FY 2008

PERFORMANCE REPORT TO THE PRESIDENT AND THE 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) 2008 Prescription Drug User Fee Act (PDUFA) Performance Report to the President and Congress. This report marks the 16th year of PDUFA and the beginning of PDUFA IV (FY 2008 through FY 2012).

PDUFA IV marks a milestone for FDA and provides important new benefits related to the safety of prescription drugs. With expanded responsibilities and funding to cover postmarket safety provided under the Food and Drug Administration Amendments Act of 2007 (FDAAA), and new requirements related to premarket pediatric drug review, FDA was provided with new tools to enhance the safety of prescription drugs available to the American public.

The transition to PDUFA IV also provided unprecedented challenges to FDA. Expanding the work force, training and mentoring new staff, and adapting to new requirements including the new broad authorities under FDAAA have limited FDA's ability to review as high a percentage of applications and submissions on time as in previous years. Our priorities and focus remained on ensuring reviews were completed with the quality expected from the public and from our dedicated workforce. However, performance in many traditionally strong PDUFA goal areas decreased in FY 2008; and, therefore, this report presents a picture of mixed success. Many goals were exceeded or met, while many others were not. And potential performance for FY 2008 submissions still under review at the end of the fiscal year was not as high as in past years.

Despite these setbacks, FDA will not back down from its commitments to the public and those made under PDUFA IV. The agency has taken steps to improve performance and will continue to work to expand its ability to review drugs in a timely manner. Through these efforts, FDA will continue to improve premarket review and postmarket safety to provide the American public with the safest and highest quality prescription drugs in the world.

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

Executive Summary

The passage of FDAAA began FDA's transition into PDUFA IV during FY 2008 with the expansion of user fee funding to cover postmarket safety activities. FDAAA also expanded requirements under the reauthorized Pediatric Research Equity Act (Title IV) and the Best Pharmaceuticals for Children Act (Title V). In addition, FDAAA Title IX gave FDA substantially expanded responsibilities and authorities regarding the postmarket safety of drugs. As a result of these changes, FDA faced unprecedented challenges in FY 2008 as it began to assess and enact new requirements while addressing PDUFA review commitments.

This report presents FDA's performance in meeting annual PDUFA review goals for FY 2007 and FY 2008, with both years being impacted by the PDUFA IV transition. Review performance for submissions received in FY 2007, and initially reported in the FY 2007 report, is updated and finalized. FDA's preliminary progress in meeting review performance goals for submissions received in FY 2008, and procedural and processing goals for FY 2008, are also covered in this report. Additionally, this report describes FDA's transition into PDUFA IV and progress in accomplishing management initiatives and in meeting the information technology commitments of PDUFA IV.

Review workload varied in FY 2008; this again demonstrated the difficulty in predicting how many submissions and corresponding reviews would be needed in any given category. Overall submissions were down by over 3 percent when compared to the previous 5 years; however, original NDAs and BLAs filed were up 20 percent compared to the same time period. FDA began FY 2008 with 1,441 submissions carried over for review from FY 2007, including 95 original NDAs and BLAs. FDA ended FY 2008 with 1,101 submissions pending and not overdue, including 106 original NDAs and BLAs.

Because review performance in any given year impacts prior year performance goals as well as current year performance goals, final FY 2007 performance goals and preliminary FY 2008 performance goals showed mixed results. As of September 30, 2008, FDA completed review on virtually all (3,089 of 3,096) FY 2007 submissions. FDA can now report that it met or exceeded half (6 of 12) of PDUFA 2007 performance goals:

- priority NDAs and BLAs, including priority new molecular entities (NMEs) and BLAs;
- resubmitted Class 2 NDAs and BLAs;
- Class 2 resubmitted efficacy supplements; and
- manufacturing supplements requiring prior approval along with manufacturing supplements not requiring prior approval.

FDA was meeting or exceeding half of FY 2008 performance goals as of the end of FY 2008. However, with improved performance in FY 2009, FDA has the potential to meet or exceed up to three-quarters (9 of 12) of performance goals for FY 2008:

- standard NDAs and BLAs, including standard NMEs and BLAs;
- resubmitted Class 1 NDAs and BLAs;
- priority and standard efficacy supplements;
- Class 1 and Class 2 resubmitted efficacy supplements; and
- manufacturing supplements requiring prior approval along with manufacturing supplements not requiring prior approval.

Workload related to the meeting management procedural and processing goals generally declined in FY 2008, and only the number of responses to clinical holds experienced an increase. However, FDA did not meet any FY 2008 procedural and processing goals.

This report also describes FDA's transition into PDUFA IV and progress in accomplishing management initiatives under, and in meeting the information technology commitments of, PDUFA IV.

Table of Contents

Overview of PDUFA

On September 27, 2007, the President signed into law FDAAA, which includes the reauthorization and expansion of PDUFA (PDUFA IV) for 5 more years (FY 2008 through FY 2012). 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 traditionally high standards for approval.

PDUFA I to PDUFA III: An Evolution in Review Progress

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

- **Speeding Up Application Review (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 targets that applied to an increasing percentage of complete application submissions.

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

- **Refining the Process - From Drug Development through Application Review to Postmarket Surveillance (FY 2003 through FY 2007).** PDUFA III established several new initiatives to improve application submissions and FDA-sponsored interactions during drug development and application review. In addition, PDUFA III authorized FDA to spend user fee funds on certain aspects of postmarket risk management, including surveillance of products approved after October 1, 2002, for up to 3 years after approval.

PDUFA IV: Changes to Implement and Challenges to Meet

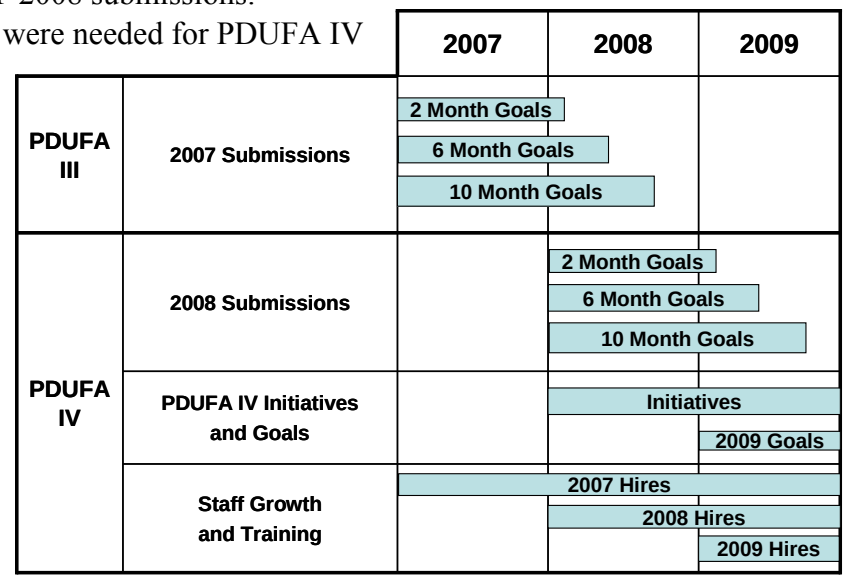
Reauthorized as Title I of FDAAA, PDUFA IV continues to provide funding for existing PDUFA performance goals and initiatives, while also expanding user fee funding to cover postmarket safety activities. FDA has committed to achieve PDUFA performance goals that apply to the review of original and resubmitted new product applications and efficacy and manufacturing supplements. FDA has also committed to achieve certain procedural and processing goals aimed at facilitating and assuring quality in new drug development. However, the changes and challenges that FDA faces in PDUFA IV as a result of the expansion of FDA's responsibilities under FDAAA place unprecedented demands on FDA reviewer workloads. These added responsibilities can also have unintended and unexpected impacts on FDA's short-term abilities to meet PDUFA IV goals.

- **Continuation of Progress.** PDUFA IV continues to provide funding for previously established PDUFA performance goals and initiatives. The first year of activity under PDUFA IV began on October 1, 2007, and ended on September 30, 2008. Preliminary performance results for FY 2008, the first year under PDUFA IV, are included in this report.

- **New Goals and Initiatives to Ensure Strong Premarket Review and Postmarket Safety.** FDAAA expanded requirements under the reauthorized Pediatric Research Equity Act (Title IV) and the Best Pharmaceuticals for Children Act (Title V). In addition, FDAAA Title IX gave FDA substantially expanded responsibilities and authorities regarding the postmarket safety of drugs. For example, FDA can now implement risk evaluation and mitigation strategies for approved drug products, require sponsors to conduct postmarket studies and clinical trials, and require safety labeling changes to address new safety information for marketed drugs. FDA is also tasked with developing systems capable of performing active postmarket risk identification and analysis. These new provisions greatly strengthen FDA's ability to perform its mission of ensuring the availability of safe and effective drugs, but they also place increasing workload demands on FDA. The added responsibilities of FDAAA Titles IV, V and IX pertaining to new drugs are now part of the process for the review of human drugs.

- **Staff Growth and Training.** FDA made great strides in FY 2008 to increase the number of staff and begin to implement the provisions of FDAAA. A significant number of new staff have been hired; however, the influx of new reviewers creates a short-term drain on experienced reviewers' and managers' time as they work to train and mentor these new staff. In FY 2009, FDA will focus on further training and integrating the new staff into the review process and continuing to develop, implement, and streamline the processes and policies required by FDAAA, while maintaining a high level of performance and efficiency of core review work.

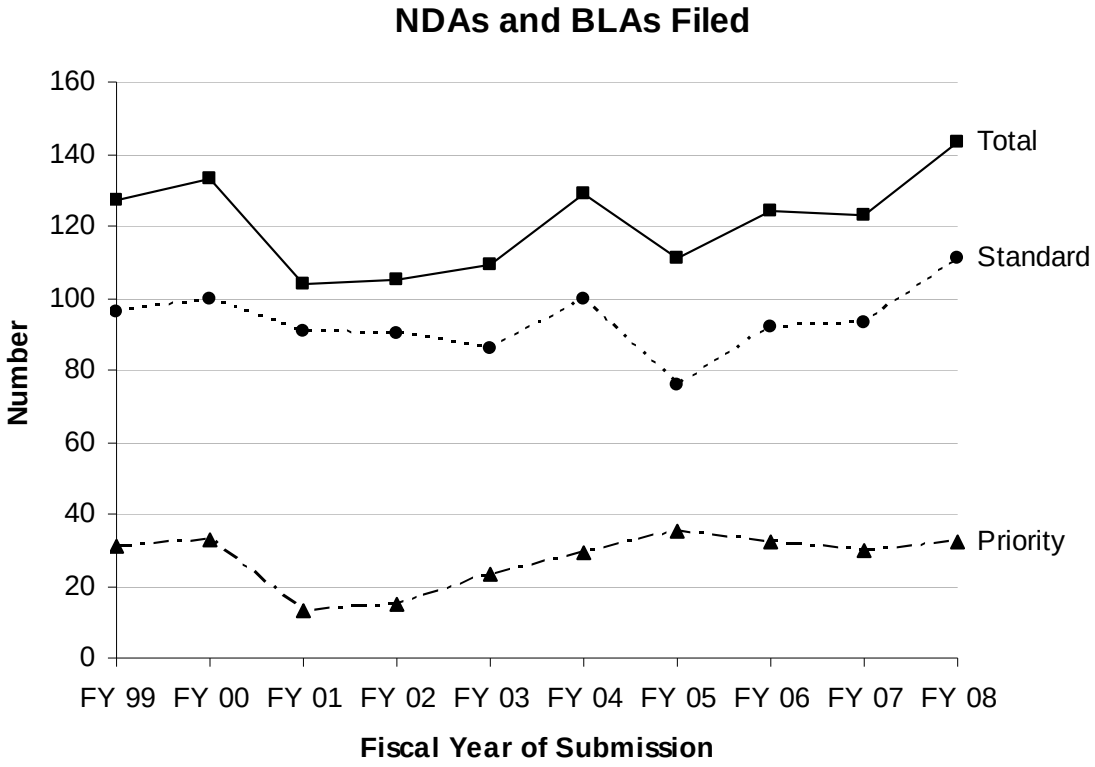
- **Adapting to FDAAA.** The changes and challenges presented by FDAAA resulted in unprecedented and unplanned demands on the workload of FDA staff (see table below). During FY 2008, the first year under PDUFA IV, FDA staff were still reviewing almost half of FY 2007 submissions. Most of these reviews were of 6-month and 10-month goals that were submitted in the second half of FY 2007. FDA reviewers also began to receive for review FY 2008 submissions. Additional resources were needed for PDUFA IV management and information technology initiatives. As referenced above, the hiring of a significant number of new staff came with the associated need for training and mentoring that can take up to 2 years before the new reviewers are able to conduct reviews independently.



