FY 2002 PERFORMANCE REPORT TO CONGRESS

for the

Prescription Drug User Fee Act of 1992

as reauthorized and amended by the

Food and Drug Administration Modernization Act of 1997

Food and Drug Administration
Department of Health and Human Services

Executive Summary

In 1992, Congress enacted the Prescription Drug User Fee Act (PDUFA). PDUFA provided FDA with additional resources to hire more medical and scientific reviewers to conduct premarket reviews as well as support staff and field investigators to speed up the application review process for human drug and biological products. In 1997, after a successful first five years, Congress reauthorized the program for five additional years (PDFUA II). Last year, Congress again extended PDUFA for five more years (PDUFA III). Each reauthorization has brought higher expectations for reviews and additional goals intended to improve FDA's responsiveness to and communication with industry sponsors. As a result of PDUFA, FDA has significantly reduced the review and approval times for new drug and biologic applications without compromising FDA's traditionally high standards for approval of new drugs and biologics.

All of the original applications submitted during FY 2001 have been reviewed and acted upon, and final performance data can now be reported. Only a preliminary performance assessment on applications submitted during FY 2002 is possible at this time. FDA exceeded all the review performance goals for original and resubmitted new drug and biological applications and for standard efficacy supplements and manufacturing supplements submitted in FY 2001. With regard to priority efficacy supplements submitted in FY 2001, FDA failed to meet the review goal for one of nine supplements, and thus failed to meet the 90 percent on-time performance goal. Although it is too early to report final results, the Agency appears to be meeting or exceeding all the application review goals for FY 2002 submissions. In FY 2002, the Agency met or exceeded three of the six "procedural and processing" goals designed to improve its responsiveness to sponsor requests during the early phases of drug development.

Notwithstanding the successes noted above, the Agency encountered significant challenges in trying to meet the PDUFA II goals. The revenue the Agency collected from fees during PDUFA II was significantly less than expected due to a reduction in the number of new drug and biologic applications submitted and an increase in the proportion of applications that met the criteria for fee waivers. This decrease in resources combined with a continuing increase in overall review workload under PDUFA resulted in significant stress to the program during the last few years of PDUFA II. The recently reauthorized PDUFA III aims to correct the balance between resources and workload over the first several years of the program, while further challenging the Agency with additional performance commitments.

Through all these reauthorizations, the goal of PDUFA has remained unchanged. The industry and FDA, working together, are bringing safe and effective new medicines to American patients and practitioners quickly without compromising FDA's traditionally high standards for safety, effectiveness, and product quality.

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Introduction

In 1992, Congress passed the Prescription Drug User Fee Act (PDUFA). PDUFA authorized FDA to collect fees from companies that produce and submit applications for marketing for human drug and biological products. The original PDUFA had a five-year life; it ended in 1997, the same year Congress passed the FDA Modernization Act (FDAMA). FDAMA contained a five-year reauthorization of PDUFA (PDUFA II). PDUFA II ended on September 30, 2002. Last year, Congress passed the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), which extended PDUFA for an additional five years (PDUFA III). Information about PDUFA III, including the text of the amendments and the performance goals and procedures, can be found at http://www.fda.gov/oc/pdufa/PDUFA3.html.

PDUFA requires FDA to submit two annual reports to Congress for each fiscal year during which fees are collected: 1) a performance report due within 60 days of the end of the fiscal year, and 2) a financial report due within 120 days of the end of the fiscal year. This document fulfills the first of these requirements for fiscal year 2002.

Overview of PDUFA

September 30, 2002 marked the end of 10 years of FDA experience with PDUFA. PDUFA has provided FDA with additional revenue to hire more reviewers and support staff and upgrade its information technology systems to speed up the application review process for new drugs and biological products without compromising FDA's traditionally high standards for approval. Under PDUFA, FDA agreed to meet certain performance goals that apply to the review of original and resubmitted new product applications and efficacy and manufacturing supplements to approved applications. FDA also agreed to meet certain procedural and processing goals aimed at speeding-up drug development. These goals were designed to become increasingly more stringent each year. To date, FDA has met or exceeded nearly every review performance goal and most of the procedural and processing goals.

PDUFA I Outcomes: New Resources and Approaches Result in Approval of New Products Sooner

The original PDUFA (PDFUA I) was generally regarded as an unqualified success. During the first few years of PDUFA I, FDA eliminated overdue backlogs of New Drug Applications (NDAs), Biological License Applications (BLAs – referred to as Product License Applications (PLAs) and Establishment License Applications (ELAs) then), and both efficacy and manufacturing supplements to NDAs and BLAs. FDA also implemented performance tracking in the Center for Biologics Evaluation and Research (CBER), project management methodology for NDA and BLA reviews, and adopted uniform standards for computer assisted NDAs.

New Directions. Over the course of PDUFA I, the Agency agreed to review and act upon a progressively increasing proportion of original NDAs, BLAs, and efficacy supplements within 12 months and resubmissions and manufacturing supplements within 6 months. The proportion of each type of submission the Agency agreed to review on time increased from 55 percent for FY 94 submissions to 90 percent for FY 97 submissions. In addition, the Agency agreed to review and act upon 90 percent of priority NDAs, BLAs, and efficacy supplements (i.e., submissions for products providing significant therapeutic gains) submitted in FY 97 within 6 months. Over the course of PDUFA I, FDA exceeded all of these performance goals.

Success Leads to Immediate Results. As a direct result of the FDA's quicker and more predictable review performance, and the improved communication between FDA and application sponsors that PDUFA fostered, new products were approved at an unprecedented pace without compromising FDA's traditionally high standards for safety, effectiveness, and quality. Under PDUFA I:

- Median total approval times[1] for NDAs and BLAs dropped from 20 months to 12 months.
- The percentage of filed NDAs and BLAs that ultimately were approved increased from approximately 66 percent in the pre-PDUFA years to 80 percent after PDUFA.
- The number of original applications the Agency refused to file, a key measure of submission quality, dropped from 34 in FY 93 to just 2 in FY 97.

