FY 2010

PERFORMANCE REPORT TO THE PRESIDENT AND CONGRESS

for the

Prescription Drug User Fee Act

Food and Drug Administration
Department of Health and Human Services

Commissioner's Report

I am pleased to present the Food and Drug Administration's (FDA) fiscal year (FY) 2010 Prescription Drug User Fee Act (PDUFA) Performance Report to the President and Congress. This report marks the 18th year of PDUFA and the third year of PDUFA IV (FY 2008 through FY 2012).

Since the passage of PDUFA, user fees have played an important role in providing FDA with the resources necessary to more efficiently review new medicines, reduce review times for innovative drugs and biologics, and therefore provide patients and doctors with earlier access to breakthrough treatments. Since the beginning of PDUFA IV, FDA has been faced with an unpredictable workload that was further complicated by unanticipated challenges and increased commitments with the implementation of the Food and Drug Administration Amendment Act (FDAAA). Faced with increased workload and new commitments in FY 2008, FDA necessarily preserved the integrity of the review process and maintained a focus on the safety of prescription drugs, which resulted in temporary delays of some reviews and lower than expected performance in FY 2008 and FY 2009. In FY 2010, the number of original new drug applications (NDAs) and biologics license applications (BLAs) fell by over one-fourth when compared to FY 2009 levels, substantially easing FDA reviewer workloads, and allowing performance to begin returning to higher levels.

This report provides final performance for the second year of PDUFA IV (FY 2009) and preliminary performance for the third year (FY 2010). FDA either met or exceeded over half (7 of 12) of review performance goals in the second year of PDUFA IV (FY 2009), an improvement from FY 2008 when FDA met only one-third (4 of 12) of the review performance goals. In addition to the improvement in meeting performance goals, the estimated median approval times for priority and standard NDAs and BLAs, which both increased in FY 2008, improved and are lower for both types of applications. Additionally, preliminary results of reviews completed during FY 2010 indicate that FDA has the potential to meet or exceed almost all (11 of 12) FY 2010 review performance goals.

These results are encouraging, but FDA still has challenges to address. We are committed to meeting or exceeding all review performance goals, and FDA's performance with FY 2010 procedural goals remained less than satisfactory. Therefore, FDA will strengthen efforts to improve performance in all areas. This will be done while maintaining a focus on ensuring that the safest, highest quality prescription drugs are approved in the shortest possible time.

Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs

Executive Summary

PDUFA was enacted in 1992 and renewed in 1997 (PDUFA II), 2002 (PDUFA III), and 2007 (PDUFA IV). It authorizes FDA to collect fees from companies that produce certain human drug and biological products. As reported in FY 2008 and FY 2009, FDA faced unprecedented challenges as it assessed and enacted new requirements and review commitments. As FDA enters the third year under PDUFA IV, improvements can be seen in the number of goals met and median approval times. In the first year of PDUFA IV (FY 2008) FDA met (or exceeded) 4 of 12 review performance goals. In this report, FDA can report that in the second year of PDUFA IV (FY 2009), FDA met (or exceeded) 7 of 12 review performance goals, and FDA is currently meeting (or exceeding) 9 of 12 review performance goals in FY 2010.

Outlined in this report is FDA's performance in meeting annual review goals for FY 2009 and FY 2010. Review performance for submissions received in FY 2009, and initially reported in the FY 2009 PDUFA Performance Report, is updated and finalized with respect to achieving FY 2009 review performance goals. FDA's preliminary work in meeting review goals for submissions received in FY 2010, as well as procedural and processing goals, and PDUFA management commitments for FY 2010, also are covered in this report.

With 2,982 review actions completed for the FY 2009 cohort, FDA met or exceeded the 90 percent performance level for over half (7 of 12) of review performance goals. The following FY 2009 review performance goals were met or exceeded (percent of submissions that met review times in parenthesis):

- Standard NDAs and BLAs (92 percent[1])
- Standard new molecular entities (NMEs) and BLAs (97 percent)
- Class 2 resubmitted NDAs and BLAs (93 percent)
- Standard efficacy supplements (91 percent)
- Class 1 resubmitted efficacy supplements (100 percent)
- NDA and BLA manufacturing supplements requiring prior approval (91 percent)
- NDA and BLA manufacturing supplements not requiring prior approval (97 percent)

The FY 2009 review performance goals that FDA did not meet are:

- Priority NDAs and BLAs (80 percent)
- Priority NMEs and BLAs (76 percent)
- Class 1 resubmitted NDAs and BLAs (81 percent)

[1] Represents FDA performance level excluding three reviews pending within goal as of September 30, 2010. FDA met the review performance goal, regardless of the final performance results of these pending reviews. FDA's final on-time review performance will range from 90 percent, if none of the applications are acted on within goal, to 93 percent if all applications are acted on within goal.

- Priority efficacy supplements (83 percent)
- Class 2 resubmitted efficacy supplements (85 percent)

Preliminary review performance data also is presented in this report for FY 2010 submissions that were acted on or were pending overdue as of September 30, 2010. This includes over half (1,642 of 2,799) of FY 2010 submissions. Preliminary data show that FDA was meeting or exceeding the goal performance level for three-fourths (9 of 12) of the FY 2010 review-time goals. With 1,157 submissions currently under review and within goal (on time), FDA has the potential to meet or exceed 11 of 12 review performance goals for FY 2010. The only FY 2010 review performance goal that FDA will not meet is for Class 2 resubmitted efficacy supplements where the highest performance level FDA can achieve is 87 percent.

Performance results related to procedural and processing goals and commitments (i.e., meeting management, procedural responses, and procedural notifications) are presented in this report as of September 30, 2010.

FDA accomplishments with respect to meeting PDUFA IV management initiatives and information technology commitments are also presented in the body of the report. Review cycle data on all original NDAs and BLAs approved during FY 2010 and final performance on procedural and processing goals and commitments not completed in FY 2009 are presented in the appendices.

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Overview of PDUFA

On September 27, 2007, the President signed Food and Drug Administration Amendment Act (FDAAA) into law, which included the reauthorization and expansion of the Prescription Drug User Fee Act (PDUFA) for 5 additional years (FY 2008 through FY 2012 and now referred to as PDUFA IV). PDUFA provides FDA revenue to hire additional reviewers and support staff and upgrade its information technology systems to maximize the efficiency of the application review process for new drugs and biological products without compromising FDA's high standards for approval.

PDUFA I to PDUFA IV: An Evolution in Review Progress

Since the implementation of PDUFA I, FDA has utilized PDUFA resources to significantly reduce the time it takes to evaluate new drugs without compromising FDA's rigorous standards for safety and efficacy. PDUFA resources have allowed the American people to gain quicker access to valuable therapies and have increased the economic incentive for sponsors to develop innovative drug and biological products. Without the funds derived from PDUFA fees, the substantial progress FDA has achieved in improving and expediting the review of human drug applications would not have been possible.

- **Reducing Application Review Time (FY 1993 through FY 1997).** During the first few years of 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 goals that incrementally increased to 90 percent levels.

- **Facilitating the Drug Development Process (FY 1998 through FY 2002).** Under PDUFA II, a number of review performance level commitments were shortened. Additionally, new procedural goals expanded the scope of work to improve communication between FDA and sponsors during the drug development process. These goals specified time frames for scheduling meetings and responding to various sponsor submissions, such as special protocol assessments (SPAs) 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.

Enhancing Drug Safety (FY 2008 through FY 2012). PDUFA IV increases user fees to enhance drug safety and establishes goals that focus on securing FDA's sound financial footing, enhancing premarket review, and creating a modern postmarket safety system. Specific changes include:

- **FDA Sound Financial Footing**. Under PDUFA IV, FDA will be able to adjust user fees based on inflation and workload to ensure FDA can continue succeeding in moving qualified drugs to market more quickly.

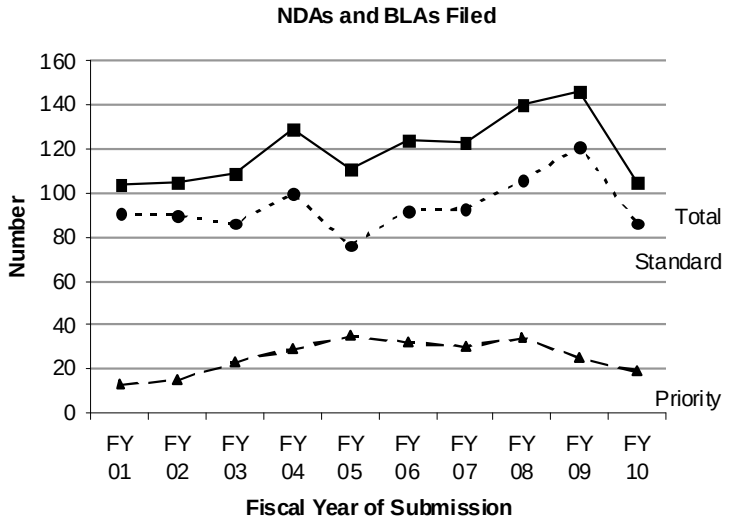
- **Enhance Process for Premarket Review**. PDUFA IV expands the implementation of the Good Review Management Practices (GRMPs) and creates additional initiatives designed to help expedite drug development.

- **Modernize and Transform the Postmarket Drug Safety System**. PDUFA IV strengthens FDA's drug safety system, particularly FDA's efforts to address the full life cycle of drug products.

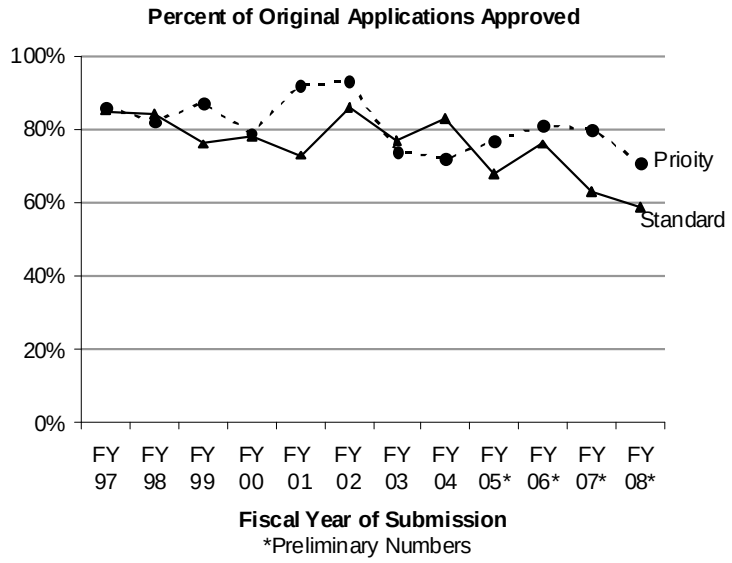
Trends in NDA and BLA Submissions and Approval Times

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 following: total number of NDA and BLA submissions, timing of submissions that can result in workload increases while resources are constant, quality of submitted applications, number of priority applications versus standard applications submitted, and number of review staff relative to the workload for applications and supplements. These factors can vary from year to year and affect FDA's ability to meet fixed performance goals and commitments. In FY 2010 the number of submissions, and accompanying reviewer workload, was down in most review categories. The following charts provide recent trends in submissions and overall approval times.

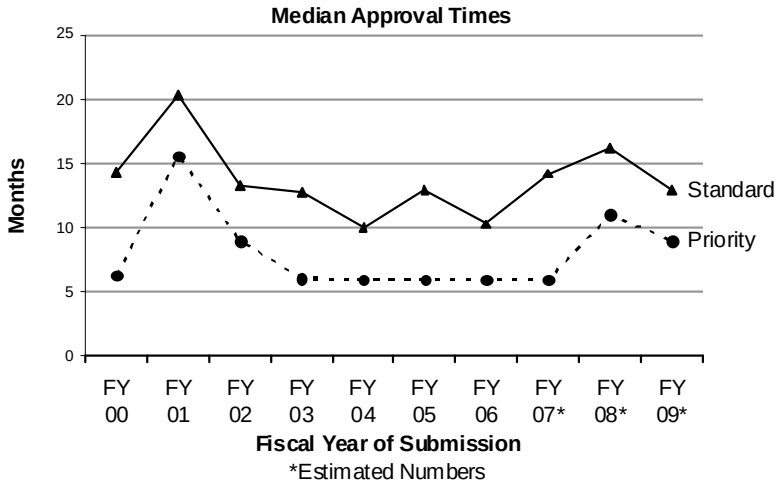
Total number of NDAs and BLAs decreased to the second lowest level in 10 years. Decreases were seen in both priority and standard applications in FY 2010. The number of priority applications, which represent significant therapeutic gains, fell for the second straight year. After four straight years (FY 2005 through FY 2008) when the number of priority applications was never less than 30 and averaged 33, the number of priority applications decreased to 25 in FY 2009 and 19 in FY 2010. The number of standard applications increased each year from FY 2005 through FY 2009, averaging 103 submissions during the past 4 years (FY 2006 through FY 2009). However, in FY 2010 the number of standard applications fell to 86.



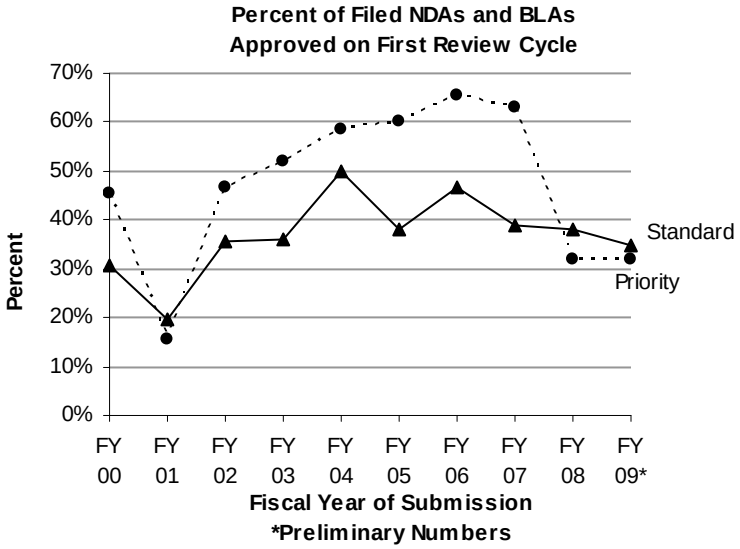
Priority applications generally are approved at a higher rate than standard applications. Historical data from FY 1997 to FY 2006 show that the percent of any fiscal year cohort that receives approval varies in any given year, but has averaged 82 percent of priority applications and 79 percent of standard applications during this time period (see graph). Historical trends have shown that almost all priority applications that eventually receive approval are approved within 3 years of submission, and almost all standard applications are approved within 5 years of submission. Based on these trends, FDA can estimate that 80 percent of applications submitted in any given year will eventually be approved and reliably use this predictor to report on key statistics such as median approval times (FY 2009 and FY 2010 data have too few approvals to meaningfully report median approval time.)



Median time to approval for priority and standard applications improved in FY 2009 when compared to FY 2008. Based on applications approved through September 30, 2010, and historical data indicating that approximately 80 percent of all filed applications will eventually be approved (see previous graph), the estimated median approval time for priority applications improved from 11.0 months in FY 2008 to 9.0 months in FY 2009 (see graph). Estimated median approval times for standard applications, which had increased two straight years (FY 2007 and FY 2008) to 16.2 months in FY 2008, also improved in FY 2009 to the lowest level (13.0 months) since FY 2006. (FY 2010 data are too few to meaningfully report.)



Percentage of first cycle approvals for standard NDAs and BLAs decreased for the third straight year. The percentage of first cycle approvals for standard NDAs and BLAs decreased for the third straight year, from 47 percent in FY 2006 to 35 percent in FY 2009. The percentage of first cycle approvals for priority NDAs and BLAs leveled off in FY 2009, but remained at historically low levels. First cycle approvals are still possible for FY 2009 standard submissions; therefore, preliminary estimates are presented for this year. Fewer first cycle approvals can result in increased resubmissions in later fiscal years and increased median times to approval (see previous median approval times graph). (FY 2010 data are too few to meaningfully report the percentage of first cycle approvals.)