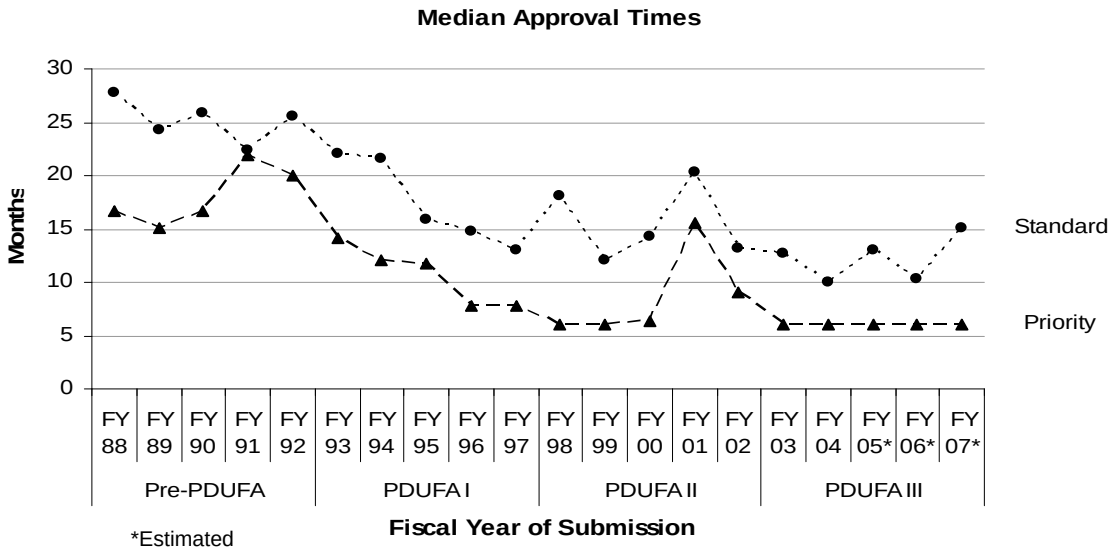
Trends in NDA and BLA Submissions and Approval Times

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

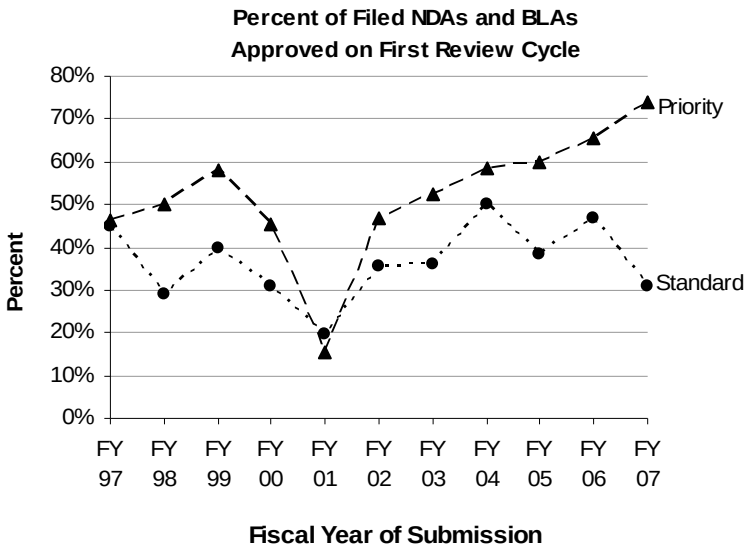
Total Number of NDAs and BLAs Filed in FY 2008 Reaches a 10-Year High. Overall numbers of NDAs and BLAs filed in FY 2008 reached a 10-year high with 143 filings (see graph below). The 10-year (FY 1999 to FY 2008) average number of filings was 121 per year with the number of NDAs versus BLAs varying somewhat from year to year. However, the total number of NDAs and BLAs has increased in five of the past 8 years, decreasing in FY 2005 and again in FY 2007. In FY 2008, 22 percent of the workload was priority applications, which represent significant therapeutic gains. This ratio is consistent with the 10-year average of priority versus standard applications, which over time represents just over one-fifth (22 percent) of the workload for reviewers.



Median Time to Approval For Priority Applications Remained at 6 Months for the Fifth Straight Year While Median Time to Approval for Standard Applications Rose. Based on applications approved through September 30, 2008, and historical data indicating approximately 80 percent of all filed applications will eventually be approved, the estimated median approval time for priority applications for FY 2007 is 6.0 months (see graph below). This is the fifth straight year (FY 2003 to FY 2007) for these historically low levels and reflects FDA's efforts to increase approvals of priority applications in the first review cycle (see next paragraph). The estimated median approval time for standard applications in FY 2007 was 15.1 months.



Percentage of First Cycle Approvals for Priority NDAs and BLAs Increased for the Sixth Straight Year. The percentage of priority NDAs and BLAs approved in the first review cycle has steadily increased from 15 percent in FY 2001 to 74 percent in FY 2007 (see graph to the right). The percentage of standard applications approved in the first review cycle decreased in FY 2007 to an estimated 31 percent. With reviews still in the first cycle as of September 30, 2008, this percentage could increase up to 37 percent.



PDUFA Workload: FY 2003 through FY 2008

Review Workload Levels Uneven in FY 2008. Review workloads for submissions and requests vary each year, and FY 2008 continued that trend (see table below). In FY 2008, the workload for original NDAs and BLAs filed was up 20 percent compared to the average for the previous 5 years, while the review workload for resubmitted NDAs and BLAs and all supplements was down. Review workload planning and review performance can be impacted by workload increases and decreases from one year to the next.

Review Workloads								
Submission/Request	**Fiscal Year**						**FY 2003 to FY 2007 (5-Year Average)**	**FY 2008 Compared to 5-Year Average**
	2003	**2004**	**2005**	**2006**	**2007**	**2008**		
Original NDAs and BLAs	109	129	111	124	123	**143**	**119.2**	**↑ 20%**
Resubmitted NDAs and BLAs	74	85	59	61	73	**54**	**70.4**	**↓ 23%**
NDA and BLA Efficacy Supplements	153	204	158	190	191	**141**	**179.2**	**↓ 21%**
Resubmitted Efficacy Supplements	59	58	48	37	46	**40**	**49.6**	**↓ 19%**
NDA and BLA Manufacturing Supplements	2,598	2,500	2,532	2,647	2,663	**2,517**	**2,588.0**	**↓ 3%**

Administrative Workloads Uneven in FY 2008. Similar to review workloads, administrative workloads also vary from one year to the next (see table below). Responses to clinical holds were up by 49 percent when compared to the 5-year average, while the number of meetings scheduled were down by 12 percent and special protocol assessments were down by 7 percent. While major dispute resolutions were even when compared to the 5-year average, the number in any given year remains difficult to plan for or predict.

Administrative Workloads								
Submission/Request	**Fiscal Year**						**FY 2003 to FY 2007 (5-Year) Average**	**FY 2008 Compared to 5-Year Average**
	2003	**2004**	**2005**	**2006**	**2007**	**2008**		
Meetings Scheduled	2,002	2,125	2,230	2,273	2,151	**1,903**	**2,156.2**	**↓ 12%**
Special Protocol Assessments	293	346	396	406	459	**354**	**380.0**	**↓ 7%**
Responses To Clinical Holds	136	135	130	145	175	**213**	**144.2**	**↑ 48%**
Major Dispute Resolutions	20	10	9	9	22	**14**	**14.0**	**Same**

Report on FY 2007 and FY 2008 PDUFA Goals

This section updates FDA's final review performance on the FY 2007 submissions and evaluates FDA's preliminary performance in reviewing FY 2008 submissions and meeting other PDUFA performance goals. The following information refers to FDA performance presented in this section.

- Preliminary performance is based on the number of submissions reviewed "on time" (acted on within goal) and "overdue" (acted on or pending past the goal date) along with the "percent on time" (preliminary performance). Final performance includes the final number of submissions on time (acted on within goal) and overdue (acted on or pending past goal) along with the percent on time (final performance).

- Final performance data was available on over 99 percent (3,089 of 3,096) of FY 2007 submissions and resubmissions. Overdue submissions were included in all final FY 2007 performance determinations and final performance with respect to achieving FY 2007 goals can now be reported.

- The counts for FY 2008 include submissions received in the last 2 months of FY 2008 and filed. When FDA files a submission, it is deemed "complete" using the PDUFA definition. FDA makes a filing decision within 60 days of an original application's receipt. All PDUFA review times are calculated from the original receipt date of the submission.

- A preliminary performance assessment based on 30 percent (863 of 2,895) of FY 2008 submissions and resubmissions is included in this report. Submissions with short (for example, 2 months) performance goals tend to have most reviews completed by the end of the fiscal year and their preliminary performance is generally close to their potential final performance. However, submissions with longer (for example, 10 months) performance goals tend to have less reviews completed and their preliminary performance may not be as close to the potential final performance.

- Preliminary performance for FY 2008 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 on time (within goal). Additionally, the highest number of potential on-time submissions is included with the highest potential percent on time given that all pending reviews end up as being completed on time.

