FY 2011

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) 2011 Prescription Drug User Fee Act (PDUFA) Performance Report to the President and Congress. This report marks the 19th year of PDUFA and the fourth year of PDUFA IV (FY 2008 through FY 2012).

This report provides final performance for the third year of PDUFA IV (FY 2010) and preliminary performance for the fourth year (FY 2011). FDA either met or exceeded almost all review performance goals in the third year of PDUFA IV (FY 2010), an improvement from FY 2009 when FDA met over half of the review performance goals. In addition to the improvement in meeting performance goals, the estimated median approval times for priority and standard New Drug Application (NDA) and Biologics License Application (BLA) were lower for both types of applications. Preliminary results of reviews completed during FY 2011 indicate that FDA has the potential to meet or exceed almost all FY 2011 review performance goals.

Since the passage of PDUFA, user fees have played an important role in providing FDA with the resources necessary to reduce review times for innovative drugs and biologics, and, therefore, provide patients and doctors with earlier access to breakthrough treatments. Under PDUFA IV, FDA has faced an unpredictable workload that was further complicated by increased commitments with the implementation of the Food and Drug Administration Amendment Act (FDAAA). Under Titles IV and V of FDAAA, additional reviews of pediatric assessments, written requests for pediatric studies, and increased focus on evaluating pediatric adverse events reports have resulted in increased time and resources devoted to pediatric functions. Submissions mandated under Title VIII have required increased staff review and follow-up to ensure compliance. Addressing drug safety issues required under Title IX, particularly with respect to risk evaluation and mitigation strategies and other postmarketing safety issues, has involved additional staff resources, public meetings, assessment of adverse event signals, and increased public reporting of FDA activities.

We are committed to meeting all PDUFA performance goals, including the procedural goals related to human drug review. The goals that apply to thousands of sponsor-requested meetings each year remain a challenge, and FDA will continue to strengthen efforts to improve performance in these areas. This will be done while maintaining a focus on ensuring that safe and effective drugs are approved in a short and predictable time frame.

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

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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 user fees from pharmaceutical and biotechnology companies for the review of certain human drug and biological products. In return, FDA commits to certain review performance goals and procedural and processing goals and commitments, agreed to with industry.

As reported in FY 2008 through FY 2010, FDA faced unprecedented challenges as it implemented new requirements and review commitments. 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 the second year of PDUFA IV (FY 2009), FDA met or exceeded 7 of 12 review performance goals. In this report, FDA can report that in the third year of PDUFA IV (FY 2010), FDA met or exceeded 11 of 12 review performance goals, and FDA is currently meeting or exceeding 10 of 12 review performance goals in FY 2011.

Outlined in this report is FDA's performance in meeting PDUFA review goals for FY 2010 and FY 2011. Review performance for submissions received in FY 2010, and initially reported in the FY 2010 PDUFA Performance Report, is updated and finalized with respect to achieving FY 2010 review performance goals. FDA's preliminary work in meeting review goals for submissions received in FY 2011, as well as procedural and processing goals, and PDUFA management commitments for FY 2011, also are covered in this report.

With 2,824 review actions completed for the FY 2010 cohort, FDA met or exceeded the 90 percent performance level for all but one (11 of 12) of the review performance goals. The following FY 2010 review performance goals were met or exceeded (percent of submissions that met review times in parenthesis):

- Priority NDAs and BLAs (100 percent)
- Priority new molecular entities (NMEs) and BLAs (100 percent)
- Standard NDAs and BLAs (98 percent[1])
- Standard NMEs and BLAs (100 percent)
- Class 1 resubmitted NDAs and BLAs (100 percent)
- Class 2 resubmitted NDAs and BLAs (95 percent)
- Priority efficacy supplements (95 percent)
- Standard efficacy supplements (97 percent)
- Class 1 resubmitted efficacy supplements (100 percent)

[1] Represents FDA's performance level excluding one review pending within goal as of September 30, 2011. FDA met the review performance goal, regardless of the final performance results of this pending review. Final on-time review performance will range from 96 percent, if the application is not acted on within goal, to 98 percent if it is acted on within goal.

- NDA and BLA manufacturing supplements requiring prior approval (90 percent)
- NDA and BLA manufacturing supplements not requiring prior approval (96 percent)

The FY 2010 review performance goal that FDA did not meet was:

- Class 2 resubmitted efficacy supplements (88 percent)

Preliminary review performance data also is presented in this report for FY 2011 submissions that were acted on or were pending overdue as of September 30, 2011. This includes over half (1,502 of 2,884) of FY 2011 submissions. Preliminary data show that FDA was meeting or exceeding the goal performance level for five-sixths (10 of 12) of the FY 2011 review-time goals. With 1,382 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 2011. FDA will not meet the FY 2011 review performance goal for Class 1 resubmitted efficacy supplements, where the highest performance level FDA can achieve is 75 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, 2011.

FDA accomplishments with respect to meeting PDUFA IV management initiatives and information technology commitments also are presented in the body of the report. Review cycle data on all original NDAs and BLAs approved during FY 2011 and final performance on procedural and processing goals and commitments not completed in FY 2010 are presented in the appendices.

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Overview of PDUFA

On September 27, 2007, the President signed FDAAA into law, which included the reauthorization and expansion of PDUFA for 5 additional years (FY 2008 through FY 2012, 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 drug safety and effectiveness. The quicker review times enabled by PDUFA resources have allowed the American people to gain quicker access to new medicines. 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 to 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 has the resources needed for the timely review of new drugs.

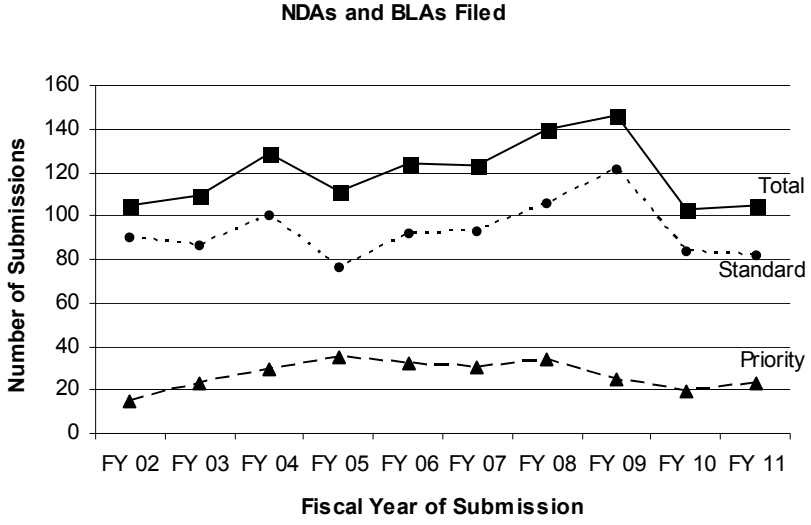
- **Enhance Process for Premarket Review**. PDUFA IV expands the implementation of the Good Review Management Practices (GRMPs) and creates additional initiatives designed to help expedite drug development.

- **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.

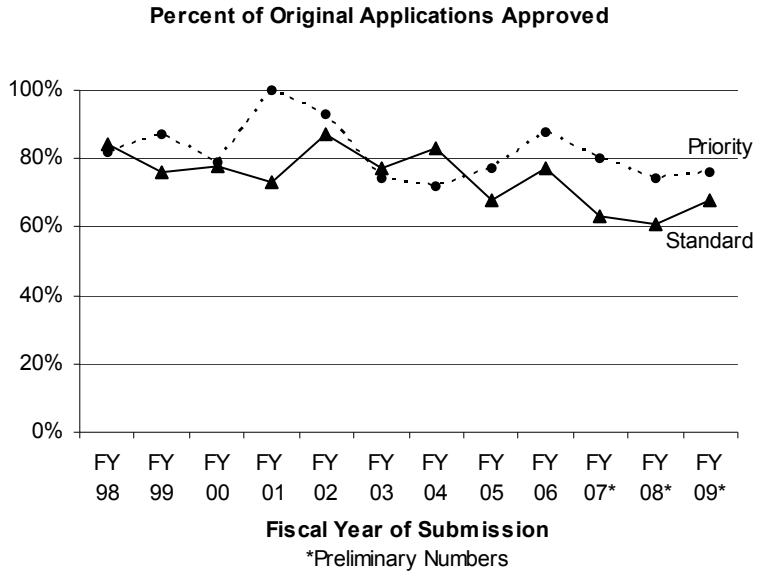
Trends in NDA and BLA Submissions and Approval Times

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 2011 the number of submissions, and accompanying reviewer workload, was below the 5-year average in most review categories. The following charts provide recent trends in submissions and overall approval times.

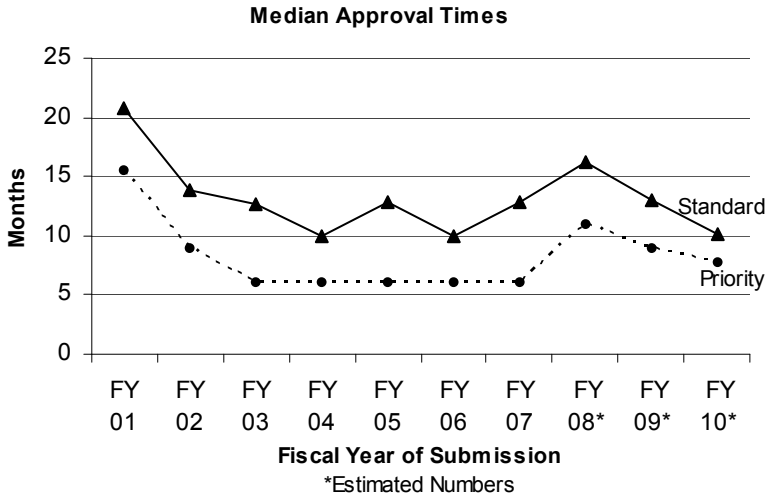
The total number of NDAs and BLAs increased from FY 2010 but matched the second lowest level in 10 years. A decrease in standard applications compared to FY 2010 was offset by an increase in priority applications in FY 2011. The number of priority applications, which represent significant therapeutic gains, increased for the first time in 3 years. Priority applications averaged 33 submissions from FY 2005 through FY 2008. The number of priority applications decreased to 25 in FY 2009 and 19 in FY 2010 before increasing to 23 in FY 2011. Standard applications averaged 103 submissions during the period from FY 2006 to FY 2009, with the number of standard applications decreasing to 84 in FY 2010 and to 82 in FY 2011.



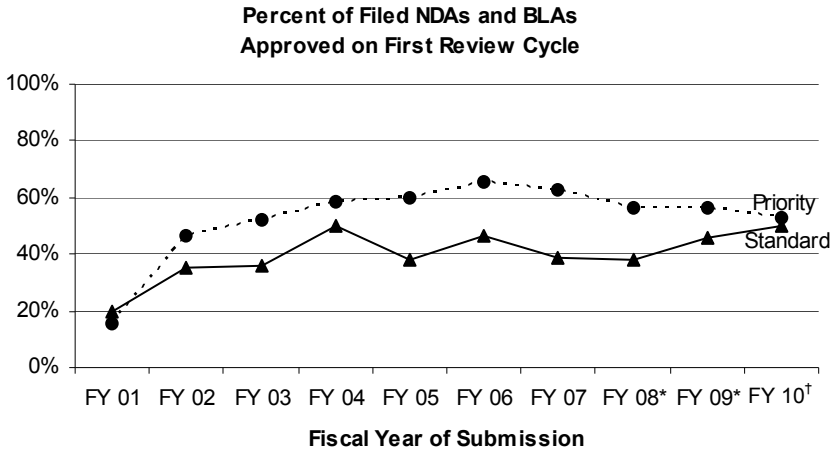
Priority applications generally are approved at a higher rate than standard applications. Historical data from FY 1998 to FY 2006 show that the percent of any fiscal year cohort that receives approval varies in any given year, but has averaged 83 percent of priority applications and 78 percent of standard 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 2010 and FY 2011 data have too few approvals to meaningfully report.)



