.

FY 2004 Accomplishments: FDA awarded a task order contract to conduct evaluations of the first cycle and CMA pilot initiatives. CDER worked with a contractor on process improvements and on aspects of a quality system for new drug review.

Independent Consultants: This PDUFA III initiative allows a sponsor to request that FDA engage an independent expert consultant during the development period for certain biotechnology products. The consultant would be selected by FDA to assist in the Agency's review of the protocol for the clinical studies that would support the claims for the product. This initiative is intended to facilitate product development.

***FY 2004 Accomplishments*:** Final guidance was published on August 18, 2004. So far no sponsors have requested assistance under the program. The final guidance is available at: http://www.fda.gov/cber/gdlns/bioclin.htm.

Risk Management: The postmarketing initiative to address postmarket risk both before an application is submitted and during the review process will facilitate postmarket risk management by helping FDA better understand any risks and by providing feedback to the sponsors. Guidances will be published for three areas: Good Risk Assessment, Risk Management, and Pharmacovigilance Practices.

***FY 2004 Accomplishments*:** FDA published draft guidances on May 5, 2004, received extensive comments, and expects to publish all three final guidances in early FY 2005. Additionally, FDA participated in the review of 23 Risk Management Plans (RMPs) (including 5 NMEs and one BLA) of which 11 were related to NDAs submitted after PDUFA III took effect. FDA also participated in 20 pre-NDA/BLA supplement review meetings, 3 pre-approval safety conferences, 3 peri-approval RMP reviews, and the evaluation/validation of 4 active RMPs.

Electronic Applications and Submissions

This section reports on goals from the "Electronic Applications and Submissions" section of the PDUFA III commitment letter. These goals relate to the Information Technology (IT) initiatives/activities of PDUFA III. A detailed description of the goals, the annual performance targets, and definitions of terms can be found in Appendix A. This section reports on accomplishments in FY 2004.

Centralize the accountability and funding for all PDUFA IT initiatives/activities under the FDA/CIO: The Agency will centralize the accountability and funding for all PDUFA Information Technology initiatives/activities for CBER, CDER, Office of Regulatory Affairs (ORA), and Office of the Commissioner (OC) under the leadership of the FDA Chief Information Officer (CIO). The July 2001 HHS IT five-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 (section XII, paragraph a).

***FY 2004 Accomplishments*:** In FY 2004, the FDA implemented a formal Agency IT investment governance process with direct involvement of the FDA's Management Council and with the establishment of an Agency Enterprise Architecture Review Board (EARB). As part of this Agency process, the PDUFA IT investment governance incorporates the oversight and approval by both the Agency CIO and Agency management with representatives from the PDUFA program and IT organizations. Specifically, the Agency integrated the PDUFA IT investment governance process with the Agency IT investment process to ensure alignment and linkage to Agency strategic goals.

To assist the governance process, an Agency IT Portfolio Management System was implemented to document and track IT investments starting with the Fiscal Year 2005 budget cycle. The initial implementation provided a mechanism to document all IT investments with input and access throughout the Agency. Since the initial implementation, the Portfolio Management tool has been enhanced to incorporate Department, Agency, and Center tracking and reporting requirements. The Portfolio Management tool is used throughout the investment process to validate and track the IT investment portfolio in support of the FDA mission and target enterprise architecture, and to facilitate prioritizing, approving, and monitoring IT investments for the entire Agency.

In March 2004, all Center, ORA, and OC IT directors and their supporting staff started reporting directly to the CIO. Through this framework the CIO is able to work more closely with IT Directors and their customers to ensure their service demands

are met, while consistently meeting the demands of the FDA, Department of Health and Human Services and Office of Management and Budget. It provides a means to drive technology change in a uniform way through direct communication and for ensuring that all IT infrastructure and IT investments support the Agency's common IT goals, fit into a common computing environment, and follow good IT management practices.

Periodically review and evaluate the progress of IT initiatives against project milestones: 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 (section XII, paragraph b).

***FY 2004 Accomplishments*:** This report satisfies this annual requirement. In addition, the Agency reported IT progress to stakeholders at the PDUFA IT quarterly briefings (October 2003, February 2004, May 2004, and September 2004) and through PhRMA/BIO PDUFA updates (January 2004, May 2004, and September 2004).

Implement a common solution for the secure exchange of application content: 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 (section XII, paragraph c).

***FY 2004 Accomplishments*:** The FDA has continued to participate in discussions on the Secure Access For Everyone (SAFE) standard for the biopharmaceutical industry. The FDA has been performing an advisory role on the SAFE initiative that is being developed by industry to deliver a regulatory compliant, industry owned, globally scaleable, and legally enforceable infrastructure standard and associated operating rules for both large and small organizations. The SAFE model will meet business requirements for authentication, signature, integrity, liability, and privacy through the use of existing technology and standards tailored to meet the trust needs of the biopharmaceutical industry. The FDA will continue to support this effort in alignment with the PDUFA electronic signature goal and the overall PDUFA objective for the FDA and industry to increase the number of electronic submissions.