- The following terminology is used throughout this document: "application" means new, original application; "supplement" means supplement to an approved

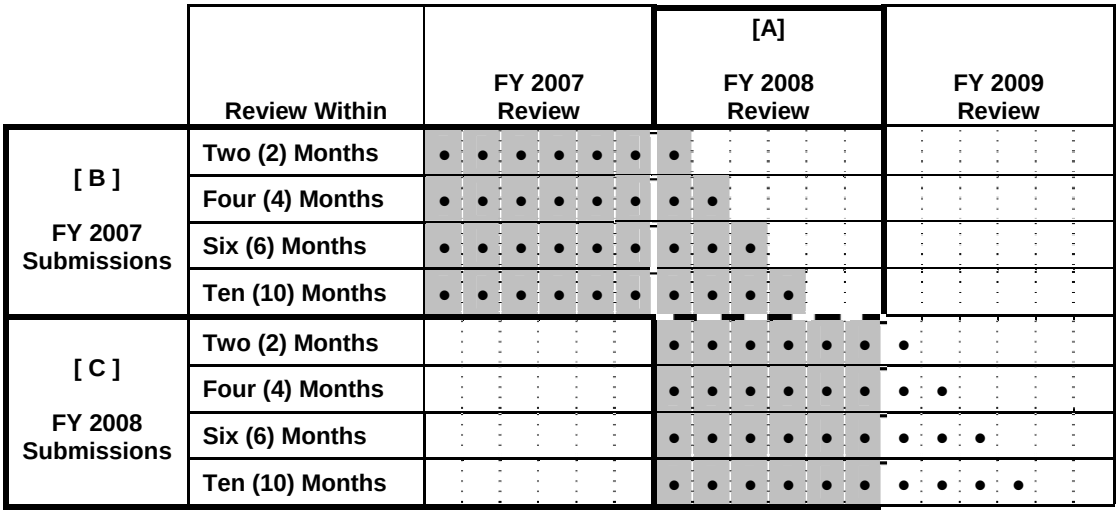
application; “resubmission” means resubmitted application or supplement; New Molecular Entity (NME) refers only to NMEs that are NDAs; and “submission” applies to all of the above.

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

- Unless otherwise noted, all performance data are as of September 30, 2008.

Review Performance Presented in This Report

In any given year, performance includes reviews ongoing from the prior fiscal year combined with submissions received during the current fiscal year. PDUFA review performance goals range from 2 months to 10 months. During each fiscal year (starting October 1 and continuing to September 30 of the following year) FDA performance can be measured for each application or submission type to provide an indication on how FDA is performing within a given fiscal year. Performance in a given fiscal year can indicate the impact of that fiscal year's performance on the 2 years of performance goals that the reviews are associated with. This report includes performance for FY 2007 and FY 2008 submissions (see table below).



Shaded area indicates results covered in this report.

Circles (●) represent 2 month review segments and illustrate potential cohort time spans depending on when submission was received during FY.

[A] FY 2008 Annual On-Time Review Performance. Annual FY 2008 performance information in this report includes on-time review results for FY 2007 submissions carried over and reviewed during FY 2008 as well as FY 2008 submissions reviewed and acted on or pending overdue. On-time review performance provides a measure of FDA overall performance on an annual basis but does not indicate FDA performance related to PDUFA performance goals.

[B] FY 2007 PDUFA Performance Goals. Performance goal results are presented for all FY 2007 submissions and include reviews completed in FY 2007 and FY 2008. This is the final report for FY 2007 submissions related to PDUFA performance goals.

[C] FY 2008 PDUFA Performance Goals. Performance goal results are presented only for FY 2008 submissions that were acted on in FY 2008, or that were pending overdue as of the final day of FY 2008. FY 2008 submissions that were pending within goal as of the final day of FY 2008 will be reported on in the FY 2009 PDUFA Performance Report. This is a preliminary report for FY 2008 submissions related to PDUFA performance goals.

Annual On-Time Review Performance for FY 2008

The table below summarizes FDA's performance for FY 2007 and FY 2008 submissions whose reviews were completed during FY 2008. For the purposes of measuring on-time performance only, a review is considered complete either when an action is taken, or when the on-time goal period has expired, whichever occurs first. The on-time review performance for FY 2008 includes reviews that were pending and not overdue from FY 2007 and reviews that were completed on time and pending overdue in FY 2008. FDA review performance for FY 2008 ranged from 71 percent of reviews on time for priority NMEs and BLAs to 95 percent on time for manufacturing supplements not requiring prior approval.

Application/Submission Type	On Time Goal	Reviews Completed On Time During FY 2008			
		Submitted In FY 2007	Submitted In FY 2008	Total	
		On Time / Reviewed*	On Time / Reviewed*	On Time / Reviewed*	Percent on Time
Priority NDAs/BLAs	6 months	14 / 16	12 / 17	26 / 33	**79%**
Priority NMEs/BLAs	6 months	6 / 7	6 / 10	12 / 17	**71%**
Standard NDAs/BLAs	10 months	69 / 79	20 / 20	89 / 99	**90%**
Standard NMEs/BLAs	10 months	19 / 23	10 / 11	29 / 34	**85%**
Resubmitted Class I NDAs/BLAs	2 months	1 / 3	15 / 16	16 / 19	**84%**
Resubmitted Class 2 NDAs/BLAs	6 months	23 / 26	15 / 20	38 / 46	**83%**
Priority Efficacy Supplements	6 months	20 / 22	20 / 21	40 / 43	**93%**
Standard Efficacy Supplements	10 months	107 / 125	14 / 16	121 / 141	**86%**
Resubmitted Class 1 Efficacy Supplements	2 months	0 / 2	9 / 9	9 / 11	**82%**
Resubmitted Class 2 Efficacy Supplements	6 months	10 / 12	13 / 14	23 / 26	**88%**
Manufacturing Supplements Requiring Prior Approval	4 months	256 / 289	537 / 608	793 / 897	**88%**
Manufacturing Supplements Not Requiring Prior Approval	6 months	807 / 837	814 / 863	1,621 / 1,700	**95%**

* Includes reviews that were completed on time, overdue, and pending action past goal.

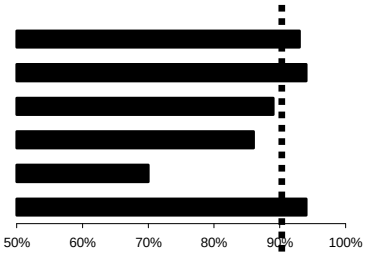
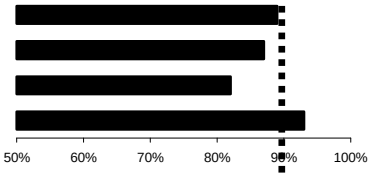
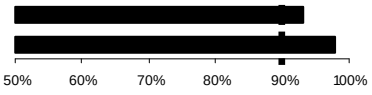
On-time review performance in any given year will impact two fiscal years of performance goals. FY 2008 reviews were a factor in the final FY 2007 performance goal calculations and preliminary FY 2008 performance goal measurements. Likewise, final FY 2008 performance goal calculations will be dependent on FY 2009 review performance.

(This page left blank intentionally.)

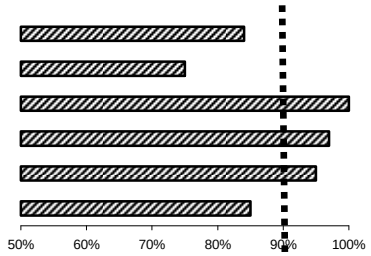
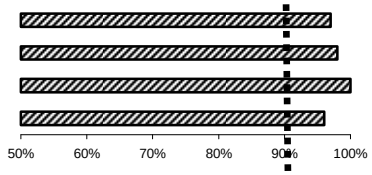
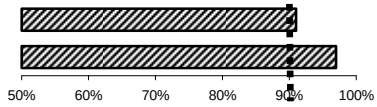
Performance Goals At-A-Glance: FY 2007 and FY 2008

The tables below summarize FDA's review performance for FY 2007 submissions and FY 2008 submissions with respect to meeting performance goals.

Final review performance can now be provided for FY 2007 and FDA exceeded performance for half (6 of 12) of the FY 2007 PDUFA review performance goals.

FY 2007 Goal Area		Final Percent on Time (▬) vs. PDUFA Performance Goal (▪)
Original and Resubmitted Applications	Priority NDAs/BLAs Priority NMEs/BLAs Standard NDAs/BLAs Standard NMEs/BLAs Resubmitted Class 1 NDAs/BLAs Resubmitted Class 2 NDAs/BLAs	
Original and Resubmitted Efficacy Supplements	Priority NDAs/BLAs Standard NDAs/BLAs Resubmitted Class 1 NDAs/BLAs within 2 months Resubmitted Class 2 NDAs/BLAs within 6 months	
Manufacturing Supplements	NDAs/BLAs requiring prior approval NDAs/BLAs not requiring prior approval	

Potential performance is presented for FY 2008 as many reviews were pending and still within the goal review time, as of September 30, 2008. Potential performance assumes all pending within goal submissions will have a first action within goal.

FY 2008 Goal Area		Potential Percent on Time (▨) vs. PDUFA Performance Goal (▪)
Original and Resubmitted Applications	Priority NDAs/BLAs Priority NMEs/BLAs Standard NDAs/BLAs Standard NMEs/BLAs Resubmitted Class 1 NDAs/BLAs Resubmitted Class 2 NDAs/BLAs	
Original and Resubmitted Efficacy Supplements	Priority NDAs/BLAs Standard NDAs/BLAs Resubmitted Class 1 NDAs/BLAs within 2 months Resubmitted Class 2 NDAs/BLAs within 6 months	
Manufacturing Supplements	NDAs/BLAs requiring prior approval NDAs/BLAs not requiring prior approval	

Additional information is provided on individual goals in this section.

Original Applications

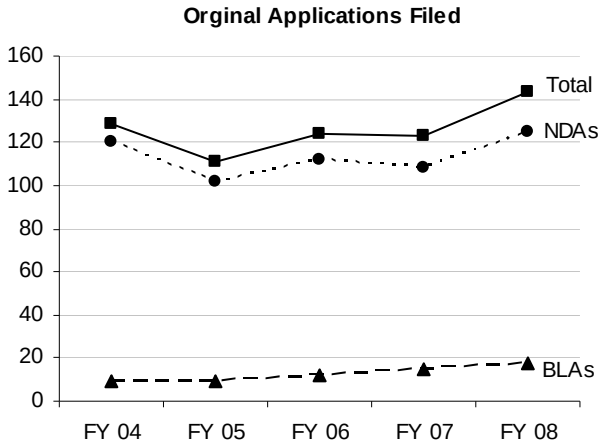
Goal: Review and Act on Original NDAs and BLAs

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 total number of original applications (PDUFA Total) has increased two of the past 3 years and in FY 2008 reached the highest level in the past 5 years. Most of the increase was with standard applications filed which have now increased for three straight years. The number of BLAs filed increased for the third straight year, as well (see corresponding graph and table).



Original Applications Filed
(Priority/Standard)

Type	FY 04	FY 05	FY 06	FY 07*	FY 08
NDAs	**120** *(26/94)*	**102** *(29/73)*	**112** *(25/87)*	**108** *(23/85)*	**125** *(26/99)*
BLAs	**9** *(3/6)*	**9** *(6/3)*	**12** *(7/5)*	**15** *(7/8)*	**18** *(6/12)*
PDUFA Total	**129** *(29/100)*	**111** *(35/76)*	**124** *(32/92)*	**123** *(30/93)*	**143** *(32/111)*
NMEs†	**29** *(16/13)*	**30** *(15/15)*	**24** *(8/16)*	**29** *(9/20)*	**30** (10/20)

* FY 2007 counts were updated to reflect corrections to the FY 2007 PDUFA Performance Report.
† FDA often receives multiple submissions for the same NME, which are all initially designated as NMEs. When FDA approves the first of the multiple submissions, the others are redesignated as non-NMEs.

Original Applications

Performance

FY 2007 Submissions

FDA reviewed on time almost all (28 of 30) priority applications and most (83 of 93) standard applications that were filed in FY 2007 (see table below). FDA exceeded the performance goals for priority applications, but did not meet the performance goals for standard applications.