PDUFA Workloads: FY 2005 through FY 2010

Direct workload related to PDUFA goals includes: 1) review of applications and submissions and preparation of documents and actions related to FDA decisions, and 2) meeting management and review goals related to procedural responses and notifications. FDA cannot predict or control the queue of applications, submissions, and requests that are submitted each fiscal year. This fact was reinforced in FY 2010 as the trend of fluctuating submissions and resulting workloads continued to vary from year-to-year.

Review workloads for applications and submissions in FY 2010 decreased below the 5-year averages in all categories. The year-to-year fluctuating workload under PDUFA IV continued in FY 2010, with all review workloads decreasing below the 5-year averages. The workload for original NDAs and BLAs and resubmitted NDAs and BLAs were both down 19 percent compared to the previous 5-year averages. The workload for NDA and BLA efficacy and resubmitted efficacy supplements also were down by over 20 percent compared to the previous 5-year averages. The number of NDA and BLA manufacturing supplements had the smallest decline in FY 2010 when compared to the previous 5-year averages.

Review Workloads for Applications and Submissions

Submission/Request	Fiscal Year						FY 2005 to FY 2009 (5-Year Average)	FY 2010 Compared to 5-Year Average
	2005	2006	2007	2008	2009*	2010		
Original NDAs and BLAs	111	124	123	140	146	**105**	129	↓**19%**
Resubmitted NDAs and BLAs	59	61	73	57	70	**52**	64	↓**19%**
NDA and BLA Efficacy Supplements	158	190	191	151	159	**130**	170	↓**24%**
Resubmitted Efficacy Supplements	48	37	46	44	35	**33**	42	↓**21%**
NDA and BLA Manufacturing Supplements	2,532	2,647	2,663	2,548	2,576	**2,479**	2,593	↓**4%**

* FY 2009 numbers were changed to reflect updates to data presented in the FY 2009 PDUFA Performance Report.

Workload related to procedural and processing goals varies from year-to-year, across categories, and is difficult to predict. The procedural and processing workload, which includes actions related to meeting management, procedural responses, and procedural notifications, increases and decreases from year-to-year, with no clear patterns. This variance in the procedural workload impacts review workload planning and performance.

The table below summarizes procedural and processing workload categories where FDA has PDUFA performance goals/commitments and presents the five-year average where data are available. The data show that workload for:

- Meeting management submissions increased in all three categories from FY 2009 to FY 2010, but was below five-year averages in two (requests and scheduled) of the three categories.

- Procedural responses decreased in all three categories from FY 2009 to FY 2010, and was below five-year averages in two (major dispute resolutions and special protocol assessments) of three categories.

- Procedural notifications increased in two (workload for drug/biological product proprietary name reviews and planned review timelines) of three categories from FY 2009 to FY 2010. The increase for notification of planned review timelines was due to new PDUFA IV requirements to include efficacy supplements for new/expanded indications. Five-year averages were not available for drug/biological product proprietary review and notification of planned review timelines categories as these are new commitments under PDUFA IV.

Workloads Related To Meeting Management, Procedural Responses, and Procedural Notifications

Workload Areas	Submission/ Request	Fiscal Year						FY 2005 to FY 2009 (5-Year Average)	FY 2010 Compared to 5-Year Average
		2005	2006	2007	2008	2009*	2010		
Meeting Management	Meeting Requests	2,487	2,565	2,502	2,344	2,192	**2,268**	**2,418**	**↓ 6%**
	Meetings Scheduled	2,230	2,273	2,151	1,903	1,881	**2,044**	**2,088**	**↓ 2%**
	Meeting Minutes	1,901	1,853	1,736	1,515	1,518	**1,705**	**1,705**	**no difference**
Procedural Responses	Responses To Clinical Holds	130	145	175	213	221	**203**	**177**	**↑ 15%**
	Major Dispute Resolutions	9	9	22	14	15	**7**	**14**	**↓ 50%**
	Special Protocol Assessments	396	406	459	354	336	**334**	**390**	**↓ 14%**
Procedural Notifications	Drug/Biological Product Proprietary Name Review†	--	--	--	--	248	**305**	**--**	**--**
	First Cycle Filing Review Notifications‡	235	265	267	259	261	**206**	**257**	**↓ 20%**
	Notification of Planned Review Timelines†	--	--	--	--	50	**81**	**--**	**--**

* FY 2009 numbers were changed to reflect updates to data presented in the FY 2009 PDUFA Performance Report.
† This information was not tracked prior to FY 2009. The 5-year average cannot be determined until FY 2013.
‡ FY 2005 through FY 2008 numbers were updated to include the first cycle filing review notifications for efficacy supplements.

Review Performance Presented in This Report

In any given year, FDA performance includes reviews of submissions pending from previous fiscal years along with submissions received during the current fiscal year. This report presents FDA on-time review performance for actions completed in FY 2010 regardless of when they were submitted. This report also presents FDA performance as compared to PDUFA review performance goals for the FY 2009 cohort (final) and the FY 2010 cohort (preliminary).

Review Performance Presented in This Report

Submissions	Review Within	[A] FY 2009 Review						[B] FY 2010 Review						[C] FY 2011 Review					
		Oct 2008 to Sep 2009						Oct 2009 to Sep 2010						Oct 2010 to Sep 2011					
[1] FY 2009 Cohort	2 Months	●	●	●	●	●	●	●											
	4 Months	●	●	●	●	●	●	●	●										
	6 Months	●	●	●	●	●	●	●	●	●									
	10 Months	●	●	●	●	●	●	●	●	●	●	●							
[2] FY 2010 Cohort	2 Months							●	●	●	●	●	●	o					
	4 Months							●	●	●	●	●	●	o	o				
	6 Months							●	●	●	●	●	●	o	o	o			
	10 Months							●	●	●	●	●	●	o	o	o	o	o	

Notes:

- Rectangular shaded areas indicate results covered in this report. Each rectangular segment represents 2 months of the fiscal year.
- Filled in circles **(●)** illustrate potential on-time completed reviews covered by this report while empty circles (o) illustrate possible on-time pending reviews depending on when the submission was received during the previous fiscal year.

FY 2010 On-Time Review Performance. FDA on-time review performance is presented for each submission type to provide an indication on how FDA is performing within a given fiscal year. On-time review performance in a given fiscal year impacts multiple years of PDUFA review performance goals. This report provides a snapshot of on-time review performance for reviews completed or due for completion during FY 2010. Included are FY 2009 submissions that were pending within goal at the beginning of FY 2010, and FY 2010 submissions that were received early enough to have a review completed or scheduled within goal for review during FY 2010 (see column B in table above).

FY 2009 and FY 2010 PDUFA Review Performance Goals. PDUFA review-time goals range from 2 months to 10 months. To meet PDUFA review performance goals, FDA must meet review-time goals at least 90 percent of the time. FDA annually reports these performance goal results for each fiscal year receipt cohort (as defined from October 1 to September 30 of the following year). Submissions received too late to be reviewed by the end of a fiscal year will be reported on after FDA takes an action, or when the review-time goal period expires, whichever comes first in subsequent years. Final performance goal results presented in this report include FY 2009 cohort submissions based on reviews in FY 2009 and FY 2010 (see row 1, columns A and B in table on previous page). Preliminary performance goal results presented in this report include FY 2010 cohort submissions that had reviews completed or overdue in FY 2010 (see row 2, column B in table on previous page). Final performance goal results for FY 2010 cohort submissions will be presented in the FY 2011 PDUFA Performance Report and will include reviews that are pending within goal as of September 30, 2010, that are due to be completed in FY 2011 (see row 2, column C in table on previous page).

The following information refers to FDA performance presented in this section.

- 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 in response to a complete response, approvable, not approvable, or tentative approval letter; NME (New Molecular Entity) refers only to NMEs that are NDAs; and “submission” applies to all of the above.

- The counts of NMEs in workload tables are of “discrete” filed NMEs. These are multiple submissions for the same NME (e.g., different dosage forms), which are often received by FDA. All are initially designated as NMEs, but when FDA approves the first of the multiple submissions, FDA redesignates the others as non-NMEs.

Reviews Completed On Time During FY 2010

This table summarizes FDA's on-time review performance for FY 2009 and FY 2010 submissions whose reviews were completed or due for completion in FY 2010. This table provides a snapshot of the on-time review performance for the given fiscal year, but not with respect to meeting PDUFA performance goals, as these are based on the fiscal year cohort of submission and are presented in the next section. For the purposes of measuring on-time performance, a review is counted when an action is taken, or when the on-time goal period has expired, whichever occurs first. Review performance for FY 2010 is based on 2,961 submissions that had action taken (within goal or overdue) or where the application was pending action past goal (overdue) as of September 30, 2010. Of these 2,961 submissions, 1,319 were from the FY 2009 cohort (representing 45 percent of the review workload) and 1,642 were from the FY 2010 cohort (representing 55 percent of the review workload). Overall, 93 percent of reviews were completed on time during FY 2010.

Application/Submission Type	On Time Goal	Reviews Completed On Time During FY 2010					
		Submitted In FY 2009		Submitted In FY 2010		Total	
		On Time / Reviewed*	Percent On Time	On Time / Reviewed*	Percent On Time	On Time / Reviewed*	Percent On Time
Priority NDAs/BLAs	6 months	7 / 11	64%	7 / 7	100%	14 / 18	**78%**
Priority NMEs/BLAs[†]	*6 months*	*5 / 8*	*63%*	*4 / 4*	*100%*	*9 / 12*	***75%***
Standard NDAs/BLAs	10 months	86 / 92	93%	8 / 8	100%	94 / 100	**94%**
Standard NMEs/BLAs[†]	*10 months*	*25 / 26*	*96%*	*3 / 3*	*100%*	*28 / 29*	***97%***
Resubmitted Class I NDAs/BLAs	2 months	0 / 1	0%	12 / 12	100%	12 /13	**92%**
Resubmitted Class 2 NDAs/BLAs	6 months	29 / 30	97%	19 / 20	95%	48 / 50	**96%**
Priority Efficacy Supplements	6 months	27 / 29	93%	4 / 4	100%	31 / 33	**94%**
Standard Efficacy Supplements	10 months	94 / 103	91%	11 / 13	85%	105 / 116	**91%**
Resubmitted Class 1 Efficacy Supplements	2 months	2 / 2	100%	16 / 16	100%	18 / 18	**100%**
Resubmitted Class 2 Efficacy Supplements	6 months	17 / 20	85%	7 / 9	78%	24 / 29	**83%**
Manufacturing Supplements Requiring Prior Approval	4 months	282 / 314	90%	656 / 747	88%	938 / 1,061	**88%**
Manufacturing Supplements Not Requiring Prior Approval	6 months	675 / 717	94%	784 / 806	97%	1,459 / 1,523	**96%**
Total Submissions[‡]		1,219 / 1,319	92%	1,524 / 1,642	93%	2,743 / 2,961	**93%**

* Includes reviews that were completed on time, overdue, and pending action past goal.
[†] NMEs/BLAs are subsets of NDA/BLA totals.
[‡] Total submissions are derived by totaling all the rows in the column, with the exception of the Priority NME/BLA and Standard NME/BLA rows. Since the NME/BLA figures are a subset of the NDA/BLA counts/rows, they are already included in those figures.

A review of on-time review performance completed during FY 2010 shows:

- The majority of FY 2009 cohort submissions had action due in the first 6 months of FY 2010. As noted in the previous section, most of the review time goals are for 6 months or less. These submissions include 1,124 of 1,319 submissions received in the final 6 months of FY 2009.

- FY 2009 cohort submissions acted on in FY 2009 ranged from 0 percent (resubmitted Class 1 NDA/BLA) to 100 percent (resubmitted Class 1 efficacy supplements) on-time performance. Two-thirds (8 of 12) submission types met or exceeded the 90-percent on-time level.

- FY 2010 cohort submissions acted on or due as of September 30, 2010, ranged from 78 percent (resubmitted Class 2 efficacy supplements) to 100 percent (7 of the performance goals) on-time performance. Three-fourths (9 of 12) of submission types met or exceeded the 90- percent on-time level.

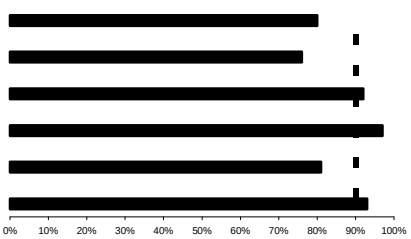
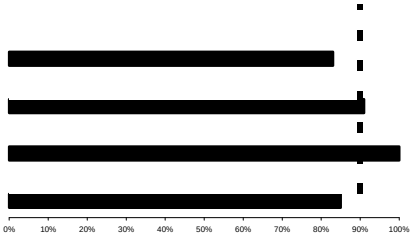
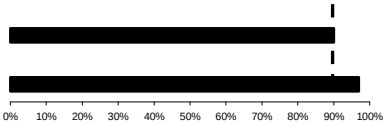
- On-time reviews in a single year impact two consecutive fiscal year's cohort performance. During FY 2010, for both the FY 2009 and FY 2010 cohort, FDA completed reviews equal to or greater than 90 percent of the time in 8 of 12 performance goal categories (see total columns percent on time).

Review Performance Goals At-A-Glance: FY 2009 and FY 2010

The tables below summarize FDA's review performance for FY 2009 submissions and FY 2010 submissions with respect to meeting performance goals.

FY 2009 Final Performance. Final review performance with respect to performance goals can now be provided for FY 2009. FDA met or exceeded FY 2009 performance goals for:

- Half (3 of 6) of original and resubmitted applications;
- Half (2 of 4) of original and resubmitted efficacy supplements; and
- All (2 of 2) manufacturing supplements.

FY 2009 Goal Area		Percent On Time ▬ vs. PDUFA Performance Goal (⋮) of 90%
Original and Resubmitted Applications	Priority NDAs/BLAs Priority NMEs/BLAs Standard NDAs/BLAs* Standard NMEs/BLAs Resubmitted Class 1 NDAs/BLAs Resubmitted Class 2 NDAs/BLAs	
Original and Resubmitted Efficacy Supplements	Priority NDAs/BLAs Standard NDAs/BLAs† Resubmitted Class 1 NDAs/BLAs within 2 months Resubmitted Class 2 NDAs/BLAs within 6 months	
Manufacturing Supplements	NDAs/BLAs requiring prior approval NDAs/BLAs not requiring prior approval	

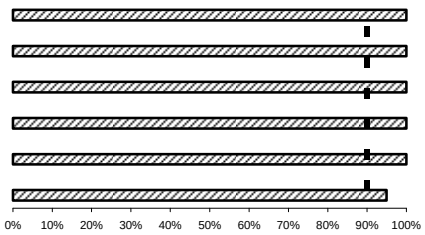
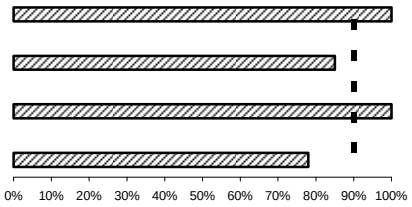
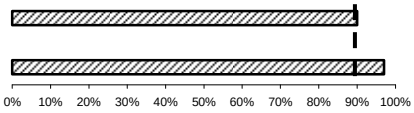
* Represents FDA performance level with three reviews pending within goal as of September 30, 2010. FDA met the review performance goal, regardless of the final performance results of these reviews. FDA's final on-time review performance will range from 90 percent, if none of the applications are acted on within goal, to 93 percent if all three applications are acted on within goal.

