FY 2007

Food and Drug Administration
Department of Health and Human Services

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) fiscal year (FY) 2007 Performance Report to the President and Congress for the Prescription Drug User Fee Act (PDUFA). This report marks the 15th year of PDUFA and completion of PDUFA III (FY 2003 through FY 2007). Resources provided to FDA under PDUFA legislation have been instrumental in new approved drugs reaching consumers in a timely manner.

PDUFA I (FY 1993 through FY 1997) challenged FDA with goals to speed FDA review of new drug applications (NDAs) and biologics licensing applications (BLAs) without compromising safety. PDUFA II (FY 1998 through FY 2002) added goals to improve the process of new drug development before submission and most review times were shortened. FDA met or exceeded nearly all its review performance goals in PDUFA I and II.

PDUFA III (FY 2003 through FY 2007) expanded fee funding to support FDA postmarket risk management and established initiatives to improve application submissions and FDA-sponsored interactions during drug development and application review. It is believed that early and more frequent consultation with FDA may help sponsors improve the quality of their drug development and related applications. This report presents the final performance of the fourth year of PDUFA III and preliminary performance for the fifth and final year.

While the overall number of submissions under PDUFA III has been close to levels under PDUFA II, FDA also experienced significant and ongoing increases in company requests for meetings and special protocol assessments that began when the PDUFA procedural and processing goals were instituted during PDUFA II. These FDA-sponsor interactions impose a substantial amount of additional work for FDA, but are important to improving the quality of the drug applications, and are expected to result in increased first cycle approvals. Supporting this expectation, the percent of first cycle approvals for priority NDAs and BLAs has increased for the past 5 years.

FDA continued to meet or exceed almost all performance goals under PDUFA III. Additionally, under PDUFA III, notable improvements were made in median approval time (6.0 months from FY 2003 through FY 2006) for priority applications, those which represented significant therapeutic gains. FDA did not meet all performance targets for procedural and processing goals, but continued to make progress in both management and information technology initiatives.

The recent reauthorization of PDUFA will provide significant additional funding to support FDA's continued efforts to improve premarket review and postmarket safety.

Andrew C. von Eschenbach, M.D.
Commissioner of Food and Drugs

Executive Summary

This report presents FDA's performance in meeting annual PDUFA review goals. Review performance for submissions received in FY 2006, and initially reported in the FY 2006 report, is updated and finalized. FDA's preliminary progress in meeting review performance goals for submissions received in FY 2007, and procedural and processing goals for FY 2007, are also covered in this report. Additionally, this report describes FDA's progress in accomplishing management initiatives and in meeting the information technology commitments of PDUFA III.

Workload related to review processes varied in FY 2007 compared to FY 2006 levels. The number of original NDAs and BLAs was unchanged, while the number of resubmitted NDAs and BLAs increased by 10 percent. NDA and BLA efficacy supplements were down by 7 percent, while resubmitted efficacy supplements increased by 19 percent. NDA and BLA manufacturing supplements decreased by 1 percent. The unpredictability of workload continued a historical trend seen in all 5 years of PDUFA III.

As of September 30, 2007, FDA completed review and acted on almost all FY 2006 submissions and resubmissions. FDA can now report that in FY 2006 it exceeded review performance goals for:

- standard and priority new molecular entities (NMEs) and BLAs;
- standard and priority NDAs and BLAs, original and resubmitted efficacy supplements, and all manufacturing supplements; and
- on-time performance goals for PDUFA III management initiatives for first cycle filing review notifications.

However, FDA did not meet the on-time performance goal for reviewable unit letter notifications.

Preliminary review performance for FY 2007 indicates FDA is meeting or exceeding most on-time performance goals for submissions and resubmissions reviewed and acted on as of September 30, 2007.

Workload related to the meeting management procedural and processing goals leveled off, while workload for the remaining procedural and processing goals for special protocol assessments; response to clinical holds; and major dispute resolutions increased in FY 2007. FDA did not meet most of the procedural and processing goals, but exceeded the 90 percent on-time processing goal for all major dispute resolutions.

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Introduction

In 1992, Congress passed PDUFA (PDUFA I), authorizing FDA to collect fees from companies that submit applications for marketing human drug and biological products. The original PDUFA had a 5-year time limit that ended in 1997. In that same year, Congress passed the FDA Modernization Act (FDAMA), which contained a 5-year reauthorization of PDUFA (PDUFA II) that ended on September 30, 2002. Congress then passed the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, which extended the PDUFA program for 5 more years (PDUFA III) through September 30, 2007. 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.

On September 27, 2007, President Bush signed into law the Food and Drug Administration Amendments Act of 2007, which includes the reauthorization and expansion of PDUFA (PDUFA IV) for 5 more years (FY 2008 through FY 2012). The reauthorization is expected to provide funding for current PDUFA performance and initiatives. Additionally, the key goals of PDUFA IV will continue enhancements to premarket review, and expand and modernize postmarket drug safety. The first year of activity under PDUFA IV ends on September 30, 2008, and will be included in the FY 2008 performance report.

PDUFA III 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 addresses the first of these requirements for FY 2007. This year's report covers FDA's progress in meeting the PDUFA review goals for FY 2006 and FY 2007 submissions and the FY 2007 procedural and processing goals. The report also describes FDA's progress in accomplishing management initiatives and in meeting the information technology commitments of PDUFA III.

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Overview of PDUFA

PDUFA provides FDA 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. FDA has committed to achieve PDUFA performance goals that apply to the review of original and resubmitted new product applications and efficacy and manufacturing supplements. FDA has also committed to achieve certain procedural and processing goals aimed at facilitating and assuring quality in new drug development. FDA has met or exceeded the majority of PDUFA performance goals over the 15 years since PDUFA was first enacted.

PDUFA I to PDUFA III: 15 Years of Progress

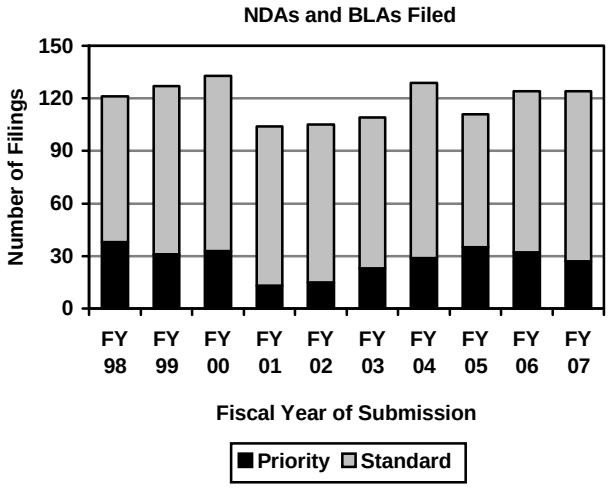
- **Speeding Up Application Review (FY 1993 through FY 1997).** During PDUFA I, FDA eliminated backlogs that had formed in earlier years when FDA had fewer resources. With increased resources under PDUFA I, FDA was able to commit to and achieve review performance targets that applied to an increasing percentage of complete application submissions.
- **Speeding Up Drug Development (FY 1998 through FY 2002).** Under PDUFA II, a number of review performance goals were shortened. Additionally, new goals expanded the scope of work to improve communication between FDA and application sponsors during the drug development process. These goals specified time frames for scheduling meetings and responding to various sponsor submissions, such as special protocols and responses to clinical holds.
- **Refining the Process - From Drug Development through Application Review to Postmarket Surveillance (FY 2003 through FY 2007).** PDUFA III established several new initiatives to improve application submissions and FDA-sponsored interactions during drug development and application review. In addition, PDUFA III authorized FDA to spend user fee funds on certain aspects of postmarket risk management, including surveillance of products approved after October 1, 2002, for up to 3 years after approval.

PDUFA IV: Ensuring Strong Premarket Review and Postmarket Safety

PDUFA IV is expected to provide funding for current PDUFA performance and initiatives. Additionally, the key goals of PDUFA IV will broaden and upgrade drug safety programs and enhance proprietary name review to help reduce medication errors. The first year of activity under PDUFA IV began on October 1, 2007, and ends on September 30, 2008, and will be included in the FY 2008 PDUFA Performance Report.

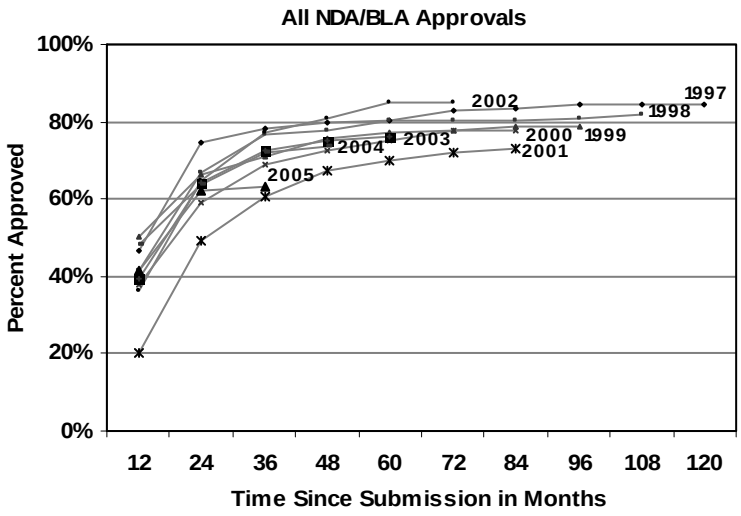
Trends in NDA and BLA Submissions and Approval Times

PDUFA-enabled improvements in application quality and review efficiency 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 as well as the overall quality of submitted applications, the number of newly submitted priority applications, and the number of review staff relative to the review workload. These factors can vary from year to year. The following charts provide an update on trends in submissions and overall approval times.

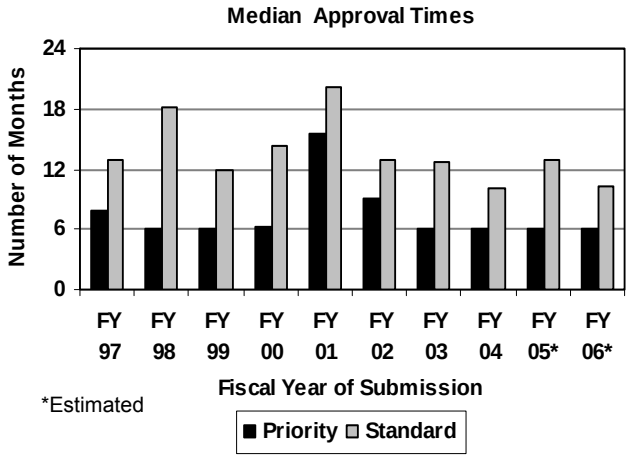


Total Number of NDAs and BLAs Filed in 3 of the Past 4 Years Higher Than Average. Overall numbers of NDAs and BLAs filed were at high levels (124) in both FY 2006 and FY 2007 (see graph to the right). The 10-year (FY 1998 to FY 2007) average number of filings was just under 119 per year. While the total number of applications varies somewhat from year to year, in general, the number of submissions does not depart markedly from the 10-year average. The number of priority applications, which represents significant therapeutic gains, was 27 in FY 2007. This meant that priority applications represented a little over one-fifth of the workload for reviewers in FY 2007. The number of priority applications in FY 2007 was close to the 10-year average (just below 28) for NDA and BLA priority applications.