Original Application Type		Performance Goal	Filed	Preliminary Performance as of September 30, 2007			Final Performance as of September 30, 2008		
				On Time	Overdue	Percent On Time	On Time	Overdue	Percent On Time
Priority	All	Act on 90 percent within 6 months	30	14	0	100%	28	2	**93%**
	NMEs & BLAs		16	9	0	100%	15	1	**94%**
Standard	All	Act on 90 percent within 10 months	93	14	0	100%	83*	10	**89%**
	NMEs & BLAs		28	5	0	100%	24	4	**86%**

*Includes four that were pending due to amendment extensions and subsequently acted on within goal.

FY 2008 Submissions

As of September 30, 2008, performance data was available for over half (17 of 32) of priority applications filed in FY 2008, and FDA was not meeting the performance goals (see table below). With 15 priority applications pending and not overdue, including 6 NMEs and BLAs, FDA has the potential to increase performance, but not enough to meet the performance goals for priority applications. Performance data was available for less than one-fifth (20 of 111) of standard applications filed in FY 2008, and FDA was exceeding the performance goal level for standard applications. With 91 standard applications pending and not overdue, including 21 NMEs and BLAs, FDA has the potential to continue to exceed the performance goals.

Original Application Type		Performance Goal	Filed	Performance as of September 30, 2008				Highest Potential Performance	
				On Time	Overdue	Percent On Time	Pending On Time	On Time	Percent On Time
Priority	All	Act on 90 percent within 6 months	32	12	5	**71%**	15	27	84%
	NMEs & BLAs		16	6	4	**60%**	6	12	75%
Standard	All	Act on 90 percent within 10 months	111	20	0	**100%**	91	111	100%
	NMEs & BLAs		32	10	1	**91%**	21	31	97%

Resubmitted Applications

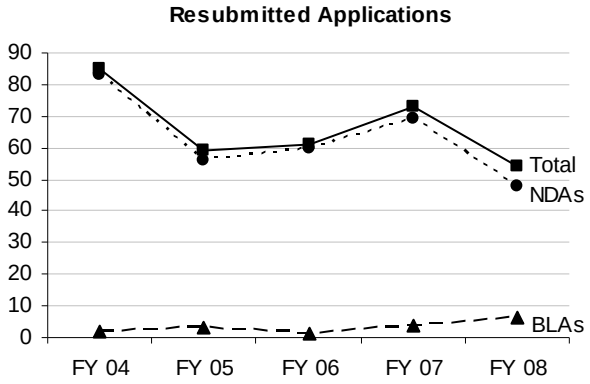
Goal: Review and Act on Resubmitted NDAs and BLAs

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 "approvable," "not approvable," or "complete response" on an application. The applicable performance goal for a resubmission is determined by the year in which the resubmission itself is received, rather than the year in which the original application was submitted.[1]

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 total number of resubmitted applications in FY 2008 fell to the lowest level in 5 years. This is consistent with the higher level of first cycle approvals. This decrease was not reflected in the number of BLAs which has increased for two straight years (see corresponding graph and table).



Resubmitted Applications
(Class 1 / Class 2)

Type	FY 04	FY 05	FY 06	FY 07*	FY 08
NDAs	**83** *(21/62)*	**56** *(21/35)*	**60** *(20/40)*	**69** *(22/47)*	**48** *(18/30)*
BLAs	**2** *(1/1)*	**3** *(0/3)*	**1** *(0/1)*	**4** *(1/3)*	**6** *(2/4)*
PDUFA Total	**85** *(22/63)*	**59** *(21/38)*	**61** *(20/41)*	**73** *(23/50)*	**54** *(20/34)*

* FY 2007 counts were updated to reflect corrections to the FY 2007 PDUFA Performance Report.

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

Resubmitted Applications

Performance

FY 2007 Resubmissions

FDA reviewed on time most (16 of 23) Class 1 resubmissions and almost all (47 of 50) Class 2 resubmissions that were submitted in FY 2007 (see table below). FDA did not meet the performance goal for Class 1 resubmissions, but exceeded the performance goal for Class 2 resubmissions.

Resubmitted Application Type	Performance Goal	Received	Performance as of September 30, 2007			Final Performance as of September 30, 2008		
			On Time	Overdue	Percent On Time	On Time	Overdue	Percent On Time
Class 1	Act on 90 percent within 2 months	23	15	5	75%	16	7	**70%**
Class 2	Act on 90 percent within 6 months	50	24	0	100%	47	3	**94%**

FY 2008 Resubmissions

As of September 30, 2008, performance data was available for over three-fourths (16 of 20) of Class 1 resubmissions received in FY 2008, and FDA was exceeding the performance goal for Class 1 resubmissions (see table below). With four resubmissions pending action and not overdue, FDA has the potential to continue to exceed the performance goal. Performance data was available for over half (20 of 34) of Class 2 resubmissions received in FY 2008, and FDA was not meeting the performance goal. With 14 Class 2 resubmissions pending and not overdue, FDA has the potential to raise overall performance, but not enough to meet the performance goal.

Resubmitted Application Type	Performance Goal	Received	Performance as of September 30, 2008				Highest Potential Performance	
			On Time	Overdue	Percent On Time	Pending On Time	On Time	Percent On Time
Class 1	Act on 90 percent within 2 months	20	15	1	**94%**	4	19	95%
Class 2	Act on 90 percent within 6 months	34	15	5	**75%**	14	29	85%

Efficacy Supplements

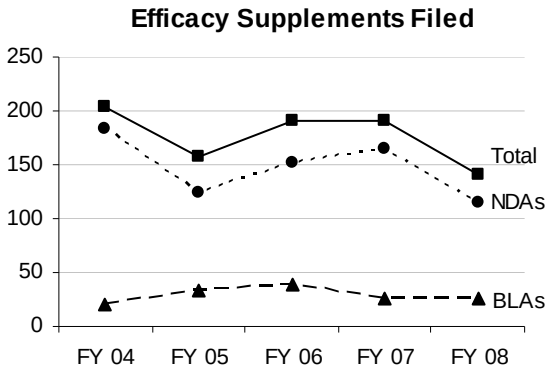
Goal: Review and Act on Complete Efficacy Supplements to NDAs and BLAs

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 total number of efficacy supplements received in FY 2008 decreased to the lowest level in 5 years (see corresponding graph and table). While the total number of BLA efficacy supplements stayed at the FY 2007 level, the number of priority BLA efficacy supplements increased in FY 2008 to levels seen in FY 2005 and FY 2006.



Efficacy Supplements Filed
(Priority / Standard)

Type	FY 04	FY 05	FY 06	FY 07*	FY 08
NDAs	**183** *(48/135)*	**125** *(34/91)*	**151** *(36/115)*	**165** *(43/122)*	**115** *(30/85)*
BLAs	**21** *(2/19)*	**33** *(7/26)*	**39** *(8/31)*	**26** *(3/23)*	**26** *(8/18)*
PDUFA Total	**204** *(50/154)*	**158** *(41/117)*	**190** *(44/146)*	**191** *(46/145)*	**141** (38/103)

* FY 2007 counts were updated to reflect corrections to the FY 2007 PDUFA Performance Report.

Efficacy Supplements

Performance

FY 2007 Submissions

FDA reviewed on time most (41 of 46) priority efficacy supplements and most (126 of 145) standard efficacy supplements submitted in FY 2007 (see table below). However, FDA did not meet the performance goals for priority or standard efficacy supplements.

Efficacy Supplement Type	Performance Goal	Filed	Performance as of September 30, 2007			Final Performance as of September 30, 2008		
			On Time	Overdue	Percent On Time	On Time	Overdue	Percent On Time
Priority	Act on 90 percent within 6 months	46	21	3	88%	41	5	**89%**
Standard	Act on 90 percent within 10 months	145	19	1	95%	126*	19	**87%**

*Includes one that was pending due to an amendment extension and subsequently acted on within goal.

FY 2008 Submissions

As of September 30, 2008, performance data was available for over half (21 of 38) of priority efficacy supplements filed in FY 2008, and FDA was exceeding the performance goal (see table below). With 17 priority efficacy submissions pending action and not overdue, FDA has the potential to continue to exceed the performance goal. Performance data was available for less than one-fifth (16 of 103) of standard efficacy supplements filed in FY 2008, and FDA was not meeting the performance goal. However, with 87 standard efficacy submissions pending action and not overdue, FDA has the potential to increase overall performance and exceed the performance goal.

Efficacy Supplement Type	Performance Goal	Filed	Performance as of September 30, 2008				Highest Potential Performance	
			On Time	Overdue	Percent On Time	Pending On Time	On Time	Percent On Time
Priority	Act on 90 percent within 6 months	38	20	1	**95%**	17	37	97%
Standard	Act on 90 percent within 10 months	103	14	2	**88%**	87	101	98%

Resubmitted Efficacy Supplements

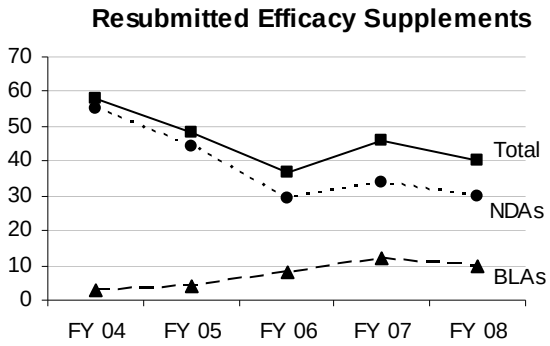
Goal: Review and Act on Resubmitted Efficacy Supplements to NDAs and BLAs

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

After a decrease in FY 2006, the level of NDA resubmitted efficacy supplements has averaged 31 over the past 3 years (FY 2006 to FY 2008). The level of BLA resubmitted efficacy supplements has averaged 10 per year during the same period (see corresponding graph and table).



Resubmitted Efficacy Supplements
(Class 1 / Class 2)

Type	FY 04	FY 05	FY 06	FY 07*	FY 08
NDAs	**55** *(32/23)*	**44** *(23/21)*	**29** *(13/16)*	**34** *(16/18)*	**30** *(12/18)*
BLAs	**3** *(3/0)*	**4** *(1/3)*	**8** *(1/7)*	**12** *(1/11)*	**10** *(3/7)*
PDUFA Total	**58** *(35/23)*	**48** *(24/24)*	**37** *(14/23)*	**46** *(17/29)*	**40** *(15/25)*

* FY 2007 counts were updated to reflect corrections to the FY 2007 PDUFA Performance Report.

Resubmitted Efficacy Supplements

Performance

FY 2007 Resubmissions

FDA reviewed on time most (14 of 17) Class 1 and almost all (27 of 29) Class 2 efficacy supplement resubmissions submitted in FY 2007 (see table below). FDA did not meet the performance goal for Class 1 resubmissions, but exceeded the performance goal for Class 2 resubmissions.