† Represents FDA performance level with one review pending within goal as of September 30, 2010. FDA met the review performance goal, regardless of the final performance results of this review. FDA's final on-time review performance will remain at 91 percent, if the application is not acted on within goal or is acted on within goal.

FY 2010 Preliminary Percent On-Time Review Performance. Preliminary review performance is based on 59 percent (1,642 of 2,799) of FY 2010 submissions with reviews pending within goal for the remaining 41 percent (1,157 of 2,799) as of September 30, 2010. FDA is meeting or exceeding FY 2010 performance goal levels for:

- All (6 of 6) of original and resubmitted applications;
- Half (2 of 4) of original and resubmitted efficacy supplements; and
- Half (1 of 2) manufacturing supplements.

With additional reviews still pending within goal as of September 30, 2010, FDA has the potential to improve overall performance for FY 2010 and meet almost all (11 of 12) review performance goals.

	FY 2010 Goal Area	Preliminary Percent On Time vs. PDUFA Performance Goal (▪) of 90%
Original and Resubmitted Applications	Priority NDAs/BLAs Priority NMEs/BLAs Standard NDAs/BLAs Standard NMEs/BLAs Resubmitted Class 1 NDAs/BLAs Resubmitted Class 2 NDAs/BLAs	
Original and Resubmitted Efficacy Supplements	Priority NDAs/BLAs Standard NDAs/BLAs Resubmitted Class 1 NDAs/BLAs within 2 months Resubmitted Class 2 NDAs/BLAs within 6 months	
Manufacturing Supplements	NDAs/BLAs requiring prior approval NDAs/BLAs not requiring prior approval	

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Report on FY 2009 and FY 2010 PDUFA Review Goals

This section updates FDA's final on-time review performance on the FY 2009 submissions and presents FDA's preliminary on-time performance in reviewing FY 2010 submissions for all PDUFA review performance goals.

Type of Submissions	Goals
Original and Resubmitted Applications	Priority and Standard NDAs/BLAs
	Priority and Standard NME/BLAs
	Resubmitted Class 1 and Class 2 NDAs/BLAs
Efficacy Supplements	Priority and Standard NDAs and BLAs
	Resubmitted Class 1 and Class 2 NDAs/BLAs
Manufacturing Supplements	NDAs/BLAs requiring prior approval
	NDAs/BLAs not requiring prior approval

The following information refers to FDA performance presented in this section.

- Final performance data were available on virtually all (2,982 of 2,986) FY 2009 review performance submissions and resubmissions. Four submissions were pending within goal as of September 30, 2010. FDA can now report final performance with respect to achieving FY 2009 review goals.

- 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 submission.

- Preliminary performance is based on the number of submissions reviewed "on-time" (acted on within goal) and "overdue" (acted on past goal or pending past the goal date) and presented as percent on time (preliminary performance excludes actions pending within goal). Final performance is based on the final number of submissions on- time (acted on within goal) and overdue (acted on past goal or pending past the goal) and presented as percent on- time (final performance with no actions pending within goal).

- Preliminary performance for FY 2010 review submissions includes the number of submissions filed or received, reviewed on-time, and overdue by the end of the current fiscal year, as well as the number pending within goal (on time).

- Preliminary review performance assessments in this report are based on 59 percent (1,642 of 2,799) of FY 2010 review performance submissions and resubmissions. Submission types (e.g., resubmitted Class 1 NDAs and BLAs) with short (e.g., 2 months) performance goals tend to have a larger percentage of reviews completed by the end of the fiscal year, and their preliminary performance is a more reliable indicator of their final performance. However, submission types (e.g., standard efficacy supplement submissions) with longer (e.g., 10 months) performance goals tend to have a smaller percentage of reviews completed, and their preliminary performance is a less reliable indicator of their final performance.

- Unless otherwise noted, all performance data are as of September 30, 2010.

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Original Applications

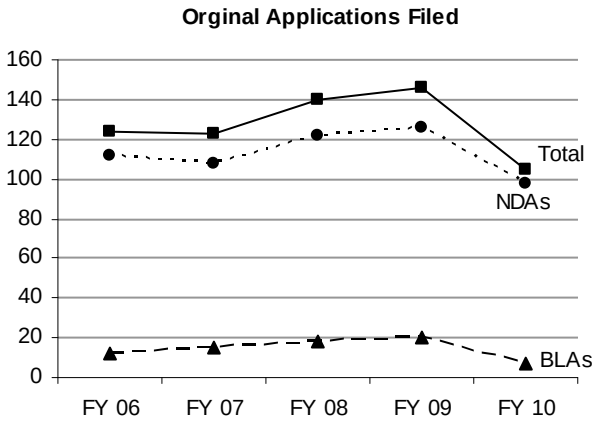
Goal: Review and act on original NDAs and BLAs

The table below summarizes the annual review-time and performance goals for original NDAs and BLAs.

Original Application Type	Review-Time Goal	Performance Goal FY 2008 – FY 2012 Submissions
Priority	6 months	90% on time
Standard	10 months	

Workload

The PDUFA total for original applications filed in FY 2010 was the lowest number filed in 5 years and the first decrease in 3 years. The decrease in applications filed occurred with standard NDAs and priority and standard BLAs. Priority NDAs remained at FY 2009 levels (see corresponding graph and table).



Original Applications Filed
(Priority/Standard)

Type	FY 06	FY 07	FY 08	FY 09*	FY 10
NDAs	**112** *(25/87)*	**108** *(23/85)*	**122** *(27/95)*	**126** *(16/110)*	**98** *(16/82)*
BLAs	**12** *(7/5)*	**15** *(7/8)*	**18** *(7/11)*	**20** *(9/11)*	**7** *(3/4)*
PDUFA Total	**124** *(32/92)*	**123** *(30/93)*	***140*** *(34/106)*	**146** *(25/121)*	**105** *(19/86)*
NMEs[†]	**24** *(8/16)*	**29** *(9/20)*	**29** *(10/19)*	**30** *(8/22)*	**22** *(8/14)*

* FY 2009 numbers were changed to reflect updates to data presented in the FY 2009 PDUFA Performance Report.
[†] FDA often receives multiple submissions for the same NME that are all initially designated as NMEs. When FDA approves the first of the multiple submissions, the others are redesignated as non-NMEs.

Original Applications

Performance

FY 2009 Submissions

FDA reviewed on time most priority (20 of 25) and standard (109 of 121) applications that were filed in FY 2009 (see table below). This included reviewing on time 13 of 17 priority NMEs and BLAs and 32 of 33 standard NMEs and BLAs. FDA did not meet performance goals for original priority applications. With three submissions pending within goal, FDA will meet or exceed the performance goals for original standard applications.

Original Application Type		Performance Goal	Filed	Performance as of September 30, 2009			Final Performance		
				On Time	Overdue	Percent On Time	On Time	Overdue	Percent On Time
Priority	All	Act on 90 percent within 6 months	25*	13	1	**93%**	20	5	**80%**
	NMEs & BLAs		17*	8	1	**89%**	13	4	**76%**
Standard	All	Act on 90 percent within 10 months	121*	23	3	**88%**	109	9	**92%**[†]
	NMEs & BLAs		33*	7	0	**100%**	32	1	**97%**

* FY 2009 counts were changed to reflect updates to data presented in the FY 2009 PDUFA Performance Report.
[†] Represents FDA performance level with three reviews pending within goal as of September 30, 2010. FDA met the review performance goal, regardless of the final performance results of these individual reviews. FDA's final on-time review performance will range from 90 percent, if none of the applications are acted on within goal, to 93 percent if all three applications are acted on within goal.

FY 2010 Submissions

As of September 30, 2010, performance data were available for over one-third (7 of 19) of priority applications and less than one-tenth (8 of 86) of standard applications filed in FY 2010. FDA met the review-time goal for all of these applications. With priority and standard applications pending within goal, FDA has the potential to exceed all FY 2010 performance goals for original NDAs and BLAs.

Original Application Type		Performance Goal	Filed	Performance as of September 30, 2010			
				On Time	Overdue	Percent On Time	Pending Within Goal
Priority	All	Act on 90 percent within 6 months	19	7	0	**100%**	12
	NMEs & BLAs		11	4	0	**100%**	7
Standard	All	Act on 90 percent within 10 months	86	8	0	**100%**	78
	NMEs & BLAs		18	3	0	**100%**	15

Resubmitted Applications

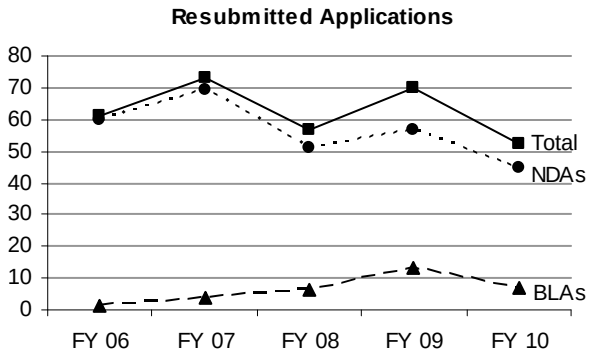
Goal: Review and act on resubmitted NDAs and BLAs

The table below summarizes the annual review-time and performance goals for resubmitted NDAs and BLAs. A resubmission is a firm's response to an FDA action of complete response, approvable, not approvable, or tentative approval on an application. The applicable performance goal for a resubmission is determined by the year in which the resubmission is received, rather than the year in which the original application was submitted.[2]

Resubmitted Application Type	Review-Time Goal	Performance Goal FY 2008 – FY 2012 Submissions
Class 1	2 months	90% on time
Class 2	6 months	

Workload

The PDUFA total for resubmitted applications decreased in FY 2010, as both Class 1 and Class 2 NDA resubmitted applications were at the lowest levels in 5 years (see corresponding graph and table).



Resubmitted Applications (Class 1 / Class 2)

Type	FY 06	FY 07	FY 08	FY 09*	FY 10
NDAs	**60** *(20/40)*	**69** *(22/47)*	**51** *(17/34)*	**57** *(14/43)*	**45** *(13/32)*
BLAs	**1** *(0/1)*	**4** *(1/3)*	**6** *(2/4)*	**13** *(2/11)*	**7** *(0/7)*
PDUFA Total	**61** *(20/41)*	**73** *(23/50)*	**57** *(19/38)*	**70** *(16/54)*	**52** *(13/39)*

* FY 2009 numbers were changed to reflect updates to data presented in the FY 2009 PDUFA Performance Report.

[2] Class 1 and Class 2 resubmissions are defined in the "Definition of Terms" in Appendix A.

Resubmitted Applications

Performance

FY 2009 Resubmissions

FDA reviewed on time most Class 1 (13 of 16) and Class 2 (50 of 54) resubmissions in FY 2009 (see table below). FDA did not meet the performance goal for Class 1 resubmission applications but exceeded the performance goal for Class 2 resubmitted applications.

Resubmitted Application Type	Performance Goal	Received	Performance as of September 30, 2009			Final Performance		
			On Time	Overdue	Percent On Time	On Time	Overdue	Percent On Time
Class 1	Act on 90 percent within 2 months	16*	13	2	**87%**	13	3	**81%**
Class 2	Act on 90 percent within 6 months	54	21	3	**88%**	50	4	**93%**

* FY 2009 numbers were changed to reflect updates to data presented in the FY 2009 PDUFA Performance Report.

FY 2010 Resubmissions

As of September 30, 2010, performance data were available for almost all (12 of 13) Class 1 resubmissions and over half (20 of 39) of the Class 2 resubmissions received in FY 2010. FDA met the review-time goal for all but one of them. With resubmissions pending within goal, FDA will exceed the performance goal for Class 1 resubmitted applications and has the potential to exceed the performance goal for Class 2 resubmitted applications.

Resubmitted Application Type	Performance Goal	Received	Performance as of September 30, 2010			
			On Time	Overdue	Percent On Time	Pending Within Goal
Class 1	Act on 90 percent within 2 months	13	12	0	**100%**	1
Class 2	Act on 90 percent within 6 months	39	19	1	**95%**	19

Efficacy Supplements

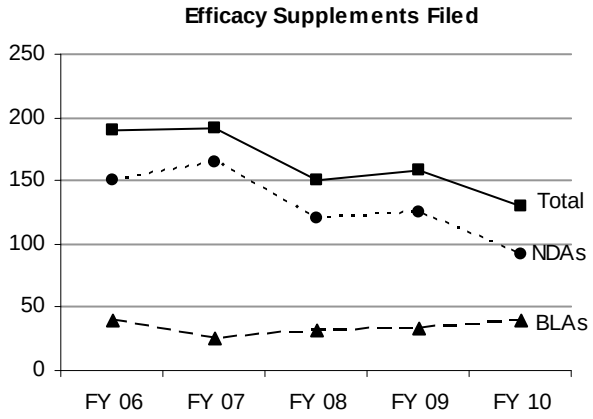
Goal: Review and act on complete efficacy supplements to NDAs and BLAs

The table below summarizes the annual review-time and performance goals for original efficacy supplements to NDAs and BLAs.

Efficacy Supplement Type	Review-Time Goal	Performance Goal FY 2008 – FY 2012 Submissions
Priority	6 months	90% on time
Standard	10 months	

Workload

The PDUFA total for efficacy supplements filed in FY 2010 decreased to the lowest level in 5 years. The decrease was due to the decline in the number of NDA efficacy supplements filed. However, the number of BLA efficacy supplements increased in FY 2010 as the number of standard BLA efficacy supplements filed reached a 5-year high (see corresponding graph and table).



Efficacy Supplements Filed
(Priority / Standard)

Type	FY 06	FY 07	FY 08	FY 09*	FY 10
NDAs	**151** *(36/115)*	**165** *(43/122)*	**120** *(31/89)*	**125** *(36/89)*	**91** *(14/77)*
BLAs	**39** *(8/31)*	**26** *(3/23)*	**31** *(8/23)*	**34** *(6/28)*	**39** *(3/36)*
PDUFA Total	**190** *(44/146)*	**191** *(46/145)*	**151** *(39/112)*	**159** *(42/117)*	**130** *(17/113)*

* FY 2009 numbers were changed to reflect updates to data presented in the FY 2009 PDUFA Performance Report.

Efficacy Supplements

Performance

FY 2009 Submissions

FDA reviewed on time most priority (35 of 42) and standard (106 of 117) efficacy supplements filed in FY 2009 (see table below). FDA did not meet the performance goal for priority efficacy supplements. With one submission pending within goal, FDA will exceed the performance goal for standard efficacy supplements.

Efficacy Supplement Type	Performance Goal	Filed	Performance as of September 30, 2009			Final Performance		
			On Time	Overdue	Percent On Time	On Time	Overdue	Percent On Time
Priority	Act on 90 percent within 6 months	42*	8	5	**62%**	35	7	**83%**
Standard	Act on 90 percent within 10 months	117*	12	1	**92%**	106	10	**91%**[†]

* FY 2009 numbers were changed to reflect updates to data presented in the FY 2009 PDUFA Performance Report.
[†] Represents FDA performance level with one review pending within goal as of September 30, 2010. FDA met the review performance goal, regardless of the final performance results of this review. FDA's final on-time review performance will remain at 91 percent, if the application is not acted on within goal or is acted on within goal.

FY 2010 Submissions

As of September 30, 2010, performance data were available for almost one-fourth (4 of 17) of the priority efficacy supplements, and over one-tenth (13 of 113) of standard efficacy supplements filed in FY 2010. FDA met the review-time goal for all priority efficacy supplements and for most (11 of 13) of the standard efficacy supplements (see table below). With submissions pending within goal, FDA has the potential to exceed the performance goals for priority and standard efficacy supplements.