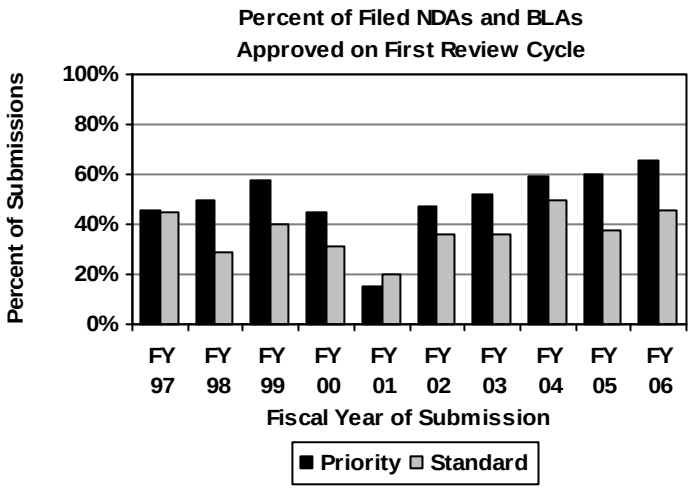
Historical Data Indicate that a Large Percentage of New Drug Marketing Applications Submitted Will Ultimately Reach Approval. A review of NDA and BLA approvals between FY 1997 and FY 2005 shows that on average 63 percent of applications are approved by FDA within the first 24 months of submission to FDA (see graph to the right). It should be noted that the 24-month time frame typically includes more than one cycle of FDA review and resubmission of applications not approved in an earlier cycle of review. The percentage of approvals within the first 24 months ranged from 49 percent in FY 2001 to 74 percent in FY 1997, with most cohorts between the 60 to 70 percent level.



Median Time to Approval For Priority Applications Was 6 Months for the Fourth Straight Year While Median Approval Time For Standard Applications Dropped to Almost 10 months in FY 2006. Based on applications approved through September 30, 2007, and historical data indicating approximately 80 percent of all filed applications will eventually be approved, the estimated median approval time for priority applications for FY 2006 is 6.0 months (see graph to the right). This is the fourth straight year (FY 2003 to FY 2006) for these historically low levels. The estimated median approval time for standard applications in FY 2006 was 10.3 months, the second lowest in 9 years.



Percentage of First Cycle Approvals for Priority NDAs and BLAs Increased for the Fourth Straight Year. The percentage of priority NDAs and BLAs approved in the first review cycle has steadily increased from 52 percent in FY 2003 to 66 percent in FY 2006 (see graph to the right). The percentage of standard applications approved in the first review cycle also increased in FY 2006 to 46 percent, the second highest level in the past 9 years.



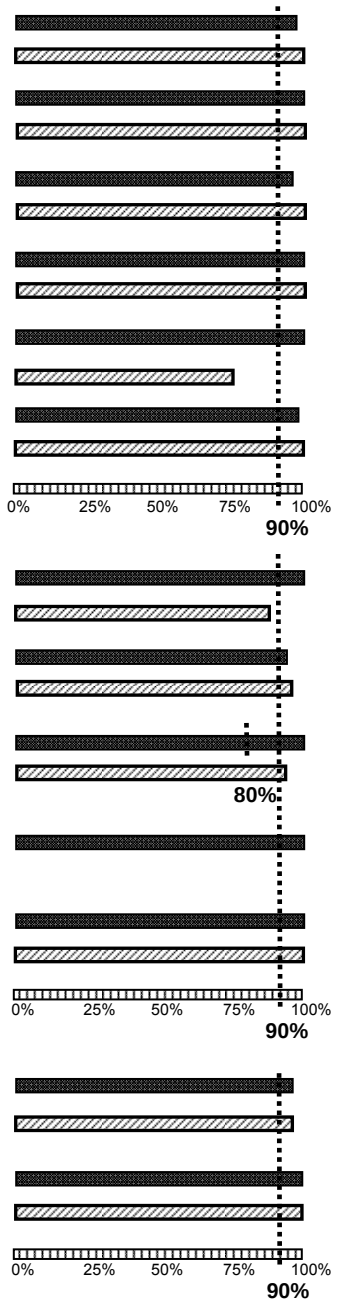
Workload Continued to Increase in FY 2007. The most notable growth in workload in FY 2007 compared to the average for the previous 4 years (FY 2003 to FY 2006) involved activities other than original or resubmitted application reviews. Special protocol assessments and responses to clinical holds were up 27 percent and major dispute resolutions grew by 83 percent.

Submission/Request	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007	FY 2007 Compared to FY 2006	FY 2003 to FY 2006 Average	FY 2007 Compared To Previous 4-Year Average
Original NDAs and BLAs Filed	109	129	111	124	**124**	0%	118	+ 5%
Resubmitted NDAs and BLAs	74	85	59	61	**67**	+ 10%	70	- 4%
NDA and BLA Efficacy Supplements	153	204	158	190	**177**	- 7%	176	+ 1%
Resubmitted Efficacy Supplements	59	58	48	37	**44**	+ 19%	51	- 14%
NDA and BLA Manufacturing Supplements	2,598	2,500	2,532	2,647	**2,621**	- 1%	2,569	+ 2%
Meetings Scheduled	2,002	2,125	2,230	2,273	**2,151**	- 5%	2,158	0%
Special Protocol Assessments	293	346	396	406	**456**	+ 12%	360	+ 27%
Responses To Clinical Holds	136	135	130	145	**174**	+ 20%	137	+ 27%
Major Dispute Resolutions	20	10	9	9	**22**	+ 144%	12	+ 83%

Review Performance At-A-Glance for FY 2006 and FY 2007

The tables below summarize FDA's review performance on the FY 2006 submissions, the preliminary performance in reviewing FY 2007 submissions, and meeting other performance goals. Additional discussion of the individual goals follows in a later section.

	Goal Area	Percent on Time vs. PDUFA Review Performance Goal
Original and Resubmitted Applications	Priority NDAs and BLAs	FY 2006 / FY 2007
	Priority NMEs and BLAs	FY 2006 / FY 2007
	Standard NDAs and BLAs	FY 2006 / FY 2007
	Standard NMEs and BLAs	FY 2006 / FY 2007
	Resubmitted Class 1† NDAs and BLAs	FY 2006 / FY 2007
	Resubmitted Class 2† NDAs and BLAs	FY 2006 / FY 2007
Original and Resubmitted Efficacy Supplements	Priority NDAs and BLAs	FY 2006 / FY 2007
	Standard NDAs and BLAs	FY 2006 / FY 2007
	Resubmitted Class 1 NDAs and BLAs within 2 months	FY 2006 / FY 2007
	Resubmitted Class 1 NDAs and BLAs within 4 months*	FY 2006
	Resubmitted Class 2 NDAs and BLAs within 6 months	FY 2006 / FY 2007
Manufacturing Supplements	NDAs and BLAs requiring prior approval	FY 2006 / FY 2007
	NDAs and BLAs not requiring prior approval	FY 2006 / FY 2007

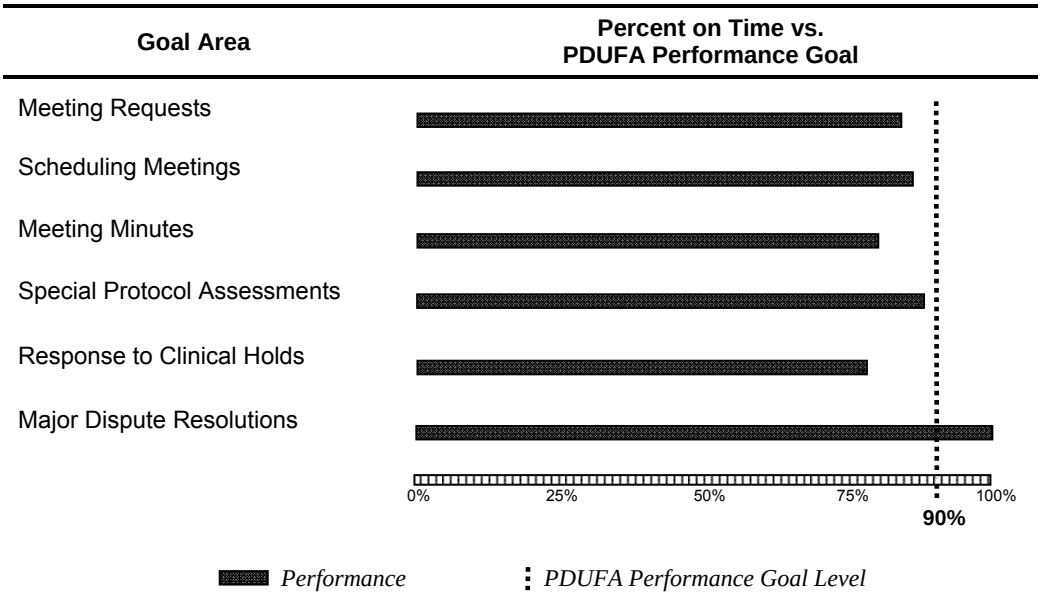


† Defined in Appendix A "Definition of Terms," page A-7.

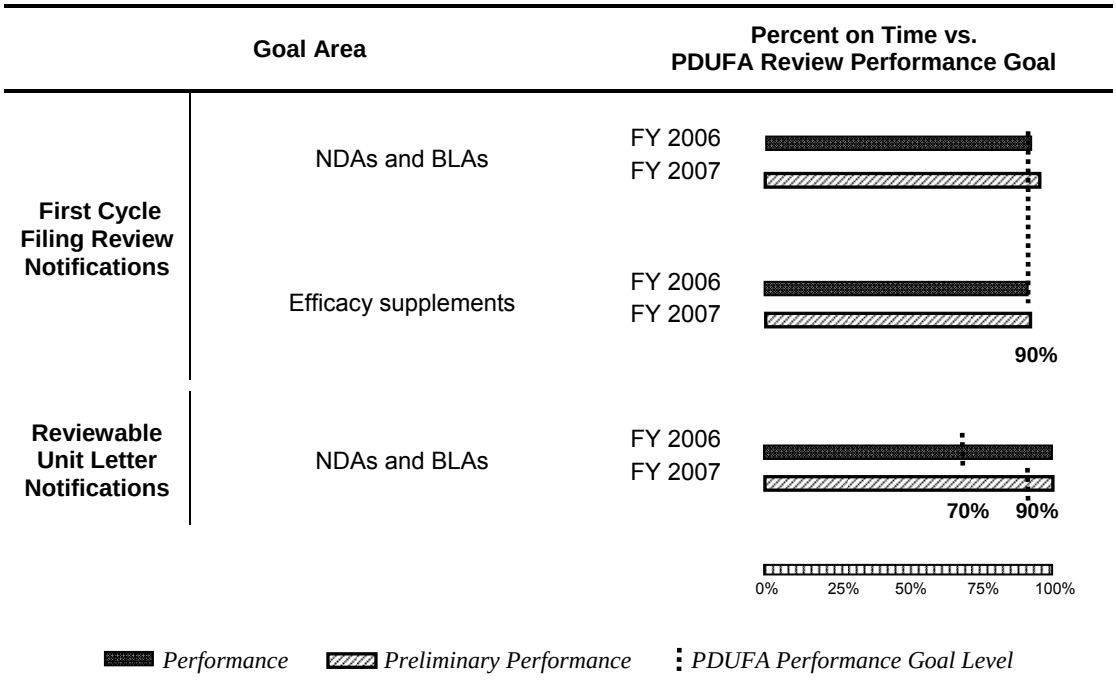
* No longer a goal after FY 2006.