Resubmitted Efficacy Supplement Type	Performance Goal	Received	Performance as of September 30, 2007			Final Performance as of September 30, 2008		
			On Time	Overdue	Percent On Time	On Time	Overdue	Percent On Time
Class 1	Act on 90 percent within 2 months	17	14	1	93%	14	3	**82%**
Class 2	Act on 90 percent within 6 months	29	17	0	100%	27	2	**93%**

FY 2008 Resubmissions

As of September 30, 2008, performance data was available for over half (9 of 15) of Class 1 resubmitted efficacy supplements submitted in FY 2008, and FDA was exceeding the performance goal (see table below). With 6 Class 1 resubmitted efficacy supplements pending action and not overdue, FDA has the potential to continue to exceed the performance goal. Performance data was available for over half (14 of 25) of Class 2 resubmitted efficacy supplements submitted in FY 2008, and FDA was exceeding the performance goal. With 11 Class 2 resubmitted efficacy submissions pending and not overdue, FDA has the potential to continue to exceed the performance goal.

Resubmitted Efficacy Supplement Type	Performance Goal	Received	Performance as of September 30, 2008				Highest Potential Performance	
			On Time	Overdue	Percent On Time	Pending On Time	On Time	Percent On Time
Class 1	Act on 90 percent within 2 months	15	9	0	**100%**	6	15	100%
Class 2	Act on 90 percent within 6 months	25	13	1	**93%**	11	24	96%

Manufacturing Supplements

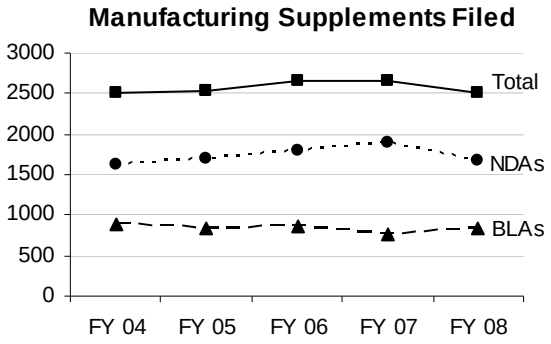
Goal: Review and Act on Manufacturing Supplements to NDAs and BLAs

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

Total manufacturing supplements filed increased in FY 2005, FY 2006 and FY 2007, then decreased by 5 percent in FY 2008, returning to levels similar to FY 2004 and FY 2005. Most of the decrease was with NDA manufacturing supplements. While BLA supplements not requiring prior approval decreased (by 5 percent), the number of BLA supplements filed requiring prior approval increased by 38 percent in FY 2008, as compared to FY 2007, to the highest level for this category in 5 years (see corresponding graph and table).



Manufacturing Supplements Filed
(Prior Approval / No Prior Approval)

Type	FY 04	FY 05	FY 06	FY 07*	FY 08
NDAs	**1,617** *(524/1,093)*	**1,695** *(630/1,065)*	**1,788** *(574/1,214)*	**1,889** *(612/1,277)*	**1,678** *(573/1,105)*
BLAs	**883** *(299/584)*	**837** *(257/580)*	**859** *(310/549)*	**774** *(242/532)*	**839** *(333/506)*
PDUFA Total	**2,500** *(823/1,677)*	**2,532** *(887/1,645)*	**2,647** *(884/1,763)*	**2,663** *(854/1,809)*	**2,517** *(906/1,611)*

* FY 2007 counts were updated to reflect corrections to the FY 2007 PDUFA Performance Report.

Manufacturing Supplements

Performance

FY 2007 Submissions

FDA reviewed on time almost all (2,570 of 2,663) manufacturing supplements received in FY 2007 (see table below). FDA exceeded the performance goals for manufacturing supplements where prior approval was required and where prior approval was not required.

Manufacturing Supplement Type	Performance Goal	Received	Performance as of September 30, 2007			Final Performance as of September 30, 2008		
			On Time	Overdue	Percent On Time	On Time	Overdue	Percent On Time
Prior Approval Required	Act on 90 percent within 4 months	854	541	24	96%	797	57	**93%**
Prior Approval Not Required	Act on 90 percent within 6 months	1,809	966	6	99%	1,773	36	**98%**

FY 2008 Submissions

As of September 30, 2008, performance data was available for two-thirds (608 of 906) of manufacturing supplements received in FY 2008 requiring prior approval, and FDA was not meeting the performance goal (see table below). However, with 298 supplements pending and not overdue, FDA has the potential to increase overall performance and exceed the performance goal. Performance data was available for just over half (863 of 1,611) of supplements not requiring prior approval received in FY 2008, and FDA was exceeding the performance goal. With 748 supplements pending action and not overdue, FDA has the potential to continue to exceed the performance goal.

Manufacturing Supplement Type	Performance Goal	Received	Performance as of September 30, 2008				Highest Potential Performance	
			On Time	Overdue	Percent On Time	Pending On Time	On Time	Percent On Time
Prior Approval Required	Act on 90 percent within 4 months	906	537	71	**88%**	298	835	92%
Prior Approval Not Required	Act on 90 percent within 6 months	1,611	814	49	**94%**	748	1,562	97%

(This page left blank intentionally.)

Report on FY 2008 PDUFA Procedural and Processing Goals, Initiatives, and Commitments

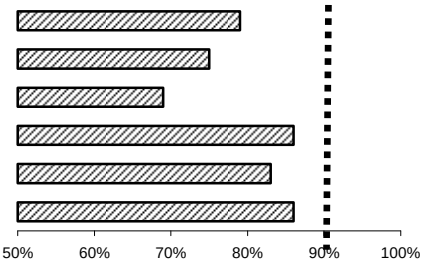
This section presents FDA's performance in achieving the FY 2008 procedural and processing goals and accomplishments for PDUFA IV initiatives and commitments. The following information refers to FDA performance presented in this section. Unless otherwise noted, performance data is reported as of September 30, 2008.

- The procedural and processing goals reflect performance related to the Investigational New Drug Application (IND) phase of drug development. The procedural and processing goals FDA committed to achieve were designed to improve application submissions and FDA-sponsor interactions during new drug development and application review.
- The management initiatives under PDUFA IV relate to improving the overall application review process.
- The electronic applications and submissions commitments relate to the Information Technology (IT) initiatives and activities of PDUFA IV.

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

Performance At-A-Glance for FY 2008

The table below summarizes FDA's preliminary performance for the FY 2008 Procedural and Processing goals. FDA will not meet administrative performance goals for FY 2008. Some administrative activities are still pending action and not overdue as of September 30, 2008; however, completing these activities on time will not raise the overall performance sufficiently to meet the performance goals. Additional discussion of the individual goals is located in this section.

FY 2008 Goal Area	Preliminary Percent on Time (▨) vs. PDUFA Review Performance Goal (⋮)
Meeting Requests*	
Scheduling Meetings*	
Meeting Minutes	
Special Protocol Assessments	
Response to Clinical Holds	
Major Dispute Resolutions	

* Weighted average performance for Type A, Type B, and Type C meetings combined.

Procedural and Processing Goals – Meeting Management

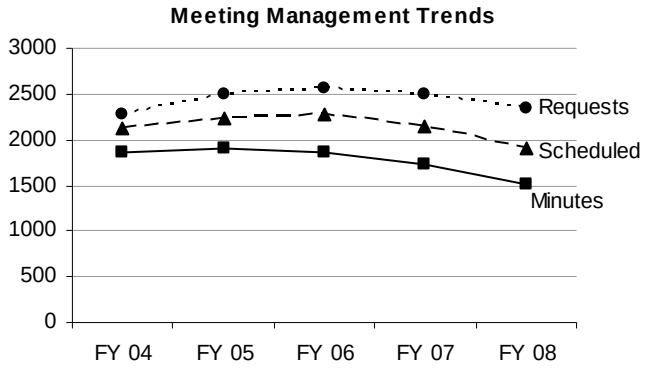
The table below summarizes the meeting management goals that address meeting requests, scheduling meetings, and preparing meeting minutes.

Action	Review Time Goal	Performance Goal FY 2008 – FY 2012
Meeting Requests	Notify requestor of formal meeting in writing within 14 days of request.	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 meeting management activities continued to decrease in FY 2008. Meeting requests and scheduling of meetings have decreased for two straight years and meeting minutes have decreased for three straight years (see corresponding graph and table).



Meeting Management

Type	FY 04	FY 05	FY 06	FY 07	FY 08
Meeting Request Notifications	2,284	2,487	2,565	2,502	2,344
Scheduling Meetings	2,125	2,230	2,273	2,151	1,903
Meeting Minutes	1,854	1,901	1,853	1,736	1,515

Procedural and Processing Goals – Meeting Management

FY 2008 Performance

As of September 30, 2008, FDA was not meeting performance goals for meeting management in FY 2008 (see table below). With activities still pending action and not overdue, completing these activities on time will increase overall performance in most areas, but not enough to meet review time goals.

Type		Performance Goal – Review 90 percent within	Received	Performance as of September 30, 2008				Highest Potential Performance	
				On Time	Overdue	Percent On Time	Pending On Time	On Time	Percent On Time
Meeting Requests	**Type A**	14 Days	362	216	128	**63%**	18	234	65%
	Type B	21 Days	1,330	1,086	231	**83%**	13	1,099	83%
	Type C		652	517	124	**81%**	11	528	81%
Scheduling Meetings*	**Type A**	30 Days	260	128	91	**58%**	41	169	65%
	Type B	60 Days	1,157	852	259	**77%**	46	898	78%
	Type C	75 Days	486	361	96	**79%**	29	390	80%
Meeting Minutes		30 Days	1,515	789	516	**61%**	210	999	66%

***** Not all meeting requests are granted.

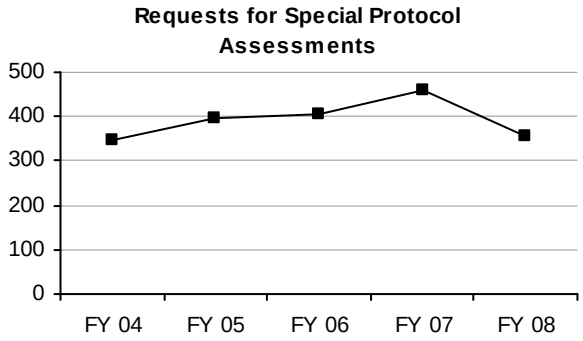
Procedural and Processing Goals – Special Protocol Assessments

The table below summarizes the annual review time and performance goals for the response to the 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 2008, special protocol assessment requests reversed a three-year trend of increases, decreasing to levels close to FY 2004 (see corresponding graph and table).



Requests for Special Protocol Assessments

FY 04	FY 05	FY 06	FY 07*	FY 08
346	396	406	459	354

* FY 2007 counts were updated to reflect corrections to the FY 2007 PDUFA Performance Report.

FY 2008 Performance

As of September 30, 2008, performance data was available for over four-fifths (313 of 354) of the sponsors' requests for evaluation of protocol designs received in FY 2008, and FDA was not meeting the performance goal (see table below). With 41 assessments pending action and not overdue, FDA can increase performance, but not enough to meet the performance goal.

Performance Goal	Total Received	Performance as of September 30, 2008				Highest Potential Performance	
		On Time	Overdue	Percent On Time	Pending On Time	On Time	Percent On Time
Respond to 90 percent within 45 Days	354	269	44	**86%**	41	310	88%

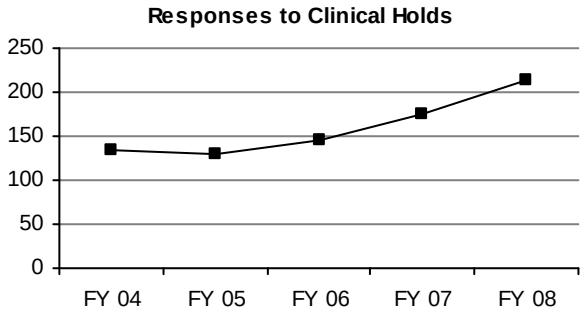
Procedural and Processing Goals – Responses to Clinical Holds

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 increased by 22 percent in FY 2008. This represented the third increase in 3 years and the highest level in 5 years (see corresponding graph and table).