Efficacy Supplement Type	Performance Goal	Filed	Performance as of September 30, 2010			
			On Time	Overdue	Percent On Time	Pending Within Goal
Priority	Act on 90 percent within 6 months	17	4	0	**100%**	13
Standard	Act on 90 percent within 10 months	113	11	2	**85%**	100

Resubmitted Efficacy Supplements

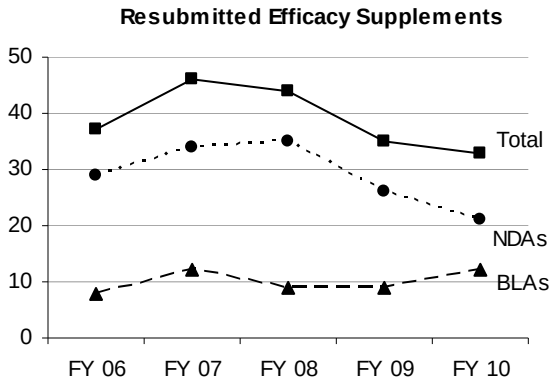
Goal: Review and act on resubmitted efficacy supplements to NDAs and BLAs

The table below summarizes the annual review-time and performance goals for resubmitted efficacy supplements to NDAs and BLAs.

Resubmitted Efficacy Supplement Type	Review-Time Goal	Performance Goal FY 2008 – FY 2012 Submissions
Class 1	2 months	90% on time
Class 2	6 months	

Workload

The PDUFA total for resubmitted efficacy supplements decreased for the third consecutive year in FY 2010 to the lowest level in 5 years. The decrease was solely due to the lowest number of Class 2 NDA resubmitted efficacy supplements filed in 5 years (see corresponding graph and table).



Resubmitted Efficacy Supplements
(Class 1 / Class 2)

Type	FY 06	FY 07	FY 08	FY 09*	FY 10
NDAs	**29** *(13/16)*	**34** *(16/18)*	**35** *(9/26)*	**26** *(4/22)*	**21** *(13/8)*
BLAs	**8** *(1/7)*	**12** *(1/11)*	**9** *(3/6)*	**9** *(4/5)*	**12** *(5/7)*
PDUFA Total	**37** *(14/23)*	**46** *(17/29)*	**44** *(12/32)*	**35** *(8/27)*	**33** *(18/15)*

* FY 2009 numbers were changed to reflect updates to data presented in the FY 2009 PDUFA Performance Report.

Resubmitted Efficacy Supplements

Performance

FY 2009 Resubmissions

FDA reviewed on time all Class 1 and most (23 of 27) Class 2 resubmissions submitted in FY 2009 (see table below). FDA exceeded the performance goal for Class 1 resubmitted efficacy supplements, but did not meet the performance goal for Class 2 resubmitted efficacy supplements.

Resubmitted Efficacy Supplement Type	Performance Goal	Received	Performance as of September 30, 2009			Final Performance		
			On Time	Overdue	Percent On Time	On Time	Overdue	Percent On Time
Class 1	Act on 90 percent within 2 months	8*	6	0	**100%**	8	0	**100%**
Class 2	Act on 90 percent within 6 months	27*	6	1	**86%**	23	4	**85%**

* FY 2009 numbers were changed to reflect updates to data presented in the FY 2009 PDUFA Performance Report.

FY 2010 Resubmissions

As of September 30, 2010, performance data were available for over three-fourths (16 of 18) of Class 1 and over half (9 of 15) of Class 2 resubmissions submitted in FY 2010. FDA met the review-time goal for all of the Class 1 and for most (7 of 9) of the Class 2 resubmissions (see table below). With resubmissions pending within goal, FDA has the potential to exceed the performance goal for Class 1 resubmitted efficacy supplements and can increase the on-time review percentage for Class 2 resubmitted efficacy supplements, but will not be able to meet the performance goal.

Resubmitted Efficacy Supplement Type	Performance Goal	Received	Performance as of September 30, 2010			
			On Time	Overdue	Percent On Time	Pending Within Goal
Class 1	Act on 90 percent within 2 months	18	16	0	**100%**	2
Class 2	Act on 90 percent within 6 months	15	7	2	**78%**	6

Manufacturing Supplements

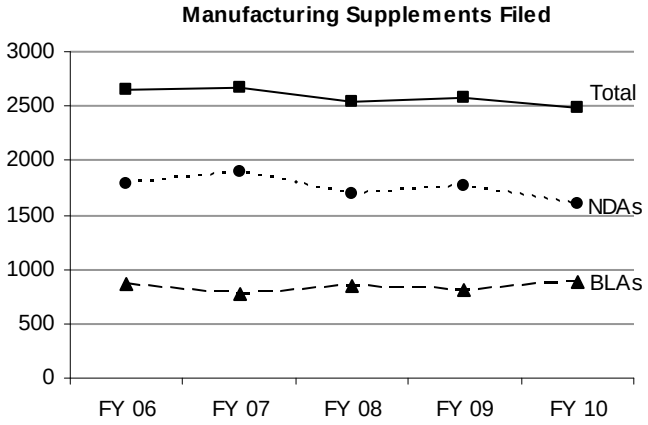
Goal: Review and act on manufacturing supplements to NDAs and BLAs

The table below summarizes the annual review-time and performance goals for NDA and BLA manufacturing supplements.

Manufacturing Supplement Type	Review-Time Goal	Performance Goal FY 2008 – FY 2012 Submissions
Prior Approval Required	4 months	90% on time
Prior Approval Not Required	6 months	

Workload

The PDUFA total for manufacturing supplements was at the lowest level in 5 years. Even though NDA manufacturing supplements requiring approval and BLA manufacturing supplements not requiring prior approval rose to the highest levels in 5 years, the increase was offset by a larger decrease in NDA manufacturing supplements not requiring prior approval (see corresponding graph and table).



Manufacturing Supplements Filed
(Prior Approval / No Prior Approval)

Type	FY 06	FY 07	FY 08	FY 09*	FY 10
NDAs	**1,788** *(574/1,214)*	**1,889** *(612/1,277)*	**1,695** *(575/1,120)*	**1,760** *(633/1,127)*	**1,599** *(747/852)*
BLAs	**859** *(310/549)*	**774** *(242/532)*	**853** *(335/518)*	**816** *(338/478)*	**880** *(320/560)*
PDUFA Total	**2,647** *(884/1,763)*	**2,663** *(854/1,809)*	**2,548** *(910/1,638)*	**2,576** *(971/1,605)*	**2,479** *(1,067/1,412)*

* FY 2009 numbers were changed to reflect updates to data presented in the FY 2009 PDUFA Performance Report.

Manufacturing Supplements

Performance

FY 2009 Submissions

FDA reviewed on time most manufacturing supplements requiring prior approval (881 of 971) and manufacturing supplements not requiring prior approval (1,549 of 1,605) filed in FY 2009 (see table below). FDA exceeded the performance goals for both types of manufacturing supplements.

Manufacturing Supplement Type	Performance Goal	Filed	Performance as of September 30, 2009			Final Performance		
			On Time	Overdue	Percent On Time	On Time	Overdue	Percent On Time
Prior Approval Required	Act on 90 percent within 4 months	971*	599	58*	**91%**	881	90	**91%**
Prior Approval Not Required	Act on 90 percent within 6 months	1,605*	874	14*	**98%**	1,549	56	**97%**

* FY 2009 numbers were changed to reflect updates to data presented in the FY 2009 PDUFA Performance Report.

FY 2010 Submissions

As of September 30, 2010, performance data were available for over two-thirds (747 of 1,067) of supplements requiring prior approval and over half (806 of 1,412) of supplements not requiring prior approval. FDA met the review-time goal for most (656 of 747) of supplements where prior approval is required and almost all (784 of 806) of supplements where prior approval is not required (see table below). With submissions pending within goal, FDA has the potential to exceed the FY 2010 performance goals for both manufacturing supplements where prior approval is required and where prior approval is not required.

Manufacturing Supplement Type	Performance Goal	Filed	Performance as of September 30, 2010			
			On Time	Overdue	Percent On Time	Pending Within Goal
Prior Approval Required	Act on 90 percent within 4 months	1,067	656	91	**88%**	320
Prior Approval Not Required	Act on 90 percent within 6 months	1,412	784	22	**97%**	606

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Report on FY 2010 PDUFA Procedural and Processing Goals and Commitments

This section presents FDA's performance in achieving the FY 2010 goals related to meeting management, procedural responses, and procedural notifications as outlined under PDUFA IV in which performance levels have been defined. These goals and commitments are intended to improve application submissions and FDA-sponsor interactions during new drug development and application review, as well as to reduce medication errors and enhance first-cycle review performance. These interactions often represent critical points in the regulatory process as it encourages FDA and industry to work collaboratively. Updated data on FY 2009 procedural and processing performance goals are presented in Appendix C.

Performance Area	Type of Goal/Commitment
Procedural and Processing Goals	Meeting Requests – Type A, B, & C
	Scheduling Meetings – Type A, B, & C
	Meeting Minutes
	Clinical Holds
	Major Dispute Resolution
	Special Protocol Assessments
Review of Proprietary Names to Reduce Medication Errors	Review of Proprietary Names Submitted During investigational new drug (IND) Phase
	Review of Proprietary Names Submitted with NDA/BLA
First Cycle Review Performance Proposal	First Cycle Filing Review Notification – Original NDA
	First Cycle Filing Review Notification – Efficacy Supplements
	Notification of Planned Review Timelines – Original NMEs and BLAs
	Notification of Planned Review Timelines – Efficacy Supplements for New/Expanded Indications

Additional discussion of the individual goals is presented in this section.

Meeting Management

Goal: Adhere to meeting management performance goals for meeting requests, scheduling meetings, and meeting minutes

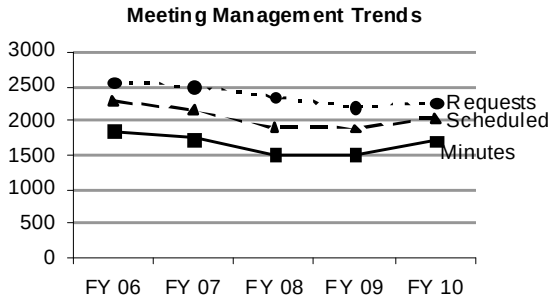
The table below summarizes the meeting management goals that address meeting requests, scheduling meetings, and preparing meeting minutes.

Action	Review-Time Goal	Performance Goal FY 2008 – FY 2012
Meeting Requests	Notify requestor of formal meeting in writing within 14 days of request for Type A meetings; within 21 days of request for Type B and Type C meetings.	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 the "Definition of Terms" in Appendix A.

Workload

The numbers of meeting requests and scheduling of meetings increased from FY 2009 to FY 2010, ending 3-year declines. The number of meeting minutes prepared increased to the highest level in 3 years (see corresponding graph and table).



Meeting Management

Type	FY 06	FY 07	FY 08	FY 09*	FY 10
Meeting Requests	2,565	2,502	2,344	2,192	2,268
Scheduling Meetings	2,273	2,151	1,903	1,881	2,044
Meeting Minutes	1,853	1,736	1,515	1,518	1,705

* FY 2009 numbers were changed to reflect updates to data presented in the FY 2009 PDUFA Performance Report.

Meeting Management

FY 2010 Performance

As of September 30, 2010, FDA acted on 1,897 meeting requests, scheduled 1,651 meetings, and prepared 1,393 meeting minutes.[3] Most of these actions (1,498 of 1,897 meeting requests; 1,197 of 1,651 meetings scheduled; and 738 of 1,393 meeting minutes) were acted on within goal. With meeting requests, scheduling meetings, and meeting minutes pending within goal, FDA can increase on-time percentage level but will not meet the performance goals for meeting management in FY 2010 (see table below).

Type		Performance Goal – Review 90 percent within	Received	Performance as of September 30, 2010*			
				On Time	Overdue	Percent On Time	Pending Within Goal
Meeting Requests	Type A	14 Days	184	140	44	**76%**	0
	Type B	21 Days	1,147	892	235	**79%**	20
	Type C		590	466	120	**80%**	4
Scheduling Meetings†	Type A	30 Days	173	113	58	**66%**	2
	Type B	60 Days	1,055	703	299	**70%**	53
	Type C	75 Days	503	381	97	**80%**	25
Meeting Minutes‡		30 Days	1,705	738	655	**53%**	312

* Performance in all categories will change once determinations are made for meeting requests and scheduled meetings initially coded as undetermined. Approximately 15 percent (347 meeting requests and 313 scheduling of meetings) of data were pending recoding as of September 30, 2010.

† Not all meeting requests are granted; therefore, the number of meetings scheduled may differ from the number of meeting requests received.

‡ Not all scheduled meetings are held; therefore, the number of meeting minutes may differ from the number of meetings scheduled.

[3] Some meeting requests and subsequent scheduling of meetings are for requests where the "Type" can not be initially determined. Once these requests are determined performance can be reassessed, and therefore, final numbers and performance will be updated in Appendix C of the FY 2011 PDUFA performance report.

Responses to Clinical Holds

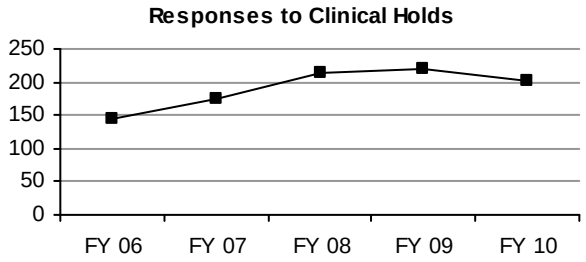
Goal: Respond to a sponsor's complete response to a clinical hold within 30 days of receipt

The table below summarizes the annual review-time and performance goals for the response to clinical holds.

Action	Review-Time Goal	Performance Goal FY 2008 – FY 2012
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 decreased for the first time in 4 years, but was near the level of the previous 2 years (see corresponding graph and table).



Responses to Clinical Holds

FY 06	FY 07	FY 08	FY 09*	FY 10
145	175	213	221	203

* FY 2009 counts were updated to reflect corrections to the FY 2009 PDUFA Performance Report.

FY 2010 Performance

As of September 30, 2010, performance data were available for almost all (191 of 203) of FDA's responses to sponsors' complete responses to clinical holds received in FY 2010. FDA met the review-time goal for most (154 of 191) of these requests (see table below). With responses pending within goal, FDA can increase the on-time percentage level but will not meet the performance goal.

Performance Goal	Total Received	Performance as of September 30, 2010			
		On Time	Overdue	Percent on Time	Pending Within Goal
Respond to 90 percent within 30 days	203	154	37	**81%**	12

Major Dispute Resolutions

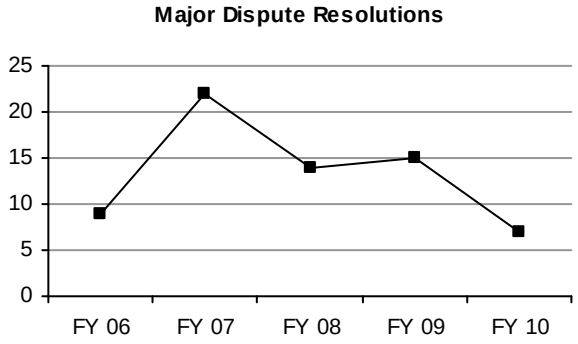
Goal: Provide a response to a sponsor's appeal of decision within 30 days of receipt

The table below summarizes the annual review-time and performance goals for responses to major dispute resolutions.

Action	Review-Time Goal	Performance Goal FY 2008 – FY 2012
Major Dispute Resolution	Respond to sponsor's appeal of decision within 30 days of receipt.	90% on time

Workload

The number of major dispute resolution appeals that FDA responded to in FY 2010 was the lowest in 5 years (see corresponding graph and table).



Major Dispute Resolutions

FY 06	FY 07	FY 08	FY 09	FY 10
9	22	14	15	7

FY 2010 Performance

As of September 30, 2010, performance data were available on all sponsors' appeals of decisions received in FY 2010. FDA did not meet the performance goal (see table below).