Performance *Preliminary Performance* *PDUFA Performance Goal Level*

FY 2007 Procedural and Processing Goals



PDUFA III Management Initiatives Performance for FY 2006 and FY 2007



Report on FY 2006 and FY 2007 PDUFA Goals

This section updates FDA's final review performance on the FY 2006 submissions and evaluates FDA's performance in reviewing FY 2007 submissions and meeting other PDUFA performance goals. The following information refers to FDA performance presented in this section.

- FDA reviewed and acted on all but two of the original applications submitted during FY 2006. Final performance with respect to achieving FY 2006 goals can now be reported.

- The counts for FY 2007 include submissions received in the last 2 months of FY 2007 as filed. When FDA files a submission, it is deemed "complete" using the 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.

- Only a preliminary performance assessment on submissions received during FY 2007 is possible. For submissions with a 10-month review goal, it is too early to measure review performance. For those submissions with a review goal shorter than 10 months, performance on submissions received early in the fiscal year provides a reasonable predictor of final review performance.

- 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; NME refers only to NMEs that are NDAs; and "submission" applies to all of the above. For FDAMA purposes, all BLAs are equivalent to NMEs; however, for some of the workload and performance statistics that follow, 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 FDA approves the first of the multiple submissions, FDA redesignates the others as non-NMEs.

- Unless otherwise noted, all performance data are as of September 30, 2007.

Original Applications

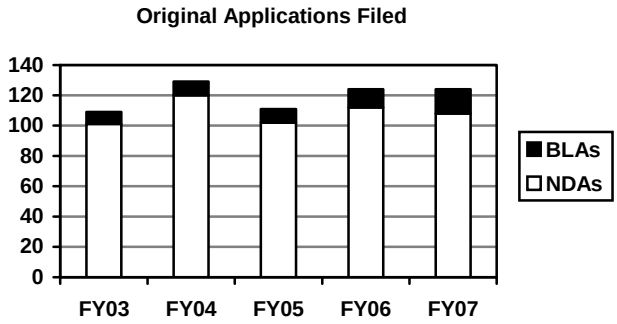
Goal: Review and Act on Original NDAs and BLAs

The table below summarizes the annual review time goals for original NDAs and BLAs. Over the 5-year period defined by PDUFA III, the performance goal of reviewing 90 percent of priority applications within 6 months and standard applications within 10 months remained constant.

Original Application Type	Review Time Goal	Performance Goal FY 2003 – FY 2007 Submissions
Priority	6 months	90% on time
Standard	10 months	

Workload

The total number of original applications (PDUFA Total) in FY 2007 was the same as FY 2006. However, within this total, the number of BLAs and NMEs increased while the number of non-NME NDAs decreased. Additionally, the number of priority applications (NDA only) decreased over the past 2 years while all standard applications increased during this same period (see corresponding graph and table).



Original Applications Filed
(Priority / Standard)

Type	FY 03	FY 04	FY 05	FY 06*	FY 07
NDAs	**101** *(19/82)*	**120** *(26/94)*	**102** *(29/73)*	**112** *(25/87)*	**108** *(20/88)*
BLAs	**8** *(4/4)*	**9** *(3/6)*	**9** *(6/3)*	**12** *(7/5)*	**16** *(7/9)*
PDUFA Total	**109** *(23/86)*	**129** *(29/100)*	**111** *(35/76)*	**124** *(32/92)*	**124** *(27/97)*
NMEs†	**28** *(12/16)*	**29‡** *(16/13‡)*	**30** *(15/15)*	**24** *(8/16)*	**29** *(9/20)*

* FY 2006 counts were updated to reflect corrections to the FY 2006 Performance Report.
† FDA often receives multiple submissions for the same NME, which are all initially designated as NMEs. When FDA approves the first of the multiple submissions, the others are redesignated as non-NMEs.
‡ FY 2004 NME counts were updated to reflect corrections to the FY 2006 PDUFA Performance Report.

Original Applications

Performance

FY 2006 Submissions

FDA exceeded the performance goals for original NDAs and BLAs in FY 2006 (see table below). FDA reviewed and acted on all but one (31 of 32) priority applications within the 6-month review time goal and almost all (86 of 90) standard applications within the 10-month review time goal. With two standard applications pending action and not overdue as of September 30, 2007, FDA will exceed the performance goal for standard applications.

Original Application Type	Review Within	Type	Reviewed and Acted On	Number on Time	Percent on Time	PDUFA Performance Goal
Priority	6 months	All Applications	32	31	**97%**	90%
		NMEs & BLAs	15	15	**100%**	90%
Standard	10 months	All Applications	90	86	**96%**	90%
		NMEs & BLAs	21	21	**100%**	90%

FY 2007 Submissions

As of September 30, 2007, over half (14 of 27) of the priority applications filed in FY 2007 were reviewed and acted on; all met the 6-month review time goal (see table below). About one-seventh (14 of 97) of the standard applications filed were reviewed and acted on and all met the 10-month review time goal. With submissions still pending action and not overdue, it is too early to make a final performance determination for FY 2007.

Original Application Type	Review Within	Type	Reviewed and Acted On	Number on Time	Percent on Time	PDUFA Performance Goal
Priority	6 months	All Applications	14	14	**100%**	90%
		NMEs & BLAs	9	9	**100%**	90%
Standard	10 months	All Applications	14	14	**100%**	90%
		NMEs & BLAs	5	5	**100%**	90%

Resubmitted Applications

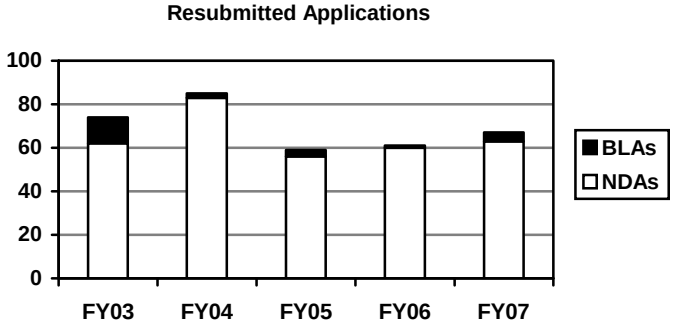
Goal: Review and Act on Resubmitted NDAs and BLAs

The table below summarizes the annual review time goals for resubmitted NDAs and BLAs. A resubmission is a firm's response to 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. Over the 5-year period defined by PDUFA III, the performance goal of reviewing 90 percent of Class 1 resubmitted applications within 2 months and Class 2 resubmitted applications within 6 months remained constant.[1]

Resubmitted Application Type	Review Time Goal	Performance Goal FY 2003 – FY 2007 Submissions
Class 1	2 months	90% on time
Class 2	6 months	

Workload

The total number of FY 2007 resubmitted applications increased by 10 percent over FY 2006. While the number of NDAs resubmitted increased during the past 2 years, the level remained below numbers submitted in FY 2003 and FY 2004 (see corresponding graph and table).



Resubmitted Applications *(Class 1 / Class 2)*					
Type	**FY 03**	**FY 04**	**FY 05**	**FY 06**	**FY 07**
NDAs	**62** *(24/38)*	**83** *(21/62)*	**56** *(21/35)*	**60** *(20/40)*	***63*** *(23/40)*
BLAs	**12** *(1/11)*	**2** *(1/1)*	**3** *(0/3)*	**1** *(0/1)*	***4*** *(1/3)*
PDUFA Total	**74** *(25/49)*	**85** *(22/63)*	**59** *(21/38)*	**61** *(20/41)*	***67*** *(24/43)*

[1] Class 1 resubmissions are applications resubmitted after a complete response letter (or a not approvable or approvable letter) that include items listed on page A-7 in Appendix A. Class 2 resubmissions are applications resubmitted that include other items, such as those presented to an advisory committee.

Resubmitted Applications

Performance

FY 2006 Resubmissions

FDA exceeded the performance goal for both Class 1 and Class 2 resubmissions in FY 2006 (see table below). FDA reviewed and acted on all (20 of 20) Class 1 resubmitted applications within the 2-month review time goal and reviewed and acted on all but one (39 of 40) Class 2 resubmitted applications within the 6-month review time goal. With one Class 2 submission still pending action and overdue, FDA will exceed the performance goal for resubmitted applications in FY 2006.

Resubmitted Application Type	Review Within	Reviewed and Acted On	Number on Time	Percent on Time	PDUFA Performance Goal
Class 1	2 months	20	20	**100%**	90%
Class 2	6 months	40	39	**98%**	90%

FY 2007 Resubmissions

As of September 30, 2007, over four-fifths (20 of 24) of the Class 1 resubmissions received in FY 2007 were reviewed and acted on; 75 percent had met the 2-month review time goal (see table below). With four Class 1 resubmissions pending action, it is too early to determine a final on-time percentage; however, even if all remaining reviews are completed on time, the performance goal will not be met for FY 2007. Over half (24 of 43) of the Class 2 resubmissions received in FY 2007 were reviewed and acted on and all met the 6-month review time goal. With submissions still pending action and not overdue, it is too early to make a final performance determination for Class 2 resubmitted applications for FY 2007.

Resubmitted Application Type	Review Within	Reviewed and Acted On	Number on Time	Percent on Time	PDUFA Performance Goal
Class 1	2 months	20	15	**75%**	90%
Class 2	6 months	24	24	**100%**	90%

Efficacy Supplements

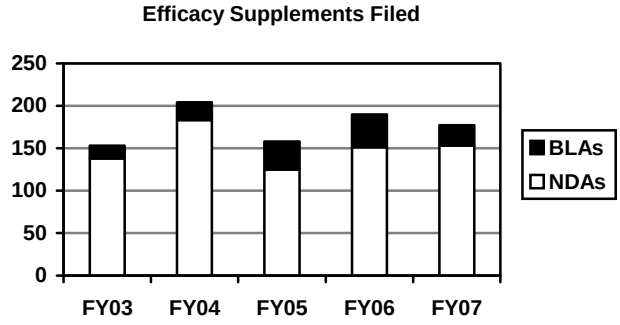
Goal: Review and Act on Complete Efficacy Supplements to NDAs and BLAs

The table below summarizes the annual review time goals for original efficacy supplements to NDAs and BLAs. Over the 5-year period defined by PDUFA III, the performance goal of reviewing 90 percent of priority supplements within 6 months and standard supplements within 10 months remained constant.

Efficacy Supplement Type	Review Time Goal	Performance Goal FY 2003 – FY 2007 Submissions
Priority	6 months	90% on time
Standard	10 months	

Workload

The total number of efficacy supplements received during the 5-year period increased and decreased alternately each year. For the first 4 years (FY 2003 through FY 2006), this fluctuation was a direct result of the number of NDA efficacy supplements filed; BLA efficacy supplements filed increased each year from FY 2003 to FY 2006 with the number decreasing in FY 2007 (see corresponding graph and table).