Responses to Clinical Holds

FY 04	FY 05	FY 06	FY 07*	FY 08
135	130	145	175	213

* FY 2007 counts were updated to reflect corrections to the FY 2007 PDUFA Performance Report.

FY 2008 Performance

As of September 30, 2008, performance data was available for almost all (200 of 213) of sponsors' complete responses to clinical holds received in FY 2008, and FDA was not meeting the performance goal (see table below). With 13 responses pending and not overdue, FDA can increase performance, but not enough to meet the goal.

Performance Goal	Total Received	Performance as of September 30, 2008				Highest Potential Performance	
		On Time	Overdue	Percent On Time	Pending On Time	On Time	Percent On Time
Respond to 90 percent within 30 Days	213	165	35	**83%**	13	178	84%

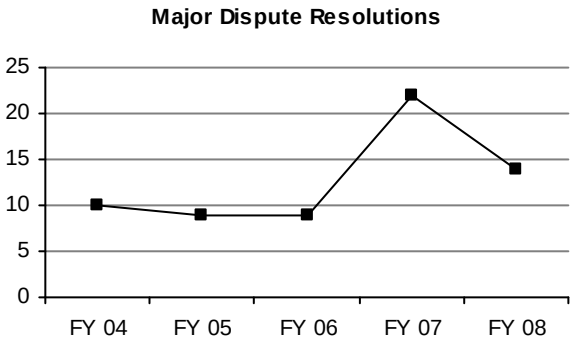
Procedural and Processing Goals – Major Dispute Resolutions

The table below summarizes the annual review time and performance goals for a response 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 resolutions decreased from the FY 2007 five-year high but was still above FY 2004 through FY 2006 levels (see corresponding graph and table).



Major Dispute Resolutions

FY 04	FY 05	FY 06	FY 07	FY 08
10	9	9	22	14

FY 2008 Performance

As of September 30, 2008, performance data was available on all sponsors' appeals of decisions received in FY 2008, and FDA did not meet the performance goal (see table below).

Performance Goal	Total Received	Performance as of September 30, 2008				Highest Potential Performance	
		On Time	Overdue	Percent On Time	Pending On Time	On Time	Percent On Time
Respond to 90 percent within 30 Days	14	12	2	**86%**	0	12	86%

(This page left blank intentionally.)

First Cycle Filing Review Notification

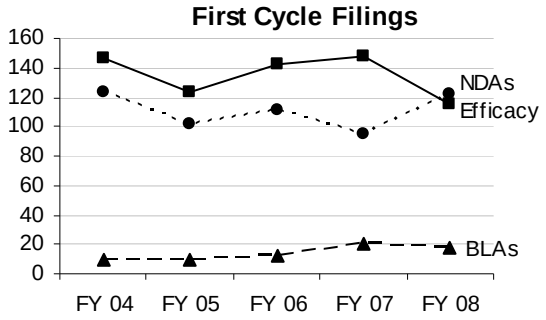
Goal: Report Substantive Deficiencies (or Lack of Same) Within 14 Days After the 60-Day Filing Date for Original NDAs/BLAs and Efficacy Supplements

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

First Cycle Filing Review Notification Type	Review Time Goal	Performance Goal				
		FY 08	FY 09	FY 10	FY 11	FY 12
Original NDAs/BLAs	Within 14 days after 60-day filing date	90% on time				
Efficacy Supplements						

Workload

The number of first cycle filings for NDAs fluctuated over the past 5 years, returning in FY 2008 to near the FY 2004 level. BLAs decreased in FY 2008, but remained at a level higher than FY 2004 to FY 2006. Efficacy supplements decreased in FY 2008 to their lowest levels in 5 years (see corresponding graph and table).



First Cycle Filings

Type	FY 04	FY 05	FY 06	FY 07*	FY 08
NDAs	123	102	111	95	122
BLAs	9	9	12	20	18
Total NDAs and BLAs	132	111	123	115	140
Efficacy Supplements†	147	124	142	148	115

* FY 2007 counts were updated to reflect corrections to the FY 2007 Performance Report.

† The First Cycle Filing Review Notification goal applies to original NDAs/BLAs and efficacy supplements only. It does not apply to NDA labeling supplements that contain clinical data, even though these are counted as efficacy supplements for other PDUFA performance purposes. Therefore, the number of filing review notifications for efficacy supplements is less than the total number of efficacy supplements filed (as shown on page 18).

First Cycle Filing Review Notification

Performance

FY 2007 Submissions

FDA issued first cycle filing review notifications on time for almost all (109 of 115) of NDAs/BLAs and most efficacy supplements filed in FY 2007 (see table below). FDA exceeded the performance goal for NDAs/BLAs but did not meet the performance goal for efficacy supplements.

First Cycle Filing Review Notification Type	Performance Goal	Filed	Performance as of September 30, 2007			Final Performance as of September 30, 2008		
			On Time	Overdue	Percent On Time	On Time	Overdue	Percent On Time
NDAs/BLAs	Within 14 days after 60-day filing date	115	90	5	95%	109	6	**95%**
Efficacy Supplements		148	95	8	92%	126	22	**85%**

FY 2008 Submissions

As of September 30, 2008, first cycle performance data was available for over four-fifths (118 of 140) of NDAs/BLAs filed in FY 2008, and FDA was not meeting the performance goal (see table below). With 22 NDA/BLA notifications pending and not overdue, FDA can increase performance but not enough to meet the performance goal. Performance data was available for over four-fifths (101 of 115) of efficacy supplements filed in FY 2008, and FDA was not meeting the performance goal. With 14 efficacy supplement notifications pending and not overdue, FDA can increase performance but not enough to meet the performance goal.

First Cycle Filing Review Notification Type	Performance Goal	Filed	Performance as of September 30, 2008				Highest Potential Performance	
			On Time	Overdue	Percent On Time	Pending On Time	On Time	Percent On Time
NDAs/BLAs	Within 14 days after 60-day filing date	140	101	17	**86%**	22	123	88%
Efficacy Supplements		115	82	19	**81%**	14	96	83%

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.

Performance Area	Management Initiatives	FY 2008 Accomplishments
Enhancement of Drug safety	Publish a PDUFA IV Drug Safety 5-Year Plan.	FDA published the draft PDUFA IV Drug Safety 5-Year Plan on FDA web site in April 2008.
	Publish a request for proposals (RFP) for best ways to assess public health benefit of collecting adverse event reports throughout product life cycle.	FDA held a public workshop in January 2008. FDA issued a request for information (RFI) in April 2008.
	Hold a public workshop to identify epidemiology best practices.	FDA held a public workshop in May 2008 to gather information to develop a guidance document on epidemiology best practices.
	Expand access to database resources.	FDA developed a collaboration process with several federal agencies that enable access to large databases for drug safety effects and signals.
	Enhance adverse event reporting systems and surveillance tools.	Commercial product demonstrations were completed in August 2008 as part of FDA's effort to modernize CDER's adverse event reporting system to add signal detection and tracking tools.
Proprietary Names	Final guidance document on contents of a complete submission package for a proposed proprietary drug/ biological product name	FDA drafted a guidance titled "Complete Submission for the Evaluation of Proprietary Names."
	Public technical meeting to discuss elements necessary to create a concept paper describing the pilot program	The draft concept paper was prepared for the public workshop which was held in June 2008.
First Cycle Review Performance Proposal	Harmonized standard operating procedures for notification of planned review timelines	CDER Manual of Policies and Procedures posted in July 2008. CBER standard operating procedures and policies were under review as of September 30, 2008.
	Training on standard operating procedures.	Staff training completed.
Expediting Drug Development	Draft guidance documents on clinical hepatotoxicity, non-inferiority trials, adaptive trail designs, and end of Phase 2(a) meetings	Guidances were being worked on and in final phases of completion as of September 30, 2008.

Performance Area	Management Initiatives	FY 2008 Accomplishments
Postmarketing Study Commitments – Standard Operating Procedures	Harmonized Standard Operating Procedures for Requesting Applicants to Agree in Writing to Voluntary Postmarketing Study Commitments	CBER and CDER standard operating policies and procedures manual and MAPP respectively were in clearance process as of September 30, 2008.
Improving FDA Performance Management	Conduct 3 major program assessments: 1) PDUFA IV adjustment for changes in review activities used in the PDUFA workload adjuster 2) Good Review Management Principles (GRMPs) implementation 3) Impact of the electronic submission and review environment on the drug review process Conduct other studies and evaluations of the drug review process as needed to improve performance management.	• FDA awarded a contract in 2008 to perform an independent evaluation of the PDUFA IV adjustment for changes in review activities used in the PDUFA workload adjuster. • The procurements for GRMPs implementation and the electronic review impact were in the planning stages as of September 30, 2008. • A contract was awarded in 2008 to implement CDER's quality management plan for the chemistry and manufacturing controls (CMC) quality management system.

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 2008 Accomplishments
Develop and periodically update an IT plan, covering a rolling 5-year planning horizon.	The final PDUFA IV IT Plan was published in June 2008.
Develop, implement, and maintain new information systems consistently across all organizational divisions participating in the process for the review of human drug applications.	The Bioinformatics Board coordinates and oversees all activities related to business automation planning, acquisition, and implementation decisions throughout FDA, under a strategic framework for automation established by the Commissioner and implemented by the FDA Management Council. The Bioinformatics Board has approved the following projects to support the review of human drug applications across the FDA Centers: Common Electronic Document Room, Information Computing Technologies for the 21st Century, the Janus Initiative and Regulated Product Submission.
Update technical specifications and IT-related guidance documents as necessary.	• FDA published the final guidance: Providing Regulatory Submissions in Electronic Format--Human Pharmaceutical Applications and Related Submissions Using the eCTD Specifications. • FDA published: Providing Regulatory Submissions in Electronic Format –Drug Establishment Registration and Drug Listing. • FDA published: Indexing Structured Product Labeling. • FDA published the draft guidance: Providing Regulatory Submissions in Electronic format – Postmarketing Individual Case Safety Reports. • FDA published the technical specification: Specifications for eCTD Validation Criteria.
Extend the capability of the secure electronic single point of entry to include two-way transmission of regulatory correspondence.	• Regulated Product Submission (RPS) is a data exchange standard to facilitate the processing and review of regulated product information. (RPS) Release 2 will support two-way communication and was approved as a Health Level 7 project. FDA finalized the concept proposal in September 2008.