Median time to approval for priority and standard applications improved in FY 2010 when compared to the last 5 years. Based on applications approved through September 30, 2011, 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 9.0 months in FY 2009 to 7.9 months in FY 2010 (see graph). Estimated median approval times for standard applications continued to decrease from the FY 2008 high of 16.2 months to 13.0 months in FY 2009 to 10.1 months in FY 2010, the lowest level since FY 2004. (FY 2011 data are too few to meaningfully report median approval time.)



The percentage of first cycle approvals for standard NDAs and BLAs increased to a 10-year high. The percentage of first cycle approvals for standard NDAs and BLAs increased for the second year in a row in FY 2010, reaching 50 percent, a 10-year high last seen in FY 2004. The percentage of first cycle approvals for priority NDAs and BLAs decreased from 56 percent in FY 2009 to 53 percent in FY 2010. An additional first cycle approval is still possible for FY 2010 standard submissions; therefore, a preliminary estimate is presented for this year. More first cycle approvals can result in decreased resubmissions in later fiscal years and decreased median times to approval (see previous median approval times graph). (FY 2011 data are too few to meaningfully report the percentage of first cycle approvals.)



* FY 2008 and FY 2009 numbers for priority NDAs and BLAs were changed to reflect updates to data presented in the FY 2010 PDUFA Performance Report.

† Preliminary Numbers

PDUFA Workloads: FY 2006 through FY 2011

The components of PDUFA review workload for which there are specific PDUFA goals include: 1) review of applications and submissions and preparation of documents and action letters related to FDA decisions, and 2) meeting management and review goals related to procedural responses and notifications. Components of PDUFA workload not captured by PDUFA goals include review of investigational new drug (IND) applications, labeling supplements, annual reports, and the ongoing monitoring of drug safety in the postmarket setting. FDA cannot predict or control the volume and frequency of applications and other submissions for review or meeting requests that sponsors submit each fiscal year. This fact was reinforced in FY 2011 as the trend of fluctuating submissions and resulting workloads continued to vary from year to year.

Review workloads for applications and submissions in FY 2011 were lower than the 5-year averages in 4 out of 5 submission categories. The workload in FY 2011 was similar to that seen in FY 2010, with review workloads remaining below the 5-year average in all but one category. The workload for original NDAs and BLAs was 17 percent below the preceding 5-year average. Resubmitted NDAs and BLAs increased to 2 percent above the preceding 5-year average. The workload for NDA and BLA efficacy supplements reached a 6-year low, down 22 percent compared to the 5-year average. Workloads for resubmitted efficacy supplements and NDA and BLA manufacturing supplements both increased over FY 2010 but remained lower than the preceding 5-year average.

Review Workloads for Applications and Submissions

Submission/Request	FY 06	FY 07	FY 08	FY 09	FY 10*	FY 11	FY 06 to FY 10 5-Year Average	FY 11 Compared to 5-Year Average
Original NDAs and BLAs	124	123	140	146	103	**105**	127	**↓17%**
Resubmitted NDAs and BLAs	61	73	57	70	53	**64**	63	**↑2%**
NDA and BLA Efficacy Supplements	190	191	151	159	144	**131**	167	**↓22%**
Resubmitted Efficacy Supplements	37	46	44	35	34	**36**	39	**↓8%**
NDA and BLA Manufacturing Supplements	2,647	2,663	2,548	2,576	2,491	**2,548**	2,585	**↓1%**

* FY 2010 numbers were changed to reflect updates to data presented in the FY 2010 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 trends. This variability 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 5-year average where data are available. The data show that workload for:

- Meeting management workload numbers increased in two of three categories (meetings scheduled and meeting minutes) from FY 2010 to FY 2011, but remained below the 5-year averages in two (meeting requests and meeting minutes) of the three categories.
- Procedural responses decreased in one category (responses to clinical holds), increased in another (major dispute resolutions), and stayed the same in the third (special protocol assessments) from FY 2010 to FY 2011. Workloads were below the 5-year averages in two (responses to clinical holds and special protocol assessments) of the three categories.
- Procedural notifications increased in two (drug/biological product proprietary name reviews and planned review timelines) of the three categories from FY 2010 to FY 2011. The increase for notification of planned review timelines was due to new PDUFA IV requirements to include all original NDAs and BLAs. 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 Categories	Submission/ Request	FY 06	FY 07	FY 08	FY 09	FY 10*	FY 11	FY 06 to FY 10 5-Year Average	FY 11 Compared to 5-Year Average
Meeting Management	Meeting Requests	2,565	2,502	2,344	2,192	2,257	**2,244**	2,372	**↓5%**
	Meetings Scheduled	2,273	2,151	1,903	1,881	2,028	**2,093**	2,047	**↑2%**
	Meeting Minutes	1,853	1,736	1,515	1,518	1,580	**1,625**	1,640	**↓1%**
Procedural Responses	Responses To Clinical Holds	145	175	213	221	204	**178**	192	**↓7%**
	Major Dispute Resolutions	9	22	14	15	7	**18**	13	**↑38%**
	Special Protocol Assessments	406	459	354	336	309	**309**	373	**↓17%**
Procedural Notifications	Drug/Biological Product Proprietary Name Reviews†	--	--	--	248	309	**313**	--	**--**
	First Cycle Filing Review Notifications	265	267	259	261	217	**201**	254	**↓21%**
	Notification of Planned Review Timelines†	--	--	--	50	85	**152**	--	**--**

* FY 2010 numbers were changed to reflect updates to data presented in the FY 2010 PDUFA Performance Report.
† This information was not tracked prior to FY 2009.

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's on-time review performance for actions completed in FY 2011 regardless of when they were submitted. This report also presents FDA performance as compared to PDUFA review performance goals for the FY 2010 cohort (final) and the FY 2011 cohort (preliminary).

FY 2011 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 2011. Included are FY 2010 submissions that were pending within goal at the beginning of FY 2011 and FY 2011 submissions that were received early enough to have a review completed or scheduled within goal for review during FY 2011.

FY 2010 and FY 2011 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 2010 cohort submissions based on reviews in FY 2010 and FY 2011. Preliminary performance goal results presented in this report include FY 2011 cohort submissions that had reviews completed or overdue in FY 2011. Final performance goal results for FY 2011 cohort submissions will be presented in the FY 2012 PDUFA Performance Report and will include reviews that are pending within goal as of September 30, 2011, that are due to be completed in FY 2012.

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

- The following terminology is used throughout this document: "application" means a new, original application; "supplement" means a supplement to an approved application; "resubmission" means a resubmitted application or supplement in response to a complete response, approvable, not approvable, or tentative approval letter; "NME" 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 or Due for Completion During FY 2011

This table summarizes FDA's on-time review performance for FY 2010 and FY 2011 submissions whose reviews were completed or due for completion in FY 2011. 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 2011 is based on 2,684 submissions that had action taken (within goal or overdue) or where the application was pending action past goal (overdue) as of September 30, 2011. Of these 2,684 submissions, 1,182 were from the FY 2010 cohort (representing 44 percent of the review workload) and 1,502 were from the FY 2011 cohort (representing 56 percent of the review workload). Overall, 96 percent of reviews were completed on time during FY 2011.

Application/Submission Type	On Time Goal	Submitted In FY 2010		Submitted In FY 2011		Total	
		On Time / Reviewed*	Percent On Time	On Time / Reviewed*	Percent On Time	On Time / Reviewed*	Percent On Time
Priority NDAs/BLAs	6 months	12/ 12	100%	12 / 13	92%	24 / 25	**96%**
Priority NMEs/BLAs†	*6 months*	*7 / 7*	*100%*	*8 / 9*	*89%*	*15 / 16*	***94%***
Standard NDAs/BLAs	10 months	73 / 75	97%	11 / 11	100%	84 / 86	**98%**
Standard NMEs/BLAs†	*10 months*	*15 / 15*	*100%*	*2 / 2*	*100%*	*17 / 17*	***100%***
Resubmitted Class I NDAs/BLAs	2 months	0 / 0	--	8 / 8	100%	8 /8	**100%**
Resubmitted Class 2 NDAs/BLAs	6 months	20 / 21	95%	29 / 29	100%	49 / 50	**98%**
Priority Efficacy Supplements	6 months	14 / 15	93%	11 / 12	92%	25 / 27	**93%**
Standard Efficacy Supplements	10 months	110 / 112	98%	16 / 16	100%	126 / 128	**98%**
Resubmitted Class 1 Efficacy Supplements	2 months	1 / 1	100%	8 / 12	67%	9 / 13	**69%**
Resubmitted Class 2 Efficacy Supplements	6 months	8 / 8	100%	11 / 12	92%	19 / 20	**95%**
Manufacturing Supplements Requiring Prior Approval	4 months	217 / 220	99%	526 / 554	95%	743 / 774	**96%**
Manufacturing Supplements Not Requiring Prior Approval	6 months	675 / 718	94%	820 / 835	98%	1,495 / 1,553	**96%**
Total Submissions‡		**1,130 / 1,182**	**96%**	**1,452 / 1,502**	**97%**	**2,582 / 2,684**	**96%**

* 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 subset rows for priority NMEs/BLAs and standard NMEs/BLAs.

A review of on-time review performance completed during FY 2011 shows:

- The majority of FY 2010 cohort submissions had action due in the first 6 months of FY 2011. As noted in the previous section, most of the review time goals are for 6 months or less. These submissions included 995 of 1,182 submissions received in the final 6 months of FY 2010.

- FY 2010 cohort submissions acted on in FY 2011 ranged from 93 percent (priority efficacy supplements) to 100 percent (priority NDAs/BLAs, priority NMEs/BLAs, standard NMEs/BLAs, and resubmitted Class 1 and Class 2 efficacy supplements) on-time performance. All submission types met or exceeded the 90 percent on-time level.

- FY 2011 cohort submissions acted on or due as of September 30, 2011, ranged from 67 percent (resubmitted Class 1 efficacy supplements) to 100 percent (standard NDAs/BLAs, standard NMEs/BLAs, resubmitted Class 1 and Class 2 NDAs/BLAs, and standard efficacy supplements) on-time performance. Five-sixths (10 of 12) of submission types met or exceeded the 90 percent on-time level.

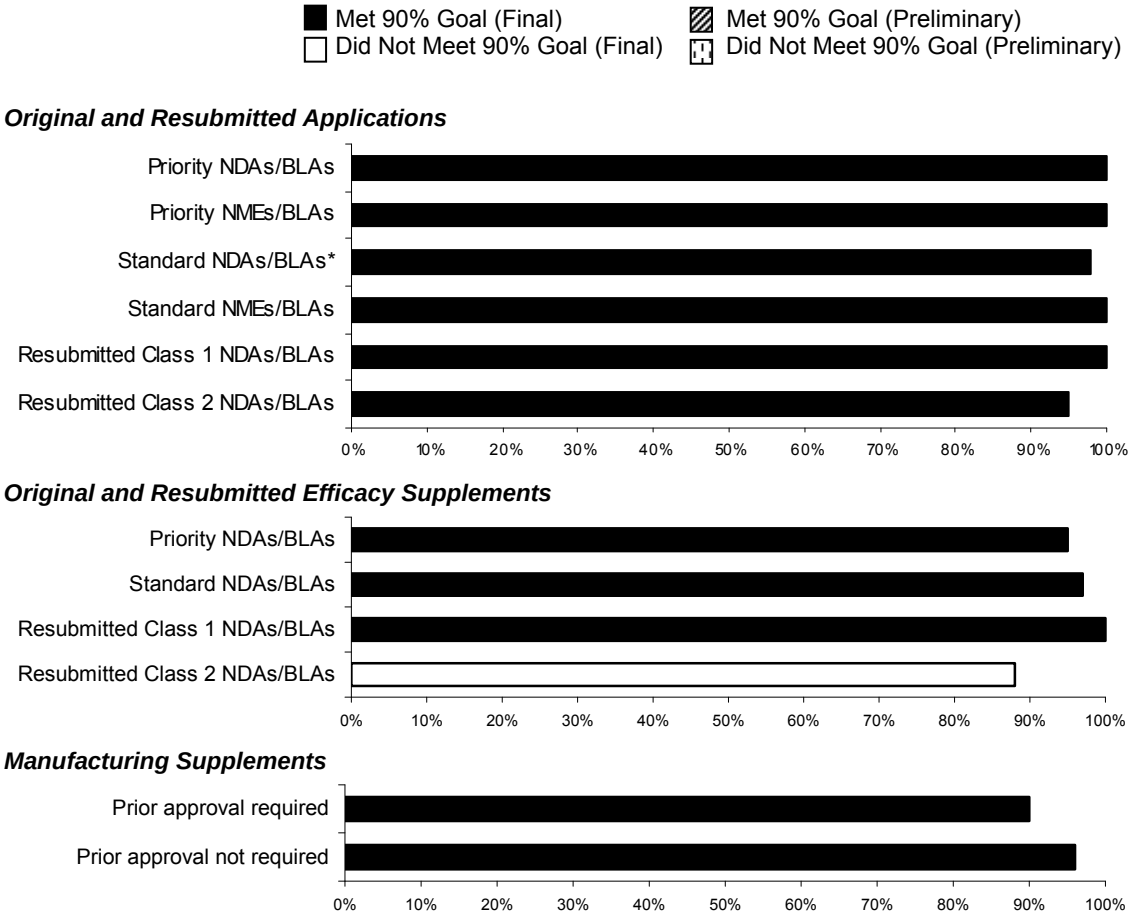
- On-time reviews in a single year impact two consecutive fiscal years' cohort performance. During FY 2011, for both the FY 2010 and FY 2011 cohort, FDA completed reviews equal to or greater than 90 percent of the time in 11 of 12 performance goal categories (see total columns percent on time).