Deliver a single point of entry for the receipt and processing of all electronic submissions in a highly secure environment: 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 (section XII, paragraph d).

> ***FY 2004 Accomplishments*:** The FDA, working through the PDUFA Business Workgroup, initiated an electronic submission gateway project. This project is a replacement of the current electronic gateway used for mandatory safety reporting by drug and biologic manufacturers. Requirements from each of the FDA organizations are included in the overall system requirements and architecture documents. The initial implementation of the electronic gateway will handle PDUFA applications and submissions, and will include the functionality of the current electronic gateway. At the end of FY2004, the FDA was in the process of reviewing contractor proposals and plans on awarding the contract in the first quarter of FY2005.

Provide a format and review system for the electronic submission of the Common Technical Document (e-CTD): 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 (section XII, paragraph e).

> ***FY 2004 Accomplishments*:** In FY 2004, 12 marketing applications (NDA and BLA), 2 INDs, and over 100 supporting submissions were received by CDER and CBER in the eCTD format. The eCTD guidance, specifications, and software are available at http://www.fda.gov/cder/regulatory/ersr/ectd.htm.

Conduct an objective analysis and develop a plan for consolidation of PDUFA III IT infrastructure: 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, FDA will 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 (section XII, paragraph f).

***FY 2004 Accomplishments*:** FDA has consolidated IT support and infrastructure services following a "Shared Services" concept. In October 2003 the FDA Office of IT Shared Services (OITSS) was established to support the FDA mission by delivering infrastructure support services. The OITSS is responsible for on-site desktop management, server/network management, help desk services, e-mail administration, telecommunications, IT asset and inventory management, remote access, and IT security and training. Each Center is assigned a Client Services Representative to improve support and communications between OITSS and the Center.

As a new organization, the OITSS has been establishing processes and procedures in an effort to consolidate a number of functions. These include:

- Continuity of Operations Plan (COOP) – Established a call center process for handling COOP exercises requested by the COOP coordinators across the agency; established an IT COOP team from across the IT functional areas.
- Service Level Agreements (SLA) have been developed between IT Shared Services and its customers. Performance metrics is reported to the customers on a monthly basis.
- Centralized the personal computer procurement process to facilitate lower prices and support costs.
- Change Control Board was established to ensure that all infrastructure changes are coordinated across organizations.
- Implemented additional after hour support coverage for remote access users.
- Development of a Blackberry (handheld electronic mail) procurement and support process.
- Development of an improved telecommunications process to address gaps in the office move process.
- Consolidation of infrastructure support contracts into a single contract. One of the performance goals of this contract is server consolidation.

Implement Capability Maturity Model (CMM) and include other industry best practices to ensure quality, efficiency, and cost effectiveness: FDA will implement 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 (section XII, paragraph g).

FY 2004 Accomplishments: In FY 2004, the Agency continued to strengthen the FDA's IT project management capabilities.

- The Project Management Office (PMO), working through the IT PM Steering Committee, approved the first formal Software Development Life Cycle (SDLC) process for the Agency in December 2003.
- The PMO established a Web-based Process Asset Library for project management tools and templates. The PMO has also provided and will provide on-site consulting from project management experts.
- In the beginning of FY 2004, the project management certification-training program was initiated for over 60 project managers. The IT project management certification training program is continuing, and the FDA will have certified project managers by the end of 2004.

Use same software applications where common business needs exist: Where common business needs exist, CBER, CDER, ORA, and OC will use the same software applications, such as eCTD software, and commercial off-the-shelf (COTS) solutions (section XII, paragraph h).

***FY 2004 Accomplishments*:** During FY2004 the FDA decided to address this objective by separating our Electronic Regulatory Submission Review program into two functional areas, Electronic Submissions, and Regulatory Review and Tracking Systems.

Based on this decision the FDA focused on the electronic submission process within FDA and industry as part of the FDA Enterprise Architecture (EA) effort. The goal of this effort is to develop a target PDUFA electronic submission architecture. The PDUFA electronic submissions target architecture will include the strategic imperatives, stakeholders, business processes, data, application functions, and the relationships of each of these components to each other. The objective is to build on the implementation of the eCTD and the development of the electronic submission gateway to define a common process for the electronic submission of PDUFA submission types.

Develop a PDUFA III IT 5-year plan. Within six months of authorization, a PDUFA III IT five-year plan will be developed. Progress will be measured against the milestones described in the plan (section XII, paragraph i).

FY 2004 Accomplishments: An update to the March 2003 PDUFA IT Plan was completed in June 2004 and released at the September 2004 PDUFA IT quarterly briefing.

APPENDIX A: PDUFA Performance Goals, FY 2002 - FY 2007

The table below summarizes, by fiscal year, the performance measures set forth in the letters referenced in the Food and Drug Administration Modernization Act of 1997 (PDUFA II) and in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (PDUFA III). Goal summaries for the earlier years of PDUFA II can be found in the Appendix of earlier PDUFA Performance Reports. The complete text of the commitment letters is on the Internet at http://www.fda.gov/oc/pdufa/default.htm.