Electronic Applications and Submissions Initiative	FY 2008 Accomplishments
Establish an automated standards-based regulatory submission and review environment for INDs, NDAs, and BLAs, and their supplements.	• The FDA Common Electronic Document Room project will establish a common, agency-wide, standards based electronic document room. The Bioinformatics Board approved the Concept proposal in February 2008, Boundary document in February 2008 and Project Charter in November 2007. Contracts were awarded to support business modeling and provide technical services for this project in September 2008.
Establish a system for electronic exchange and management of human drug labeling information in a modular manner that is based on FDA standards and that enables revision tracking.	• FDA participated in the development of the Health Level 7 data exchange standard, Structured Product Labeling, as a component to support automated, standards-based exchange of human drug labeling information. • FDA tested a prototype of a collaboration portal system that would support the Health Level 7 Structured Product Labeling standard. FDA is currently evaluating the next steps for the program.
Establish standards-based information systems to support how FDA obtains and analyzes post-market drug safety data and manages emerging drug safety information.	• In May 2008, FDA launched the Sentinel Initiative which will enable FDA to query multiple, existing data sources for information about medical products. FDA hosted several public information sharing meetings in FY 2008 with external stakeholders for the Sentinel Initiative. • In March 2008, FDA awarded a contract to support the MedWatch Plus initiative which will develop a "portal through which adverse event, consumer complaint, and product problem reports are received and processed to make the information available to adverse event analysis systems." Based on the HL7 ICSR standard, this portal is intended to include a "Rational Questionnaire" that consumers could use to complete an on-line form that has imbedded logic to support the distribution of adverse event reports to appropriate government agencies. FDA completed the following activities for the MedWatch Plus Initiative: - Conducted demonstrations of commercial products - Completed the Paper Reduction Act 60 Day Notice estimating the reporting burden for MedWatch Plus and the Rational Questionnaire

(This page left blank intentionally.)

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 the Food and Drug Administration Amendments Act of 2007 (PDUFA IV). Goal summaries for the earlier years of PDUFA can be found in the Appendix of earlier PDUFA Performance Reports.

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.[2]	90% on time				
Review and act on standard original NDAs and BLAs within 10 months of receipt.[2]					
Review and act on priority efficacy supplements within 6 months of receipt.[2]					
Review and act on standard efficacy supplements within 10 months of receipt.[2]					
Review and act on all manufacturing supplements within 6 months of receipt and those requiring prior approval within 4 months of receipt.[3]					
Review and act on Class 1 resubmitted original applications within 2 months of receipt.					
Review and act on Class 2 resubmitted original applications within 6 months of receipt.[2]					
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.[2]					

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

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

II. NME Performance Goals

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

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

III. Procedural and Processing Goals

Performance Area	FDA Activity	Performance Goal	Performance Level FY 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 prepared minutes, clearly outlining agreements, disagreements, issues for further discussion and action times will be available to sponsor.	Within 30 days of meeting.	
Clinical Holds	Response to sponsor's complete response to a clinical hold.	Within 30 days of receipt of sponsor's response.	
Major Dispute Resolution	Response to sponsor's appeal of decision.	Within 30 days of receipt of sponsor's appeal.	
Special Protocol Question Assessment and Agreement	Response to sponsor's request for evaluation of protocol design.	Within 45 days of receipt of protocol and questions.	

IV. Review of Proprietary Names To Reduce Medication Errors

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 sponsor 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 a 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 a 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 two 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="3">Performance Area</th><th rowspan="3">Initiative</th><th rowspan="3">Commitment</th><th colspan="5">Performance Level and/or Implementation Timeline by Fiscal Year
-- Not applicable
X Action due</th></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 sponsor 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 study commitments (PMCs) the Agency will be requesting.</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			
	FDA will report its performance in meeting review timelines for labeling and PMCs in the annual PDUFA performance report.	--		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	--	--	--	--

Performance Area	Initiative	Commitment	Performance Level and/or Implementation Timeline by Fiscal Year -- Not applicable X Action due				
			2008	2009	2010	2011	2012
Standard Operating Procedures and Training (continued)	Training	All new review staff and refresher training will be provided to all review staff as necessary through FY 2012.	X	X	X	X	X

VI. Expediting Drug Development

Performance Area	Initiative	Commitment	Performance Level and/or Implementation Timeline by Fiscal Year -- Not applicable X Action due				
			2008	2009	2010	2011	2012
Guidance Development	FDA will develop and publish for comment draft guidances on the following topics by the end of the indicated Fiscal Year of PDUFA-IV. FDA will complete the final guidances 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	--

Performance Area	Initiative	Commitment	Performance Level and/or Implementation Timeline by Fiscal Year -- Not applicable X Action due				
			2008	2009	2010	2011	2012
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
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

XIII. 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	---	---	---

V. 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 five-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.

APPENDIX B: List of Approved Applications

This appendix updates the detailed review histories of the NDAs and BLAs submitted and approved under PDUFA in FY 2008. Approvals are grouped by submission year and priority designation and listed in order of total approval time. Review histories of all other PDUFA submissions approved prior to FY 2008 can be found in the appendices of the earlier PDUFA Performance Reports that are available at http://www.fda.gov.

Terms and Coding Used in Tables

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

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

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

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

Table 1
FY 2008 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	
2008	DIFLUPREDNATE	Sirion Therap	Y	First	5.9	AP	5.9	Y
	ABICAVIRE SULFATE TABLETS	Aurobindo Pharm	N	First	5.9	TA	5.9	Y◊
	IOBENUANE I 123 INJECTION	GE Healthcare	Y	First	6.0	AP	6.0	Y
	LAMIVUDINE/ STAVUDINE TABLETS FOR ORAL SUSPENSION	Cipla	N	First	6.0	TA	6.0	Y◊
	TENOFAVIR DISO-PROXYL FUR-MATE/LAMIVUDINE	Matrix Labs Ltd.	N	First	6.0	TA	6.0	Y◊
	TIPRANAVIR 2-PYRIDINESULFONANI-LIDE	Boehringer Pharms	N	First	6.1	AP	6.1	Y†
2007	IXABEPILONE	Bristol Myers Squibb	Y	First	6.0	AP	6.0	Y
	RALTEGRAVIR POTASSIUM	Merck And Co. Inc.	Y	First	6.0	AP	6.0	Y
	TMC 125 ETRAVIRINE	Tibotec	Y	First	6.0	AP	6.0	Y
	BENDAMUSTINE HCL	Cephalon	Y	First	6.0	AP	6.0	Y
	TOPOTECAN HCL	Smithkline Beecham	N	First	6.0	AP	6.0	Y
	TRIAMCINOLONE ACETONIDE INJECTABLE SUSP	Alcon	N	First	6.0	AP	6.0	Y
	SAPROPTERIN DIHYDROCHLORIDE	Biomarin Pharm	Y	First	6.7	AP	6.7	N
	STAVUDINE / LAMIVUDINE	Matrix Labs Inc.	N	First	7.2	TA	7.2	N◊
	STAVUDINE / LAMIVUDINE / NEVIRAPINE	Strides Inc.	N	First	6.0	CR	6.0	Y
				Sponsor	0.3	--	6.3	--
				Second	4.4	TA	10.7	Y◊

† An exception was granted to extend the review time goal date by two business days due to an unscheduled emergency closure of the FDA facility.

Receipt Cohort (FY)	Established/Proper Name	Applicant	NME (Y/N)	Approval Time (Months)				Goal Met
				Review Cycle	Cycle Time	Cycle Result	Total Time	
2007	STAVUDINE / LAMIVUDINE / NEVIRAPINE	Strides Arcolab	N	First	9.0	CR	9.0	Y+
				Sponsor	0.2	--	9.2	--
				Second	6.0	TA	15.2	Y◊
2005	TIPRANAVIR ORAL SOLUTION	Boehringer Pharms	Y	First	6.0	CR	6.0	Y
				Sponsor	30.0	--	36.0	--
				Second	6.1	AP	42.1	Y†
	TETRABENAZINE	Biovail Ameri-cas	Y	First	5.9	CR	5.9	Y
				Sponsor	12.4	--	18.3	--
				Second	8.8	CR	27.1	Y+
				Sponsor	0.8	--	27.9	--
				Third	2.0	CR	29.9	Y
				Sponsor	3.0	--	32.9	--
				Fourth	2.0	AP	34.9	Y

† An exception was granted to extend the review time goal date by two business days due to an unscheduled emergency closure of the FDA facility.

Table 2
FY 2008 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	
2008	REPAGLINIDE METFORMIN	Novo Nordisk Inc.	N	First	1.0	AP	1.0	Y
	NICARDINE	Teva Parenteral	N	First	9.8	AP	9.8	Y
	PALONOSETRAN HCL	Helsinn Hlthcare	N	First	10.0	AP	10.0	Y
	LEVETIRACETAM	Ucb Inc.	N	First	10.0	AP	10.0	Y
2007	MORPHINE SULFATE IMMEDIATE RELEASE TABS	Roxane	N	First	9.3	AP	9.3	Y
	FIBRIN SEALANT (HUMAN)	Baxter Health-care Corpora-tion	Y	First	9.6	AP	9.6	Y
	ANTIHEMOPHILIC FAC-TOR (RECOMBINANT), PLASMA/ALBUMIN FREE	Wyeth Phar-maceuticals Inc.	Y	First	9.9	AP	9.9	Y
	DICLOFENAC SODIUM TOPICAL GEL 1%	Novartis cons	N	First	9.9	AP	9.9	Y
	ROTAVIRUS VACCINE, LIVE, ORAL	Glaxosmith-kline Biologi-cals	Y	First	10.0	AP	10.0	Y
	TRIAMCINOLONE	Allergan	N	First	10.0	AP	10.0	Y
	DORIPENEM	Johnson and Johnson	Y	First	10.0	AP	10.0	Y
	SEVELAMER CARBONATE	Genzyme	N	First	10.0	AP	10.0	Y+
	STERILE INTRAOCULAR IRRIGATING SOLUTION	Alcon	N	First	10.0	AP	10.0	Y
	NIACIN/SIMVASTATIN	Abbott Labs	N	First	10.0	AP	10.0	Y
	ALISKIREN HYDRO-CHLOROTHIAZIDE	Novartis Pharms	N	First	10.0	AP	10.0	Y
	AVOBEN-ZENE/ECAMSULE/OCTO CRYLENE/TITANIUM	Loreal USA Prods	N	First	10.0	AP	10.0	Y
	EPOPROSTENOL SO-DIUM	Generamedix	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	
2007	MORPHINE SULPHATE ORAL SOLUTION	Roxane	N	First	10.0	AP	10.0	Y
	CETIRIZINE HCL	McNeil Consumer	N	First	10.0	AP	10.0	Y
	LEVOCETIRZINE DIHY-DROCHLORIDE	Ucb Inc.	N	First	10.0	AP	10.0	Y
	AMOXICILLIN / APC-111	Middlebrook Pharms	N	First	10.0	AP	10.0	Y
	CALCIPOTRIENE HY-DRATE AND BE-TAMETHASONE	Leo Pharm Prods	N	First	10.4	TA	10.4	N
	REGADENOSON	Astellas	Y	First	10.9	AP	10.9	N
	GADOXETATE DISO-DIUM	Bayer Healthcare	Y	First	12.1	AP	12.1	N
	VALPROIC ACID DE-LAYED RELEASE CAP-SULES	Banner Pharmacaps	N	First	10.0	CR	10.0	Y
				Sponsor	0.3	--	10.3	--
				Second	1.8	TA	12.1	Y
	METHYLNALTREXONE BROMIDE SUBCUTANE-OUS INJECTION	Progenics	Y	First	12.9	AP	12.9	Y+
	THROMBIN TOPIC (RECOMBINANT)	ZymoGenetics, Inc.	Y	First	13.0	AP	13.0	Y+
	CLEVIDIPINE IV EMUL-SION	Meds Co.	Y	First	13.0	AP	13.0	Y+
	PHENTOLAMINE MESY-LATE	Novalar	N	First	13.0	AP	13.0	Y+
	DOCETAXEL INJECTION	Hospira inc	N	First	13.0	TA	13.0	Y+
	GRAINSETRON TRANSDERMAL SYSTEM / GRANISETR	Strakan	N	First	14.4	AP	14.4	N
	DIPHTHERIA AND TETA-NUS TOXOIDS, ACELLU-LAR PERTUSSIS VAC-CINE ADSORBED AND POLIOVIRUS VACCINE INACTIVATED COM-BINED	Glaxosmith-kline Biologi-cals	Y	First	9.9	CR	9.9	Y
				Sponsor	3.0	--	12.9	--
				Second	1.6	AP	14.5	Y