Review Performance Goals At-A-Glance: FY 2010 and FY 2011

The following graphs summarize FDA's review performance for FY 2010 and FY 2011 submissions with respect to meeting performance goals.

FY 2010 Final Performance. Final review performance with respect to performance goals can now be provided for FY 2010. FDA met or exceeded FY 2010 performance goals for:

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

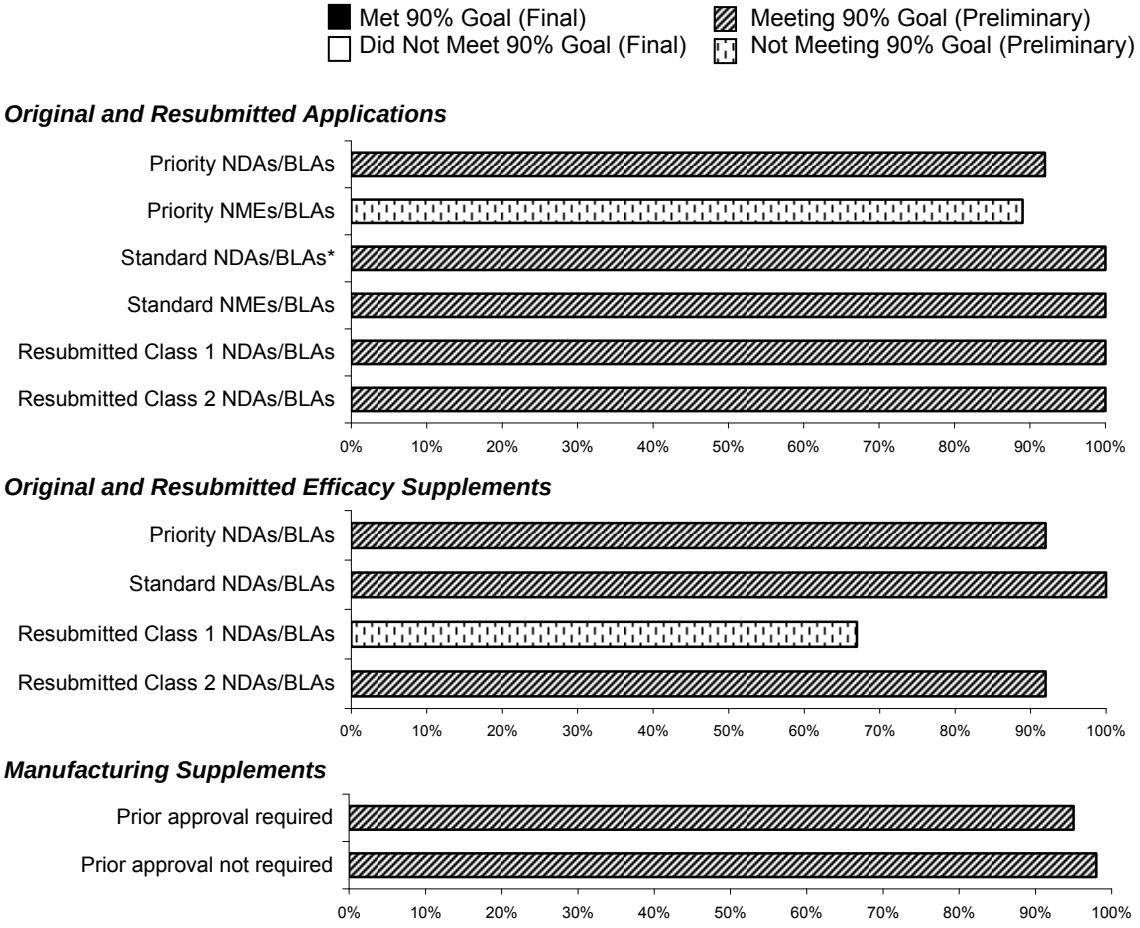


* Represents FDA performance level with one review pending within goal as of September 30, 2011. FDA met the review performance goal, regardless of the final performance results of this review. FDA's final on-time review performance will range from 96 percent, if the application is not acted on within goal, to 98 percent if it is acted on within goal.

FY 2011 Preliminary Percent On-Time Review Performance. Preliminary review performance is based on 52 percent (1,502 of 2,884) of FY 2011 submissions with reviews pending within goal for the remaining 48 percent (1,382 of 2,884) as of September 30, 2011. FDA is meeting or exceeding FY 2011 performance goal levels for:

- Five-sixths (5 of 6) of original and resubmitted applications;
- Three-fourths (3 of 4) of original and resubmitted efficacy supplements; and
- All (2 of 2) manufacturing supplements.

With additional reviews still pending within goal as of September 30, 2011, FDA has the potential to improve overall performance for FY 2011 and meet almost all (11 of 12) review performance goals.



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Report on FY 2010 and FY 2011 PDUFA Review Goals

This section updates FDA's final on-time review performance on the FY 2010 submissions and presents FDA's preliminary on-time performance in reviewing FY 2011 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 (2,824 of 2,825) FY 2010 review performance submissions and resubmissions. One submission was pending within goal as of September 30, 2011. FDA can now report final performance with respect to achieving FY 2010 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 2011 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 52 percent (1,502 of 2,884) of FY 2011 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, 2011.

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Original Applications

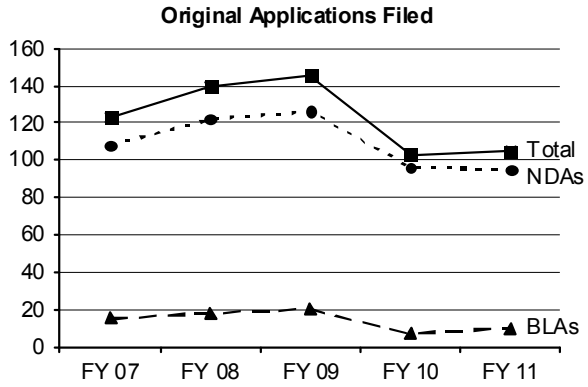
Goal: Review and act on original NDAs and BLAs

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 increased in FY 2011 but was the second lowest number filed in 5 years. Overall, the increase in applications filed occurred with priority NDAs and priority and standard BLAs. Notably, priority NMEs were at the highest level in 5 years (see corresponding graph and table).



Original Applications Filed
(Priority / Standard)

Type	FY 07	FY 08	FY 09	FY 10*	FY 11
NDAs	**108** *(23/85)*	**122** *(27/95)*	**126** *(16/110)*	**96** *(16/80)*	**95** *(18/77)*
BLAs	**15** *(7/8)*	**18** *(7/11)*	**20** *(9/11)*	**7** *(3/4)*	**10** *(5/5)*
PDUFA Total	**123** *(30/93)*	***140*** *(34/106)*	**146** *(25/121)*	**103** *(19/84)*	**105** *(23/82)*
NMEs†	**29** *(9/20)*	**29** *(10/19)*	**30** *(8/22)*	**22** *(8/14)*	**27** *(11/16)*

* FY 2010 numbers were changed to reflect updates to data presented in the FY 2010 PDUFA Performance Report.
† FDA often receives multiple applications for the same NME that are all initially designated as NMEs. When FDA approves the first of the multiple applications, the others are redesignated as non-NMEs.

Original Applications

Performance

FY 2010 Submissions

FDA reviewed on time all (19 of 19) priority and most (81 of 84) standard applications that were filed in FY 2010 (see table below). This included reviewing on time 11 of 11 priority NMEs and BLAs and 18 of 18 standard NMEs and BLAs. With one submission pending within goal, FDA will exceed the performance goals for priority and standard original applications.

Original Application Type		Performance Goal	Filed	Performance as of September 30, 2010			Final Performance		
				On Time	Overdue	Percent On Time	On Time	Overdue	Percent On Time
Priority	All	Act on 90 percent within 6 months	19	7	0	**100%**	19	0	**100%**
	NMEs & BLAs		11	4	0	**100%**	11	0	**100%**
Standard	All	Act on 90 percent within 10 months	84*	8	0	**100%**	81	2	**98%**†
	NMEs & BLAs		18	3	0	**100%**	18	0	**100%**

* FY 2010 counts were changed to reflect updates to data presented in the FY 2010 PDUFA Performance Report.
† Represents FDA performance level with one review pending within goal as of September 30, 2011. FDA met the review performance goal, regardless of the final performance results of this review. FDA's final on-time review performance will range from 96% if the application is not acted on within goal to 98% if the application is acted on within goal.

FY 2011 Submissions

As of September 30, 2011, performance data were available for more than half (13 of 23) of priority applications and less than one-seventh (11 of 82) of standard applications filed in FY 2011. FDA met the review time goal for almost all (12 of 13) of the priority applications and all (11 of 11) of the standard applications (see table below). With priority and standard applications pending within goal, FDA has the potential to exceed the performance goals for priority and standard NDAs and BLAs and for priority and standard NMEs and BLAs.

Original Application Type		Performance Goal	Filed	Performance as of September 30, 2011			
				On Time	Overdue	Percent On Time	Pending Within Goal
Priority	All	Act on 90 percent within 6 months	23	12	1	**92%**	10
	NMEs & BLAs		16	8	1	**89%**	7
Standard	All	Act on 90 percent within 10 months	82	11	0	**100%**	71
	NMEs & BLAs		21	2	0	**100%**	19

Resubmitted Applications

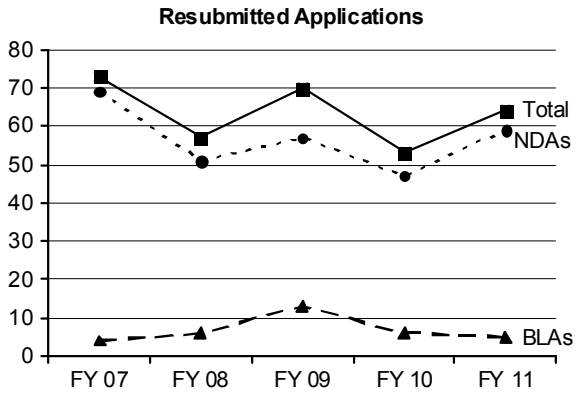
Goal: Review and act on resubmitted NDAs and BLAs

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 increased in FY 2011 but remained below the 5-year high in FY 2007. Class 1 NDA resubmitted applications were at the lowest level in 5 years; however, Class 2 NDA resubmissions reached a 5-year high (see corresponding graph and table).



Resubmitted Applications (Class 1 / Class 2)

Type	FY 07	FY 08	FY 09	FY 10*	FY 11
NDAs	**69** *(22/47)*	**51** *(17/34)*	**57** *(14/43)*	**47** *(12/35)*	**59** *(11/48)*
BLAs	**4** *(1/3)*	**6** *(2/4)*	**13** *(2/11)*	**6** *(0/6)*	**5** *(0/5)*
PDUFA Total	**73** *(23/50)*	**57** *(19/38)*	**70** *(16/54)*	**53** *(12/41)*	**64** *(11/53)*

* FY 2010 numbers were changed to reflect updates to data presented in the FY 2010 PDUFA Performance Report.