Efficacy Supplements Filed *(Priority / Standard)*					
Type	**FY 03**	**FY 04**	**FY 05**	**FY 06**	**FY 07**
NDAs	**138** *(35/103)*	**183** *(48/135)*	**125** *(34/91)*	**151** *(36/115)*	**153** *(31/122)*
BLAs	**15** *(2/13)*	**21** *(2/19)*	**33** *(7/26)*	**39** *(8/31)*	**24** *(3/21)*
PDUFA Total	**153** *(37/116)*	**204** *(50/154)*	**158** *(41/117)*	**190** *(44/146)*	**177** *(34/143)*

Efficacy Supplements

Performance

FY 2006 Submissions

FDA exceeded both performance goals for priority and standard efficacy supplements in FY 2006 (see table below). FDA reviewed and acted on all priority efficacy supplements within the 6-month review time goal. FDA reviewed and acted on almost all (136 of 144) standard efficacy supplements within the 10-month review time goal. With two standard efficacy supplements pending action and not overdue as of September 30, 2007, FDA will exceed the performance goal for standard efficacy supplements.

Efficacy Supplement Type	Review Within	Reviewed and Acted On	Number on Time	Percent on Time	PDUFA Performance Goal
Priority	6 months	44	44	**100%**	90%
Standard	10 months	144	136	**94%**	90%

FY 2007 Submissions

As of September 30, 2007, over two-thirds (24 of 34) of the priority efficacy supplements filed in FY 2007 were reviewed and acted on and 88 percent met the 6-month review time goal (see table below). About one-seventh (20 of 143) of the standard efficacy supplements received were reviewed and acted on; 95 percent met the 10-month review time goal. With submissions still pending action and not overdue, it is too early to make a final performance determination for FY 2007.

Efficacy Supplement Type	Review Within	Reviewed and Acted On	Number on Time	Percent on Time	PDUFA Performance Goal
Priority	6 months	24	21	**88%**	90%
Standard	10 months	20	19	**95%**	90%

Resubmitted Efficacy Supplements

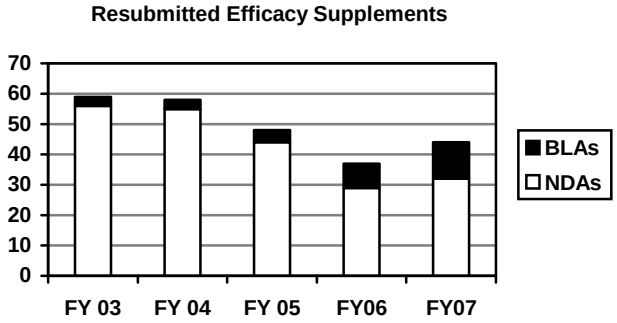
Goal: Review and Act on Resubmitted Efficacy Supplements to NDAs and BLAs

The table below summarizes the annual review time goals for resubmitted efficacy supplements to NDAs and BLAs. For Class 1 resubmissions, the performance goal progresses from reviewing 30 percent of FY 2003 resubmissions in 2 months to 90 percent by FY 2007. Over the 5-year period defined by PDUFA III, the goal of reviewing 90 percent of Class 2 resubmissions within 6 months remained constant.

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

FY 2007 experienced an increase in the total number of resubmitted efficacy supplements compared to the previous year, but the level was below that of earlier years. Although Class 1 BLA efficacy supplements remained at about the same level, Class 2 BLA efficacy supplement resubmissions showed an increase over the previous year (see corresponding graph and table).



Resubmitted Efficacy Supplements *(Class 1 / Class 2)*					
Type	**FY 03**	**FY 04**	**FY 05**	**FY 06**	**FY 07**
NDAs	**56** *(16/40)*	**55** *(32/23)*	**44** *(23/21)*	**29** *(13/16)*	**32** *(15/17)*
BLAs	**3** *(1/2)*	**3** *(3/0)*	**4** *(1/3)*	**8** *(1/7)*	**12** *(1/11)*
PDUFA Total	**59** *(17/42)*	**58** *(35/23)*	**48** *(24/24)*	**37** *(14/23)*	**44** *(16/28)*

Resubmitted Efficacy Supplements

Performance

FY 2006 Resubmissions

FDA exceeded the performance goals for both Class 1 and Class 2 efficacy supplement resubmissions in FY 2006 (see table below). FDA reviewed and acted on all (13 of 13) Class 1 resubmitted efficacy supplements within both the 2-month and 4-month review time goals. With one Class 1 resubmitted efficacy supplement still pending action and overdue, FDA will exceed the performance goal for Class 1 resubmissions. FDA reviewed and acted on all Class 2 resubmitted efficacy supplements within the 6-month review time goal.

Resubmitted Efficacy Supplement Type	Review Within	Reviewed and Acted On	Number on Time	Percent on Time	PDUFA Performance Goal
Class 1	2 months	13	13	**100%**	80%
	4 months		13	**100%**	90%
Class 2	6 months	23	23	**100%**	90%

FY 2007 Resubmissions

As of September 30, 2007, all but one (15 of 16) of the Class 1 resubmitted efficacy supplements were reviewed and acted on and 93 percent (14 of 15) met the 2-month review time goal (see table below). Over half (17 of 28) of the Class 2 resubmitted efficacy supplements were reviewed and acted on; all met the 6-month review time goal. With resubmissions still pending action and not overdue, it is too early to make a final performance determination for FY 2007.

Resubmitted Efficacy Supplement Type	Review Within	Reviewed and Acted On	Number on Time	Percent on Time	PDUFA Performance Goal
Class 1	2 months	15	14	**93%**	90%
Class 2	6 months	17	17	**100%**	90%

Manufacturing Supplements

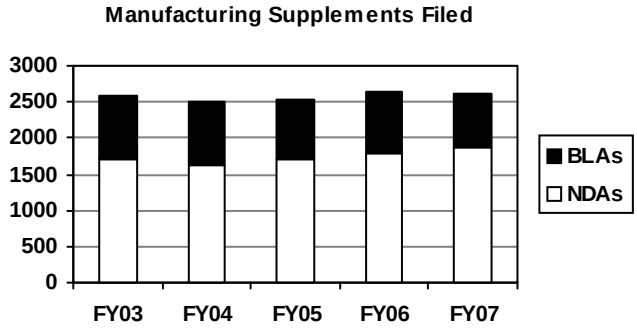
Goal: Review and Act on Manufacturing Supplements to NDAs and BLAs

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

Manufacturing Supplement Type	Review Time Goal	Performance Goal FY 2003 – FY 2007 Submissions
Prior Approval Required	4 months	90% on time
Prior Approval Not Required	6 months	

Workload

Total manufacturing supplements filed over the last 5 years showed relatively small increases and decreases. However, the total number of BLA manufacturing supplements filed decreased over the same period while the number of NDA manufacturing supplements increased. As a result, BLA supplements in FY 2007 represented the smallest proportion (less than 3 of 10) of manufacturing supplements over the past 5 years (see corresponding graph and table).



Manufacturing Supplements Filed *(Prior Approval / No Prior Approval)*					
Type	**FY 03**	**FY 04**	**FY 05**	**FY 06**	**FY 07**
NDAs	**1,696** *(617/1,079)*	**1,617** *(524/1,093)*	**1,695** *(630/1,065)*	**1,788** *(574/1,214)*	**1,874** *(604/1,270)*
BLAs	**902** *(303/599)*	**883** *(299/584)*	**837** *(257/580)*	**859** *(310/549)*	**747** *(233/514)*
PDUFA Total	**2,598** *(920/1,678)*	**2,500** *(823/1,677)*	**2,532** *(887/1,645)*	**2,647** *(884/1,763)*	**2,621** *(837/1,784)*

Manufacturing Supplements

Performance

FY 2006 Submissions

FDA exceeded both performance goals for manufacturing supplements in FY 2006 (see table below). FDA reviewed and acted on almost all (848 of 884) manufacturing supplements that required prior approval within the 4-month review time goal. FDA also reviewed and acted on virtually all (1,739 of 1,760) manufacturing supplements not requiring prior approval within the 6-month review time goal. With three manufacturing supplements not requiring prior approval, pending action, and overdue as of September 30, 2007, FDA will exceed the performance goal.

Manufacturing Supplement Type	Review Within	Reviewed and Acted On	Number on Time	Percent on Time	PDUFA Performance Goal
Prior Approval Required	4 months	884	848	**96%**	90%
Prior Approval Not Required	6 months	1760	1739	**99%**	90%

FY 2007 Submissions

As of September 30, 2007, two-thirds (565 of 837) of the manufacturing supplements requiring prior approval were reviewed and acted on and 96 percent (541 of 565) were reviewed within the 4-month review time goal (see table below). Over half (972 of 1,784) of the manufacturing supplements not requiring prior approval were reviewed and acted on while 99 percent (966 of 972) were reviewed within the 6-month review time goal. With submissions still pending action and not overdue, it is too early to make a final performance determination for FY 2007.

Manufacturing Supplement Type	Review Within	Reviewed and Acted On	Number on Time	Percent on Time	PDUFA Performance Goal
Prior Approval Required	4 months	565	541	**96%**	90%
Prior Approval Not Required	6 months	972	966	**99%**	90%

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Report on Other FY 2007 PDUFA Goals, Initiatives, and Commitments

This section presents FDA's performance in achieving the FY 2007 procedural and processing goals and accomplishments for PDUFA III initiatives and commitments. The following information refers to FDA performance presented in this section.

- The procedural and processing goals reflect performance related to the Investigational New Drug Application (IND) phase of drug development.

- The management initiatives under PDUFA III relate to improving the overall application review process.

- The electronic applications and submissions commitments relate to the Information Technology (IT) initiatives and activities of PDUFA III.

A detailed description of the goals, commitments, the annual performance targets, and definitions of terms can be found in Appendix A.

Procedural and Processing Goals – Meeting Management

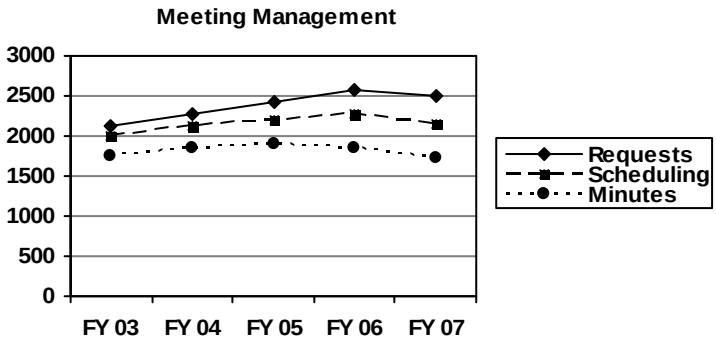
The procedural and processing goals FDA committed to achieve were designed to improve application submissions and FDA-sponsor interactions during new drug development and application review. The table below summarizes the meeting management goals that address meeting requests, scheduling meetings, and preparing meeting minutes. The performance goal of 90 percent has remained constant.

Action	Review Time Goal	Performance Goal FY 2003 – FY 2007
Meeting Requests	Notify requestor of formal meeting in writing within 14 days of request.	90% on time
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 FDA, the meeting date should be within 14 days of the requested date.	
Meeting Minutes	FDA-prepared minutes, clearly outlining agreements, disagreements, issues for further discussion, and action items will be available to the sponsor within 30 days of meeting.	