Receipt Cohort (FY)	Established/Proper Name	Applicant	NME (Y/N)	Approval Time (Months)				Goal Met
				Review Cycle	Cycle Time	Cycle Result	Total Time	
2007	OMEPRAZOLE MAGNESIUM	Astrazeneca	N	First	10.0	CR	10.0	Y
				Sponsor	2.9	--	12.9	--
				Second	2.2	AP	15.1	N
	FLUORESCEIN INJECTION	Akorn	N	First	10.0	CR	10.0	Y
				Sponsor	1.8	--	11.8	--
				Second	4.3	AP	16.1	Y
	ROPINIROLE HYDROCLORIDE	Smithkline Beecham	N	First	9.9	CR	9.9	Y
				Sponsor	0.4	--	10.3	--
				Second	5.9	AP	16.2	Y
	CEFEPIME INJECTION	Baxter	N	First	9.7	CR	9.7	Y
				Sponsor	1.6	--	11.3	--
				Second	6.0	AP	17.3	Y
	VENLAFAXINE HCL	Osmotica Pharm	N	First	9.8	CR	9.8	Y
				Sponsor	2.3	--	12.1	--
				Second	2.5	CR	14.6	Y
				Sponsor	0.8	--	15.4	--
				Third	2.0	AP	17.4	Y
2006	NILOTINIB	Novartis Pharms	Y	First	13.0	AP	13.0	Y+
	ESOMEPRAZOLE MAGNESIUM	Astrazeneca	N	First	10.0	CR	10.0	Y
				Sponsor	5.1	--	15.1	--
				Second	2.1	AP	17.2	Y
	PREDNISOLONEACETATE ORAL SUSPENSION	Taro Pharms (US)	N	First	13.0	CR	13.0	Y+
				Sponsor	2.3	--	15.3	--
				Second	1.9	AP	17.2	Y
	PANTOPRAZOLE SODIUM	Wyeth Pharms Inc	N	First	10.0	CR	10.0	Y
				Sponsor	4.7	--	14.7	--
				Second	3.5	AP	18.2	N

Receipt Cohort (FY)	Established/Proper Name	Applicant	NME (Y/N)	Approval Time (Months)				Goal Met
				Review Cycle	Cycle Time	Cycle Result	Total Time	
2006	BUPROPION / HYDRO-BROMIDE	Biovail Labs Intl.	N	First	9.7	CR	9.7	Y
				Sponsor	3.2	--	12.9	--
				Second	6.0	AP	18.9	Y
	FOSAPREPITANT DIMEGLUMINE	Merck and Co. Inc.	N	First	13.0	CR	13.0	Y+
				Sponsor	2.8	--	15.8	--
				Second	6.0	AP	21.8	Y
	OMEPRAZOLE DELAYED RELEASE TABLETS 20MG	Dexcel Phar-ma	N	First	9.9	CR	9.9	Y
				Sponsor	10.1	--	20.0	--
				Second	2.0	AP	22.0	Y
	FLUVOXAMINE MALEATE	Jazz	N	First	10.0	CR	10.0	Y
				Sponsor	3.8	--	13.8	--
				Second	6.0	CR	19.8	Y
				Sponsor	0.4	--	20.2	--
				Third	2.0	AP	22.2	Y
	10 % METHYL SALICY-LATE & 3 % MENTHOL	Hisamitsu Pharm	N	First	10.0	CR	10.0	Y
				Sponsor	7.8	--	17.8	--
				Second	6.0	AP	23.8	Y
	COSYNTROPIN INJEC-TION	Sandoz	N	First	10.0	CR	10.0	Y
				Sponsor	8.5	--	18.5	--
				Second	6.0	AP	24.5	Y
	DESVENLAFAXINE EX-TENDED-RELEASE TAB-LETS	Wyeth Pharms Inc.	Y	First	13.0	CR	13.0	Y+
				Sponsor	7.3	--	20.3	--
				Second	6.0	AP	26.3	Y
	SOMATROPIN RECOM-BINANT HUMAN GROWTH HORM	Cangene	N	First	10.0	CR	10.0	Y
				Sponsor	4.6	--	14.6	--
				Second	12.0	AP	26.6	N
	LORATADINE 10MG	Schering plough	N	First	10.0	CR	10.0	Y
				Sponsor	11.3	--	21.3	--
				Second	5.9	AP	27.2	Y

Receipt Cohort (FY)	Established/Proper Name	Applicant	NME (Y/N)	Approval Time (Months)				Goal Met
2005	SIMVASTATIN 10/20/40/80MG TABLETS	Synthon Pharms	N	First	9.9	CR	9.9	Y
				Sponsor	10.8	--	20.7	--
				Second	5.8	AP	26.5	Y
	SUMATRI-TAM/NAPROXEN	Glaxosmith-kline	N	First	10.0	CR	10.0	Y
				Sponsor	7.9	--	17.9	--
				Second	6.0	CR	23.9	Y
				Sponsor	2.5	--	26.4	--
				Third	6.0	AP	32.4	Y
	HAEMOPHILIS B CON-JUGATE VACCINE (TETANUS TOXOID CONJUGATE) RECON-STITUTED WITH DIPH-THERIA AND TETANUS TOXOIDS AND ACELLU-LAR PERTUSSIS VAC-CINE ADSORBED COM-BINED WITH POLIOVI-RUS VACCINE INACTI-VATED	Sanofi Pasteur Limited	Y	First	10.0	CR	10.0	Y
				Sponsor	3.4	--	13.4	--
				Second	7.5	CR	20.9	Y+
				Sponsor	0.4	--	21.3	--
				Third	1.2	CR	22.5	Y
				Sponsor	6.4	--	28.9	--
				Fourth	6.0	AP	34.9	Y
	DESMOPRESSIN ACETATE TABLETS	Ferring Pharms	N	First	9.7	CR	9.7	Y
				Sponsor	21.2	--	30.9	--
				Second	7.4	AP	38.3	N
	BIPHASIC INSULIN ASPART 50/50	Novo Nordisk Inc.	N	First	6.0	CR	6.0	Y
				Sponsor	16.0	--	22.0	--
				Second	2.0	AP	24.0	Y
	MESALAMINE	Proctor and Gamble	N	First	10.0	CR	10.0	Y
				Sponsor	25.8	--	35.8	--
				Second	7.3	AP	43.1	N
2004	OLOPATADINE HCL 0.6%	Alcon	N	First	10.0	CR	10.0	Y
				Sponsor	23.1	--	33.1	--
				Second	6.7	AP	39.8	N

Receipt Cohort (FY)	Established/Proper Name	Applicant	NME (Y/N)	Approval Time (Months)				Goal Met
2004	NEBIVOLOL TABLETS 1.25/2.5/5/10/20MG	Forest Labs	Y	First	13.1	CR	13.1	Y
				Sponsor	24.0	--	37.1	--
				Second	6.0	CR	43.1	Y
				Sponsor	0.2	--	43.3	--
				Third	0.4	AP	43.7	Y
	ALVIMOPAN	Adolor	Y	First	12.9	CR	12.9	Y+
				Sponsor	9.7	--	22.6	--
				Second	6.9	CR	29.5	Y+
				Sponsor	9.3	--	38.8	--
				Third	9.4	AP	48.2	N
	CICLESONIDE	Nycomed US	N	First	10.0	CR	10.0	Y
				Sponsor	32.7	--	42.7	--
				Second	6.0	AP	48.7	Y
2002	FLUVOXAMINE MALEATE TABS 25/50/100 MG	Jazz	N	First	19.4	CR	19.4	Y‡
				Sponsor	27.3	--	46.7	--
				Second	6.0	CR	52.7	Y
				Sponsor	7.2	--	59.9	--
				Third	6.0	AP	65.9	Y
2001	BRIMONIDINE TAR-TRATE 0.2%/ TIMOLOL 0.5%	Allergan	N	First	8.6	CR	8.6	Y
				Sponsor	27.4	--	36.0	--
				Second	6.0	CR	42.0	Y
				Sponsor	15.6	--	57.6	--
				Third	5.7	CR	63.3	Y
				Sponsor	4.5	--	67.8	--
				Fourth	6.0	AP	73.8	Y

‡ Application was on the review clock for 10.0 months of the 19.4 month first review cycle, and therefore it met the PDUFA 10 month review time goal.

(This page left blank intentionally.)

Appendix C: Completion of PDUFA III Goals Not Part of PDUFA IV

PDUFA III Management Initiatives Performance – Reviewable Unit Letter Notification

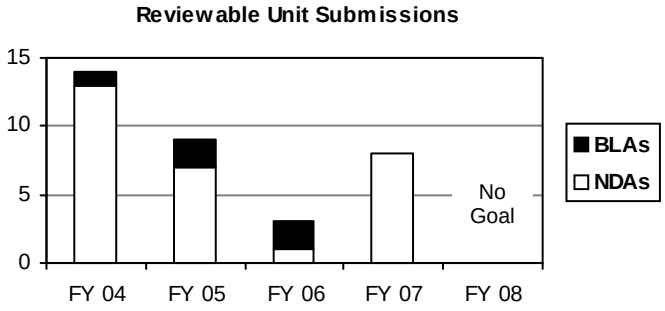
Goal: Issue Discipline Review Letters for Pre-submitted "Reviewable Units" of NDAs and BLAs

The table below summarizes the annual review time and performance goals for reviewable unit letter notifications for NDAs and BLAs.

Reviewable Unit Type	Review Time Goal	Performance Goal				
		FY 04	FY 05	FY 06	FY 07	FY 08
NDA	6 months	30%	50%	70%	90%	No Goal
BLA						

Workload

There were no reviewable unit submissions for a PDUFA goal in FY 2008 (see corresponding graph and table).



Reviewable Unit Submissions

Type	FY 04	FY 05	FY 06	FY 07	FY 08
NDAs	13	7	1	8	n/a
BLAs	1	2	2	0	n/a
PDUFA Total	**14**	**9**	**3**	**8**	**n/a**

FY 2007 Submissions

Performance

FDA reviewed on time most (5 of 8) pre-submitted reviewable units of NDAs and BLAs submitted in FY 2007 but did not meet the performance goal (see table below). This goal does not continue beyond FY 2007.

Reviewable Unit Type	Performance Goal	Received	Performance as of September 30, 2007			Final Performance as of September 30, 2008		
			On Time	Overdue	Percent On Time	On Time	Overdue	Percent On Time
NDAs and BLAs	Act On 90 Percent Within 6 months	8	3	0	100%	5	3	**63%**

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:

Office of Planning
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002
Phone: 301-796-4850
FAX: 301-847-3541

This report is available on the FDA Home Page at http://www.fda.gov.