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

Resubmitted Applications

Performance

FY 2010 Resubmissions

FDA reviewed on time all (12 of 12) Class 1 and almost all (39 of 41) Class 2 resubmissions in FY 2010 (see table below). FDA exceeded the performance goal for both Class 1 and Class 2 resubmitted applications.

Resubmitted Application Type	Performance Goal	Received	Performance as of September 30, 2010			Final Performance		
			On Time	Overdue	Percent On Time	On Time	Overdue	Percent On Time
Class 1	Act on 90 percent within 2 months	12*	12	0	**100%**	12	0	**100%**
Class 2	Act on 90 percent within 6 months	41*	19	1	**95%**	39	2	**95%**

* FY 2010 numbers were changed to reflect updates to data presented in the FY 2010 PDUFA Performance Report.

FY 2011 Resubmissions

As of September 30, 2011, performance data were available for most (8 of 11) Class 1 resubmissions and over half (29 of 53) of the Class 2 resubmissions received in FY 2011. FDA met the review-time goal for all of the resubmitted applications. With resubmissions pending within goal, FDA has the potential to exceed the performance goal for Class 1 and Class 2 resubmitted applications.

Resubmitted Application Type	Performance Goal	Received	Performance as of September 30, 2011			
			On Time	Overdue	Percent On Time	Pending Within Goal
Class 1	Act on 90 percent within 2 months	11	8	0	**100%**	3
Class 2	Act on 90 percent within 6 months	53	29	0	**100%**	24

Efficacy Supplements

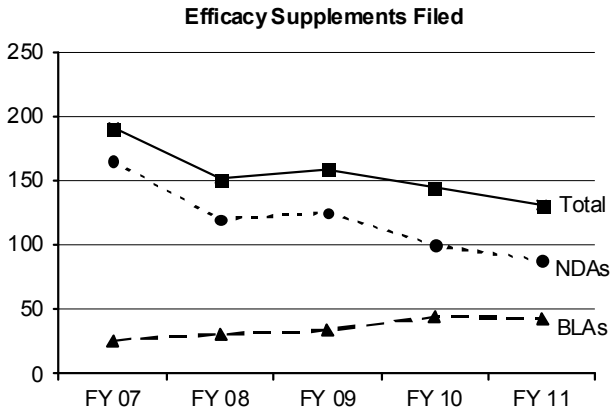
Goal: Review and act on complete efficacy supplements to NDAs and BLAs

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 2011 decreased to the lowest level in 5 years. The decrease was due to the decline in the number of priority and standard NDA and standard BLA efficacy supplements filed, though the number of priority BLA efficacy supplements filed matched the 5-year high seen in FY 2008 (see corresponding graph and table).



Efficacy Supplements Filed
(Priority / Standard)

Type	FY 07	FY 08	FY 09	FY 10*	FY 11
NDAs	**165** *(43/122)*	**120** *(31/89)*	**125** *(36/89)*	**100** *(16/84)*	**88** *(15/73)*
BLAs	**26** *(3/23)*	**31** *(8/23)*	**34** *(6/28)*	**44** *(3/41)*	**43** *(8/35)*
PDUFA Total	**191** *(46/145)*	**151** *(39/112)*	**159** *(42/117)*	**144** *(19/125)*	**131** *(23/108)*

* FY 2010 numbers were changed to reflect updates to data presented in the FY 2010 PDUFA Performance Report.

Efficacy Supplements

Performance

FY 2010 Submissions

FDA reviewed on time almost all (18 of 19) priority and most (121 of 125) standard efficacy supplements filed in FY 2010 (see table below). FDA exceeded the performance goals for priority and standard efficacy supplements.

Efficacy Supplement Type	Performance Goal	Filed	Performance as of September 30, 2010			Final Performance		
			On Time	Overdue	Percent On Time	On Time	Overdue	Percent On Time
Priority	Act on 90 percent within 6 months	19*	4	0	**100%**	18	1	**95%**
Standard	Act on 90 percent within 10 months	125*	11	2	**85%**	121	4	**97%**

* FY 2010 numbers were changed to reflect updates to data presented in the FY 2010 PDUFA Performance Report.

FY 2011 Submissions

As of September 30, 2011, performance data were available for over half (12 of 23) of the priority efficacy supplements, and over one-tenth (16 of 108) of standard efficacy supplements filed in FY 2011. FDA met the review-time goal for almost all (11 of 12) priority efficacy supplements and for all (16 of 16) 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, 2011			
			On Time	Overdue	Percent On Time	Pending Within Goal
Priority	Act on 90 percent within 6 months	23	11	1	**92%**	11
Standard	Act on 90 percent within 10 months	108	16	0	**100%**	92

Resubmitted Efficacy Supplements

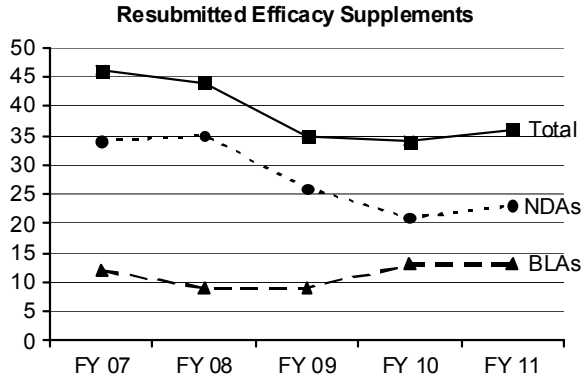
Goal: Review and act on resubmitted efficacy supplements to NDAs and BLAs

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 increased in FY 2011 to the highest level in 3 years. The increase was due to increases in the number of Class 2 NDA and Class 1 BLA resubmitted efficacy supplements. The total number of BLA resubmitted efficacy supplements matched the 5-year high seen in FY 2010 (see corresponding graph and table).



Resubmitted Efficacy Supplements
(Class 1 / Class 2)

Type	FY 07	FY 08	FY 09	FY 10*	FY 11
NDAs	**34** *(16/18)*	**35** *(9/26)*	**26** *(4/22)*	**21** *(12/9)*	**23** *(10/13)*
BLAs	**12** *(1/11)*	**9** *(3/6)*	**9** *(4/5)*	**13** *(5/8)*	**13** *(6/7)*
PDUFA Total	**46** *(17/29)*	**44** *(12/32)*	**35** *(8/27)*	**34** *(17/17)*	**36** *(16/20)*

* FY 2010 numbers were changed to reflect updates to data presented in the FY 2010 PDUFA Performance Report.

Resubmitted Efficacy Supplements

Performance

FY 2010 Resubmissions

FDA reviewed on time all (17 of 17) Class 1 and most (15 of 17) Class 2 resubmissions submitted in FY 2010 (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, 2010			Final Performance		
			On Time	Overdue	Percent On Time	On Time	Overdue	Percent On Time
Class 1	Act on 90 percent within 2 months	17*	16	0	**100%**	17	0	**100%**
Class 2	Act on 90 percent within 6 months	17*	7	2	**78%**	15	2	**88%**

* FY 2010 numbers were changed to reflect updates to data presented in the FY 2010 PDUFA Performance Report.

FY 2011 Resubmissions

As of September 30, 2011, performance data were available for three-fourths (12 of 16) of Class 1 and three-fifths (12 of 20) of Class 2 resubmissions submitted in FY 2011. FDA met the review-time goal for most (8 of 12) Class 1 and almost all (11 of 12) Class 2 resubmissions (see table below). With resubmissions pending within goal, FDA has the potential to exceed the performance goal for Class 2 resubmitted efficacy supplements and can increase the on-time review percentage for Class 1 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, 2011			
			On Time	Overdue	Percent On Time	Pending Within Goal
Class 1	Act on 90 percent within 2 months	16	8	4	**67%**	4
Class 2	Act on 90 percent within 6 months	20	11	1	**92%**	8

Manufacturing Supplements

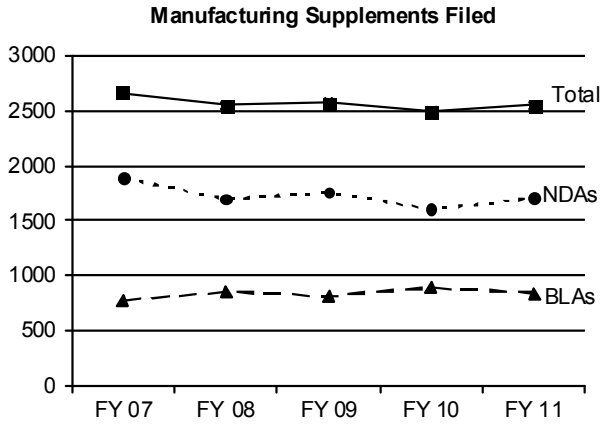
Goal: Review and act on manufacturing supplements to NDAs and BLAs

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 increased in FY 2011 but remained at the second lowest level in 5 years. Total manufacturing supplement submissions have remained fairly consistent over the past 5 years, with less than a 5 percent variation from year to year (see corresponding graph and table).



Manufacturing Supplements Filed
(Prior Approval / No Prior Approval)

Type	FY 07	FY 08	FY 09	FY 10*	FY 11
NDAs	**1,889** *(612/1,277)*	**1,695** *(575/1,120)*	**1,760** *(633/1,127)*	**1,603** *(635/968)*	**1,705** *(559/1,146)*
BLAs	**774** *(242/532)*	**853** *(335/518)*	**816** *(338/478)*	**888** *(332/556)*	**843** *(302/541)*
PDUFA Total	**2,663** *(854/1,809)*	**2,548** *(910/1,638)*	**2,576** *(971/1,605)*	**2,491** *(967/1,524)*	**2,548** *(861/1,687)*

* FY 2010 numbers were changed to reflect updates to data presented in the FY 2010 PDUFA Performance Report.

Manufacturing Supplements

Performance

FY 2010 Submissions

FDA reviewed on time most (873 of 967) manufacturing supplements requiring prior approval and most (1,459 of 1,524) manufacturing supplements not requiring prior approval filed in FY 2010 (see table below). FDA met the performance goal for supplements requiring prior approval and exceeded the performance goal for supplements where prior approval was not required.

Manufacturing Supplement Type	Performance Goal	Filed	Performance as of September 30, 2010			Final Performance		
			On Time	Overdue	Percent On Time	On Time	Overdue	Percent On Time
Prior Approval Required	Act on 90 percent within 4 months	967*	656	91	**88%**	873	94	**90%**
Prior Approval Not Required	Act on 90 percent within 6 months	1,524*	784	22	**97%**	1,459	65	**96%**

* FY 2010 numbers were changed to reflect updates to data presented in the FY 2010 PDUFA Performance Report.

FY 2011 Submissions

As of September 30, 2011, performance data were available for almost two-thirds (554 of 861) of supplements requiring prior approval and almost half (835 of 1,687) of supplements not requiring prior approval. FDA met the review-time goal for most (526 of 554) of supplements where prior approval was required and almost all (820 of 835) of supplements where prior approval was not required (see table below). With submissions pending within goal, FDA has the potential to exceed the performance goals for both types of manufacturing supplements.

Manufacturing Supplement Type	Performance Goal	Filed	Performance as of September 30, 2011			
			On Time	Overdue	Percent On Time	Pending Within Goal
Prior Approval Required	Act on 90 percent within 4 months	861	526	28	**95%**	307
Prior Approval Not Required	Act on 90 percent within 6 months	1,687	820	15	**98%**	852

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Report on FY 2011 PDUFA Procedural and Processing Goals and Commitments

This section presents FDA's performance in achieving the FY 2011 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 2010 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 Resolutions
	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
	Notification of Planned Review Timelines – All Original NDAs and BLAs

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

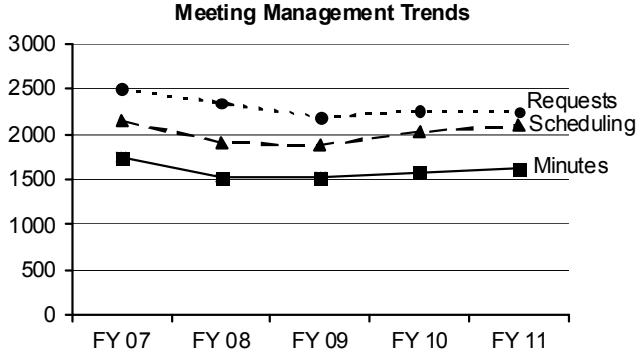
The table below summarizes the meeting management goals that address meeting requests, scheduling meetings, and preparing meeting minutes.