I. Review Performance Goals

		On-time Performance Level for Fiscal Year of Filing or Receipt					
		2002	**2003**	**2004**	**2005**	**2006**	**2007**
Review and act on standard original NDAs and PLA/BLAs within 10 months of receipt.[10]		90% on time					
Review and act on priority original NDAs and BLAs within 6 months of receipt.[10]							
Review and act on standard efficacy supplements within 10 months of receipt.[10]							
Review and act on priority efficacy supplements within 6 months of receipt.[10]							
Review and act on all manufacturing supplements within 6 months of receipt and those requiring prior approval within 4 months of receipt.[11]							
Review and act on Class 1 resubmitted original applications within 2 months of receipt.							
Review and act on Class 2 resubmitted original applications within 6 months of receipt.[10]							
Review and act on Class 1 resubmitted efficacy supplements within	2 months of receipt	--	30%	50%	70%	80%	90%
	4 months of receipt		--	90%			--
	6 months of receipt	--	90%	--			
Review and act on Class 2 resubmitted efficacy supplements within 6 months of receipt.[10]		--	90%				
Issue discipline review letters for pre-submitted "Reviewable Units" of NDAs/BLAs in 6 months.[10]		--	--	30%	50%	70%	90%
Report substantive deficiencies (or lack of same) within 14 days after 60 day filing date for original NDAs, BLAs, and efficacy supplements.		--	50%	70%	90%		

[10] Receipt of a major amendment in the last 3 months extends the goal date by 3 months. Under PDUFA II (i.e. through FY 2002), this extension applied to original NDAs and BLAs only. Under PDUFA III, it also applies to efficacy supplements and Class 2 resubmitted NDAs, BLAs, and efficacy supplements.

[11] Receipt of a major amendment in the last 2 months extends the goal date by 2 months (PDUFA III submissions only).

II. New Molecular Entity (NME) Performance Goals

The performance goals for standard and priority original NMEs will be the same as for all of the original NDAs but will be reported separately.

For biological products, for purposes of this performance goal, all original PLA/BLAs will be considered to be NMEs.

III. Procedural and Processing Goals

Performance Area	Agency Activity	Performance Goal	Performance Level FY 2002 – FY 2007
Meeting Management	Meeting Requests -- Notify requestor of formal meeting in writing (date, time, place, and participants)	within 14 days of receipt of request	90% on time
	Scheduling Meetings -- Schedule meetings within goal date or within 14 days of requested date if longer than goal date.	Type A Meetings within 30 days of receipt of request Type B Meetings within 60 days of receipt of request Type C Meetings within 75 days of receipt of request	
	Meeting Minutes -- Agency prepared minutes, clearly outlining agreements, disagreements, issues for further discussion and action times will be available to sponsor	within 30 calendar days of meeting	
Clinical Holds	Response to sponsor's complete response to a clinical hold	within 30 days of receipt of sponsor's response	
Major Dispute Resolution	Response to sponsor's appeal of decision	within 30 days of receipt of sponsor's appeal	
Special Protocol Question Assessment and Agreement	Response to sponsor's request for evaluation of protocol design	within 45 days of receipt of protocol and questions	

IV. PDUFA III Management Initiatives

Performance Area	Initiative	Commitment	Performance Level and/or Implementation Timeline By Fiscal Year -- Not applicable X Action due					
			2002	**2003**	**2004**	**2005**	**2006**	**2007**
Continuous Marketing Application	To test whether providing early review of selected applications and additional feedback and advice to sponsors during drug development for selected products can further shorten drug development and review times.	Discipline review team of a "reviewable unit" for a Fast Track drug or biologic will be completed and a DRL issued within 6 months of the date of the submission	---	---	30%	50%	70%	90%
Independent Consultants for Biotechnology Clinical Trial Protocols	During the development period for a biotechnology product, a sponsor may request that FDA engage an independent expert consultant, selected by FDA, to participate in the Agency's review of the protocol for the clinical studies that are expected to serve as the primary basis for a claim.	If FDA denies request, it must provide a written rationale within 14 days of receipt	---	100%				
First Cycle Review Performance Proposal	For original NDA/BLA applications and efficacy supplements, FDA will report substantive deficiencies (or lack of same) identified in the initial filing review to the sponsor by letter, telephone conference, facsimile, secure e-mail, or other expedient means.	FDA will provide the sponsor a notification of deficiencies (or lack of same) within 14 calendar days after the 60-day filing date.	---	50%	70%	90%		

Performance Area	Initiative	Commitment	Performance Level and/or Implementation Timeline By Fiscal Year -- Not applicable X Action due					
			2002	2003	2004	2005	2006	2007
Improving FDA Performance Management	Two specific initiatives will begin early in PDUFA III, supported from performance management initiative funds: 1) evaluation of first cycle review performance, and 2) process review and analysis within the two centers.	In FY 2003, FDA will contract with an outside consultant to conduct a comprehensive process review and analysis within CDER and CBER.	---	X				
Risk Management	Pre-NDA/BLA Meeting with Industry: The intent of these discussions will be for FDA to get a better understanding of the safety issues associated with the particular drug/biologic and the proposed risk management plans, and to provide industry with feedback on these proposals so that they can be included in the NDA/BLA submission.	By the end of FY 2004, CDER and CBER will jointly develop final guidance documents that address good risk assessment, risk management, and pharmacovigilance practices.	---	---	X			

