EXHIBIT 2

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.

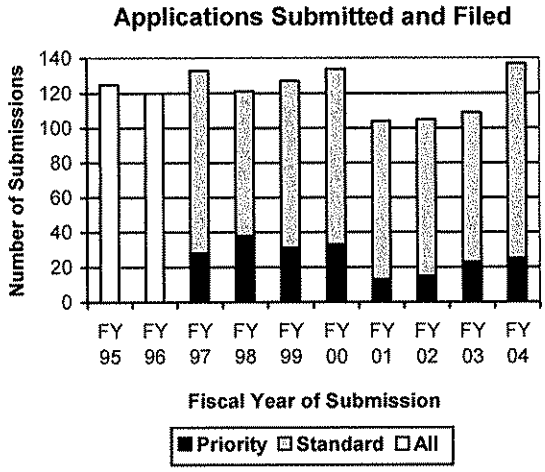
PDUFA III: Refining the Process - From Drug Development Through Application Review to Postmarket Surveillance

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.

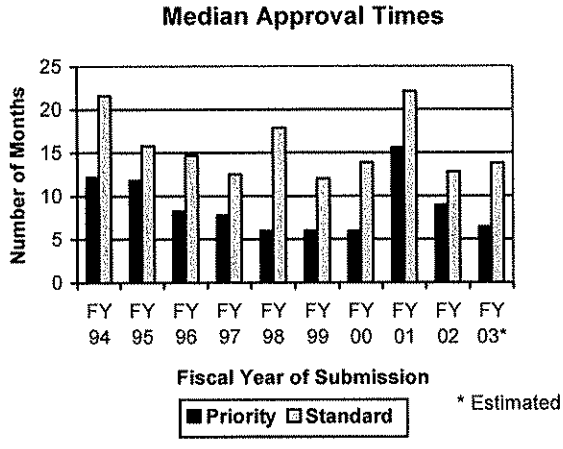
Trends in NDA/BLA Submissions and Approval Times

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.

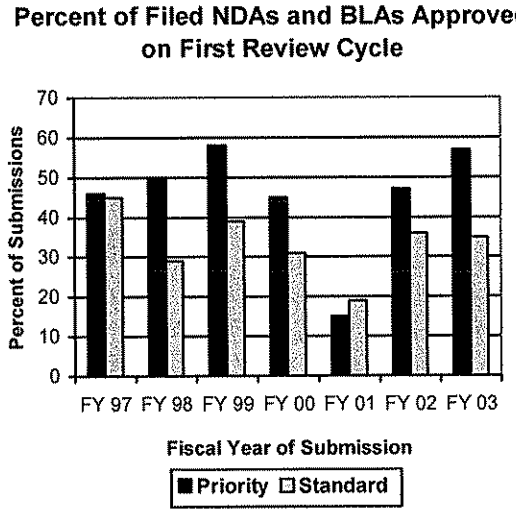
Number of Applications and Priority Applications Increased in FY 2004. The total number of submitted and filed applications increased from 109 in FY 2003 to 137 in FY 2004, and the number of priority applications increased from 23 in FY 2003 to 25 in FY 2004. Priority applications represent significant 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

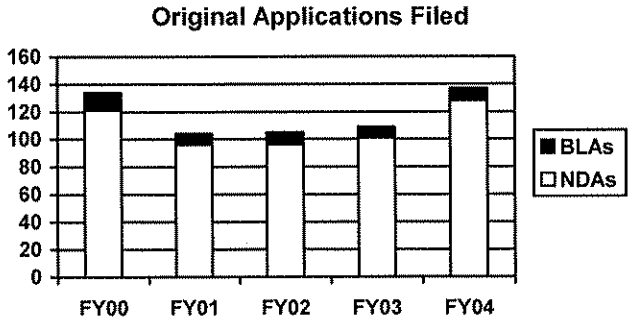
Goal - Review and act on complete original NDAs and BLAs