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 number of FY 2011 meetings scheduled and meeting minutes prepared increased to the highest levels in 4 years. Notably, the data shows that 93 percent of requested meetings were scheduled, the highest percentage in the past 5 years (see corresponding graph and table).



Meeting Management

Type	FY 07	FY 08	FY 09	FY 10*	FY 11
Meeting Requests	2,502	2,344	2,192	2,257	2,244
Scheduling Meetings	2,151	1,903	1,881	2,028	2,093
Meeting Minutes	1,736	1,515	1,518	1,580	1,625

* FY 2010 numbers were changed to reflect updates to data presented in the FY 2010 PDUFA Performance Report.

Meeting Management

FY 2011 Performance

As of September 30, 2011, FDA acted on 2,144 meeting requests, scheduled 1,923 meetings, and prepared 1,184 meeting minutes.[3] Most of these actions (1,794 of 2,144 meeting requests; 1,726 of 1,923 meetings scheduled; and 881 of 1,184 meeting minutes) were acted on within goal. With meeting requests, scheduling meetings, and meeting minutes pending within goal, FDA has the potential to exceed the performance goal for scheduling Type B meetings. FDA can increase the on-time percentage levels but will not meet the remaining performance goals for meeting management in FY 2011 (see table below).

Type		Performance Goal: Review 90 percent within	Received	Performance as of September 30, 2011*			
				On Time	Overdue	Percent On Time	Pending Within Goal
Meeting Requests	Type A	14 Days	188	153	33	**82%**	2
	Type B	21 Days	1,297	1,086	189	**85%**	22
	Type C		695	555	128	**81%**	12
Scheduling Meetings†	Type A	30 Days	170	147	21	**88%**	2
	Type B	60 Days	1,232	1,072	104	**91%**	56
	Type C	75 Days	629	507	72	**88%**	50
Meeting Minutes‡		30 Days	1,625	881	303	**74%**	441

* Performance in all categories will change once determinations are made for meeting requests and scheduled meetings initially coded as undetermined. Approximately 2 percent (64 meeting requests and 62 scheduling of meetings) of data were pending recoding as of September 30, 2011.

† 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" cannot 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 2012 PDUFA Performance Report.

Responses to Clinical Holds

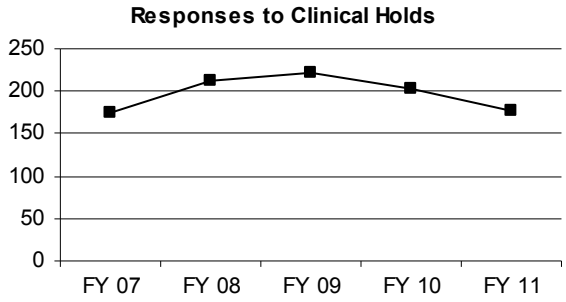
Goal: Respond to a sponsor's complete response to a clinical hold within 30 days of receipt

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 in FY 2011 to the lowest level in 4 years (see corresponding graph and table).



Responses to Clinical Holds

FY 07	FY 08	FY 09	FY 10*	FY 11
175	213	221	204	178

* FY 2010 counts were updated to reflect corrections to the FY 2010 PDUFA Performance Report.

FY 2011 Performance

As of September 30, 2011, performance data were available for almost all (169 of 178) of FDA's responses to sponsors' complete responses to clinical holds received in FY 2011. FDA met the review-time goal for most (144 of 169) 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, 2011			
		On Time	Overdue	Percent on Time	Pending Within Goal
Respond to 90 percent within 30 days	178	144	25	**85%**	9

Major Dispute Resolutions

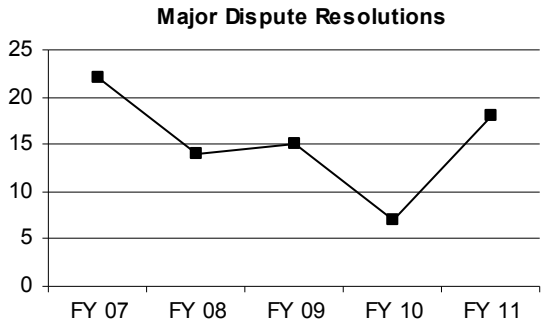
Goal: Provide a response to a sponsor's appeal of decision within 30 days of receipt

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 to which FDA responded in FY 2011 increased to the highest level in 4 years (see corresponding graph and table).



Major Dispute Resolutions

FY 07	FY 08	FY 09	FY 10	FY 11
22	14	15	7	18

FY 2011 Performance

As of September 30, 2011, performance data were available on all (18 of 18) sponsors' appeals of decisions received in FY 2011. FDA did not meet the performance goal (see table below).

Performance Goal	Total Received	Performance as of September 30, 2011			
		On Time	Overdue	Percent on Time	Pending Within Goal
Respond to 90 percent within 30 days	18	16	2	**89%**	0

Special Protocol Assessments

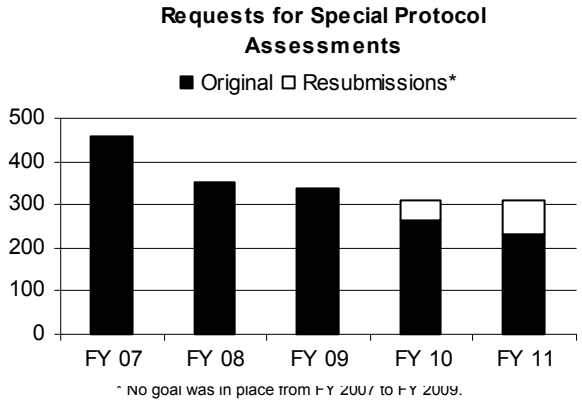
Goal: Respond to a sponsor's request for evaluation of protocol design within 45 days of receipt of protocol and questions

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 2011, the total number of special protocol assessment requests, which include originals and resubmissions, remained at the FY 2010 level, the lowest in 5 years. FDA received a total of 77 resubmitted special protocol assessments with 60 original requests receiving 1 resubmission each, 7 original requests receiving 2 resubmissions each, and 1 original request receiving 3 resubmissions, representing approximately 1 resubmission for every 4 original assessments (see corresponding graph and table).



Requests for Special Protocol Assessments

Type	FY 07	FY 08	FY 09	FY 10*	FY 11
Original Requests	459	354	336	264	232
Resubmissions†	--	--	--	45	77‡
All Requests	459	354	336	309	309

* FY 2010 numbers were changed to reflect updates to data presented in the FY 2010 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 a total of 77 resubmitted special protocol assessments with 1 resubmission each for 60 original requests, 2 resubmissions each for 7 original requests, and 3 resubmissions for 1 original request. Therefore, 29 percent (68 of 232) of original requests received at least 1 resubmission, or 1 resubmission for every 4 original requests.

Special Protocol Assessments

FY 2011 Performance

As of September 30, 2011, performance data were available for most (281 of 309) special protocol assessments received in FY 2011 (see table below). With special protocol assessments pending within goal, FDA has the potential to meet the performance goal.

Performance Goal	Total Received	Performance as of September 30, 2011			
		On Time	Overdue	Percent on Time	Pending Within Goal
Respond to 90 percent within 45 days	309	250	31	**89%**	28

Drug/Biological Product Proprietary Names

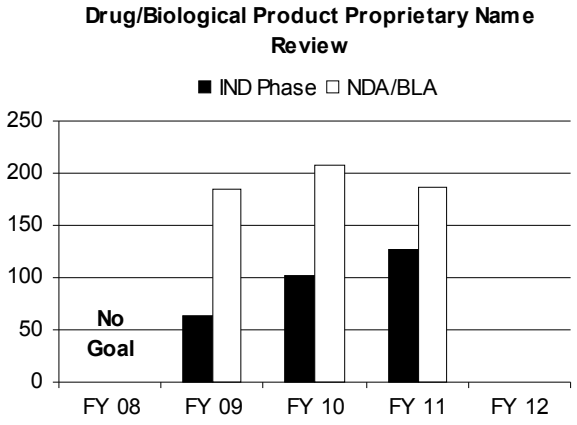
Commitment: Review and tentatively accept proprietary names

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 progressed 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 2011, the third year of this commitment, 127 proprietary names were submitted during the IND phase, an increase of nearly 25 percent from FY 2010. The number of proprietary names submitted with an NDA or BLA in FY 2011 reached 186, which represents a 10 percent decrease from FY 2010 (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	102	127	--
Proprietary Names Submitted with NDA/BLA	--	185	207	186	--

* FY 2010 numbers were changed to reflect updates to data presented in the FY 2010 PDUFA Performance Report.

Drug/Biological Product Proprietary Names

FY 2011 Performance

As of September 30, 2011, performance data were available for over half (68 of 127) of proprietary names submitted during the IND phase and over three-fourths (146 of 186) of proprietary names submitted with NDAs and BLAs submitted in FY 2011. FDA met the review-time commitment for almost all (65 of 68) proprietary names submitted during the IND phase and all (146 of 146) proprietary names submitted with NDAs and BLAs. With submissions pending, FDA has the potential to exceed the performance commitment for proprietary names submitted during the IND phase and for proprietary names submitted with NDAs and BLAs.

Submission Type	Performance Commitment	Received	Performance as of September 30, 2011			
			On Time	Overdue	Percent On Time	Pending Within Goal
Proprietary Names Submitted During IND Phase	Act on 90 percent within 180 days of receipt	127	65	3	**96%**	59
Proprietary Names Submitted with NDA/BLA	Act on 90 percent within 90 days of receipt	186	146	0	**100%**	40

First Cycle Filing Review Notification

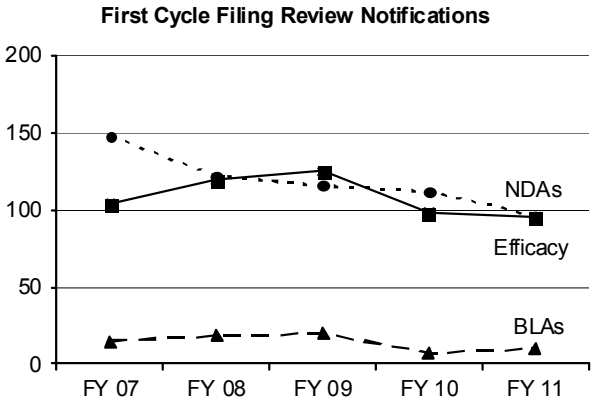
Commitment: Report substantive review issues (or lack thereof) within 14 Days after the 60-Day filing date for original NDAs/BLAs and efficacy supplements

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 NDA and BLA first cycle filing review notifications issued in FY 2011 remained at the FY 2010 level, which was the lowest number issued in 5 years. This is consistent with the decrease in the total number of filed NDA, BLA, and efficacy supplement submissions (see earlier sections as well as corresponding graph and table).



First Cycle Filing Review Notifications

Type	FY 07	FY 08	FY 09	FY 10*	FY 11
NDAs	104	119	125	98	95
BLAs	15	18	20	7	10
PDUFA Total	119	137	145	105	105
Efficacy Supplements†	148	122	116	112	96

* 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 2010 numbers were changed to reflect updates to data presented in the FY 2010 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 certain 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 2011 Performance

As of September 30, 2011, performance data were available for over three-fourths (82 of 105) of NDA/BLA notifications and most (84 of 96) efficacy supplement notifications in FY 2011. FDA met the review-time commitment for most (79 of 82) NDA/BLA notifications and most (75 of 84) efficacy supplement notifications. With notifications pending within the commitment-time period, FDA has the potential to exceed the performance commitments for NDA and BLA first cycle filing review notifications and for efficacy supplement first cycle filing review notifications.