Performance Goal	Total Received	Performance as of September 30, 2010			
		On Time	Overdue	Percent on Time	Pending Within Goal
Respond to 90 percent within 30 days	7	5	2	**71%**	0

Special Protocol Assessments

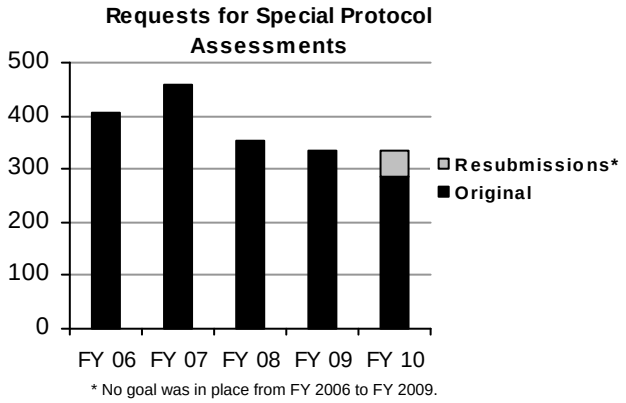
Goal: Respond to a sponsor's request for evaluation of protocol design within 45 days of receipt of protocol and questions

Upon specific request by a sponsor FDA will evaluate certain protocols and issues to assess whether the design is adequate to meet scientific and regulatory requirements identified by the sponsor. The table below summarizes the annual review-time and performance goals for responses to requests for special protocol assessments.

Action	Review-Time Goal	Performance Goal FY 2008 – FY 2012
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

In FY 2010, the total number of special protocol assessment requests, which include originals and resubmissions, declined for the third straight year to the lowest level in 5 years. FDA received a total of 47 resubmitted special protocol assessments with 41 original requests receiving 1 resubmission each and 3 original requests receiving 2 resubmissions each representing approximately 1 resubmission for every 6 original assessments (see corresponding graph and table).



Requests for Special Protocol Assessments

	FY 06	FY 07	FY 08	FY 09*	FY 10
Original Requests	406	459	354	336	287
Resubmissions[†]	--	--	--	--	47
All Requests	406	459	354	336	334

* FY 2009 numbers were changed to reflect updates to data presented in the FY 2009 PDUFA Performance Report.

[†] FDA began reporting resubmissions separately in FY 2010. Prior to FY 2010, resubmitted requests for Special Protocol Assessments were included in the original counts.

[‡] FDA received 1 resubmission for 41 original requests, and 2 resubmissions each for 3 original requests, for a total of 47 resubmissions. This computes to approximately 15 percent (44 of 287) of original requests receiving at least one resubmission, or one resubmission for each six original requests.

Special Protocol Assessments

FY 2010 Performance

As of September 30, 2010, performance data were available for over four-fifths (289 of 334) of special protocol assessments received in FY 2010 (see table below). With special protocol assessments pending within goal, FDA can increase on-time percentage level, but will not be able to meet the performance goal.

Performance Goal	Total Received*	Performance as of September 30, 2010			
		On Time	Overdue	Percent on Time	Pending Within Goal
Respond to 90 percent within 45 days	334	233	56	**81%**	45

* The total number of resubmissions received includes multiple resubmissions to the same original request for special protocol assessments.

Drug/Biological Product Proprietary Names

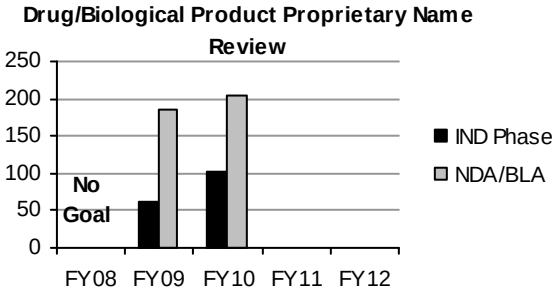
Commitment: Review and tentatively accept proprietary names

The table below summarizes the annual review-time commitment related to the timeliness of notifications to applicants of tentative acceptance or non-acceptance for the use of drug and biological product proprietary names (refer to table below for timelines of review). This commitment is progressive as performance levels will progress from 50 percent on time for FY 2009 submissions to 90 percent for FY 2011 and beyond (see table below).

Submission Type	Review-Time Commitment	Performance Level				
		2008	2009	2010	2011	2012
Proprietary Names Submitted During IND Phase	Within 180 days Of receipt	None	50%	70%	90%	
Proprietary Names Submitted with NDA/BLA	Within 90 days Of receipt					

Workload

During FY 2010, the second year of this commitment, 101 proprietary names were submitted during the IND phase, an increase of 60 percent from FY 2009. The number of proprietary names submitted with an NDA or BLA in FY 2010, at 204, represents a 10 percent increase over FY 2009 (see corresponding graph and table).



Drug/Biological Product Proprietary Name Review

Type	FY 08	FY 09*	FY 10	FY 11	FY 12
Proprietary Names Submitted During IND Phase	--	63	101	--	--
Proprietary Names Submitted with NDA/BLA	--	185	204	--	--

* FY 2009 numbers were changed to reflect updates to data presented in the FY 2009 PDUFA Performance Report.

Drug/Biological Product Proprietary Names

FY 2010 Performance

As of September 30, 2010, performance data were available for over half (53 of 101) of proprietary names submitted during the IND phase and over four-fifths (176 of 204) of proprietary names submitted with NDAs and BLAs submitted in FY 2010. FDA met the review-time commitment for almost all proprietary names submitted during the IND phase (49 of 53) as well as proprietary names submitted with NDAs and BLAs (163 of 176). With submissions pending, FDA has the potential to exceed the performance commitment for proprietary names submitted during the IND phase and will exceed the performance commitment for proprietary names submitted with NDAs and BLAs.

Submission Type	Performance Commitment	Received	Performance as of September 30, 2010			
			On Time	Overdue	Percent On Time	Pending Within Goal
Proprietary Names Submitted During IND Phase	Act on 70 percent within 180 days of receipt	101	49	4	**92%**	48
Proprietary Names Submitted with NDA/BLA	Act on 70 percent within 90 days of receipt	204	163	13	**93%**	28

First Cycle Filing Review Notification

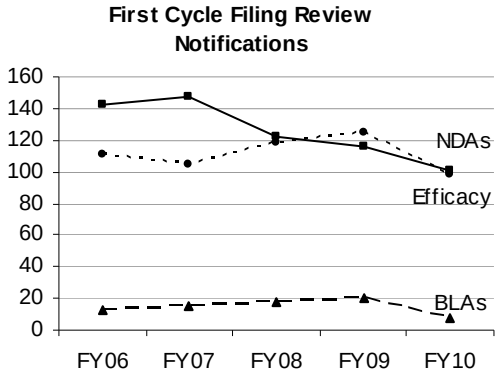
Commitment: Report substantive review issues (or lack thereof) within 14 Days after the 60-Day filing date for original NDAs/BLAs and efficacy supplements

The table below summarizes the annual review-time commitments for first cycle filing review notifications for original NDAs and BLAs and efficacy supplements. FDA is to report substantive review issues (or lack thereof) identified during the initial filing review to the applicant by letter, telephone conference, facsimile, secure e-mail, or other expedient means within 14 days after the 60-day filing date.

First Cycle Filing Review Notification Type	Review-Time Commitment	Performance Level FY 2008 – FY 2012
Original NDAs/BLAs	Within 14 days after 60-day filing date	90% on time
Efficacy Supplements		

Workload

The PDUFA total for first cycle filing review notifications filed in FY 2010 was the lowest number filed in 5 years and consistent with declines in the numbers of NDAs, BLAs, and efficacy supplements filed (see earlier sections as well as corresponding graph and table).



First Cycle Filing Review Notifications

Type	FY 06	FY 07	FY 08	FY 09*	FY 10
NDAs	111	104	119	125	98
BLAs	12	15	18	20	7
PDUFA Total	123	119	137	145	105
Efficacy Supplements†	142	148	122	116	101

* The number of original applications filed in any given year may not match the number of first cycle notifications due to the status of an application at the time the data are closed for reporting. Numbers are updated as appropriate in later FY reports. FY 2009 numbers were changed to reflect updates to data presented in the FY 2009 PDUFA Performance Report.

† The first cycle filing review notification commitment applies to original NDAs and BLAs and efficacy supplements only. First cycle filing review commitments do not apply to NDA labeling supplements, even though these are counted as efficacy supplements for other PDUFA performance purposes. Therefore, the number of filing review notifications for efficacy supplements is generally less than the total number of efficacy supplements filed.

First Cycle Filing Review Notification

FY 2010 Performance

As of September 30, 2010, performance data were available for almost all NDA/BLA notifications (91 of 105) and efficacy supplement notifications (88 of 101) in FY 2010. FDA met the review-time commitment for most NDA/BLA notifications (80 of 91) and efficacy supplement notifications (75 of 88). With notifications pending within the commitment-time period, FDA has the potential to meet the performance commitment for NDA and BLA first cycle filing review notifications, but will not be able to meet the performance commitment for efficacy supplement first cycle filing review notifications.

First Cycle Filing Review Notification Type	Performance Commitment	Filed	Performance as of September 30, 2010			
			On Time	Overdue	Percent On Time	Pending Within Goal
NDAs/BLAs	Act on 90 percent within 14 days after 60-day filing date	105	80	11	**88%**	14
Efficacy Supplements		101	75	13	**85%**	13

Notification of Planned Review Timelines

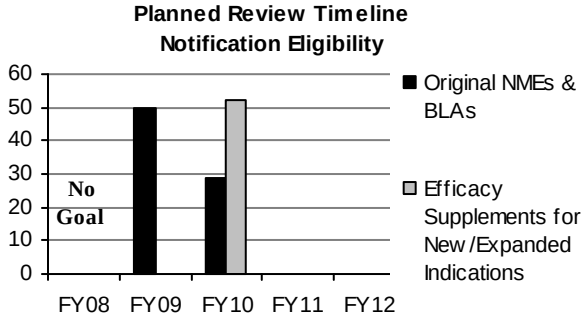
Commitment: Notify applicant of planned review timeline for labeling and postmarketing study requirements (PMRs) and postmarketing study commitments (PMCs)

The table below summarizes the annual review-time commitment for planned review timeline notifications. FDA is to inform the applicant of the planned timeline for feedback related to labeling and PMRs and PMCs. This commitment is progressive with the implementation of additional applications each fiscal year. The commitment began in FY 2009 with the inclusion of original NMEs and BLAs, and expanded in FY 2010 to include efficacy supplements for new and expanded indications. All original NDAs will be included in FY 2011 and all efficacy supplements in FY 2012 (see table below).

Application Type	Timeline Notification Commitment	Performance Level				
		FY 08	FY 09	FY 10	FY 11	FY 12
Original NMEs and BLAs	Within 14 days after the 60 day filing date	Not Applicable	90% (of applications)			
Efficacy Supplements for New/ Expanded Indications				90%		
All Original NDAs					90%	
All Efficacy Supplements						90%

Workload

In FY 2010, 29 original NME and BLA applicants were eligible for a planned review timeline notification, a decrease of over 40 percent from FY 2009, corresponding to the decrease in the number of NME and BLAs filed. In FY 2010, FDA's commitment expanded to include efficacy supplements for new/expanded indications (see corresponding graph and table).



Planned Review Timeline Notification Eligibility

Type	FY 08	FY 09*	FY 10	FY11	FY 12
Original NMEs and BLAs	--	50	29	--	--
Efficacy Supplements for New/Expanded Indications	--	--	52	--	--

* FY 2009 numbers were changed to reflect updates to data presented in the FY 2009 PDUFA Performance Report.

Notification of Planned Review Timelines

FY 2010 Performance

As of September 30, 2010, performance data were available for over four-fifths of notifications for both original NMEs and BLAs (24 of 29) and efficacy supplements for new/expanded indications (42 of 52). FDA met the commitment for almost all (23 of 24) of notifications for original NMEs and BLAs and for most (36 of 42) of notifications for efficacy supplements (see table below). With notifications pending, FDA has the potential to exceed the performance commitment for applicant notification of planned review timelines in the filing review notification letters for original NMEs and BLAs. However, while FDA has the potential to increase the percent of applicants notified of planned review timelines in the filing review notification letters for efficacy supplements, FDA will not to meet the performance commitment level.

Application Type	Performance Commitment	Applications Filed*	Notifications Issued as of September 30, 2010			Pending Notification†
			In 74 Day Letter	Not In 74 Day Letter	Percent In 74 Day Letters	
Original NMEs and BLAs	Planned review timelines are in 90 percent of the 74 day filing review notification letters	29	23	1	**96%**	5
Efficacy Supplements for New/Expanded Indications		52	36	6	**86%**	10

* The number of original applications filed in any given year may not match the number of first cycle notifications due to the status of an application at the time the data are closed for reporting. Numbers are updated as appropriate in later fiscal year reports.

† Pending includes only those notification commitments that have not been acted on and are not past 74 days.

Meeting Planned Review Timeline Target Dates

FDA committed under PDUFA IV to report its performance in meeting the planned review timeline for communication of labeling comments and PMR/PMC requests. This commitment includes reporting on the number and percentage of applications for which the planned target dates for communication on labeling comments and PMRs/PMCs were met. As of September 30, 2010, preliminary data showed FDA met the planned target date for 22 percent of NMEs and BLAs and for 27 percent of efficacy supplements for new/expanded indications. With applications pending, FDA can increase the percent of applications meeting the target date.

Application Type	Number of 74 Day Letters With Timelines	Target Date Met	Target Date Not Met	Percent of Applications Target Date Met	Target Date Inapplicable	Applications Pending within Target Date	Withdrawn
NMEs and BLAs	23	2	7	**22%**	0	14	0
Efficacy Supplements	35*	3	8	**27%**	0	24	1

* Does not include withdrawals in count.

Included as part of this commitment, FDA agreed to report on:

- The number of times FDA met the target date where significant deficiencies in the application precluded discussion of labeling or PMRs/PMCs and FDA notified the applicant by the target date of this finding.

- The number of review timelines that were inapplicable due to FDA's decision to:
    - review solicited major amendments.
    - review unsolicited major amendments.

Significant Deficiencies/Major Amendments		
FDA Performance	NMEs and BLAs	Efficacy Supplements
Met Target Date by Communicating Deficiencies	0	0
Target Date Inapplicable – Solicited Amendment	0	0
Target Date Inapplicable – Unsolicited Amendment	0	0

FDA will update the FY 2010 data in Appendix C of the FY 2011 PDUFA Performance Report.

PDUFA IV Management Accomplishments

PDUFA IV Management Initiatives - Accomplishments

The management initiatives FDA committed to achieve under PDUFA IV were designed to improve the overall application review process. Please see Appendix A for specific details about the initiatives. No review performance levels are associated with these initiatives. A detailed description of the goals, commitments, the annual performance targets, definitions of terms, and an acronym list also can be found in Appendix A.

Performance Area	Management Initiatives	FY 2010 Accomplishments
Enhancement of Drug safety	Publish annual assessment of the PDUFA IV Drug Safety 5-Year Plan.	• FDA published the annual assessment on its website in June 2010.
	Expand access to database resources.	• FDA continued to expand a collaboration process in FY 2010 with several federal agencies that enables access to large databases for drug safety effects and signals. These collaborations include several feasibility studies with CMS; four studies with Agency for Healthcare Research and Quality (AHRQ); four ongoing studies with Veterans Health Administration; software enhancement for signal identification and confirmation via epidemiologic studies with Department of Defense (DoD); and enhancement of a Centers for Disease Control and Prevention (CDC) database for use by Center for Drug Evaluation and Research (CDER) Office of Surveillance and Epidemiology (OSE) safety evaluators and epidemiologists. FDA also has a new contract with the American Association of Poison Control Centers (AAPCC) to use the National Poison Data Base to provide FDA with data on unintentional and intentional poisonings, overdoses, and medication errors associated with select commonly used medications.
	Conduct Benefit/Risk Assessments.	• FDA held a public meeting in July 2010 to obtain public input on various aspects of REMS.
Proprietary Names	Publish final guidance document on contents of a complete submission package for a proposed proprietary drug/biological product name.	• FDA published guidance for industry titled: “Contents of a Complete Submission for the Evaluation of Proprietary Names” in February 2010.