* Defined in Appendix A "Definition of Terms," page A-7.

Workload

After 4 straight years of increases, the number of annual meeting requests decreased by approximately 2 percent in FY 2007, but remained over 2,500. Consequentially, the number of meetings scheduled and meeting minutes decreased (see corresponding graph and table).



Meeting Management					
Type	**FY 03**	**FY 04**	**FY 05**	**FY 06**	**FY 07**
Meeting Request Notifications	2,119	2,284	2,487	2,565	2,502
Scheduling Meetings	2,002	2,125	2,230	2,273	2,151
Meeting Minutes	1,761	1,854	1,901	1,853	1,736

Procedural and Processing Goals – Meeting Management

FY 2007 Performance

As of September 30, 2007, FDA had responded to virtually all of the meeting requests (see table below). Preliminary performance indicates FDA will not meet the performance goals for meeting management. While activities are still pending action and not overdue, completing these activities on time will not raise the overall performance sufficiently to meet the performance goals.

			Total	Met Goal	Missed Goal*	Pending Within Goal	Percent on Time†	PDUFA Performance Goal
Meeting Requests		CBER	278	268	10	0		
		CDER	2,224	1,822	379	23		
		Combined	**2,502**	**2,090**	**389**	**23**	**84%**	**90%**
Scheduling Meetings‡	Type A	CBER	11	10	0	1		
		CDER	261	156	59	46		
	Type B	CBER	154	121	8	25		
		CDER	1,145	962	168	15		
	Type C	CBER	80	62	3	15		
		CDER	500	444	46	10		
	All	CBER	245	193	11	41		
		CDER	1,906	1,562	273	71		
		Combined	**2,151**	**1,755**	**284**	**112**	**86%**	**90%**
Meeting Minutes		CBER	158	139	3	16		
		CDER	1,578	915	257	406		
		Combined	**1,736**	**1,054**	**260**	**422**	**80%**	**90%**

* Includes those with late actions and those still pending where the goal date has passed and which have not had actions.

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

‡ Not all meeting requests are granted.

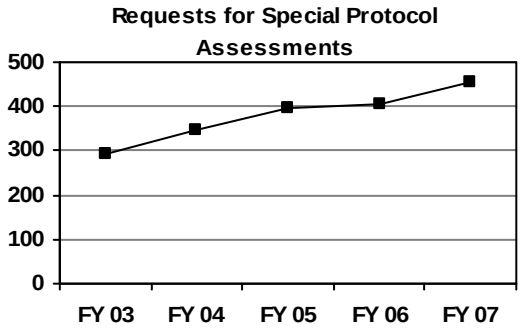
Procedural and Processing Goals – Special Protocol Assessments

The table below summarizes the annual review time goal for the response to the requests for special protocol assessments. Over the 5-year period defined by PDUFA III, the goal of responding to 90 percent of sponsors' requests for evaluation of protocol design within 45 days of receipt remained constant.

Action	Review Time Goal	Performance Goal FY 2003 – FY 2007
Special Protocol Question Assessment and Agreement	Respond to sponsor's request for evaluation of protocol design within 45 days of receipt.	90% on time

Workload

Special protocol assessment requests increased for the fifth straight year, although at a slower rate from FY 2006 to FY 2007 (see corresponding graph and table).



Requests for Special Protocol Assessments				
FY 03	**FY 04**	**FY 05**	**FY 06**	**FY 07**
293	346	396	406	456

FY 2007 Performance

As of September 30, 2007, FDA responded to most (401 of 456) of the sponsors' requests for evaluation of protocol designs received in FY 2007 (see table below). Preliminary performance indicated FDA was below the performance goal to respond to requests for special protocol assessments. While assessments are still pending action and not overdue, completing them on time will not raise the overall performance sufficiently to meet the performance goal.

Requests for Special Protocol Assessments *(CBER / CDER)*					
Total	**Met Goal**	**Missed Goal**	**Pending Within Goal**	**Percent on Time**	**PDUFA Performance Goal**
456 *(10/446)*	**352** *(9/343)*	**49** *(0/49)*	**55** *(1/54)*	**88%**	90%

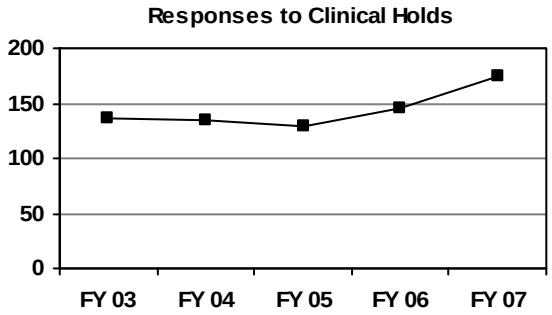
Procedural and Processing Goals – Responses to Clinical Holds

The table below summarizes the annual review time goal for the response to clinical holds. Over the 5-year period defined by PDUFA III, the performance goal of responding to a sponsor's complete response to a clinical hold within 30 days of receipt remained constant.

Action	Review Time Goal	Performance Goal FY 2003 – FY 2007
Response to Clinical Hold	Respond to sponsor's complete response to a clinical hold within 30 days of receipt.	90% on time

Workload

The number of responses to clinical holds increased by 20 percent in FY 2007. This represented the second increase in 2 years and the highest level in 5 years (see corresponding graph and table).



Responses to Clinical Holds				
FY 03	FY 04	FY 05	FY 06	FY 07
136	135	130	145	174

FY 2007 Performance

As of September 30, 2007, FDA responded to almost all (165 of 174) of the sponsors' complete responses to clinical holds received in FY 2007 (see table below). However, FDA did not meet the performance goal for responses to clinical holds. While responses are still pending action and not overdue, completing them on time will not raise the overall performance enough to meet the performance goal.

Responses to Clinical Holds *(CBER / CDER)*					
Total	**Met Goal**	**Missed Goal**	**Pending Within Goal**	**Percent on Time**	**PDUFA Performance Goal**
174 *(37/137)*	**128** *(31/97)*	**37** *(1/36)*	**9** *(5/4)*	**78%**	90%

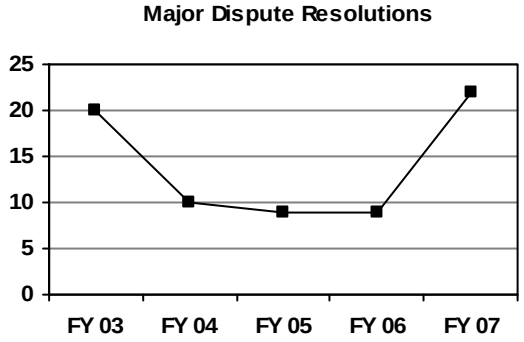
Procedural and Processing Goals – Major Dispute Resolutions

The table below summarizes the annual review time goal for a response to major dispute resolutions. Over the 5-year period defined by PDUFA III, the goal of responding to a sponsor's appeal of a decision within 30 days of receipt remained constant.

Action	Review Time Goal	Performance Goal FY 2003 – FY 2007
Major Dispute Resolution	Respond to sponsor's appeal of decision within 30 days of receipt.	90% on time

Workload

The number of major dispute resolutions requested during FY 2007 represents the highest number in 5 years as the requests more than doubled when compared to the number requested in each of the previous 3 years (FY 2004 through FY 2006) (see corresponding graph and table).



Major Dispute Resolutions				
FY 03	**FY 04**	**FY 05**	**FY 06**	**FY 07**
20	10	9	9	22

FY 2007 Performance

As of September 30, 2007, FDA had responded to all sponsors' appeals of decisions received in FY 2007 and exceeded the performance goal (see table below).

Major Dispute Resolutions *(CBER / CDER)*					
Total	**Met Goal**	**Missed Goal**	**Pending Within Goal**	**Percent on Time**	**PDUFA Performance Goal**
22 *(0/22)*	**22** *(0/22)*	**0** *(0/0)*	**0** *(0/0)*	**100%**	90%

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PDUFA III Management Initiatives Performance – First Cycle Filing Review Notification

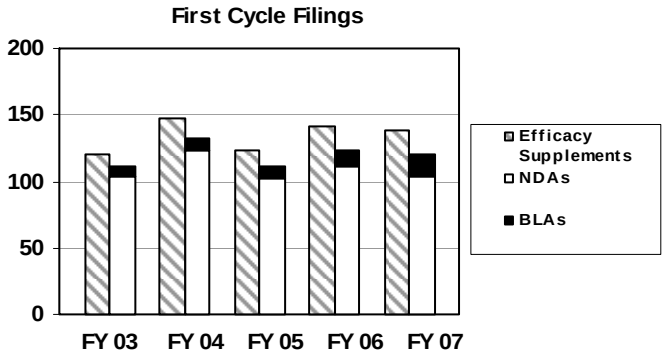
Goal: Report Substantive Deficiencies (or Lack of Same) Within 14 Days After the 60-Day Filing Date for Original NDAs/BLAs and Efficacy Supplements

The table below summarizes the annual review time goals for first cycle filing review notifications for original NDAs/BLAs, and efficacy supplements. 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 goals increased from 50 percent review notifications 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 Goal				
		FY 03	FY 04	FY 05	FY 06	FY 07
Original NDAs/BLAs	Within 14 days after 60-day filing date	50%	70%	90%		
Efficacy Supplements						

Workload

The number of first cycle filings for NDAs fluctuated over the past 5 years, decreasing in FY 2007. Efficacy supplements followed a similar pattern. However, the number of first cycle filings for BLAs increased in FY 2007, the third time in 5 years (see corresponding graph and table).



First Cycle Filings					
Type	FY 03	FY 04	FY 05	FY 06	FY 07
NDAs	104	123	102	111	104
BLAs	8	9	9	12	17
Total	112	132	111	123	121
Efficacy Supplements*	121	147	124	142	138

* The First Cycle Filing Review Notification goal applies to original NDAs/BLAs and efficacy supplements only. It does not apply to NDA 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 page 15).

PDUFA III Management Initiatives Performance – First Cycle Filing Review Notification

Performance

FY 2006 Submissions

FDA issued initial filing review notifications for all NDAs/BLAs and efficacy supplements and exceeded the performance goals in FY 2006 (see table below).

First Cycle Filing Review Notification Type	Review Within	Initial Filing Reviews	Number on Time	Percent on Time	PDUFA Performanc e Goal
NDAs/BLAs	Within 14 days after 60-day filing date	123	113	**92%**	90%
Efficacy Supplements		142	129	**91%**	90%

FY 2007 Submissions

As of September 30, 2007, almost four-fifths (95 of 121) of NDAs/BLAs had received an initial filing review and 95 percent (90 of 95) were reviewed within the review time goal (see table below). Three-fourths (103 of 138) of efficacy supplements were reviewed with 92 percent (95 of 103) reviewed within the review time goal. With submissions still pending action and not overdue, it is too early to make a final performance determination for FY 2007.