V. Electronic Applications And Submissions

Initiatives	Implementation Deadline by Fiscal Year -- Not applicable X Action due					
	2002	**2003**	**2004**	**2005**	**2006**	**2007**
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.	---	X	X	X	X	X
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.	---	X	X	X	X	X
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.	---	---	---	---	---	X
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.	---	---	---	---	---	X
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.	---	---	---	---	---	X

Initiatives	Implementation Deadline by Fiscal Year -- Not applicable X Action due					
	2002	**2003**	**2004**	**2005**	**2006**	**2007**
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.	---	---	X			
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.	---	---	---	---	---	X
Where common business needs exist, CBER, CDER, ORA, and OC will use the same software applications, such as eCTD software, and COTS solutions.	---	---	---	---	---	X
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.	---	X				

Definitions of Terms:

A. The term "review and act on" is understood to mean the issuance of a complete action letter after the complete review of a filed complete application. The action letter, if it is not an approval, will set forth in detail the specific deficiencies and, where appropriate, the actions necessary to place the application in condition for approval.

B. Under PDUFA I and II, receipt of a major amendment to original NDAs and BLAs in the last 3 months extended the goal date by 3 months. Under PDUFA III, this extension also applies to efficacy supplements and Class 2 resubmitted NDAs, BLAs, and efficacy supplements. Receipt of a major amendment to a manufacturing supplement in the last 2 months extends the goal date by 2 months (PDUFA III submissions only).

C. A resubmitted original application is a complete response to an action letter addressing all identified deficiencies.

D. Class 1 resubmitted applications are applications resubmitted after a complete response letter (or a not approvable or approvable letter) that include the following items only (or combinations of these items):

1. Final printed labeling
2. Draft labeling
3. Safety updates submitted in the same format, including tabulations, as the original safety submission with new data and changes highlighted (except when large amounts of new information, including important new adverse experiences not previously reported with the product, are presented in the resubmission)
4. Stability updates to support provisional or final dating periods
5. Commitments to perform Phase 4 studies, including proposals for such studies
6. Assay validation data
7. Final release testing on the last 1-2 lots used to support approval
8. A minor reanalysis of data previously submitted to the application (determined by the agency as fitting the Class 1 category)
9. Other minor clarifying information (determined by the Agency as fitting the Class 1 category)
10. Other specific items may be added later as the Agency gains experience with the scheme and will be communicated via guidance documents to industry.

E. Class 2 resubmissions are resubmissions that include any other items, including any item that would require presentation to an advisory committee.

F. A Type A Meeting is a meeting that is necessary for an otherwise stalled drug development program to proceed (a "critical path" meeting).

G. A Type B Meeting is a 1) pre-IND, 2) end of Phase 1 (for Subpart E or Subpart H or similar products) or end of Phase 2/pre-Phase 3, or 3) a pre- NDA/PLA/BLA meeting. Each requestor should usually only request 1 each of these Type B meetings for each potential application (NDA/PLA/BLA) (or combination of closely related products, i.e., same active ingredient but different dosage forms being developed concurrently).

H. A Type C Meeting is any other type of meeting.

APPENDIX B: List of Approved Applications

This appendix updates the detailed review histories of the NDAs and BLAs submitted and approved under PDUFA. It shows approvals of all PDUFA-related submissions that took place in FY 2004 as well as FY 2003 approvals of FY 2003 submissions. Earlier PDUFA approvals were listed in previous performance reports.

The following two tables summarize the review histories for all approved applications submitted from FY 1997 through FY 2003. The tables show the average first review, second review, and approval times. Note that times are in months, not all applications required a second review, and some required more than two reviews. The mean total approval times shown in the tables will increase in the future as additional applications are approved.

Approved Priority NDAs/BLAs

	1st Review		2nd Review			Mean Total Approval Time
Receipt Cohort	n	FDA Review	n	Sponsor Response	FDA Review	
FY97	23	6.3	10	4.4	3.6	9.5
FY98	31	6.1	12	1.5	2.7	8.3
FY99	27	6.2	9	2.6	2.7	10.0
FY00	25	6.0	10	4.1	4.6	11.5
FY01	12	6.4	10	7.1	4.9	17.0
FY02	13	5.8	6	9.2	5.1	12.4
FY03	15	5.9	3	4.9	6.0	8.1

Approved Standard NDAs/BLAs

	1st Review		2nd Review			Mean Total Approval Time
Receipt Cohort	n	FDA Review	n	Sponsor Response	FDA Review	
FY97	89	11.6	42	8.1	4.1	19.5
FY98	65	11.4	41	5.4	4.9	19.3
FY99	74	10.7	37	5.2	4.2	18.1
FY00	76	10.6	45	8.0	4.4	18.9
FY01	53	10.5	35	6.4	4.8	18.5
FY02	63	10.1	31	4.3	3.9	14.5
FY03	42	9.8	12	2.3	2.7	11.3

The remainder of this appendix shows the individual review histories. Approvals are grouped by submission year and priority designation and listed in order of total approval time. Review histories of all other PDUFA submissions approved prior to FY 2004 can be found in the appendices of the earlier PDUFA Performance Reports that are available at http://www.fda.gov.