Performance Area	Management Initiatives	FY 2010 Accomplishments
Proprietary Names (Continued)	Publish draft guidance on best practices for naming, labeling, and packaging drugs and biologics to reduce medication errors by the end of FY 2010.	• Public workshop held in June 2010 to obtain public consultation with industry, academia, and others from the general public on best practices for naming, labeling, and packaging drugs and biologics to reduce medication errors.
	Begin enrollment into the pilot program by the end of FY 2009.	• The pilot program was initiated for enrollment in October 2009.
First Cycle Review Performance Proposal	Harmonized standard operating procedures for notification of planned review timelines.	• Center for Biologics Evaluation and Research's (CBER) standard operating procedures and policies were posted on the FDA website in August 2010.
Expediting Drug Development	Develop guidance documents on clinical hepatotoxicity, non-inferiority trials, adaptive trial designs, end of Phase 2(a) meetings, multiple endpoints in clinical trials, and enriched trial designs.	• Draft guidance for non-inferiority trials published in March 2010. • Draft guidance for adaptive trial designs published in February 2010.
Improving FDA Performance Management	Conduct three major program assessments: 1) PDUFA IV adjustment for changes in review activities used in the PDUFA workload adjuster 2) Good Review Management Principles (GRMPs) implementation 3) Impact of the electronic submission and review environment on the drug review process Conduct other studies and evaluations of the drug review process as needed to improve performance management.	• In FY 2010, FDA awarded a PDUFA IV task order contract and task orders for assessing the GRMPs implementation and the electronic review environment impact. Work began on both assessments in FY 2010 and is expected to be completed in FY 2011. • In FY 2010, the PDUFA IV Performance Management Initiative funded contracts to improve the new drug review process in CDER, gain International Organization for Standardization (ISO) certification for laboratories in CDER, improve the management of postmarketing drug studies, and improve quality systems in CBER.

PDUFA IV Electronic Applications and Submissions - Accomplishments

The electronic applications and submissions initiatives FDA committed to achieve under PDUFA IV were designed to improve the overall application review process. Please see Appendix A for specific details about the initiatives.

Electronic Applications and Submissions Initiative	FY 2010 Accomplishments
Update technical specifications and IT-related guidance documents as necessary.	• Draft Guidance for industry – Structure Product Labeling (SPL) Standard for Content of Labeling Technical Qs & As, October 2009
Extend the capability of the secure electronic single point of entry to include two-way transmission of regulatory correspondence. Establish an automated standards-based regulatory submission and review environment for INDs, NDAs, BLAs, and their supplements.	• Testing regulated product submission (RPS) release 2 message – July through September 2010 • Passed health level seven (HL7) draft standard for trial use (DSTU) ballot – January 2010
Establish standards-based information systems to support how FDA obtains and analyzes postmarket drug safety data and manages emerging drug safety information.	• First Prototype for FAERS was delivered to FDA (by SRA) with focus on CDER and CBER in March 2010. • Delivered FAERS prototype training to CDER, CBER, and Data Entry in May 2010. • Delivered final FAERS Boundary Document and was approved at the initiation stage gate review held on July 15, 2010. • Completed FAERS evaluation feedback from CDER and data entry based on prototype training in August 2010. • Completed FAERS product dictionary requirements document in September 2010.

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APPENDICES

APPENDIX A: PDUFA IV Performance Goals FY 2008 – FY 2012

The table below summarizes, by fiscal year, the performance measures set forth in the letters referenced in Title I of the FDAAA for PDUFA IV. Goal summaries for the earlier years of PDUFA can be found in the Appendix of earlier PDUFA Performance Reports at http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/UserFeeReports/PerformanceReports/PDUFA/default.htm.

I. Review Performance Goals

	On-Time Performance Level for Fiscal Year of Filing or Receipt				
	2008	2009	2010	2011	2012
Review and act on priority original NDAs and BLAs within 6 months of receipt.[4]	90% on time				
Review and act on standard original NDAs and BLAs within 10 months of receipt.[4]					
Review and act on priority efficacy supplements within 6 months of receipt.[4]					
Review and act on standard efficacy supplements within 10 months of receipt.[4]					
Review and act on all manufacturing supplements within 6 months of receipt and those requiring prior approval within 4 months of receipt.[5]					
Review and act on Class 1 resubmitted original applications within 2 months of receipt.[4]					
Review and act on Class 2 resubmitted original applications within 6 months of receipt.[4]					
Review and act on Class 1 resubmitted efficacy supplements within 2 months of receipt.					
Review and act on Class 2 resubmitted efficacy supplements within 6 months of receipt.[4]					

II. NME Performance Goals

	On-Time Performance Level for Fiscal Year of Filing or Receipt				
	2008	2009	2010	2011	2012
Review and act on priority original NMEs and BLAs within 6 months of receipt.	90% on time				
Review and act on standard original NMEs and BLAs within 10 months of receipt.					

[4] 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 and IV, it also applies to efficacy supplements and Class 2 resubmitted NDAs, BLAs, and efficacy supplements.

[5] 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.

III. Procedural and Processing Goals

Performance Area	FDA Activity	Performance Goal	Performance Level FY 2008 – FY 2012
Meeting Management	Meeting Requests -- Notify requestor of formal meeting in writing (date, time, place, and participants).	Type A Meetings within 14 days of receipt of request.	90% on time
		Type B Meetings within 21 days of receipt of request.	
		Type C Meetings within 21 days of receipt of request.	
	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 prepares and provides to the sponsor minutes clearly outlining agreements, disagreements, issues for further discussion and action items.	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.	
Major Dispute Resolution	Response to sponsor's appeal of decision.	Within 30 days of receipt of sponsor's appeal.	
Special Protocol Assessment*	Response to sponsor's request for evaluation of protocol design.	Within 45 days of receipt of protocol and questions.	

* FDA also agreed to track and report the number of resubmissions per original special protocol assessment.

IV. Review of Proprietary Names To Reduce Medication Errors Commitments

Performance Area	Initiative	Commitment	Performance Level and/or Implementation Timeline by Fiscal Year -- Not applicable X Action due				
			2008	2009	2010	2011	2012
Enhancement and Modernization of the Drug Safety System	Development of 5-year plan and communication and technical interactions	FDA will publish a draft 5-year plan by March 31, 2008.	X	--	--	--	--
		FDA will publish the final 5-year plan no later than December 31, 2008.	--	X	--	--	--
		Conduct and publish an annual assessment of progress against the 5-year plan by September 30, 2009.	--	X	--	--	--
	Conduct and support activities designed to modernize the process of pharmaco-vigilance	Maximize the public health benefit of adverse event collection throughout the product lifecycle. Publish a request for proposals (RFP) by September 30, 2008. Award contracts during FY 2009. Complete contract studies by FY 2011.	X	X	X	X	--
		Epidemiology best practices and guidance document development During FY 2008 hold a public workshop to identify epidemiology best practices. Develop joint CDER and CBER draft guidance by the end of FY 2010. Issue final guidance in FY 2011.	X	--	X	X	--

Performance Area	Initiative	Commitment	Performance Level and/or Implementation Timeline by Fiscal Year -- Not applicable X Action due				
			2008	2009	2010	2011	2012
Enhancement and Modernization of the Drug Safety System (continued)	Conduct and support activities designed to modernize the process of pharmaco-vigilance (continued)	Develop and validate risk management and risk communication tools. During FY 2008 develop a plan to identify risk management tools and programs and conduct assessments of current tools and RiskMAPS. During FY 2009 hold a public workshop to obtain stakeholder input on evaluations. Starting in FY 2009 conduct annual effectiveness reviews of risk management programs and tools.	X	X	--	--	--
Review Performance Goals – Drug/Biological Product Proprietary Names	Review of proprietary names submitted during IND phase (as early as end-of-phase 2)	Within 180 days of receipt. Notify sponsor of tentative acceptance or non-acceptance.	--	50%	70%	90%	
	Review of proprietary names submitted with NDA/BLA	Within 90 days of receipt. Notify applicant of tentative acceptance or non-acceptance.					
	Guidance document development	By the end of FY 2008, FDA will publish a final guidance on the contents of a complete submission package for a proposed proprietary drug/biological product name.	X	--	--	--	--

Performance Area	Initiative	Commitment	Performance Level and/or Implementation Timeline by Fiscal Year -- Not applicable X Action due				
			2008	2009	2010	2011	2012
Review Performance Goals – Drug/Biological Product Proprietary Names (continued)	Guidance document development (continued)	By the end of FY 2009, FDA will prepare a MaPP (Manual of Policies and Procedures) to ensure that FDA internal processes are consistent with meeting the proprietary name review goals.	--	X	--	--	--
		By the end of FY 2010, FDA will publish draft guidance on best practices for naming, labeling and packaging drugs and biologics to reduce medication errors. Final guidance will be published by the end of FY 2011.	--	--	X	X	--
		By the end of FY 2012 FDA will publish draft guidance on proprietary name evaluation best practices. Publication of final guidance on proprietary name evaluation best practices will follow as soon as feasible.	--	--	--	--	X
Pilot Program	During PDUFA IV, FDA will develop and implement a pilot program to enable pharmaceutical firms participating in the pilot to evaluate proposed proprietary names and submit the data generated from those evaluations to the FDA for review.	FDA will hold a public technical meeting to discuss the elements necessary to create a concept paper describing the logistics of the pilot program, the contents of a proprietary name review submission, and the criteria to be used by FDA to review submissions under the pilot program. Subsequently, by the end of FY 2008, FDA will publish the concept paper.	X	--	--	--	--

Performance Area	Initiative	Commitment	Performance Level and/or Implementation Timeline by Fiscal Year -- Not applicable X Action due				
			2008	2009	2010	2011	2012
Pilot Program (continued)	During PDUFA IV, FDA will develop and implement a pilot program to enable pharmaceutical firms participating in the pilot to evaluate proposed proprietary names and submit the data generated from those evaluations to the FDA for review. (continued)	By the end of FY 2009, FDA will begin enrollment into the pilot program.	--	X	--	--	--
		By the end of FY 2011, or subsequent to accruing 2 years of experience with pilot submissions, FDA will evaluate the pilot program.	--	--	--	X	--
Other Activities	FDA and industry are interested in exploring the possibility of "reserving" proprietary names for companies once the names have been tentatively accepted by the Agency.	By the end of FY 2008, FDA will initiate a public process to discuss issues around "reserving" proprietary names.	X	--	--	--	--
		FDA will provide the full source code and supporting technical documentation for the Phonetic and Orthographic Computer Analysis (POCA) tool and make it available on disk for use by industry and others from the general public by end of FY 2008.	X	--	--	--	--

V. FIRST CYCLE REVIEW PERFORMANCE PROPOSAL

<table>
<tr><th rowspan="4">Performance Area</th><th rowspan="4">Initiative</th><th rowspan="4">Commitment</th><th colspan="5">Performance Level and/or Implementation Timeline by Fiscal Year</th></tr>
<tr><td colspan="5">-- Not applicable</td></tr>
<tr><td colspan="5">X Action due</td></tr>
<tr><th>2008</th><th>2009</th><th>2010</th><th>2011</th><th>2012</th></tr>
<tr><td>Notification of Issues Identified during the filing review</td><td>For original NDA/BLA applications and efficacy supplements, FDA will report substantive review issues (or lack thereof) identified in the initial filing review to the sponsor by letter, telephone conference, facsimile, secure e-mail, or other expedient means.</td><td>FDA will provide the applicant a notification of substantive review issues (or lack thereof) within 14 days after the 60-day filing date.</td><td colspan="5">90%</td></tr>
<tr><td rowspan="4">Notification of Planned Review Timelines</td><td rowspan="4">For original NDA/BLA applications and efficacy supplements, FDA will inform the applicant of the planned timeline for review of the application. The information conveyed will include a target date for communication of feedback from the review division to the applicant regarding proposed labeling and postmarketing requirements and postmarketing commitments (PMCs) the Agency will be proposing.</td><td>Original BLAs and NME NDAs within 14 calendar days after the 60-day filing date.</td><td>--</td><td colspan="4">90%</td></tr>
<tr><td>Efficacy supplements for new/expanded indications within 14 calendar days after the 60-day filing date.</td><td>--</td><td>--</td><td colspan="3">90%</td></tr>
<tr><td>All original NDAs within 14 calendar days after the 60-day filing date.</td><td>--</td><td>--</td><td>--</td><td colspan="2">90%</td></tr>
<tr><td>All efficacy supplements within 14 calendar days after the 60-day filing date.</td><td>--</td><td>--</td><td>--</td><td>--</td><td>90%</td></tr>
</table>

Performance Area	Initiative	Commitment	Performance Level and/or Implementation Timeline by Fiscal Year -- Not applicable X Action due				
			2008	2009	2010	2011	2012
Report on Review Timeline Performance	FDA will report its performance in meeting goals for notification of review timelines in the annual PDUFA performance Report.	--	--	X	X	X	X
	Engage an independent consultant to analyze FDA's success in meeting review timelines. A final report will be due to FDA by March 31, 2011.	--	--	--	--	X	--
Standard Operating Procedures and Training	FDA will develop harmonized (CBER/CDER) standard operating procedures (SOPs) regarding the notification of planned review timelines. Training will be provided to all CBER and CDER review staff on the harmonized (CBER/CDER) standard operating procedures.	These SOPs will be finalized and implemented by the end of FY 2008.	X	--	--	--	--
Standard Operating Procedures and Training (continued)	Training	All new review staff and refresher training will be provided to all review staff as necessary through FY 2012.	X	X	X	X	X

VI. Expediting Drug Development

Performance Area	Initiative	Commitment	Performance Level and/or Implementation Timeline by Fiscal Year -- Not applicable X Action due				
			2008	2009	2010	2011	2012
Guidance Development	FDA will develop and publish for comment draft guidance on the following topics by the end of the indicated fiscal year of PDUFA-IV. FDA will complete the final guidance within one year of the close of the public comment period.	Clinical Hepatotoxicity	X	--	--	--	--
		Non-inferiority Trials	X	--	--	--	--
		Adaptive Trial Designs	X	--	--	--	--
		End of Phase 2(a) Meetings	X	--	--	--	--
		Multiple Endpoints in Clinical Trials	--	X	--	--	--
		Enriched Trial Designs	--	--	X	--	--
		Imaging Standards for Use as an End Point in Clinical Trials	--	--	--	X	--
Ongoing Scientific Collaboration	Workshops	FDA will participate in workshops with scientific stakeholders to further the science toward development of guidance documents in the following areas: Predictive Toxicology, Biomarker Qualification, Missing Data	X	X	X	X	X

Performance Area	Initiative	Commitment	Performance Level and/or Implementation Timeline by Fiscal Year -- Not applicable X Action due				
			2008	2009	2010	2011	2012
Benefit/Risk Assessment	Workshops and public meetings	Participate in workshops and public meetings to explore new approaches to a structured model for benefit/risk assessment. Determine if pilots should be conducted or guidance documents issued.	X	X	X	X	X

VII. Postmarketing Study Commitments

Performance Area	Initiative	Commitment	Performance Level and/or Implementation Timeline by Fiscal Year -- Not applicable X Action due				
			2008	2009	2010	2011	2012
Postmarketing Study Commitments	FDA will develop harmonized (CBER/CDER) standard operating procedures that articulate the Agency's policy and procedures (e.g., timing, content, rationale and vetting process) for requesting that applicants agree in writing to voluntary postmarketing study commitments.	The SOPs will be finalized prior to the end of FY 2008.	X	--	--	--	--
		In developing these SOPs, the Agency will take into consideration the findings of the contractor study of current Agency procedures to be completed during FY 2007. FDA will make available a releasable version of the final report within 2 months of receipt from the contractor.	X	X	--	--	--
		Training will be provided to all CBER and CDER review staff on the harmonized (CBER/CDER) standard operating procedures. Training will continue for all new review staff and refresher training will be provided to all review staff as necessary through FY 2012.	X	X	X	X	X