First Cycle Filing Review Notification Type	Performance Commitment	Filed	Performance as of September 30, 2011			
			On Time	Overdue	Percent On Time	Pending Within Goal
NDAs/BLAs	Act on 90 percent within 14 days after 60-day filing date	105	79	3	**96%**	23
Efficacy Supplements		96	75	9	**89%**	12

Notification of Planned Review Timelines

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

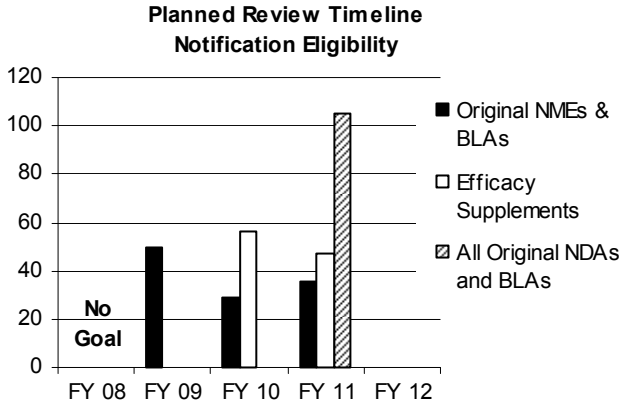
The table below summarizes the annual review-time commitment for planned review timeline notifications. FDA is to inform the applicant of the planned timeline for feedback related to labeling and PMRs and PMCs. The commitment began in FY 2009 with the inclusion of original NMEs and BLAs, and expanded in FY 2010 to include efficacy supplements for new and expanded indications. All original NDAs are included in FY 2011 and all efficacy supplements will be included 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 and BLAs*					90%	
All Efficacy Supplements						90%

* NMEs were included in the count for All Original NDAs and BLAs starting in FY 2011 as required under PDUFA IV.

Workload

In FY 2011, 36 original NME and BLA applicants were eligible for a planned review timeline notification, an increase from FY 2010 that corresponds to the increase in the number of NMEs and BLAs filed. The number of efficacy supplements for new or expanded indications decreased in FY 2011. In FY 2011, FDA's commitment expanded to include all original NDAs and BLAs (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	36	--
Efficacy Supplements for New/Expanded Indications	--	--	56	47	--
All Original NDAs and BLAs†	--	--	--	105	--

* FY 2010 numbers were changed to reflect updates to data presented in the FY 2010 PDUFA Performance Report.
† NMEs were included in the count for All Original NDAs and BLAs starting in FY 2011 as required under PDUFA IV.

Notification of Planned Review Timelines

FY 2011 Performance

As of September 30, 2011, performance data were available for over two-thirds (25 of 36), of notifications for original NMEs and BLAs, over five-sixths (41 of 47) of efficacy supplements for new/expanded indications, and over three-fourths (82 of 105) of notifications for all original NDAs and BLAs. FDA met the commitment for almost all (23 of 25) notifications for original NMEs and BLAs, most (34 of 41) notification for efficacy supplements, and for almost all (80 of 82) of the notifications for all original NDAs and BLAs (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 as well as for all original NDAs 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 be able to meet the performance commitment level.

Application Type	Performance Commitment	Applications Filed*	Notifications Issued as of September 30, 2011			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	36	23	2	**92%**	11
Efficacy Supplements for New/Expanded Indications		47	34	7	**83%**	6
All Original NDAs and BLAs‡		105	80	2	**98%**	23

* 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.

‡ NMEs were included in the count for All Original NDAs and BLAs starting in FY 2011 as required under PDUFA IV.

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, 2011, preliminary data showed FDA met the planned target date for 64 percent of original NMEs and BLAs, for 54 percent of efficacy supplements for new/expanded indications, and for 64 percent of all original NDAs and BLAs. 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
Original NMEs and BLAs	23	9	5	**64%**	0	9	0
Efficacy Supplements for New/Expanded Indications	34	7	6	**54%**	2	19	0
All Original NDAs and BLAs†	80	21	12	**64%**	0	47	0

* Some target dates were met due to communicating deficiencies. See the table at the bottom of the page for details.
† NMEs were included in the count for All Original NDAs and BLAs starting in FY 2011 as required under PDUFA IV.

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	All Original NDAs and BLAs
Met Target Date by Communicating Deficiencies	3	2	3
Target Date Inapplicable – Solicited Amendment	0	0	0
Target Date Inapplicable – Unsolicited Amendment	0	2	0

FDA will update the FY 2011 data in Appendix C of the FY 2012 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 2011 Accomplishments
Enhancement of Drug Safety	Modernize the process for monitoring the safety of FDA-regulated medical products.	• Launched the "Mini-Sentinel" safety pilot program, the first step towards building a nationwide rapid-response electronic safety surveillance system for drugs and other medical products, vaccines, and regulated blood and blood-derived products. The pilot encompasses nearly 100 million patients through 17 data partners across the United States. • Completed a contract study on FDA's spontaneous adverse event surveillance system.
	Expand access to database resources.	• Studies are underway with the Centers for Medicare and Medicaid Services (CMS), the Agency for Healthcare Research and Quality (AHRQ), and the Veterans Health Administration (VHA) to access large databases for drug safety information. • Continued efforts with the Department of Defense (DoD) to enhance signal identification and with the Centers for Disease Control (CDC) on database enhancements. • Continued work with private organizations, such as the Kaiser Foundation Research Institute, the Health Maintenance Organization (HMO) Research Network, and with the United Kingdom's health care system to improve FDA's ability to enhance drug safety.
Proprietary Names	Evaluate the pilot program, begun in October 2009, after 2 years of experience with the pilot program.	• The pilot program has been terminated due to only minimal participation by industry. A Federal Register Notice was published in October 2011.

Performance Area	Management Initiatives	FY 2011 Accomplishments
First Cycle Review Performance Proposal	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.	• The evaluation was completed and the final report received by FDA on March 31, 2011. The report is posted on FDA's website.
Expediting Drug Development	Develop and publish guidance on imaging standards for use as an end point in clinical trials.	• Published draft guidance in August 2011.
	Develop guidance for biomarker qualification.	• Published draft guidance in October 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 (Completed in March 2009) 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.	• Completed the GRMPs implementation assessment in June 2011. The final report is posted on FDA's website. • Completed the assessment of the electronic submission and review environment on the drug review process in September 2011. The final report is posted on FDA's website. • PDUFA IV Performance Management Initiative funded contracts to develop a concept of operations for CDER's Office of Surveillance and Epidemiology and to continue process improvement of the new drug review process in CDER's Office of New Drugs.

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 2011 Accomplishments
Update technical specifications and IT-related guidance documents as necessary.	• Published draft guidance for comment -- Electronic Source Documentation in Clinical Investigations, January 2011
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, and BLAs, and their supplements.	• Regulated product submission (RPS) release 2 draft standard for trial use (DSTU) 1 - October 2010 through January 2011 - Completed phase 1 and 2 test scenarios and RPS messages. • RPS Release 2 DSTU 2 - February 2011 through September 2011 - Completed International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) regional requirements and provided input on the development of the ballot materials. • Passed health level seven (HL7) DSTU 2 Ballot and Reconciliation – September 2011
Establish standards-based information systems to support how FDA obtains and analyzes postmarket drug safety data and manages emerging drug safety information.	• Finalized the FDA Improvement Plan (Version 6) – January 2011 • Completed the implementation of Release 0.5 that contained Oracle Adverse Event Reporting System (AERS) out-of-the-box functionality with limited customization – January 2011 • Completed the implementation of Release 1.0, which was mandated by the Office of Management and Budget (OMB) – April 2011 • Completed the development and testing of Release 1.5 that migrated 6 million AERS records and also implemented the product dictionary – August 2011

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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	--	--	--	--
	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

BLA – Biologics License Application

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

NDA – New Drug Application

NME – New Molecular Entity

PDUFA – Prescription Drug User Fee Act

PEPFAR – President's Emergency Plan for AIDS Relief

PMC – Postmarketing Commitment

PMR – Postmarketing Requirement

POCA – Phonetic and Orthographic Computer Analysis

RFP – Request for Proposals

SOP – Standard Operating Procedure

SPA – Special Protocol Assessment

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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 IV in FY 2011. Approvals are grouped by priority designation and submission year and listed in order of total approval time. Review histories of NDA and BLA submissions approved prior to FY 2011 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.

Please note: When determining total time, FDA calculates the numbers and rounds them to the nearest tenth. However, when cycle times are added, rounding discrepancies can occur. That is, the rounding of individual cycles and applicant times to the nearest tenth can, in some cases, result in times that, when added, may not appear to add correctly (differing by 0.1 month). For example on page B-9, the submission GEMCITABINE INJECTION (38MG/ML) had a rounded first cycle time of 13.0 months, a rounded applicant time of 4.9 months, and a rounded second review cycle time of 1.8 months. Adding these times together suggests a total time to approval of 19.7 months; however, the actual rounded total time was 19.8 months. Another case is seen with the submission BRILINTA (TICAGRELOR), also on page B-9, where the rounded total time to approval equaled 20.1 months, but adding the rounded cycle and applicant times (13.0 months, plus 1.2 months, plus 6.0 months) suggests a total time of 20.2 months.

Because months consist of varying numbers of days, FDA uses the average number of days in a month to calculate months. Therefore, a submission may appear overdue even though it was approved on the goal date. For example, the submission ZIDOVUDINE 100MG TABLETS on page B-7 was received on 04/23/2010 and had a 10-month review goal date of 02/23/2011. FDA approved the submission on the goal date but because FDA uses the average number of days in a month to calculate months, the 306 days taken to review the submission is reported as 10.1 months and the review appears overdue.

Terms and Coding Used in Tables

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

◊ Expedited review and TA of an 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.

▲ Denotes Class 1 Resubmission (2 months review-time goal)

△ Denotes Class 2 Resubmission (6 months review-time goal)

Impact of Severe Weather on Applications Approved During FY 2011

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 the 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 were 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. Some applications approved during FY 2011 after multiple review cycles may have been impacted by the FY 2010 closures during previous cycles.

Table 1
FY 2011 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	
FY 2011	VEMURAFENIB	HOFFMANN LA ROCHE INC	Y	First	3.6	AP	3.6	Y
	ZYTIGA (ABIRATERONE ACETATE) TABLETS	JANSSEN BIOTECH INC	Y	First	4.2	AP	4.2	Y
	CRIZOTINIB	PFIZER INC	Y	First	4.9	AP	4.9	Y
	Brentuximab vedotin	Seattle Genetics, Inc.	Y	First	5.7	AP	5.7	Y
	Brentuximab vedotin	Seattle Genetics, Inc.	N	First	5.7	AP	5.7	Y
	DIFICID (FIDAXOMICIN)	OPTIMER PHARMACEUTICALS INC	Y	First	5.9	AP	5.9	Y
	BOCEPREVIR	SCHERING CORP	Y	First	5.9	AP	5.9	Y
	TELAPREVIR	VERTEX PHARMACEUTICALS INC	Y	First	6.0	AP	6.0	Y
	ABACAVIR SULFATE/LAMIVUDINE FDC SCORED TABS FOR ORAL SUSPENSION (60MG/30MG)	CIPLA LTD	N	First	6.0	TA	6.0	Y◊
	OXECTA	KING PHARMACEUTICALS RESEARCH DEVELOPMENT INC	N	First	6.0	AP	6.0	Y
	EMTRICITABINE/ RILPIVIRINE HYDROCHLORIDE/ TENOFOVIR DISOPROXIL FUMARATE FIXED-DOSE COMBINATION TABLETS (FTC/RPV/TDF)	GILEAD SCIENCES INC	N	First	6.0	AP	6.0	Y
FY 2010	Factor XIII Concentrate (Human)	CSL Behring GmbH	Y	First	6.0	AP	6.0	Y
	PRADAXA (DABIGATRAN ETEXILATE MESYLATE)	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	Y	First	6.0	AP	6.0	Y
	HALAVEN (ERIBULIN MESYLATE)	EISAI INC	Y	First	7.6	AP	7.6	Y+
	NITHIODOTE	HOPE PHARMACEUTICALS	N	First	6.0	CR	6.0	Y
				Applicant	1.1	--	7.1	--
				Second	0.8	AP	7.8	Y▲
	CAPRELSA (VANDETANIB)	IPR PHARMACEUTICALS INC	Y	First	9.0	AP	9.0	Y+