Terms and Coding Used in Tables

**	Major amendment was received within 3 months of the action due date, which extended the review timeframes by 3 months.
	Action Codes: AE = Approvable AP = Approved NA = Not Approvable RL = Complete Response WD = Withdrawn

Table 1
FY 2004 Priority NDA and BLA Approvals (by FY of receipt)

Receipt Cohort (FY)	Established/Proper Name	Applicant	Approval Time (Months)		Review Goal Met
			Total Time	Resubmissions (if necessary)	
2004	PENTETATE ZINC TRISODIUM	HAMELN PHARMS	3.5		Y
	PENTETATE CALCIUM TRISODIUM	HAMELN PHARMS	3.5		Y
	TENOFOVIR DISOPROXIL FUMARATE; EMTRICITABINE	GILEAD	4.7		Y
	AZACITIDINE	PHARMION	4.7		Y
2003	PEMETREXED DISODIUM	LILLY	4.2		Y
	BEVACIZUMAB (BLA)	GENENTECH, INC.	5.0		Y
	CINACALCET HYDROCHLORIDE	AMGEN	6.0		Y
	CETUXIMAB (BLA)	IMCLONE SYSTEMS, INC.	6.0		Y
	FERRIC HEXACYANOFERRATE	HEYL CHEMISCH	6.7		Y**
	HYALURONIDASE	ISTA PHARMS	9.0		Y**
	OLANZAPINE; FLUOXETINE HYDROCHLORIDE	LILLY	13.6	FDA First Action: (AE) 6.0 Sponsor Response: 1.6 FDA Second Action: (AP) 6.0	Y Y
	APOMORPHINE HYDROCHLORIDE	MYLAN BERTEK	15.6	FDA First Action: (AE) 6.0 Sponsor Response: 3.6 FDA Second Action: (AP) 6.0	Y Y
	DESLORATADINE	SCHERING	20.9	FDA First Action: (AE) 5.3 Sponsor Response: 9.6 FDA Second Action: (AP) 6.0	Y Y
2002	STERILE TALC POWDER	BRYAN	14.7	FDA First Action: (AE) 5.9 Sponsor Response: 3.5 FDA Second Action: (AP) 5.3	Y Y
	ACETYLCYSTEINE	CUMBERLAND PHARMS	18.8	FDA First Action: (NA) 6.0 Sponsor Response: 6.8 FDA Second Action: (AP) 6	Y Y
	BOTULISM IMMUNE GLOBULIN INTRAVENOUS (HUMAN) (BLA)	CALIFORNIA DEPARTMENT OF HEALTH SERVICES (THE)	22.2	FDA First Action: 6.1 (RL) Sponsor Response: 10.1 FDA Second Action: 6.0 (AP)	Y Y
	NITAZOXANIDE	ROMARK	25.8	FDA First Action: (AE) 5.8 Sponsor Response: 14.3 FDA Second Action: (AP) 5.7	Y Y
	ACAMPROSATE CALCIUM	FOREST	31.1	FDA First Action: (NA) 6.0 Sponsor Response: 19.3 FDA Second Action: (AP) 5.8	Y Y

Table 1 (continued)

Receipt Cohort (FY)	Established/Proper Name	Applicant	Approval Time (Months)		Review Goal Met
			Total Time	Resubmissions (if necessary)	
2001	SYNTHETIC HUMAN SECRETIN	CHIRHOCLIN	33.9	FDA First Action: (AE) 6.0 Sponsor Response: 21.9 FDA Second Action: (AP) 6.0	Y Y
	ABARELIX	PRAECIS	35.4	FDA First Action: (NA) 6.0 Sponsor Response: 20.5 FDA Second Action: (AP) 8.9	Y Y**

Table 2
FY 2004 Standard NDA and BLA Approvals (by FY of receipt)