VIII. IMPROVING FDA PERFORMANCE MANAGEMENT

Performance Area	Initiative	Commitment	Performance Level and/or Implementation Timeline by Fiscal Year -- Not applicable X Action due				
			2008	2009	2010	2011	2012
Improving FDA Performance Management	Studies will include: 1. Assessment of the impact of the electronic submission and review environment on the efficiency and effectiveness of the overall process for the review of human drugs. 2. Assessment of the progress toward full implementation of Good Review Management Principles, focusing on both FDA reviewer practices and industry sponsor practices affecting successful implementation. 3. Assessment by an independent accounting firm of the review activity adjustment methodology (as described in section 736(c)(2) that is applied in FY 2009 with recommendations for changes, if warranted.	Complete the assessment of the review activity adjustment methodology in FY 2009 prior to fee setting for FY 2010. Complete the electronic review and GRMPs assessments as appropriate during PDUFA IV.	---	X	---	---	---

IX. INFORMATION TECHNOLOGY GOALS

Initiatives	Implementation Deadline by Fiscal Year -- Not applicable X Action due				
	2008	**2009**	**2010**	**2011**	**2012**
Develop and periodically update an IT plan, covering a rolling 5-year planning horizon.	X	X	X	X	X
Develop, implement, and maintain new information systems consistently across all organizational divisions participating in the process for the review of human drug applications, and in compliance with the IT plan, the FDA's program-wide governance process, the FDA's target enterprise architecture, and with HHS enterprise architecture standards. The consistency of development, implementation, and maintenance of new information systems will be determined by the FDA based on considerations of program efficiency and effectiveness. Emphasis will be placed on the consistency of interactions with regulated parties and other external stakeholders	X	X	X	X	X
Update technical specifications and IT-related guidance documents as necessary to reflect consistent program-wide implementation of new information systems supporting electronic information exchange between FDA and regulated parties and other external stakeholders.	X	X	X	X	X
Extend the capability of the secure electronic single point of entry to include two-way transmission of regulatory correspondence.	X	X	X	X	X
Establish an automated standards-based regulatory submission and review environment for INDs, NDAs, and BLAs, and their supplements, that enables the following functions over the life cycle of the product: (1) Electronic IND, NDA, and BLA submissions received by FDA can be archived to enable retrieval through standardized automated links; (2) Electronic IND, NDA, and BLA submissions can include cross-references to previously submitted electronic materials through standardized automated links; and (3) Archived electronic IND, NDA, and BLA submissions can be retrieved through standardized automated links.	X	X	X	X	X
Establish a system for electronic exchange and management of human drug labeling information in a modular manner (e.g., at the label section level) that is based on FDA standards and that enables revision tracking.	X	X	X	X	X
Establish standards-based information systems to support how FDA obtains and analyzes post-market drug safety data and manages emerging drug safety information, as described in Section VIII addressing the enhancement and modernization of the FDA drug safety system.	X	X	X	X	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.

Acronyms

BLAs – Biologics License Applications

CBER – Center for Biologics Evaluation and Research

CDER – Center for Drug Evaluation and Research

FDA – Food and Drug Administration

FDAAA – Food and Drug Administration Amendments Act of 2007

FY – Fiscal Year

GRMP – Good Review Management Principles

HHS – Department of Health and Human Services

IND – Investigational New Drug

MAPP – Manual of Policies and Procedures

NDAs – New Drug Applications

NMEs – New Molecular Entities

PDUFA – Prescription Drug User Fee Act

PEPFAR – President's Emergency Plan for AIDS Relief

PMC – Postmarketing Commitments

PMR – Postmarketing Requirements

POCA – Phonetic and Orthographic Computer Analysis

REMS – Risk Evaluation and Mitigation Strategy

RFP – Request for Proposals

SOP – Standard Operating Procedure

SPAs – Special Protocol Assessments

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APPENDIX B: List of Approved Applications

This appendix updates the detailed review histories of the NDA and BLA submissions approved under PDUFA in FY 2010. Approvals are grouped by submission year and priority designation and listed in order of total approval time. Review histories of NDA and BLA submissions approved prior to FY 2010 can be found in the appendices of the earlier PDUFA Performance Reports that are available at http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/UserFeeReports/PerformanceReports/PDUFA/default.htm.

Terms and Coding Used in Tables

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

◊ 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 (PEPFAR).

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

Impact of Severe Weather on Approving Applications for FY 2010

Due to the extreme weather conditions, Federal Government offices in the Washington, DC, metropolitan area, including those of the FDA, were closed from February 8, 2010, to February 11, 2010. In addition, the building at FDA's White Oak campus that houses most of the new drug review staff for FDA as well as the document room was closed for an additional day on Friday, February 12, 2010, due to emergency building maintenance.

Due to these closures, FDA put procedures in place to manage PDUFA goals that came due during, or soon after, the closure of our offices. These procedures apply to all PDUFA goals, including those related to the review of INDs, NDAs, BLAs, and supplemental applications to NDAs and BLAs. The FDA extended the PDUFA goals to February 22, 2010 (5 business days after reopening on February 16, 2010) for any PDUFA goals that came due during the week of February 8, 2010. For goals due the week of February 15, 2010, the PDUFA goal was extended by 5 business days.

For PDUFA goals that were due February 22, 2010, and beyond, FDA assessed the practicality of meeting the goal and extended the goal as needed on a case-by-case basis, but no more than 5 business days.

Table 1
FY 2010 Priority NDA and BLA Approvals (by FY of receipt)

Receipt Cohort (FY)	Established/Proper Name	Applicant	NME (Y/N)	Approval Time (Months)				Goal Met
				Review Cycle	Cycle Time	Cycle Result	Total Time	
2010	JEVTANA	SANOFI AVENTIS US INC	Y	First	2.6	AP	2.6	Y
	PILOCARPINE HYDROCHLORIDE OPHTHALMIC SOLUTION, 1%, 2% AND 4%	ALCON INC	N	First	6.0	AP	6.0	Y
	LAMIVUDINE/NEVIRAPINE/ZIDOVUDINE TABLETS FOR ORAL SUSPENSION (30MG/50MG/60MG)	MATRIX LABORATORIES LTD	N	First	6.0	TA	6.0	Y◊
	FINGOLIMOD HCL ORAL CAPSULES	NOVARTIS PHARMACEUTICALS CORP	Y	First	9.0	AP	9.0	Y+
2009	VELAGLUCERASE ALFA	SHIRE HUMAN GENETIC THERAPIES INC	Y	First	5.9	AP	5.9	Y
	Ofatumumab	Glaxo Group Limited d/b/a GlaxoSmithKline	Y	First	8.9	AP	8.9	Y+
	CARBAGLU (CARGLUMIC ACID)	ORPHAN EUROPE	Y	First	9.0	AP	9.0	Y+
	XIFAXAN	SALIX PHARMACEUTICALS INC	N	First	9.0	AP	9.0	Y+
	FAMPRIDINE TABLETS	ACORDA THERAPEUTICS INC	N	First	9.0	AP	9.0	Y+
	LYSTEDA	FERRING PHARMACEUTICALS AS	N	First	9.5	AP	9.5	N
	Pneumococcal 13-valent Conjugate Vaccine (Diphtheria CRM197 Protein)	WYETH PHARMACEUTICALS INC.	Y	First	10.8	AP	10.8	N+
	HEXVIX	PHOTOCURE ASA	N	First	6.0	CR	6.0	Y
				Applicant	3.1	--	9.1	--
				Second	1.9	AP	11.0	Y
	Clostridial Collagenase	AUXILIUM PHARMACEUTICAL INC	Y	First	11.2	AP	11.2	N

Receipt Cohort (FY)	Established/Proper Name	Applicant	NME (Y/N)	Approval Time (Months)				Goal Met
				Review Cycle	Cycle Time	Cycle Result	Total Time	
2008	C1 Esterase Inhibitor (Human)	CSL BEHRING GMBH	Y	First	8.9	CR	8.9	Y+
				Applicant	4.1	--	13.0	--
				Second	6.0	AP	19.0	Y
	OXYCONTIN	PURDUE PHARMA LP	N	First	10.2	CR	10.2	N
				Applicant	16.2	--	26.4	--
				Second	2.0	AP	28.4	Y
2007	Sipuleucel-T	DENDREON CORPORATION	Y	First	5.8	CR	5.8	Y
				Applicant	29.7	--	35.5	--
				Second	6.0	AP	41.5	Y

Table 2
FY 2010 Standard NDA and BLA Approvals (by FY of receipt)

Receipt Cohort (FY)	Established/Proper Name	Applicant	NME (Y/N)	Approval Time (Months)				Goal Met
				Review Cycle	Cycle Time	Cycle Result	Total Time	
2010	CETIRIZINE HCL ORALLY 10MG TABS	MCNEIL CONSUMER HEALTHCARE DIV MCNEIL PPC INC	N	First	9.8	AP	9.8	Y
	ALISKIREN/AMLODPINE(SPA 100A)FIXED COMBO	NOVARTIS PHARMACEUTICALS CORP	N	First	9.9	AP	9.9	Y
	ELLA , ULIPRISTAL ACETATE	LABORATOIRE HRA PHARMA	Y	First	10.0	AP	10.0	Y
	LAMIVUDINE/NEVIRAPINE/STAVUDINE FDC TABS (150MG/200MG/30MG)	MACLEODS PHARMACEUTICALS LTD	N	First	10.0	TA	10.0	Y◊
	LAMIVUDINE/NEVIRAPINE/STAVUDINE FDC TABS (150MG/200MG/30MG)	HETERO DRUGS LTD UNIT III	N	First	10.0	TA	10.0	Y
2009	GATIFLOXACIN OPHTHALMIC SOLUTION 0.5%	ALLERGAN	N	First	9.6	AP	9.6	Y
	PANCREAZE	ORTHO MCNEIL JANSSEN PHARMACEUTICALS INC	N	First	9.7	AP	9.7	Y
	VARDENAFIL HCL	BAYER HEALTHCARE PHARMACEUTICALS INC	N	First	9.7	AP	9.7	Y
	CS-8635 COMBINATION OF OLMESARTAN MEDOXOMIL/AMLODIPINE/HYDROCHLOROTHIAZIDE	DAIICHI SANKYO INC	N	First	9.8	AP	9.8	Y
	ROMIDEPSIN FOR INFUSION	CELGENE CORP	Y	First	9.8	AP	9.8	Y
	TBD (PRAMIPEXOLE DIHYDROCHLORIDE)ER TABS	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	N	First	9.9	AP	9.9	Y
	TELMISARTAN/AMLODIPINE FIXED DOSE COM TB	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	N	First	9.9	AP	9.9	Y
	DONEPEZIL HYDROCHLORIDE	EISAI INC	N	First	9.9	AP	9.9	Y

Receipt Cohort (FY)	Established/Proper Name	Applicant	NME (Y/N)	Approval Time (Months)				Goal Met
				Review Cycle	Cycle Time	Cycle Result	Total Time	
2009	INDOMETHACIN PATCH	APP PHARMACEUTICALS LLC	N	First	9.9	AP	9.9	Y
	EFAVIRENZ NONSCORED TABS (50MG, 100MG, 200MG)	MATRIX LABORATORIES LTD	N	First	9.9	TA	9.9	Y◊
	LAMIVUDINE/NEVIRAPINE/ZIDOVUDIN TABS (150MG/200MG/300MG)	STRIDES ARCOLAB LTD	N	First	9.9	TA	9.9	Y◊
	REVATIO	PFIZER INC	N	First	9.9	AP	9.9	Y
	CLONIDINE POLISTIREX ER ORAL SUSPENSION	TRIS PHARMA INC	N	First	10.0	AP	10.0	Y
	CLONIDINE POLISTIREX ER ORAL TABLETS	TRIS PHARMA INC	N	First	10.0	AP	10.0	Y
	GLYCOPYRROLATE ORAL SOLUTION	SHIONOGI PHARMA INC	N	First	10.0	AP	10.0	Y
	KETOPROFEN ORAL-ORAL DISSOLVING STRIPS	NOVARTIS CONSUMER HEALTH INC	N	First	10.0	AP	10.0	Y
	LAMICTAL XR(LAMOTRIGINE) ORAL TABLETS	SMITHKLINE BEECHAM CORP DBA GLAXOSMITHKLINE	N	First	10.0	AP	10.0	Y
	LASTACAFT (ALCAFTADINE OPHTHALMIC SOLUTION) 0.25%	VISTAKON PHARMACEUTICALS LLC	Y	First	10.0	AP	10.0	Y
	LYRICA (PREGABALIN)	PFIZER INC	N	First	10.0	AP	10.0	Y
	NAMENDA XR(MEMANTINE HCL)ER CAPSULES	FOREST LABORATORIES INC	N	First	10.0	AP	10.0	Y
	NATAZIA	BAYER HEALTHCARE PHARMACEUTICALS INC	N	First	10.0	AP	10.0	Y[6]
	ORAVIG (MICONAZOLE) BUCCAL TABLETS	BIOALLIANCE PHARMA	N	First	10.0	AP	10.0	Y
	PN 400 NAPROXEN/ESOMEPRAZOLE MAGNESIUM	ASTRAZENECA LP	N	First	10.0	AP	10.0	Y
	VOTRIENT TABLETS	GLAXOSMITHKLINE	N	First	10.0	AP	10.0	Y+

[6] This application was approved for one indication and issued a complete response for another indication. The action for the second indication will be reported as an efficacy supplement.

Receipt Cohort (FY)	Established/Proper Name	Applicant	NME (Y/N)	Approval Time (Months)				Goal Met
				Review Cycle	Cycle Time	Cycle Result	Total Time	
2009	ZEGERID	SANTARUS INC	N	First	10.0	AP	10.0	Y
	Fibrin Sealant Patch	NYCOMED DANMARK APS	Y	First	10.0	AP	10.0	Y
	LAMIVUDINE/STAVUDINE FDC TABS (150MG/30MG)	HETERO DRUGS LTD	N	First	10.0	TA	10.0	Y◊
	LAMIVUDINE/TENOFOVIR DISOPROXIL FUMARATE FDC TABS (300MG/300MG)	HETERO DRUGS LTD	N	First	10.0	TA	10.0	Y◊
	ADVIL CONGESTION RELIEF	WYETH CONSUMER HEALTHCARE	N	First	10.0	AP	10.0	Y
	DOCEFREZ INJECTION (20/80 MG/VIAL)	SUN PHARMA GLOBAL FZE	N	First	10.0	TA	10.0	Y
	Immune Globulin Subcutaneous (Human), 20% Liquid	CSL BEHRING AG	Y	First	10.2	AP	10.2	Y[7]
	NEVIRAPINE TABS FOR ORAL SUSPENSION (50MG)	AUROBINDO PHARMA LTD	N	First	10.2	TA	10.2	Y◊+[7]
	COLCRYS (COLCHICINE, USP) TABLETS, 0.6 MG	MUTUAL PHARMACEUTICAL CO INC	N	First	10.7	AP	10.7	N
	EFAVIRENZ 200MG SCORED TABLETS	STRIDES ARCOLAB LTD	N	First	5.2	CR	5.2	Y◊
				Applicant	4.3	--	9.5	--
				Second	2.1	TA	11.6	Y◊+[7]
	DIFFERIN LOTION	GALDERMA RESEARCH AND DEVELOPMENT INC	N	First	12.5	AP	12.5	Y+
	Botulinum Neurotoxin Type A	MERZ PHARMACEUTICALS GMBH	Y	First	12.9	AP	12.9	Y+
	Lamivudine/Stavudine FDC Tabs (150mg/30mg)	MACLEODS PHARMACEUTICALS LTD	N	First	12.9	TA	12.9	Y◊+
	Alpha-1-Proteinase Inhibitor (Human)	KAMADA LTD	Y	First	13.0	AP	13.0	Y+

[7] Goal extensions were made to this submission due to the February blizzard, and subsequent closing of the Government for 1 week (see page B-1 for additional information).