Receipt Cohort (FY)	Established/Proper Name	Applicant	NME (Y/N)	Approval Time (Months)				Goal Met
				Review Cycle	Cycle Time	Cycle Result	Total Time	
FY 2010	Belimumab	Human Genome Sciences, Inc.	Y	First	9.0	AP	9.0	Y+
	Ipilimumab	Bristol-Myers Squibb Company	Y	First	9.0	AP	9.0	Y+
FY 2009	OFIRMEV (ACETAMINOPHEN FOR INJECTION)	CADENCE PHARMACEUTICALS INC	N	First	9.0	CR	9.0	Y+
				Applicant	2.7	--	11.7	--
				Second	6.0	AP	17.7	Y△
	DA TSCAN	GE HEALTHCARE INC	Y	First	6.0	CR	6.0	Y
				Applicant	1.6	--	7.6	--
				Second	1.9	CR	9.5	Y▲
				Applicant	10.8	--	20.3	--
				Third	1.9	AP	22.2	Y▲
	SODIUM FLUORIDE F-18	NATIONAL INSTITUTES HEALTH NATIONAL CANCER INSTITUTE DIV CANCER TREATMENT AND DIAGNOSIS	N	First	5.9	CR	5.9	Y
				Applicant	12.9	--	18.8	--
				Second	6.0	AP	24.9	Y△
	Centruroides (Scorpion) Immune F(ab')2 (Equine) Injection	Rare Disease Therapeutics, Inc. (RDT)	Y	First	6.0	CR	6.0	Y
				Applicant	18.3	--	24.3	--
				Second	6.0	AP	30.3	Y△
FY 2008	FIRAZYR SOLUTION FOR INJECTION	SHIRE ORPHAN THERAPIES INC	Y	First	5.9	NA	5.9	Y
				Applicant	34.1	--	40.0	--
				Second	6.0	AP	46.0	Y△
FY 2006	NEURODEX (DEXTROMETHORPHAN PLUS QUINIDINE)	AVANIR PHARMACEUTICALS INC	N	First	9.0	AE	9.0	Y+
				Applicant	42.0	--	51.0	--
				Second	6.0	AP	57.0	Y△
	MAKENA (HYDROXYPROGESTERONE CAPROATE)	KV PHARMACEUTICAL CO	N	First	6.0	AE	6.0	Y
				Applicant	18.2	--	24.2	--
				Second	9.0	CR	33.2	Y+△
				Applicant	17.6	--	50.8	--
				Third	6.7	AP	57.5	Y+△

Receipt Cohort (FY)	Established/Proper Name	Applicant	NME (Y/N)	Approval Time (Months)				Goal Met
				Review Cycle	Cycle Time	Cycle Result	Total Time	
FY 2001	RECTIV (NITROGLYCERIN) OINTMENT 0.4%	PROSTRAKAN INC	N	First	10.0	WD	10.0	--
				Applicant	26.2	--	36.2	--
				Second	5.8	NA	42.0	Y*
				Applicant	3.7	--	45.7	--
				Third	14.7	AE	60.4	N▲
				Applicant	38.8	--	99.2	--
				Fourth	6.0	CR	105.2	Y△
				Applicant	8.7	--	113.9	--
				Fifth	6.0	AP	119.9	Y△

* Since this submission was withdrawn in the first cycle, the second cycle was treated as a new submission.

Table 2
FY 2011 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	
FY 2011	EYE WASH	NIAGARA PHARMACEUTICALS INC	N	First	10.0	AP	10.0	Y
	LAMIVUDINE/ZIDOVUDINE FDC SCORED TABS (30MG/60MG)	CIPLA LTD	N	First	10.0	TA	10.0	Y◊
	LAMIVUDINE AND TENOFOVIR DISOPROXIL FUMARATE TABLETS, 300 MG/300 MG, CO-PACKAGED WITH NEVIRAPINE TABLETS, 200 MG	MATRIX LABORATORIES LTD	N	First	10.0	TA	10.0	Y◊
FY 2010	CODEINE SULFATE	ROXANE LABORATORIES INC	N	First	9.1	AP	9.1	Y
	DOCETAXEL	SANDOZ INC	N	First	9.4	AP	9.4	Y
	CALCIPOTRIEN FOAM 0.005%	STIEFEL LABORATORIES INC	N	First	9.5	AP	9.5	Y
	NEVIRAPINE EXTENDED RELEASE TABLETS	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	N	First	9.7	AP	9.7	Y
	LEVOTHYROXINE SODIUM FOR INJECTION	APP PHARMACEUTICALS	N	First	9.8	AP	9.8	Y
	ALISKIREN/AMLODIPINE/ HCTZ TABLETS	NOVARTIS PHARMACEUTICALS CORP	N	First	9.8	AP	9.8	Y
	HYDROMORPHONE HYDROCHLORIDE INJECTION 1,2,4 MG/ML	HOSPIRA INC	N	First	9.9	TA	9.9	Y
	RILPIVIRINE	TIBOTEC INC	Y	First	9.9	AP	9.9	Y
	TESTOSTERONE	ELI LILLY AND CO	N	First	9.9	AP	9.9	Y
	OXYCODONE HCL CAPSULES	LEHIGH VALLEY TECHNOLOGIES INC	N	First	9.9	AP	9.9	Y
	LATUDA (LURASIDONE) TABLETS	SUNOVION PHARMACEUTICALS INC	Y	First	9.9	AP	9.9	Y
	OXYCODONE ORAL SOLUTION 20MG/ML (100MG/5ML)	LEHIGH VALLEY TECHNOLOGIES INC	N	First	9.9	AP	9.9	Y
	Albumin (Human)	Kedrion, S.p.A.	Y	First	10.0	AP	10.0	Y
	EPINEPHRINE	INTELLIJECT INC	N	First	10.0	TA	10.0	Y
	AZILSARTAN MEDOXOMIL	TAKEDA PHARMACEUTICALS NORTH AMERICA INC	Y	First	10.0	AP	10.0	Y
	PHENTERMINE HCL 15,30,37.5 MG ODT	CITIUS PHARMACEUTICALS LLC	N	First	10.0	AP	10.0	Y

Receipt Cohort (FY)	Established/Proper Name	Applicant	NME (Y/N)	Approval Time (Months)				Goal Met
				Review Cycle	Cycle Time	Cycle Result	Total Time	
FY 2010	FEXOFENADINE HCL	SANOFI AVENTIS US LLC	N	First	10.0	AP	10.0	Y
	CEFTAZIDIME INJ/ DEXTROSE INJ 1G/2G DUPLE	B BRAUN MEDICAL INC	N	First	10.0	AP	10.0	Y
	LAMIVUDINE/TENOFOVIR DISOPROXIL FUMARATE FDC TABLETS (300MG/300MG)	CIPLA LTD	N	First	10.0	TA	10.0	Y◊
	LAMIVUDINE/TENOFOVIR DIXOPROXIL FUMARATE FDC TABLETS (300 MG/300)	AUROBINDO PHARMA LIMITED	N	First	10.0	TA	10.0	Y◊
	GADOBUTROL INJECTION	BAYER HEALTHCARE PHARMACEUTICALS INC	Y	First	10.0	AP	10.0	Y
	CEFTAROLINE FOSAMIL FOR INJECTION	CEREXA INC	Y	First	10.0	AP	10.0	Y
	TRADJENTA (LINAGLIPTIN) TABLETS	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	Y	First	10.0	AP	10.0	Y
	GRALISE	DEPOMED INC	N	First	10.0	AP	10.0	Y
	ABACAVIR SULFATE SCORED TABLETS 60MG	MATRIX LABORATORIES LTD	N	First	10.0	TA	10.0	Y◊
	ABACAVIR SULFATE TABS FOR ORAL SUSPENSION (60MG)	CIPLA LTD	N	First	10.0	TA	10.0	Y◊
	RUFINAMIDE ORAL SUSPENSION	EISAI INC	N	First	10.0	AP	10.0	Y
	VIIBRYD (VILAZODONE HCL) TABLETS	FOREST LABORATORIES INC	Y	First	10.0	AP	10.0	Y
	LAMIVUDINE AND ZIDOVUDINE TABLETS, 30 MG/60 MG	MATRIX LABORATORIES LTD	N	First	10.1	AP	10.1	Y◊*
	ZIDOVUDINE 100MG TABLETS	MATRIX LABORATORIES LTD	N	First	10.1	AP	10.1	Y◊*
	KOMBIGLYZE XR (SAXAGLIPTIN/METFORMIN HYDROCHLORIDE EXTENDED-RELEASE) TABLETS	BRISTOL MYERS SQUIBB	N	First	10.2	AP	10.2	N
	ROSUVASTATIN ZINC TABLETS 5, 10, 20 AND 40 MG	WATSON LABORATORIES INC	N	First	12.6	TA	12.6	Y+
	ARGATROBAN INJECTION 1 MG/ML	SANDOZ INC	N	First	9.9	TA	9.9	Y
				Applicant	2.5	--	12.4	--
				Second	0.4	AP	12.8	Y▲

* This submission met the review goal, but due to rounding, it appears overdue.

Receipt Cohort (FY)	Established/Proper Name	Applicant	NME (Y/N)	Approval Time (Months)				Goal Met
				Review Cycle	Cycle Time	Cycle Result	Total Time	
FY 2010	NORETHINDRONE AND ETHINYL ESTRADIOL TABLETS, CHEWABLE AND FERROUS FUMARATE TABLETS, CHEWABLE	WATSON LABORATORIES INC	N	First	12.9	AP	12.9	Y+
	SAFYRAL	BAYER HEALTHCARE PHARMACEUTICALS INC	N	First	12.9	AP	12.9	Y+
	HZT-501	HORIZON PHARMA INC	N	First	13.0	AP	13.0	Y+
	TOPOTECAN HYDROCHLORIDE INJECTION	SANDOZ INC	N	First	13.0	AP	13.0	Y+
	ZYCLARA (IMIQUIMOD) CREAM 3.75%	GRACEWAY PHARMACEUTICALS LLC	N	First	13.3	AP	13.3	N
	ARGATROBAN INJECTION 1 MG/ML	SANDOZ INC	N	First	9.9	TA	9.9	Y
				Applicant	3.2	--	13.2	--
				Second	0.6	AP	13.7	Y▲
	TOPOTECAN INJ	HOSPIRA INC	N	First	12.9	CR	12.9	Y+
				Applicant	0.2	--	13.1	--
				Second	2.0	AP	15.2	Y▲
	LOTEMAX (LOTEPREDNOL ETABONATE OPHTHALMIC OINTMENT) 0.5%	BAUSCH AND LOMB INC	N	First	9.9	CR	9.9	Y
				Applicant	3.2	--	13.1	--
				Second	2.6	AP	15.7	Y△
	MORPHINE SULFATE ORAL SOLUTION 20 MG/ML	LANNETT HOLDINGS INC	N	First	9.3	CR	9.3	Y
				Applicant	0.4	--	9.8	--
				Second	6.0	AP	15.7	Y△
	HEPARIN SODIUM INJECTION	PFIZER INC	N	First	13.0	CR	13.0	Y+
				Applicant	0.1	--	13.1	--
				Second	3.3	AP	16.4	Y△
	DOCETAXEL INJECTION 20 MG AND 80 MG	ACCORD HEALTHCARE INC	N	First	10.0	CR	10.0	Y
				Applicant	1.6	--	11.6	--
				Second	5.9	AP	17.5	Y△

Receipt Cohort (FY)	Established/Proper Name	Applicant	NME (Y/N)	Approval Time (Months)				Goal Met
				Review Cycle	Cycle Time	Cycle Result	Total Time	
FY 2010	POTIGA (EZOGABINE)	GLAXOSMITHKLINE	Y	First	13.0	CR	13.0	Y+
				Applicant	4.5	--	17.5	--
				Second	1.8	AP	19.3	Y▲
	GEMCITABINE INJECTION (38MG/ML)	HOSPIRA INC	N	First	13.0	CR	13.0	Y+
				Applicant	4.9	--	17.9	--
				Second	1.8	AP	19.8	Y▲
	BRILINTA (TICAGRELOR)	ASTRAZENECA LP	Y	First	13.0	CR	13.0	Y+
				Applicant	1.2	--	14.2	--
				Second	6.0	AP	20.1	Y△
	TAPENTADOL	ORTHO MCNEIL JANSSEN PHARMACEUTICALS INC	N	First	10.0	CR	10.0	Y
				Applicant	4.9	--	14.9	--
				Second	5.9	AP	20.8	Y△
FY 2009	ATELVIA	WARNER CHILCOTT CO LLC	N	First	12.5	AP	12.5	Y+
	ABSTRAL (FENTANYL) SUBLINGUAL TABLETS	PROSTRAKAN INC	N	First	17.1	AP	17.1	N
	EGRIFTA (TESAMORELIN FOR INJECTION)	EMD SERONO INC	Y	First	17.4	AP	17.4	N
	CYMBALTA	ELI LILLY AND CO	N	First	17.7	AP	17.7	N
	LOESTRIN 1/10 FE	WARNER CHILCOTT CO INC	N	First	10.1	CR	10.1	Y*
				Applicant	2.8	--	12.9	--
				Second	6.0	AP	18.9	Y△
	ARIDOL POWDER FOR INHALATION	PHARMAXIS INC	N	First	9.8	CR	9.8	Y
				Applicant	3.5	--	13.3	--
				Second	6.0	AP	19.2	Y△
	DALIRESP (ROFLUMILAST) 500 MCG TABLETS	FOREST RESEARCH INSTITUTE INC	Y	First	10.0	CR	10.0	Y
				Applicant	3.5	--	13.5	--
				Second	6.0	AP	19.4	Y△

* This submission met the review goal, but due to rounding, it appears overdue.