Receipt Cohort (FY)	Established/Proper Name	Applicant	Approval Time (Months)		Review Goal Met
			Total Time	Resubmissions (if necessary)	
2004	FLUDEOXYGLUCOSE F-18	WEILL MEDICAL COLLEGE	4.4		Y
	AMLEXANOX	ACCESS	9.7		Y
	ABACAVIR SULFATE; LAMIVUDINE	GLAXOSMITHKLINE	9.8		Y
	GATIFLOXACIN	BRISTOL-MYERS SQUIBB	10.0		Y
	ESTRADIOL ACETATE	WARNER CHILCOTT	10.0		Y
	FAMOTIDINE	SCHWARZ	10.0		Y
	RANITIDINE HYDROCHLORIDE	PFIZER	10.0		Y
2003	CLOBETASOL PROPIONATE	GALDERMA LABS	9.0		Y
	VORICONAZOLE	PFIZER	9.1		Y
	MELOXICAM	BOEHRINGER INGELHEIM	9.4		Y
	GADOTERIDOL	BRACCO	9.7		Y
	FOLLITROPIN ALFA	SERONO	9.9	FDA First Action (NA): 3.9 Sponsor Response: 4.0	Y
				FDA Second Action (AP): 2.0	Y
	MEMANTINE HYDROCHLORIDE	FOREST	9.9		Y
	EPINASTINE HYDROCHLORIDE	ALLERGAN	9.9		Y
	PEGINTERFERON ALFA-2A CO-PACKAGED WITH RIBAVIRIN (BLA)	HOFFMANN-LA ROCHE INC.	9.9		Y
	FOSAMPRENAVIR CALCIUM	GLAXOSMITHKLINE	10.0		Y
	LEVOFLOXACIN	SANTEN	10.0		Y
	TINIDAZOLE	PRESUTTI LABS	10.0		Y
	CETIRIZINE HYDROCHLORIDE	PFIZER	10.0		Y
	INSULIN GLULISINE	AVENTIS	10.0		Y
	BACLOFEN	SCHWARZ	10.0		Y
	SIMVASTATIN; EZETIMIBE	MSP SINGAPORE	10.0		Y
	MYCOPHENOLIC ACID	NOVARTIS	10.0		Y
	CEFOTAXIME AND DEXTROSE	B BRAUN MEDICAL	10.0		Y
	FOLLITROPIN ALFA	SERONO	10.0		Y
	OMEPRAZOLE	SANTARUS	10.0		Y
	MORPHINE SULFATE	SKYEPHARMA	10.0		Y
	L-GLUTAMINE	NUTRITIONAL RESTART	10.0		Y
	AMLODIPINE BESYLATE; ATORVASTATIN CALCIUM	PFIZER	10.0		Y

Table 2 (continued)

Receipt Cohort (FY)	Established/Proper Name	Applicant	Approval Time (Months)		Review Goal Met
			Total Time	Resubmissions (if necessary)	
2003	MULTIPLE VITAMINS FOR INFUSION	SABEX 2002	10.0		Y
	MULTIPLE VITAMINS FOR INFUSION	MAYNE	10.0		Y
	CHLORPHENIRAMINE MALEATE; IBUPROFEN; PSEUDOEPHEDRINE HYDROCHLORIDE	WYETH	10.0		Y
	EFALIZUMAB (BLA)	GENENTECH, INC.	10.0		Y
	MULTIPLE VITAMINS FOR INFUSION	MAYNE	10.9	FDA First Action (AE): 9.5 Sponsor Response: 0.2 FDA Second Action (AP): 1.2	Y Y
	IMMUNE GLOBULIN INTRAVENOUS (HUMAN) (BLA)	INSTITUTO GRIFOLS, S.A.	11.5		Y**
	IBUPROFEN	TARO	12.2	FDA First Action (AE): 10.0 Sponsor Response: 0.6 FDA Second Action (AP): 1.6	Y Y
	CLOZAPINE	ALAMO	12.3	FDA First Action (AE): 9.6 Sponsor Response: 0.7 FDA Second Action (AP): 2.0	Y Y
	TROSPIUM CHLORIDE	INDEVUS	13.0		Y**
	VALPROATE SODIUM	ANDRX	13.8	FDA First Action (AE): 10.1 Sponsor Response: 1.9 FDA Second Action (TA): 1.8	Y Y
	AMIODARONE HYDROCHLORIDE	INTERNATIONAL MEDICATION SYSTEMS	14.9	FDA First Action (AE): 9.9 Sponsor Response: 3.0 FDA Second Action (AP): 2.0	Y Y
	DIGOXIN	ROXANE	16.1	FDA First Action (AE): 10.1 Sponsor Response: 5.1 FDA Second Action (AP): 0.9	Y Y
	METFORMIN HYDROCHLORIDE	ANDRX	16.3	FDA First Action (AE): 9.9 Sponsor Response: 2.2 FDA Second Action (AE): 2.0 Sponsor Response: 0.2 FDA Third Action (AP): 2.0	Y Y Y
	FENOFIBRATE	CIPHER	16.6	FDA First Action (AE): 9.7 Sponsor Response: 3.5 FDA Second Action (AE): 2.0 Sponsor Response: 0.2 FDA Third Action (TA): 1.2	Y Y Y
	GUAIFENESIN; PSEUDOEPHEDRINE HYDROCHLORIDE	ADAMS	16.7	FDA First Action (AE): 9.8 Sponsor Response: 0.9 FDA Second Action (AP): 6.0	Y Y
	LANSOPRAZOLE	TAP	17.1	FDA First Action (AE): 10.0 Sponsor Response: 2.6 FDA Second Action (AP): 4.5	Y Y
	TOBRAMYCIN SULFATE	AMERICAN PHARMACEUTICAL PARTNERS	18.6	FDA First Action (AE): 10.0 Sponsor Response: 2.6 FDA Second Action (AP): 6.0	Y Y