Receipt Cohort (FY)	Established/Proper Name	Applicant	NME (Y/N)	Approval Time (Months)				Goal Met
				Review Cycle	Cycle Time	Cycle Result	Total Time	
2009	BEYAZ	BAYER HEALTHCARE PHARMACEUTICALS INC	N	First	13.0	AP	13.0	Y+
	HYPHANOX 200MG FILM-COATED TABLETS	STIEFEL LABORATORIES INC	N	First	13.0	AP	13.0	Y+
	MOMETASONE FUROATE/FORMOTEROL FUMARATE	SCHERING CORP	N	First	13.0	AP	13.0	Y+[6]
	QUTENZA	NEUROGESX INC	N	First	13.0	AP	13.0	Y+
	RITONAVIR TABLET	ABBOTT LABORATORIES	N	First	9.9	CR	9.9	Y
				Applicant	1.9	--	11.8	--
				Second	2.0	AP	13.8	Y
	ZUPLENZ (ONDASETRON) ORALLY-DISSOLVING F	PAR PHARMACEUTICAL	N	First	10.0	CR	10.0	Y
				Applicant	2.9	--	12.9	--
				Second	2.0	AP	14.9	Y
	ARTICAINE 4% /EPINEPHRINE 1:20000 INJ	PIERREL S.P.A.	N	First	10.0	CR	10.0	Y
				Applicant	3.2	--	13.2	--
				Second	2.0	AP	15.2	Y
	IMIQUIMOD 3.75% CREAM	GRACEWAY PHARMACEUTICALS LLC	N	First	9.9	CR	9.9	Y
				Applicant	3.5	--	13.4	--
				Second	1.8	AP	15.2	Y
	PRAMIPEXOLE DIHYDROCHLORIDE	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	N	First	10.0	CR	10.0	Y
				Applicant	3.7	--	13.7	--
				Second	2.2	AP	15.9	Y[7]
	SPRIX (KETOROLAC TROMETHAMINE) NASAL SPRAY	ROXRO PHARMA INC	N	First	10.0	CR	10.0	Y
				Applicant	1.6	--	11.6	--
				Second	5.8	AP	17.4	Y

Receipt Cohort (FY)	Established/Proper Name	Applicant	NME (Y/N)	Approval Time (Months)				Goal Met
				Review Cycle	Cycle Time	Cycle Result	Total Time	
2009	Denosumab TO	AMGEN, INC	Y	First	9.9	CR	9.9	Y
				Applicant	3.3	--	13.2	--
				Second	4.2	AP	17.4	Y
	VICTOZA (LIRAGLUTIDE)	NOVO NORDISK INC	Y	First	20.1	AP	20.1	N
	ZEGERID OTC CAPSULES	SCHERING PLOUGH HEALTHCARE PRODUCTS INC	N	First	9.9	CR	9.9	Y
				Applicant	5.1	--	15.0	--
				Second	5.8	AP	20.8	Y
	SUBOXONE (BUPRENORPHINE/NALOXONE) SUBLINGUAL FILM	RECKITT BENCKISER PHARMACEUTICALS INC	N	First	10.0	CR	10.0	Y
				Applicant	3.4	--	13.4	--
				Second	9.0	AP	22.4	Y+
2008	Influenza Vaccine	NOVARTIS VACCINES AND DIAGNOSTICS, INC.	Y	First	9.5	CR	9.5	Y
				Applicant	1.1	--	10.6	--
				Second	5.9	AP	16.5	Y
	TRAZODONE CONTRAMID OAD E-R CAPLET	LABOPHARM INC	N	First	9.9	CR	9.9	Y
				Applicant	0.9	--	10.8	--
				Second	5.8	AP	16.6	Y
	Meningococcal [Groups A, C, Y, and W 135] Oligosaccharide Diphtheria CRM197 Conjugate Vaccine	Novartis Vaccines and Diagnostics, Inc.	Y	First	9.9	CR	9.9	Y
				Applicant	1.9	--	11.8	--
				Second	5.9	AP	17.7	Y
	TRELSTAR 6-MONTH	WATSON LABORATORIES INC	N	First	9.9	CR	9.9	Y
				Applicant	2.1	--	12.0	--
				Second	5.9	AP	17.9	Y
	CEFEPIME	B BRAUN MEDICAL INC	N	First	9.8	CR	9.8	Y
				Applicant	3.6	--	13.4	--
				Second	6.0	AP	19.4	Y

Receipt Cohort (FY)	Established/Proper Name	Applicant	NME (Y/N)	Approval Time (Months)				Goal Met
				Review Cycle	Cycle Time	Cycle Result	Total Time	
2008	SUMATRIPTAN SUCCINATE AUTO-INJECTOR	KING PHARMACEUTICALS INC	N	First	9.9	CR	9.9	Y
				Applicant	7.5	--	17.4	--
				Second	6.0	AP	23.4	Y
	SUPREP BOWEL PREP KIT	BRAINTREE LABORATORIES INC	N	First	25.1	AP	25.1	N
	SILENOR (DOXEPIN HCL)	SOMAXON PHARMACEUTICALS INC	N	First	12.9	CR	12.9	Y+
				Applicant	3.3	--	16.2	--
				Second	6.0	CR	22.2	Y
				Applicant	1.6	--	23.8	--
				Third	1.8	AP	25.6	Y
	WELCHOL POWDER FOR ORAL SUSPENSION	DAIICHI SANKYO INC	N	First	27.2	AP	27.2	N
	CAYSTON(AZTREONAM FOR INHALATION SOL)	GILEAD SCIENCES INC	N	First	10.0	CR	10.0	Y
				Applicant	10.9	--	20.9	--
				Second	6.4	AP	27.3	Y[7]
	ARGATROBAN INJECTION	BAXTER HEALTHCARE CORP	N	First	13.0	CR	13.0	N
				Applicant	2.2	--	15.2	--
				Second	6.0	CR	21.2	Y
				Applicant	0.2	--	21.4	--
				Third	6.0	TA	27.4	Y
2007	Human Papillomavirus Bivalent (Types 16 and 18) Vaccine, Recombinant	GLAXOSMITHKLINE BIOLOGICALS	Y	First	8.5	CR	8.5	Y
				Applicant	15.5	--	24.0	--
				Second	6.6	AP	30.6	N
	VIMPAT	SCHWARZ BIOSCIENCES INC	N	First	13.0	CR	13.0	Y+
				Applicant	11.8	--	24.8	--
				Second	6.0	AP	30.8	Y

Receipt Cohort (FY)	Established/Proper Name	Applicant	NME (Y/N)	Approval Time (Months)				Goal Met
				Review Cycle	Cycle Time	Cycle Result	Total Time	
2007	ZYPREXA RELPREVV (OLANZAPINE)	ELI LILLY CO	N	First	9.9	NA	9.9	Y
				Applicant	3.7	--	13.6	--
				Second	6.0	CR	19.6	Y
				Applicant	2.9	--	22.5	--
				Third	9.0	AP	31.5	N
	von Willebrand Factor/Coagulation Factor VIII Complex (Human)	OCTAPHARMA PHARMAZEUTIKA PRODUKTIONSGE S.M.B.H.	Y	First	12.8	CR	12.8	Y+
				Applicant	16.9	--	29.7	--
				Second	6.0	AP	35.7	Y
2004	BYETTA (EXENATIDE) INJECTION	AMYLIN PHARMACEUTICA LS INC	N	First	9.9	AE	9.9	Y
				Applicant	34.8	--	44.7	--
				Second	19.4	AP	64.1	N
	VELTIN	STIEFEL A GSK CO	N	First	9.5	NA	9.5	Y
				Applicant	52.3	--	61.8	--
				Second	9.0	AP	70.8	Y+
	ASCLERA (POLIDOCANOL) 0.5%/1%	CHEMISCHE FABRIK KREUSSLER AND CO GMBH	Y	First	10.0	NA	10.0	Y
				Applicant	59.3	--	69.3	--
				Second	8.7	AP	78.0	Y+
2002	ZORTRESS (EVEROLIMUS) TABLETS	NOVARTIS PHARMACEUTICA LS CORP	N	First	10.0	AE	10.0	Y
				Applicant	4.3	--	14.3	--
				Second	6.0	AE	20.3	Y
				Applicant	58.2	--	78.5	--
				Third	5.8	CR	84.3	Y
				Applicant	1.0	--	85.3	--
				Fourth	2.9	AP	88.2	Y
2001	BUTRANS (BUPRENORPHINE) TRANSDERMAL SYSTEM	PURDUE PHARMA LP	N	First	9.9	NA	9.9	Y
				Applicant	97.1	--	107.0	--
				Second	9.0	AP	116.0	Y+

Receipt Cohort (FY)	Established/Proper Name	Applicant	NME (Y/N)	Approval Time (Months)				Goal Met
				Review Cycle	Cycle Time	Cycle Result	Total Time	
2000	EXALGO (HYDROMORPHONE HCL) 8/12/16	MALLINCKRODT INC	N	First	10.0	AE	10.0	Y
				Applicant	102.9	--	112.9	--
				Second	9.3	AP	122.2	Y+[7]
1998	DICLOFENAC SODIUM	MALLINCKRODT INC	N	First	12.0	NA	12.0	Y[8]
				Applicant	46.8	--	58.8	--
				Second	6.0	AE	64.8	Y
				Applicant	38.7	--	103.5	--
				Third	0.3	AP	103.8	Y

[8] Beginning in FY 1999 review-time goals decreased for original NDA/BLAs from 12 months to 10 months. The decrease in review time was progressive as it changed from requiring 30 percent of all standard original applications being reviewed in 10 months during FY 1999 to 90 percent during FY 2002. As this application was submitted prior to FY 1999, the review-time goal for this application is 12 months.

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APPENDIX C: Update on FY 2009 PDUFA Procedural and Processing Goals and Commitments

Final performance assessments for the following procedural and processing goals and commitments were not possible due to pending reviews within goal at the end of FY 2009 (as of September 30, 2009). Preliminary results were, therefore, provided in the FY 2009 PDUFA Performance Report.

Meeting Management

FY 2009 Performance

As of September 30, 2010, performance data were available on all meeting management goals. FDA completed on time most (4,086 of 5,591) meeting management activities; however, FDA did not meet any performance goals for meeting management (see table below).

Type		Performance Goal – Review 90 percent within	Received	Performance as of September 30, 2010		
				On Time	Overdue	Percent On Time
Meeting Requests	**Type A**	14 Days	222*	164	58	**74%**
	Type B	21 Days	1,297*	1,035	262	**80%**
	Type C		673*	522	151	**78%**
Scheduling Meetings†	**Type A**	30 Days	201*	129	72	**64%**
	Type B	60 Days	1,148*	792	356	**69%**
	Type C	75 Days	532*	393	139	**74%**
Meeting Minutes‡		30 Days	1,518*	1,051	467	**69%**

* FY 2009 numbers were changed to reflect updates to data presented in the FY 2009 PDUFA Performance Report.
† Not all meeting requests are granted; therefore, the number of meetings scheduled may differ from the number of meeting requests received.
‡ Not all scheduled meetings are held; therefore, the number of meeting minutes may differ from the number of meetings scheduled.

Responses to Clinical Holds

FY 2009 Performance

FDA reviewed on time most (184 of 221) sponsors' appeals of decisions received in FY 2009; however, FDA did not meet the performance goal for responses to clinical holds (see table below).

Performance Goal	Total Received	Performance as of September 30, 2009			Final Performance		
		On Time	Overdue	Percent on Time	On Time	Overdue	Percent on Time
Respond to 90 percent within 30 days	221*	175	37	**83%**	184	37	**83%**

* FY 2009 numbers were changed to reflect updates to data presented in the FY 2009 PDUFA Performance Report.

Special Protocol Assessments

FY 2009 Performance

FDA reviewed on time most (299 of 336) sponsors' requests for the evaluation of protocol designs received in FY 2009; however, FDA did not meet the performance goal for special protocol assessments (see table below).

Performance Goal	Total Received	Performance as of September 30, 2009			Final Performance		
		On Time	Overdue	Percent on Time	On Time	Overdue	Percent on Time
Respond to 90 percent within 45 days	336	267	36	**88%**	299	37	**89%**

* FY 2009 numbers were changed to reflect updates to data presented in the FY 2009 PDUFA Performance Report.

Drug/Biological Product Proprietary Names

FY 2009 Performance

FDA reviewed on time most proprietary names submitted during the IND phase (59 of 63) and proprietary names submitted with NDAs and BLAs (166 of 185). FDA exceeded the performance goals for both proprietary names submitted during the IND phase and proprietary names submitted with NDAs and BLAs (see table below).

Submission Type	Performance Level	Received	Performance as of September 30, 2009			Final Performance		
			On Time	Overdue	Percent on Time	On Time	Overdue	Percent on Time
Proprietary Names Submitted During IND Phase	Act on 50 percent within 180 days of receipt	63*	35	1	97%	59	4	**94%**
Proprietary Names Submitted with NDA/BLA	Act on 50 percent within 90 days of receipt	185*	125	18	87%	166	19	**90%**

***** FY 2009 numbers were changed to reflect updates to data presented in the FY 2009 PDUFA Performance Report.

First Cycle Filing Review Notification

FY 2009 Performance

FDA met the review-time commitment for reporting substantive review issues (or lack thereof) identified during the initial filing review for almost all (141 of 145) NDAs and BLAs and most (97 of 116) efficacy supplements filed in FY 2009 (see table below). FDA exceeded the first cycle filing review notification performance commitment for NDAs and BLAs but did not meet the performance commitment for efficacy supplements.

First Cycle Filing Review Notification Type	Performance Level	Filed	Performance as of September 30, 2009			Final Performance		
			On Time	Overdue	Percent On Time	On Time	Overdue	Percent On Time
NDAs/BLAs	Act on 90 percent within 14 days after 60-day filing date	145*	115*	4*	**97%**	141	4	**97%**
Efficacy Supplements		116*	77	13	**86%**	97	19	**84%**

* FY 2009 numbers were changed to reflect updates to data presented in the FY 2009 PDUFA Performance Report.

Notification of Planned Review Timelines

FY 2009 Performance

FDA met the review-time commitment for planned review timeline notifications for most (47 of 50) original NMEs and BLAs (see table below). FDA exceeded the performance commitment for applicant notification of planned review timelines in the filing review notification letter for original NMEs and BLAs.

Application Type	Performance Commitment	Applications Filed	Notifications Issued as of September 30, 2010 Final Notifications			Pending Notification
			In 74 Day Letter	Not In 74 Day Letter	Percent In 74 Day Letters	
Original NMEs and BLAs	Planned Review Timelines are in 90 percent of the 74 Day Filing Review Notification Letters	50	47	3	**94%**	0

* FY 2009 numbers were changed to reflect updates to data presented in the FY 2009 PDUFA Performance Report.

Meeting Planned Review Timeline Target Dates

FY 2009 Performance

FDA met the planned target date with 35 percent (15 of 43) of applications in FY 2009.

Application Type	Number of 74 Day Letters With Timelines	Target Date Met	Target Date Not Met	Percent of Applications Target Date Met	Target Date Inapplicable	Applications Pending within Target Date	Withdrawn
NMEs and BLAs	46*	15	28	**35%**	3	0	1

* Does not include withdrawals in the count.

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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