First Cycle Filing Review Notification Type	Review Within	Initial Filing Reviews	Number on Time	Percent on Time	PDUFA Performance Goal
NDAs/BLAs	Within 14 days after 60-day filing date	95	90	**95%**	90%
Efficacy Supplements		103	95	**92%**	90%

PDUFA III Management Initiatives Performance – Reviewable Unit Letter Notification

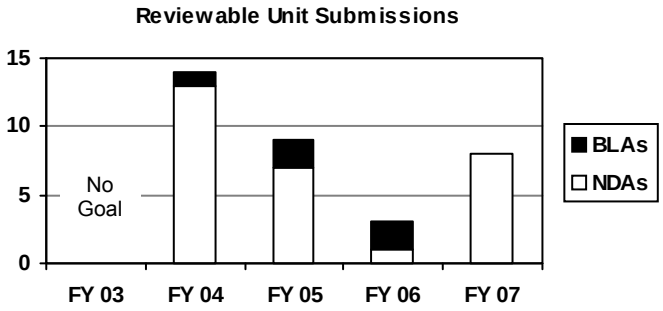
Goal: Issue Discipline Review Letters for Pre-submitted "Reviewable Units" of NDAs and BLAs

The table below summarizes the annual review time goals for reviewable unit letter notifications for NDAs and BLAs. Under the Continuous Marketing Application Pilot 1 program, 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 or 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 and BLAs within 6 months of receipt. Performance goals increased from 30 percent on time for FY 2004 submissions to 90 percent for FY 2007 submissions.

Reviewable Unit Type	Review Time Goal	Performance Goal				
		FY 03	FY 04	FY 05	FY 06	FY 07
NDA	6 months	--	30%	50%	70%	90%
BLA						

Workload

After decreasing for 2 years (FY 2005 and FY 2006), the total number of FY 2007 NDA RU submissions increased almost to the FY 2005 level. With no BLA RU submissions in FY 2007, this increase was due entirely to an increase in NDA submissions (see corresponding graph and table).



Reviewable Unit Submissions					
Type	FY 03	FY 04	FY 05	FY 06	FY 07
NDAs	--	13	7	1	8
BLAs	--	1	2	2	0
PDUFA Total	--	**14**	**9**	**3**	**8**

PDUFA III Management Initiatives Performance – Reviewable Unit Letter Notification

Performance

FY 2006 Submissions

FDA reviewed and acted on two of the three RU submissions within 6 months and both met the review time goal (see table below). However, with the final submission pending action and overdue, FDA will not meet the performance goal for FY 2006.

Reviewable Unit Type	Review Within	Reviewed and Acted On	Number on Time	Percent on Time	PDUFA Performance Goal
NDAs and BLAs	6 months	2	2	**100%**	70%

FY 2007 Submissions

As of September 30, 2007, three of the eight NDA RU submissions were reviewed and acted on; all were reviewed within the 6-month review time goal (see table below). With five RU submissions still pending action and not overdue, it is too early to make a final performance determination for FY 2007.

Reviewable Unit Type	Review Within	Reviewed and Acted On	Number on Time	Percent on Time	PDUFA Performance Goal
NDAs and BLAs	6 months	3	3	**100%**	90%

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PDUFA III Management Initiatives Accomplishments

The management initiatives FDA committed to achieve under PDUFA III were designed to improve the overall application review process.

Continuous Marketing Application (CMA) Pilots

Two pilot programs were established under PDUFA III 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.

Pilot 1 involved a commitment by FDA to review and provide an early discipline review of RUs of the sponsor's NDAs/BLAs submitted in advance of the complete application. Beginning under FDAMA, this pilot program was limited to applications that had received a Fast Track designation based on preclinical studies. Sponsors may request a Fast Track designation as early as the IND submission.

Pilot 2 involved a commitment on the part of FDA to provide more structured and extensive interaction and feedback to sponsors for up to one Fast Track application per review division during drug development. This pilot represented an extension of the usual interactions between FDA and sponsors during drug development.

FDA commissioned an independent assessment to evaluate the costs and benefits of these pilots. After review of the findings, FDA and industry representatives agreed that although the pilots demonstrated value in some areas, the overall added benefits of the programs did not justify their costs to FDA. Therefore, FDA recommended that the CMA pilot programs not be continued in PDUFA IV. The CMA Pilot 1 Evaluation and Pilot 2 Preliminary Evaluation Studies – Final Report is available on the FDA Web site at http://www.fda.gov/ope/CMA/CMAFinalReport.pdf.

> ***FY 2007 Accomplishments:*** A cumulative total of 16 products had been identified for inclusion in the Pilot 1 program and 9 products were involved in the Pilot 2 program. Eight RUs were received during FY 2007. Three of the eight RUs received were reviewed and acted on as of September 30, 2007, and all were within the review time goal.

First Cycle Review Performance

FDA committed to several new goals under PDUFA III that were focused on improving the effectiveness and efficiency of first cycle reviews. These goals were established in an attempt to decrease the number of multi-cycle reviews without compromising FDA's traditional high standards for approval.

One of the first cycle review goals was for FDA to notify the applicant of any substantive deficiencies (or lack of same) identified in an application during the initial filing review. The identification of such deficiencies was to be communicated to the applicant within 14 days of the 60-day application filing date, which is commonly referred to as a "74 day letter." The second first cycle review goal was for FDA to develop and publish a final joint CDER/CBER guidance on Good Review Management Principles (GRMPs) with provisions for both FDA reviewers and industry sponsors. FDA committed to develop and implement a training program for all CDER and CBER review staff on the GRMPs. Finally, FDA committed to commission an independent consultant evaluation of the factors associated with the conduct of first cycle reviews. The first study was a retrospective analysis of first cycle reviews for NME NDAs and original BLAs submitted in FY2002 through 2004, and is available on the FDA Web site at http://www.fda.gov/ope/pdufa/PDUFA1stCycle/pdufa1stcycle.pdf. The second study was a prospective study of first cycle reviews for NME NDAs and original BLA submissions starting in FY 2005 and continuing through FY 2007, and is currently in progress.

FDA recommended the continuation of first cycle review performance initiatives in PDUFA IV including enhancements to the GRMPs.

***FY 2007 Accomplishments*:** FDA consistently met or exceeded the goals for communication of these early deficiencies. As of September 30, 2007, 95 percent (90 of 95) of NDAs and BLAs and 92 percent (95 of 103) of efficacy supplements had received an initial filing review notification within the review time goal.

Independent Consultants

This initiative allowed applicants for certain biotechnology products to request that FDA engage an independent expert consultant to participate in FDA's review of the protocol for clinical studies that were expected to serve as the primary basis for a claim. FDA has received no requests under this initiative during PDUFA III and after discussions with industry representatives, FDA recommended that this initiative be discontinued in PDUFA IV.

***FY 2007 Accomplishments*:** No sponsors have requested assistance under the program.

Risk Management

FDA was authorized to spend user fee revenues to fund improvements in drug safety for the first time under PDUFA III. This change provided important new resources to help improve postmarket safety. As part of the PDUFA IV program, FDA recommended further enhancing the program and increasing resources from user fees.

FY 2007 Accomplishments: CDER reviewed 53 Risk Management Plans (RMPs) of which 37 were for PDUFA III products - 9 BLAs and 28 NME NDAs. CDER also

participated in 22 PDUFA III pre-NDA/BLA review meetings, 9 PDUFA III pre-approval safety conferences, 4 PDUFA III peri-approval RMP reviews, and the evaluation/validation of 7 active RMPs for non-PDUFA III products.

CBER reviewed seven Pharmacovigilance Plans and six study protocols. CBER also participated in five pre-BLA review meetings all for PDUFA III products, seven teleconferences with manufacturers, and four advisory committee meetings.

Improving FDA Performance Management

PDUFA III included a new area of goals for improved Performance Management, and provided funds for initiatives to improve the drug review process. PDUFA III performance management resources were intended to enhance the new drug review process by improving the efficiency and effectiveness of the review process, improving communications between FDA and applicants, and improving harmonization and consistency of the review process.

FDA focused on implementing a continuous improvement/quality management system for new drug review. This was accomplished using a variety of process improvements in a number of direct review and review-related areas based on the ideas and needs of review staff instead.

FY 2007 Accomplishments:

- FDA contracted to perform an independent assessment of postmarketing commitment (PMC) development and status. As a result, and as directed by PDUFA IV, CBER and CDER are developing improved and harmonized processes for developing PMCs (justifying, drafting, etc., plus reviewing PMC-related submissions) and for tracking PMC-related submissions.
- FDA awarded contracts targeted at specific PDUFA initiatives including: Strengthening Medwatch drug safety partnerships; conducting the Consumer Medication Information survey; developing a strategic plan for risk communication; supporting FDA's Bioinformatics Board; and developing a structured process to filter reports that come into the Adverse Event Reporting System so that safety evaluators will receive meaningful information in a timely manner.

During the 5 years under PDUFA III, FDA conducted numerous initiatives targeted at improving the new drug review process. FDA also contracted with outside expert consultants for analysis, training, and technical assistance to help implement a quality systems approach to the new drug review process. Additionally, FDA established a Quality Systems Group to coordinate the implementation of a quality management system for new drug review and PDUFA III performance management initiatives. The table below illustrates FDA's overall accomplishments under PDUFA III.

5-Year Summary of PDUFA III Performance Management Accomplishments

- Awarded contracts to seek improvements in the following five areas:
    1. sponsor meeting management – development of good meeting management practices to standardize procedures covering all aspects of sponsor meetings during IND and NDA reviews;
    2. managing postmarketing safety – development of a new process for managing postmarketing safety;
    3. NDA/BLA review process – development of recommendations for standardized procedures for conducting NDA/BLA reviews, including full incorporation of the processes set down in the GRMP Guidance;
    4. administrative management – development of improvements within administrative management to create more consistency and eliminate duplication of effort; and
    5. PMCs – assessment of current processes for PMC development and status (see above).
- Developed an electronic meeting minutes template to be used when recording official FDA meeting minutes with sponsors.
- Conducted a number of training courses for review consult staff including: leadership development, conflict management, presentation skills, negotiation skills, and quality management.
- Developed a quality system for the consult processes in the Office of Surveillance and Epidemiology in CDER.
- Completed 14 focus groups for physicians, pharmacists, and patients regarding drug safety to improve drug safety partnerships.
- Initiated efforts to harmonize and improve the drug review process in CBER and CDER, including improving the consistency of paper and electronic submissions in accordance with the GRMP.
- Harmonized CDER and CBER's time reporting systems in order to improve development of standard costs.

PDUFA III Electronic Applications and Submissions Accomplishments

The electronic applications and submissions commitments under PDUFA III were designed to improve the overall application review process. This includes, on an annual basis, an assessment of progress against PDUFA III IT goals and established program milestones, including appropriate changes to plans. This report satisfies the annual requirement. In addition, FDA reported IT progress to stakeholders at the PDUFA IT quarterly briefings and through Pharmaceutical Research and Manufacturers of America/Biotechnology Industry Organization PDUFA updates.

The accountability and funding for all PDUFA IT initiatives/activities were centralized under the leadership of the FDA Chief Information Officer in FY 2003. In February 2006, FDA further strengthened the IT oversight to ensure business driven, enterprise-wide direction and management through the formation of the FDA Bioinformatics Board (http://www.fda.gov/smg/vol3/2000/2010_7.html) and the PDUFA Budget Review Board.