Table 2 (continued)

Receipt Cohort (FY)	Established/Proper Name	Applicant	Approval Time (Months)		Review Goal Met
			Total Time	Resubmissions (if necessary)	
2002	LANSOPRAZOLE; NAPROXEN	TAP	14.2	FDA First Action (AE): 10.0 Sponsor Response: 0.5 FDA Second Action (AP): 3.7	Y Y
	RHO(D) IMMUNE GLOBULIN INTRAVENOUS (HUMAN) (BLA)	ZLB BIOPLASMA AG	16.5	FDA First Action: 9.9 (RL) Sponsor Response: 0.8 FDA Second Action: 5.8 (AP)	Y Y
	ETHINYL ESTRADIOL; NORETHINDRONE	WARNER CHILCOTT	19.4	FDA First Action (AE): 10.0 Sponsor Response: 3.4 FDA Second Action (AP): 6.0	Y Y
	LIDOCAINE HYDROCHLORIDE; EPINEPHRINE	VYTERIS	19.4	FDA First Action (AE): 10.0 Sponsor Response: 3.5 FDA Second Action (AP): 5.9	Y Y
	TIMOLOL MALEATE	SENJU	20.3	FDA First Action (AE): 9.9 Sponsor Response: 4.8 FDA Second Action (AP): 5.6	Y Y
	SODIUM BICARBONATE; SODIUM CHLORIDE; POLYETHYLENE GLYCOL; BISACODYL; POTASSIUM CHLORIDE	BRAINTREE	20.8	FDA First Action (AE): 10.0 Sponsor Response: 4.8 FDA Second Action (AP): 6.0	Y Y
	AMLODIPINE MALEATE	DR. REDDY'S LABS	22.3	FDA First Action (AE): 10.0 Sponsor Response: 10.4 FDA Second Action (AP): 1.9	Y Y
	LIDOCAINE; PRILOCAINE	DENTSPLY	22.9	FDA First Action (AE): 9.9 Sponsor Response: 7.0 FDA Second Action (AP): 6.0	Y Y
	IMMUNE GLOBULIN INTRAVENOUS (HUMAN) (BLA)	OCTAPHARMA PHARMAZEUTIKA PRODUKTIONSGES.M .B.H.	23.0	FDA First Action: 9.9 (RL) Sponsor Response: 4.5 FDA Second Action: 6.1 (RL) Sponsor Response: 0.5 FDA Third Action: 2.0 (AP)	Y Y Y
	LORATADINE	PERRIGO	23.8	FDA First Action (AE): 10.0 Sponsor Response: 0.4 FDA Second Action (AE): 2.0 Sponsor Response: 5.4 FDA Third Action (AP): 6.0	Y Y Y
	NIZATIDINE	RELIANT	25.5	FDA First Action (AE): 10.1 Sponsor Response: 9.4 FDA Second Action (AP): 6.0	Y Y
	SYNTHETIC CONJUGATED ESTROGENS, B	DURAMED	25.6	FDA First Action (AE): 13.0 Sponsor Response: 10.6 FDA Second Action (AP): 2.0	Y** Y
	TIOTROPIUM BROMIDE	BOEHRINGER INGEL-HEIM	25.6	FDA First Action (AE): 12.2 Sponsor Response: 7.4 FDA Second Action (AP): 6.0	N Y
	FLUTICASONE PROPIONATE	GLAXOSMITHKLINE	26.5	FDA First Action (AE): 10.0 Sponsor Response: 10.5 FDA Second Action (AP): 6.0	Y Y

Table 2 (continued)