Receipt Cohort (FY)	Established/Proper Name	Applicant	NME (Y/N)	Approval Time (Months)				Goal Met
				Review Cycle	Cycle Time	Cycle Result	Total Time	
FY 2009	OMEPRAZOLE 20MG/ AMOXOCILLIN 500MG/ CLARITHROMYCIN 500MG	GASTROENTERO LOGIC LLC	N	First	2.1	WD	2.1	--
				Applicant	1.1	--	3.2	--
				Second	9.9	CR	13.1	Y*
				Applicant	4.6	--	17.7	--
				Third	2.1	AP	19.7	Y▲[†]
	BACLOFEN INTRATHECAL INJ 0.05 MG/ML/0.5	CNS THERAPEUTICS INC	N	First	19.7	AP	19.7	N
	PHOSLYRA (CALCIUM ACETATE) ORAL SOL 667MG	FRESENIUS MEDICAL CARE NORTH AMERICA	N	First	10.0	CR	10.0	Y
				Applicant	4.9	--	14.9	--
				Second	6.0	AP	20.9	Y△
	LAZANDA	ARCHIMEDES DEVELOPMENT LTD	N	First	10.0	CR	10.0	Y
				Applicant	3.0	--	13.0	--
				Second	9.0	AP	22.0	Y+△
	MOXIFLOXACIN ALTERNATIVE FORMULATION OP	ALCON PHARMACEUTICALS LTD	N	First	9.7	CR	9.7	Y
				Applicant	7.4	--	17.2	--
				Second	6.0	AP	23.1	Y△
	Belatacept	Bristol-Myers Squibb Company	Y	First	10.0	CR	10.0	Y
				Applicant	7.5	--	17.5	--
				Second	6.0	AP	23.5	Y△
	SPINOSAD	PARAPRO PHARMACEUTICALS LLC	Y	First	9.9	CR	9.9	Y
				Applicant	8.2	--	18.1	--
				Second	5.8	AP	23.9	Y△
	Coccidioides immitis Spherule-Derived Skin Test Antigen	Allermed Laboratories, Inc.	Y	First	10.0	CR	10.0	Y
				Applicant	10.1	--	20.1	--
				Second	6.0	AP	26.1	Y△
	ANDROGEL	ABBOTT LABORATORIES	N	First	12.9	CR	12.9	Y+
				Applicant	7.6	--	20.5	--
				Second	6.0	AP	26.5	Y△

* Since this submission was withdrawn in the first cycle, the second cycle was treated as a new submission.
[†] This submission met the review goal, but due to rounding, it appears overdue.

Receipt Cohort (FY)	Established/Proper Name	Applicant	NME (Y/N)	Approval Time (Months)				Goal Met
				Review Cycle	Cycle Time	Cycle Result	Total Time	
FY 2009	HORIZANT	GLAXO GROUP LTD ENGLAND DBA GLAXOSMITHKLINE	Y	First	13.3	CR	13.3	Y+[6]
				Applicant	7.6	--	20.9	--
				Second	6.0	AP	26.9	Y△
	ARGATROBAN INJECTION	EAGLE PHARMACEUTICALS INC	N	First	10.0	CR	10.0	Y
				Applicant	11.4	--	21.4	--
				Second	5.5	AP	27.0	Y△
	Azficel-T	Fibrocell Technologies, Inc.	Y	First	9.4	CR	9.4	Y
				Applicant	12.1	--	21.5	--
				Second	6.0	AP	27.5	Y△
	ARCAPTA NEOHALER	NOVARTIS PHARMACEUTICALS CORP	Y	First	9.9	CR	9.9	Y
				Applicant	11.5	--	21.4	--
				Second	9.0	AP	30.4	Y+△
	REZIRA (HYDROCODONE BITARTRATE AND PSEU)	CYPRESS PHARMACEUTICAL INC	N	First	10.3	CR	10.3	N
				Applicant	2.8	--	13.1	--
				Second	6.0	CR	19.1	Y△
				Applicant	5.9	--	25.0	--
				Third	6.0	AP	30.9	Y△
	ZUTRIPRO (HYDROCODONE/ CHLORPHENIRAMINE/ PSEUDOEPHEDRINE)	CYPRESS PHARMACEUTICAL INC	N	First	10.4	CR	10.4	N
				Applicant	2.8	--	13.2	--
				Second	6.0	CR	19.2	Y△
				Applicant	5.9	--	25.1	--
				Third	6.0	AP	31.0	Y△
FY 2008	Adenovirus Type 4 and Type 7 Vaccine, Live, Oral	Teva Women's Health, Inc.	Y	First	9.5	CR	9.5	Y
				Applicant	13.9	--	23.4	--
				Second	6.1	AP	29.5	Y△*

* This submission met the review goal, but due to rounding, it appears overdue.

[6] Goal extensions were made to this submission due to the February 2010 blizzard and subsequent closing of the Federal Government (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	
FY 2008	XARELTO (RIVAROXABAN) ORAL 10 MG	JOHNSON AND JOHNSON PHARMACEUTICAL RESEARCH AND DEVELOPMENT LLC	Y	First	10.0	CR	10.0	Y
				Applicant	19.3	--	29.3	--
				Second	5.9	AP	35.1	Y△
FY 2006	H.P.ACTHAR GEL (REPOSITORY CORTICOTROPIN INJECTION)	QUESTCOR PHARMACEUTICALS INC	N	First	10.6	NA	10.6	N
				Applicant	31.1	--	41.7	--
				Second	10.1	AP	51.8	N△
FY 2002	FORTESTA	ENDO PHARMACEUTICALS INC	N	First	13.0	NA	13.0	Y+
				Applicant	69.5	--	82.5	--
				Second	6.0	CR	88.5	Y△
				Applicant	8.4	--	97.0	--
				Third	6.0	AP	102.9	Y△

APPENDIX C: Update on FY 2010 PDUFA Procedural and Processing Goals and Commitments

Final performance assessments for the following procedural and processing goals and commitments were not possible due to reviews pending within goal at the end of FY 2010 (as of September 30, 2010). Preliminary results were, therefore, provided in the FY 2010 PDUFA Performance Report. FY 2010 numbers in the following tables were changed to reflect updates to data presented in the FY 2010 PDUFA Performance Report.

Meeting Management

FY 2010 Performance

As of September 30, 2011, performance data were available on almost all (5,863 of 5,865) meeting management goals. FDA completed on time most (4,267 of 5,863) meeting management activities. With two meeting minutes pending within goal, FDA will not be able to meet any performance goals for meeting management (see table below).

Type		Performance Goal – Review 90 percent within	Received	Performance as of September 30, 2011		
				On Time	Overdue	Percent On Time
Meeting Requests	**Type A***	14 Days	234	153	81	**65%**
	Type B	21 Days	1,305	998	307	**76%**
	Type C		718	544	174	**76%**
Scheduling Meetings†	**Type A**	30 Days	216	143	73	**66%**
	Type B	60 Days	1,199	874	325	**73%**
	Type C	75 Days	613	476	137	**78%**
Meeting Minutes‡		30 Days	1,580	1,079	499	**68%**◊

* Includes 21 meetings denoted as Undetermined in the database.
† 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.
◊ Two meeting minutes were still pending within goal as of September 30, 2011.

Responses to Clinical Holds

FY 2010 Performance

FDA reviewed on time most (167 of 204) sponsors' appeals of decisions received in FY 2010; 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, 2010			Final Performance		
		On Time	Overdue	Percent on Time	On Time	Overdue	Percent on Time
Respond to 90 percent within 30 days	204	154	37	**81%**	167	37	**82%**

Special Protocol Assessments

FY 2010 Performance

FDA reviewed on time most (257 of 309) sponsors' requests for the evaluation of protocol designs received in FY 2010; however, FDA did not meet the performance goal for special protocol assessments (see table below).

Performance Goal	Total Received	Performance as of September 30, 2010			Final Performance		
		On Time	Overdue	Percent on Time	On Time	Overdue	Percent on Time
Respond to 90 percent within 45 days	309*	206	48	**81%**	257	52	**83%**

* FDA received 1 resubmission for 41 original requests, and 2 resubmissions each for 2 original requests, for a total of 45 resubmissions. Therefore, 16 percent (43 of 264) of original requests received at least one resubmission, or one resubmission for every six original requests.

Drug/Biological Product Proprietary Names

FY 2010 Performance

FDA reviewed on time most (95 of 102) proprietary names submitted during the IND phase and most (193 of 207) proprietary names submitted with NDAs and BLAs. 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, 2010			Final Performance		
			On Time	Overdue	Percent on Time	On Time	Overdue	Percent on Time
Proprietary Names Submitted During IND Phase	Act on 70 percent within 180 days of receipt	102	49	4	**92%**	95	7	**93%**
Proprietary Names Submitted with NDA/BLA	Act on 70 percent within 90 days of receipt	207	163	13	**93%**	193	14	**93%**

First Cycle Filing Review Notification

FY 2010 Performance

FDA met the review-time commitment for reporting substantive review issues (or lack thereof) identified during the initial filing review for most (97 of 105) NDAs and BLAs and most (101 of 112) efficacy supplements filed in FY 2010 (see table below). FDA exceeded the first cycle filing review notification performance commitment for NDAs and BLAs and met the performance commitment for efficacy supplements.

First Cycle Filing Review Notification Type	Performance Level	Filed	Performance as of September 30, 2010			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	105	80	11	**88%**	97	8	**92%**
Efficacy Supplements		112	75	13	**85%**	101	11	**90%**

Notification of Planned Review Timelines

FY 2010 Performance

FDA met the review-time commitment for planned review timeline notifications for almost all (26 of 29) original NMEs and BLAs and most (45 of 56) efficacy supplements for new or expanded indications (see table below). FDA met the performance commitment for applicant notification of planned review timelines in the filing review notification letter for original NMEs and BLAs, but did not meet the performance commitment for efficacy supplements for new or expanded indications.

Application Type	Performance Commitment	Applications Filed	Notifications Issued as of September 30, 2010 Final Notifications			Final Performance		
			In 74 Day Letter	Not In 74 Day Letter	Percent In 74 Day Letters	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%**	26	3	**90%**
Efficacy Supplements for New/Expanded Indications		56	36	6	**86%**	45	11	**80%**

Meeting Planned Review Timeline Target Dates

FY 2010 Performance

FDA met the planned target date with 35 percent (9 of 26) of applications for original NMEs and BLAs and with 43 percent (19 of 44) of applications for efficacy supplements for new or expanded indications in FY 2010.

Application Type	Number of 74 Day Letters With Timelines	Target Date Met as of September 30, 2010			Final Performance		
		Target Date Met	Target Date Not Met	Percent of Applications Target Date Met	Target Date Met	Target Date Not Met	Percent of Applications Target Date Met
Original NMEs and BLAs	26	2	7	**22%**	9	17	**35%**
Efficacy Supplements for New/Expanded Indications	44*	3	8	**27%**	19	25	**43%**

* Does not include one application that was withdrawn.

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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