Implementing the FDA Electronic Submissions Gateway

The FDA Electronic Submissions Gateway (ESG), in production since May 2006, provides the single point of entry for the receipt and processing of all PDUFA submissions in a highly secure environment. This change enables CBER and CDER to establish a common process in the exchange of secure e-mail and eliminated the Electronic Secure Messaging option for regulatory submissions.

***FY 2007 Accomplishments*:** In FY 2007, the ESG received and processed over 147,000 premarket and postmarket submissions. Most of these submissions were postmarketing safety reports. During the last 6 months of FY2007, the ESG was processing over 13,800 postmarket safety reports per month. In the premarket area, the ESG was averaging over 1,100 submissions per month. Information on the ESG process and requirements is available at http://www.fda.gov/esg/.

During FY 2007, both CBER and CDER fully automated the electronic submission process by implementing automated systems to expedite the processing and increase the availably of properly formatted ESG submissions. The electronic submission process encompasses the receipt, acknowledgment of receipt and any processing errors (to the sender), routing, notification (to a receiving Center or Office), and providing access to the review team of the electronic submission.

Electronic Submission of the Common Technical Document (eCTD)

Starting in calendar year 2008, the eCTD will be the only acceptable format for electronic submissions to CDER. To fully implement this decision, CDER announced (http://www.fda.gov/OHRMS/DOCKETS/98fr/E6-15966.htm) the withdrawal of the following CDER Electronic Submissions Guidance:

- 1999 – Providing Regulatory Submissions in Electronic Format – NDAs
- 2002 – Providing Regulatory Submissions in Electronic Format – ANDAs (Abbreviated New Drug Applications)
- 2003 – Providing Regulatory Submissions in Electronic Format – Annual Reports for NDAs and ANDAs

As part of this transition, CDER posted limited exceptions to the eCTD policy (http://www.fda.gov/ohrms/dockets/dockets/92s0251/92s-0251-m000034-vol1.pdf).

***FY 2007 Accomplishments*:** In FY 2007, the FDA eCTD review system was enhanced to provide integration with the CBER and CDER tracking systems. FDA also developed validation criteria that will be used to process eCTDs submitted to FDA. At the end of FY 2007, FDA was finalizing the validation criteria and will post the criteria on the Internet in early FY 2008.

In FY 2007, there was a dramatic increase in the number of eCTD submissions with over 8,000 eCTD submissions received. Since FY 2003, CBER and CDER have received over 14,000 eCTD submissions. The eCTD guidance and specifications are available at http://www.fda.gov/cder/regulatory/ersr/ectd.htm.

Consolidating IT Infrastructure

The construction of the White Oak Data Center will replace existing computer facilities that maintain database, application, web, storage and network servers, minicomputers, and telecommunication equipment. The data center consolidation will facilitate server consolidation efforts, which will allow FDA to realize savings on hardware and software licensing, hardware and software maintenance, systems support and training, and on hardware through purchase consolidation. The data center is scheduled to be completed in the latter part of 2008.

***FY 2007 Accomplishments*:** In FY 2007, FDA successfully completed implementation of the Department of Health and Human Services (HHS) Enterprise E-mail System (EES). The EES consolidated the various e-mail systems throughout HHS into a single enterprise e-mail and calendaring system.

Strengthening and Improving IT Project Management Capabilities

FDA continued to strengthen and improve IT project management capabilities to ensure that all IT projects follow standardized industry best practices. FDA conducts stage gate reviews, performs post-implementation lessons-learned sessions for each major IT investment, requires earned value management reporting on all IT investments, and continues to provide project management certification training.[2]

In addition, FDA has played a major role in the HHS Enterprise Performance Life Cycle (EPLC) initiative. The HHS EPLC is a mechanism to assure that IT systems meet established requirements and support the HHS Enterprise and its Operating Divisions' missions and functions. The EPLC will align Enterprise Architecture, Information Security, and Capital Planning and Investment Control. It will also delineate activities, artifacts, and milestones within each phase. The FDA IT Project Management Office is working closely with HHS to ensure the success and acceptance of this standardized department-wide life cycle.

***FY 2007 Accomplishments*:** FDA implemented standard, repeatable Risk Management, Requirements Management, Configuration Management, Quality Assurance, and Communication plans across all projects. All projects are managed via one integrated schedule, with management reports generated against that schedule week. Risk management and earned value management are automated via the internally developed Project Information Management System and Earned Value Accounting System. The readiness review board (RRB) and all stage gate criteria have been developed. The RRB reviews each project at each life cycle phase.

Using Common Systems To Meet Business Requirements

FDA initiated two major efforts to develop common systems to meet business requirements across the PDUFA Program and FDA and use the same software applications where common business needs exist.

***FY 2007 Accomplishments*:** In FY 2007, CDER and CBER collaborated on an information management system development effort to integrate electronic workflow and tracking information to process and manage regulatory submissions. The initial release handled CDER therapeutic IND submissions. In early FY 2008, the system will be expanded to include all CDER INDs. Future releases will incorporate CDER and CBER marketing applications and CBER INDs.

[2] Stage gates separate the projects in the EPLC initiative into stages. Each stage contains criteria that a project must meet before it is moved to the next stage or life cycle phase.

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APPENDIX A: PDUFA III Performance Goals FY 2003 – FY 2007

The table below summarizes, by fiscal year, the performance measures set forth in the letters referenced in the FDAMA 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				
		2003	**2004**	**2005**	**2006**	**2007**
Review and act on priority original NDAs and BLAs within 6 months of receipt.*		90% on time				
Review and act on standard original NDAs and BLAs within 10 months of receipt.*						
Review and act on priority efficacy supplements within 6 months of receipt.*						
Review and act on standard efficacy supplements within 10 months of receipt.*						
Review and act on all manufacturing supplements within 6 months of receipt and those requiring prior approval within 4 months of receipt.†						
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.*						
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.*		90%				

* Receipt of a major amendment in the last 3 months extends the goal date by 3 months. Under PDUFA II 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

† Receipt of a major amendment in the last 2 months extends the goal date by 2 months (PDUFA III submissions only). This extension applies only to manufacturing supplements.

II. NME Performance Goals

The performance goals for priority and standard 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 BLAs will be considered to be NMEs.

III. Procedural and Processing Goals

Performance Area	FDA Activity	Performance Goal	Performance Level FY 2003 – 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 -- FDA prepared minutes, clearly outlining agreements, disagreements, issues for further discussion and action times will be available to sponsor.	Within 30 days of meeting.	
Clinical Holds	Response to sponsor's complete response to a clinical hold.	Within 30 days of receipt of sponsor's response.	
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.	
Major Dispute Resolution	Response to sponsor's appeal of decision.	Within 30 days of receipt of sponsor's appeal.	

IV. PDUFA III Management Initiatives

Performance Area	Initiative	Commitment	Performance Level and/or Implementation Timeline by Fiscal Year -- Not applicable X Action due				
			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 FDA'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 will provide a written rationale within 14 days of receipt.	100%				
First Cycle Review Performance Proposal	For original NDAs/BLAs 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 days after the 60-day filing date.	50%	70%	90%		
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	---	---	---	---

Performance Area	Initiative	Commitment	Performance Level and/or Implementation Timeline by Fiscal Year -- Not applicable X Action due				
			2003	2004	2005	2006	2007
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 pharma-covigilance practices.	---	X	---	---	---

V. Electronic Applications and Submissions

Initiatives	Implementation Deadline by Fiscal Year -- Not applicable X Action due				
	2003	**2004**	**2005**	**2006**	**2007**
The agency will centralize the accountability and funding for all PDUFA IT initiatives/activities for CBER, CDER, Office of Regulatory Affairs (ORA) and Office of the Commissioner (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 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				
	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 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 e-CTD software, and Commercial Off The Shelf solutions.	---	---	---	---	X
Within 6 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" means 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/BLA meeting. Each requestor should usually only request 1 each of these Type B meetings for each potential application (NDA and 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.

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APPENDIX B: List of Approved Applications

This appendix updates the detailed review histories of the NDAs and BLAs submitted and approved under PDUFA in FY 2007. 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 2007 can be found in the appendices of the earlier PDUFA Performance Reports that are available at http://www.fda.gov/oc/pdufa/.

Terms and Coding Used in Tables

Action Codes:	AE	=	Approvable
	AP	=	Approved
	NA	=	Not Approvable
	CR	=	Complete Response
	TA	=	Tentative Approval
	WD	=	Withdrawn

* Tentative Approval (TA) is an action given to a product that meets all the requirements for approval; however, it may not be legally marketed in the United States until the market exclusivity and/or patent term of the listed reference drug product has expired.

◊ Expedited review and TA of a NDA by FDA for fixed dose combinations and co-packaged antiretroviral medications as part of the President's Emergency Plan for AIDS Relief.

+ Major amendment was received within 3 months of the action due date, which extended the action goal date by 3 months.

Table 1
FY 2007 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)	
2007	EFAVIRENZ 600MG/LAMIVUDINE 150MG/STAVUDI	Strides Arcolab	5.7		Y ◊
	EFAVIRENZ 600MG/LAMIVUDINE 150MG/ZIDOVUD	Strides Arcolab	5.7		Y ◊
	AMBRISENTAN	Gilead	5.9		Y
	PROTEIN C CONCENTRATE (HUMAN)	Baxter Healthcare Corporation	5.9		Y
	INFLUENZA VIRUS VACCINE	CSL Ltd CAN	5.9		Y
	HEPATITIS B IMMUNE GLOBULIN INTRAVENOUS (HUMAN)	Cangene Corporation	6.0		Y
	INFLUENZA VIRUS VACCINE, H5N1	Sanofi Pasteur Inc.	6.0		Y
	FOXAMPRENAVIR CALCIUM	Glaxo	6.0		Y
	ZOLEDRONIC ACID INJECTION 5MG	Novartis Pharms	6.0		Y
	MARAVIROC UK-427, 857	Pfizer Labs	7.7	FDA First Action (AE): 6.0 Sponsor Response: 0.9 FDA Second Action (AP): 0.8	Y Y
	TEMSIROLIMUS	Wyeth Pharms inc	7.8		Y +
	LAMIVUDINE 60MG/NEVIRAPINE 100MG/STAVUDI	Cipla Ltd	8.0		Y +◊
2006	HYDROXOCOBALAMIN	Merck Sante Sas	5.9		Y
	LAMUVUDINE 150MG/NEVIRAPINE 200MG/ZIDOVI	Cipla Ltd	6.0		Y ◊
	VORINOSTAT	Merck	6.0		Y
	LAMIVUDINE 150MG/STAVUDINE 30MG TABLETS	Cipla Ltd	6.0		Y ◊
	LAMIVUDINE 150MG/NEVIRAPINE 200MG/STAVUD	Cipla Ltd	6.0		Y ◊
	LAPATINIB TABLETS	Smithkline Beecham	6.0		Y
	INFLUENZA VIRUS VACCINE	ID Biomedical Corporation of Quebec	6.4		Y +
	LAMIVUDINE 150MG/STAVUDINE 40MG	Strides Arcolab Ltd	11.2	FDA First Action (AE): 5.9 Sponsor Response: 4.7 FDA Second Action (TA): 0.6	Y Y ◊

Table 1 (continued)