Receipt Cohort (FY)	Established/Proper Name	Applicant	Approval Time (Months)		Review Goal Met
			Total Time	Resubmissions (if necessary)	
2002	RIFAXIMIN	SALIX	29.0	FDA First Action (AE): 10.0 Sponsor Response: 13.0 FDA Second Action (AP): 6.0	Y Y
	DULOXETINE HYDROCHLORIDE	LILLY	32.7	FDA First Action (AE): 10.0 Sponsor Response: 6.3 FDA Second Action (AE): 6.2[12] Sponsor Response: 2.8 FDA Third Action (AP): 7.4	Y Y Y
2001	RISPERIDONE	JANSSEN	25.9	FDA First Action (NA): 9.9 Sponsor Response: 10.0 FDA Second Action (AP): 6.0	Y Y
	SERTACONAZOLE NITRATE	JOHNSON & JOHNSON	26.4	FDA First Action (AE): 9.9 Sponsor Response: 14.5 FDA Second Action (AP): 2.0	Y Y
	ESTRADIOL HEMIHYDRATE	NOVAVAX	27.4	FDA First Action (WD): 10.0 Sponsor Response: 4.5 FDA Second Action (AP): 12.9	Y Y**
	TADALAFIL	LILLY; ICOS	28.8	FDA First Action (AE): 10.0 Sponsor Response: 13.0 FDA Second Action (AP): 5.8	Y Y
	METHYL AMINOLEVULINATE	PHOTOCURE, ASA	34.0	FDA First Action (AE): 11.8 Sponsor Response: 9.9 FDA Second Action (AE): 6.0 Sponsor Response: 4.3 FDA Third Action (AP): 2.0	Y** Y Y
	CHLORPHENIRAMINE POLISTIREX; CODEINE POLISTIREX	CELLTECH	38.3	FDA First Action (AE): 10.0 Sponsor Response: 22.3 FDA Second Action (AP): 6.0	Y Y
	DESLORATADINE	SCHERING	44.8	FDA First Action (AE): 9.8 Sponsor Response: 29.0 FDA Second Action (AP): 6.0	Y Y
2000	LEVONORGESTREL; ESTRADIOL	BERLEX	40.8	FDA First Action (NA): 11.9 Sponsor Response: 9.4 FDA Second Action (NA): 6.0 Sponsor Response: 11.5 FDA Third Action (AP): 2.0	Y** Y Y
	OLANZAPINE	LILLY	45.4	FDA First Action (AE): 9.4 Sponsor Response: 31.2 FDA Second Action (AP): 4.8	Y Y
	TELITHROMYCIN	AVENTIS	49.1	FDA First Action (AE): 15.0 Sponsor Response: 13.8 FDA Second Action (AE): 6.0 Sponsor Response: 8.8 FDA Third Action (AP): 5.5	Y** Y Y

[12] Four-day review extension due to Hurricane Isabel

Table 2 (continued)

Receipt Cohort (FY)	Established/Proper Name	Applicant	Approval Time (Months)		Review Goal Met
			Total Time	Resubmissions (if necessary)	
2000	FOLLITROPIN BETA	ORGANON	49.7	FDA First Action (NA): 10.0 Sponsor Response: 24.7 FDA Second Action (NA): 6.0 Sponsor Response: 6.0 FDA Third Action (AE): 0.0 Sponsor Response: 1.0 FDA Fourth Action (AP): 2.0	Y Y Y Y
	TECHNETIUM (99M TC) FANOLESOMAB (BLA)	PALATIN TECH-NOLOGIES, INC.	55.4	FDA First Action: 10.1 (RL) Sponsor Response: 36.3 FDA Second Action: 9.0 (AP)	Y Y**
1999	ESTRADIOL	SOLVAY	10.0[13]		Y
	HYDROMORPHONE HYDROCHLORIDE	PURDUE	68.9	FDA First Action (AE): 12.0 Sponsor Response: 15.1 FDA Second Action (NA): 6.0 Sponsor Response: 5.2 FDA Third Action (AE): 6.0 Sponsor Response: 20.2 FDA Fourth Action (AE): 1.9 Sponsor Response: 0.3 FDA Fifth Action (AP): 2.0	Y Y Y Y Y
1997	TRIAMCINOLONE ACETONIDE	AVENTIS	87.7	FDA First Action (AE): 12.0 Sponsor Response: 19.5 FDA Second Action (AE): 6.0 Sponsor Response: 22.0 FDA Third Action (AE): 5.9 Sponsor Response: 9.8 FDA Fourth Action (AE): 6.0 Sponsor Response: 0.5 FDA Fifth Action (AP): 6.0	Y Y Y Y Y

[13] The approval time for estradiol has been adjusted. The review of this application was deferred under FDA's Application Integrity Policy. The approval time reflects a clock-start date of April 9, 2003, when the sponsor completed the required validity assessment.

Table 3
FY 2003 Priority NDA and BLA Submissions Approved in FY 2003

Review Type	Established/Proper Name	Applicant	Approval Time (Months)		Review Goal Met
			Total Time	Resubmissions (if necessary)	
Priority	BORTEZOMIB	MILLENNIUM	3.7		Y
	IMATINIB MESYLATE	NOVARTIS	4.0		Y
	RIBAVIRIN	SCHERING	5.9		Y
	ATAZANAVIR SULFATE	BRISTOL-MYERS SQUIBB	6.0		Y
	ALPHA-1-PROTEINASE INHIBITOR (HUMAN) (BLA)	AVENTIS BEHRING L.L.C.	6.1		Y
	DAPTOMYCIN	CUBIST	8.7		Y**

Table 4
FY 2003 Standard NDA and BLA Submissions Approved in FY 2003

Review Type	Established/Proper Name	Applicant	Approval Time (Months)		Review Goal Met
			Total Time	Resubmissions (if necessary)	
Standard	MOXIFLOXACIN HYDROCHLO-RIDE	ALCON	6.0		Y
	METFORMIN HYDROCHLORIDE	RANBAXY	9.9		Y
	ALENDRONATE SODIUM	MERCK	10.0		Y

This report was prepared by FDA's Office of Planning in collaboration with the Center for Biologics Evaluation and Research (CBER) and the Center for Drug Evaluation and Research (CDER). For information on obtaining additional copies contact:

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