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

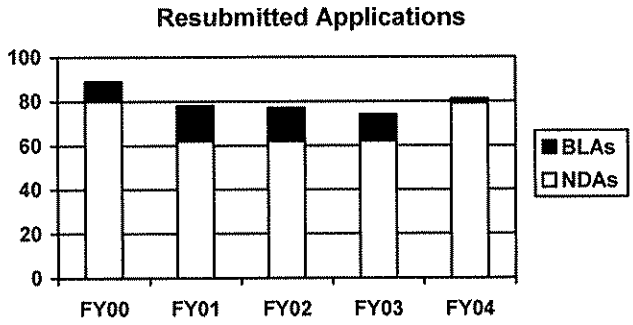
Goal - Review and act on resubmitted NDAs and BLAs

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

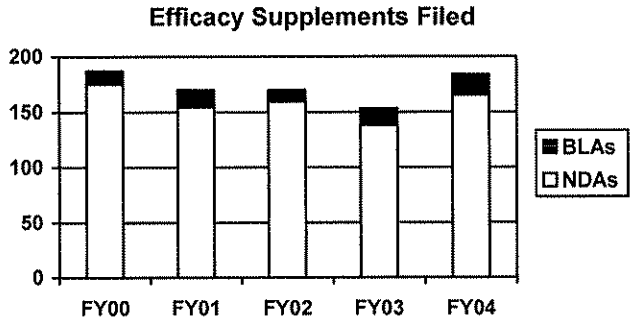
Goal - Review and act on complete efficacy supplements to NDAs and BLAs

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

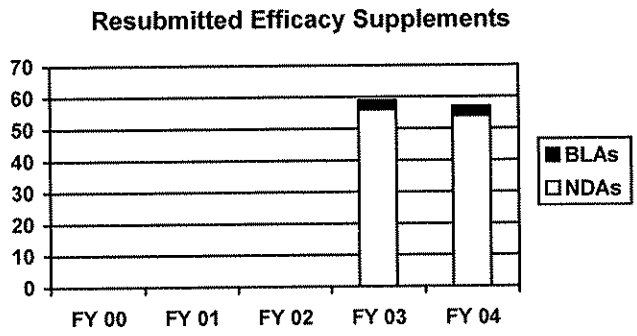
Goal - Review and act on resubmitted efficacy supplements to NDAs and BLAs

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

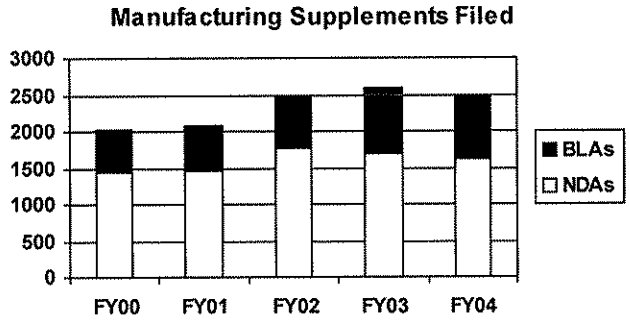
Goal - Review and act on complete manufacturing supplements to NDAs and BLAs

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

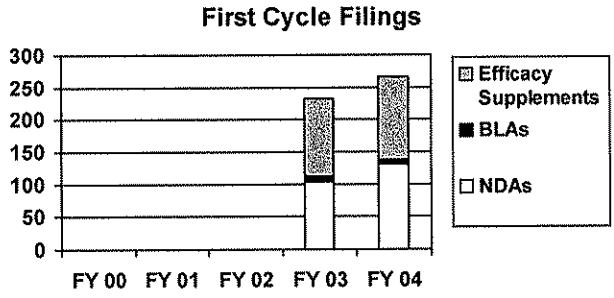
Goal - Report substantive deficiencies (or lack of same) within 14 days after the 60-day filing date for original BLAs, NDAs, and Efficacy Supplements

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

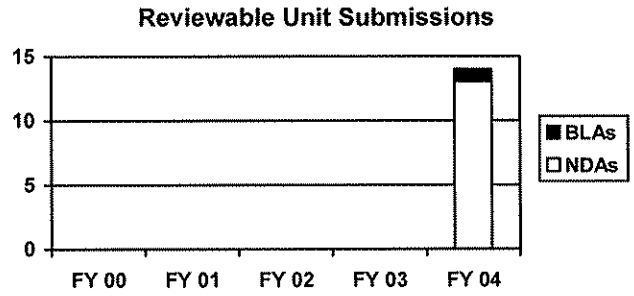
Goal – Issue discipline review letters for pre-submitted "Reviewable Units" of NDAs/BLAs

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.