Receipt Cohort (FY)	Established/Proper Name	Applicant	Approval Time (Months)		Review Goal Met
			Total Time	Resubmissions (if necessary)	
2006	LAMIVUDINE 150MG/NEVIRAPINE 200MG/STAVUD	Strides Arcolab Ltd	11.5	FDA First Action (AE): 6.0 Sponsor Response: 4.9 FDA Second Action (TA): 0.6	Y Y ◊
	LAMIVUDINE/ZIDOVUDINE/ NE-VIRAPINE	Strides	11.9	FDA First Action (AE): 6.0 Sponsor Response: 5.6 FDA Second Action (TA): 0.3	Y Y ◊
	SMALLPOX (VACCINIA) VACCINE, LIVE	Acambis, Inc.	12.5	FDA First Action (CR): 4.8 Sponsor Response: 1.7 FDA Second Action (AP): 6.0	Y Y
	DEXRAZOXANE	Topotarget	19.3	FDA First Action (AE): 6.0 Sponsor Time: 3.8 FDA Second Action (AE): 6.0 Sponsor Time: 0.9 FDA Third Action (AP): 2.6	Y Y Y
2004	ZOLEDRONIC ACID INJECTION 5MG	Novartis Pharms	31.0	FDA First Action (AE): 5.9 Sponsor Time: 5.3 FDA Second Action (AE): 6.0 Sponsor Time: 7.8 FDA Third Action (AP): 6.0	Y Y Y

Table 2
FY 2007 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)	
2007	STERILE LHM PRODUCT	Anesiva	8.7		Y
	THROMBIN, TOPICAL (HUMAN)	OMRIX biopharmaceut-icals, Ltd.	9.6		Y
	TROSPIUM CHLORIDE	Indevus	9.7		Y
	FLUDARABINE PHOSPHATE INJECTION	Ebewe Pharma	9.9		Y
	AMMONIA N 13 INJECTION	Feinstein	9.9		Y
	AMLODIPINE BESYLATE/OLMESARTAN MEDOXOMIL	Daiichi Sankyo	10.0		Y
	LANREOTIDE INJECTION	Beaufour Ipsen	10.0		Y
	FENOFIBRATE	Lifecycle Pharma AS	10.0		Y
2006	ARFORMOTEROL TARTRATE INHALATION SOLUTIO	Sepracor	9.8		Y
	TELBIVUDINE	Idenix	9.8		Y
	ALBUMIN (HUMAN)	Octapharma Pharma-zeutika Produk-tionsges.m.b.H.	9.9		Y
	IMMUNE GLOBULIN INTRAVENOUS (HUMAN), 10% LIQUID	CSL Behring AG	9.9		Y
	FEXOFENADINE HCL	Sanofi Aventis US	9.9		Y
	RIVASTIGMINE	Novartis Pharms	9.9		Y
	TRENTINOIN GEL 0.05%	Coria	9.9		Y
	ESTRADIOL	KV Pharm	9.9		Y
	CICLESONIDE	Altana Pharma	9.9		Y
	FLUTICASONE FUROATE	Glaxosmithkline	9.9		Y
	ESOMEPRAZOLE MAGNESIUM 20/40MG	Astrazeneca	9.9		Y
	HYDROCORTISONE BUTYRATE 0.1% W/W	Triax Pharms	9.9		Y
	FORMOTEROL FUMARATE INHALATION SOLUTION	Dey LP	9.9		Y *
	AMLODIPINE BESYLATE/VALSARTAN TABS	Novartis Pharms	9.9		Y *
	CLOBETASOL PROPIONA	Connetics	9.9		Y
	LORATADINE 5 MG	Schering Plough	9.9		Y

Table 2 (continued)

Receipt Cohort (FY)	Established/Proper Name	Applicant	Approval Time (Months)		Review Goal Met
			Total Time	Resubmissions (if necessary)	
2006	ESTRADIOL GEL 0.87 G AND 1.7 G	Bradley Pharms	9.9		Y
	POLYETHYLENE GLYCOL 3350 POWDER LAXATIVE	Schering Plough	9.9		Y
	DESONIDE GEL 0.05%	Skinmedica	10.0		Y
	AZITHROMYCIN	Inspire	10.0		Y
	ZILEUTON CONTROLLED RE-LEASE TABLETS	Critical	10.0		Y
	SITAGLIPTIN PHOS-PHATE/METFORMIN HCL TABS	Merck	10.0		Y
	CYANOCOBALAMIN, USP	Fleming	10.0		Y
	KETOTIFEN FUMARATE OPH-THALMIC SOL 0.025%	Bausch and Lomb	10.0		Y
	CARVEDILOL	SB Pharmco	10.0		Y
	RETAPAMULIN	Glaxo Grp Ltd	10.0		Y
	SITAGLIPTIN PHOSPHATE	Merck Co Inc	10.0		Y
	QUETIAPINE FUMARATE	Astrazeneca Pharms	10.0		Y
	FEXOFENADINE HCL	Sanofi Aventis US	10.0		Y
	PROGESTERONE VAGINAL IN-SERT	Ferring Pharms	10.0		Y
	LEVOCETIRIZINE DIHYDROCH-LORIDE	UCB Inc	10.0		Y
	HISTRELIN ACETATE SUBCU-TANEOUS IMPLANT	Indevus	10.0		Y
	LEVOTHYROXINE SODIUM CAPSULES	Inst Biochimique	10.3		N
	GADODIAMIDE	GE Healthcare	10.5	FDA First Action (AE): 9.8 Sponsor Response: 2.2 FDA Second Action (AP): 2.1	Y Y
	ALISKIREN	Novartis Pharms	12.7		Y +
	TERBINAFINE HCL	Novartis Pharms	12.7		N
	PALIPERIDONE	Janssen LP	12.7	FDA First Action (AE): 10.0 Sponsor Time: 0.7 FDA Second Action (AP): 2.0	Y Y
	MESALAMINE	Shire	12.9		Y +
	RAMIPRIL	King Pharms	12.9		Y +
	ESTRADIOL GEL 0.1%	Upsher Smith	13.0		Y +

Table 2 (continued)

Receipt Cohort (FY)	Established/Proper Name	Applicant	Approval Time (Months)		Review Goal Met
			Total Time	Resubmissions (if necessary)	
2006	LISDEXAMFETAMINE DIMESYLATE	Shire	14.8	FDA First Action (AE): 10.0 Sponsor Time: 0.7 FDA Second Action (AE): 1.9 Sponsor Time: 0.2 FDA Third Action (AP): 2.0	Y Y Y
	AMLODIPINE BESYLATE/VALSARTAN TABS	Novartis Pharms	16.1	FDA First Action (AE): 10.0 Sponsor Response: 2.6 FDA Second Action (AP): 3.5	Y Y
	OMEPRAZOLE DELAYED RELEASE TABLETS 20MG	Dexcel Pharma	16.2	FDA First Action (AE): 9.9 Sponsor Response: 0.4 FDA Second Action (TA): 5.9	Y Y *
	AZITHROMYCIN LYPHOLIZED INJ 500MG/VIAL	Teva Parenteral	16.6	FDA First Action (AE): 10.0 Sponsor Response: 0.6 FDA Second Action (AP): 6.0	Y Y
	SOMATRAPIN	LG Life	16.8	FDA First Action (AE): 11.3 Sponsor Response: 3.5 FDA Second Action (AP): 2.0	N Y
	AMLODIPINE ORALLY DISINTEGRATING TABLETS	Synthon Pharms	19.9	FDA First Action (AE): 10.0 Sponsor Response: 3.9 FDA Second Action (AP): 6.0	Y Y
	LEVOTHYROXINE SODIUM CAPSULES, 13 MCG	Inst Biochimique	20.0	FDA First Action (NA): 10.3 Sponsor Time: 0.2 FDA Second Action (NA): 2.7 Sponsor Time: 1.4 FDA Third Action (AE): 2.0 Sponsor Time: 1.4 FDA Fourth Action (AP): 2.0	N Y Y Y
2005	ECAMSULE/AVOBENZONE/OCTOCRYLENE/TITANIUM	Loreal USA Prods	12.3	FDA First Action (AE): 9.9 Sponsor Response: 0.5 FDA Second Action (AP): 1.9	Y Y
	ROTIGOTINE PATCH	Schwarz Biosciences	12.3	FDA First Action (AE): 13.0 Sponsor Response: 8.4 FDA Second Action (AP): 6.0	Y + Y
	PRISMASOL	Gambro Renal Prods	12.9		Y +
	KUNECATECHINS	Medigene	13.0		Y +
	ECAMSULE 3%/AVOBENZONE/ OCTOCRYLENE	Loreal USA Prods	16.7	FDA First Action (AE): 9.8 Sponsor Time: 2.5 FDA Second Action (AE): 2.0 Sponsor Time: 0.4 FDA Third Action (AP): 2.0	Y Y Y
	ORLISTAT 60MG CAPSULE	Glaxosmithkline Cons	19.1	FDA First Action (AE): 9.0 Sponsor Response: 4.1 FDA Second Action (AP): 6	Y Y
	ETHINYL ESTRADIOL/LEVONORGESTREL CONTINU	Wyeth Pharms Inc	23.9	FDA First Action (AE): 13.0 Sponsor Response: 1.9 FDA Second Action (AP): 9.0	Y + Y

Table 2 (continued)

Receipt Cohort (FY)	Established/Proper Name	Applicant	Approval Time (Months)		Review Goal Met
			Total Time	Resubmissions (if necessary)	
2005	ARMODAFINIL TABLETS	Cephalon	26.8	FDA First Action (AE): 13.0 Sponsor Time: 2.1 FDA Second Action (AE): 9.0 Sponsor Time: 0.7 FDA Third Action (AP): 2.0	Y + Y Y
2004	NITROGLYCERIN LINGUAL SPRAY 0.4MG/ML	Novadel	27.0	FDA First Action (AE): 9.9 Sponsor Time: 11.1 FDA Second Action (AP): 6.0	Y Y
	CLINDAMYCIN/TRETINOIN	Medicis Pharm	33.0	FDA First Action (NA): 10.0 Sponsor Time: 17.0 FDA Second Action (AP): 6.0	Y Y
	CYCLOBENZAPRINE HCL	Anesta	33.2	FDA First Action (AE): 10.0 Sponsor Time: 17.3 FDA Second Action (AP): 5.9	Y Y
	ADAPALENE GEL 0.3% GEL	Galderma Labs	38.6	FDA First Action (AE): 10.0 Sponsor Time: 22.6 FDA Second Action (AP): 6.0	Y Y
	KETOCONAZOLE 2% FOAM	Stiefel Labs Inc	40.7	FDA First Action (AE): 10.0 Sponsor Time: 24.7 FDA Second Action (AP): 6.0	Y Y
2003	FORMOTEROL FUMARATE INHAL POWDER 10MCG	Novartis Pharms	48.1	FDA First Action (AE): 10.0 Sponsor Time: 8.3 FDA Second Action (AE): 5.7 Sponsor Time: 9.9 FDA Third Action (AE): 6.0 Sponsor Time: 2.2 FDA Fourth Action (AP): 6.0	Y Y Y Y
2001	DICLOFENAC EPOLAMINE SALT 1.3% ADHESIVE	Inst Biochem	73.5	FDA First Action (NA): 10.0 Sponsor Time: 57.5 FDA Second Action (AP): 6.0	Y Y

Department of Health and Human Services
Food and Drug Administration

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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