- The number of NDAs and BLAs submitted and filed each year increased from 88 in FY 93 to 130 in FY 97.

PDUFA II Outcomes: Continued Success, but Unexpected Challenges Strain Resources and Limit Results

In 1997, Congress passed the Food and Drug Administration Modernization Act (FDAMA). Part of FDAMA reauthorized PDUFA (PDFUA II) for five additional years, FY 98 through FY 02. Under PDUFA II, the review goals continued to shorten. For submissions received in FY 2002, the PDUFA II goals called for FDA to review and act on 90 percent of:

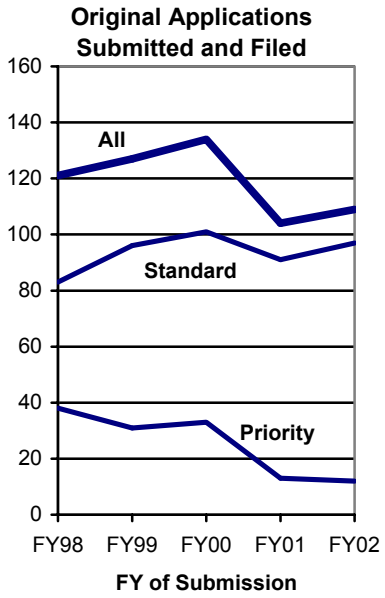
- Priority new drug and biological product applications and efficacy supplements within 6 months;
- Standard new drug and biological product applications and efficacy supplements within 10 months;
- Manufacturing supplements within 6 months, and those requiring prior approval within 4 months;
- Class 1 resubmissions of original applications within 2 months, and Class 2 resubmissions of original applications within 6 months (Definitions of Class 1 and Class 2 resubmissions can be found at the end of Appendix A.).

In addition, PDUFA II added a new set of goals intended to improve FDA's responsiveness to and communication with application sponsors during the drug development process. These goals specified timeframes for activities such as scheduling meetings and responding to various sponsor submissions such as special protocols and responses to clinical holds. Whereas PDUFA I's intent was to speed up the review process, PDUFA II's intent was to speed up the entire drug development process.

Continued Success. The Agency has met or exceeded nearly all the PDUFA II application review goals every year. The only review goals missed were for priority efficacy supplements submitted in FY 00 and FY 01 where on-time performance fell just short of the 90 percent goal. The Agency has been less successful in meeting the procedural and processing goals, although it has met or exceeded most.

Under PDUFA II, the Agency's review performance continued to accelerate and communication with and responsiveness to sponsor requests during the drug development phase improved. Several important outcomes accrued:

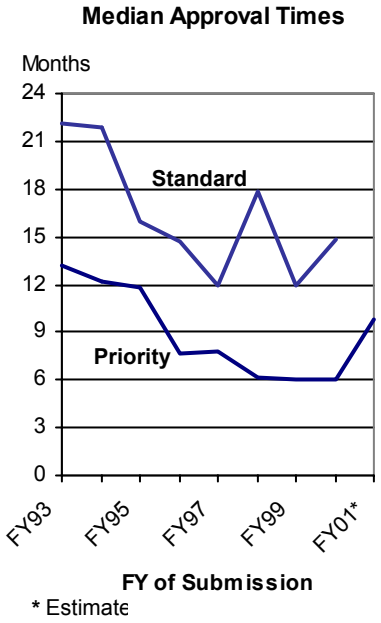
- During the early years of PDUFA II, approval times continued to decrease. The median time to approval for original priority applications submitted in FY99 was 6 months. For original standard applications submitted that year, the median approval time was 12 months.
- More New Molecular Entities (NMEs) were introduced in the U.S. first. Before PDUFA, FDA approved about 40 percent of the NMEs introduced on the world market either first or within 1 year of their introduction in another country. After PDUFA, that percentage nearly doubled providing Americans with rapid access to safe and effective new drugs.



Unexpected Challenges. During PDUFA I the number of original applications submitted to the Agency increased at a steady pace each year. During PDUFA II the number of original applications decreased from the levels predicted based on PDUFA I, and more of these applications were either exempt from fees or met the criteria for waiver of fees. As a result, during the last few years of PDUFA II, fee revenue was less than the Agency and Congress had predicted when PDUFA was reauthorized in 1997 while total FDA workload under PDUFA continued to increase. This imbalance between resources and workload resulted in significant stress to the program.

During the last years of PDUFA II:

- Median approval times for NDAs and BLAs began to increase. For standard applications submitted in FY 2000, median total approval time increased to 14.8 months. Although it is too soon to make even a preliminary assessment for standard applications submitted in FY 2001, based on the applications approved by September 30, 2002 and the queue of unapproved applications, it appears that the median approval time for the FY 2001 cohort will be even higher. The median approval time for priority applications submitted in FY 2001 is estimated to be 9.8 months based on applications approved by September 30, 2002. This increase in median approval time for priority applications occurred despite a decrease in the number of priority applications submitted to the Agency. Compared with earlier years when more than 30 priority applications were filed annually, only 13 priority applications were filed in FY 2001. Only two of these were approved on the initial review, whereas, in previous years, more than half of the priority NDAs and BLAs were approved on the initial review.



- Some FDA stakeholders, and recently the General Accounting Office[2] (GAO) have expressed concerns about the number of drugs approved under PDUFA that have been withdrawn for safety reasons. However, an analysis of the rate of withdrawal for safety reasons of New Molecular Entities approved prior to PDUFA compared to those approved under the PDUFA program shows no significant difference (2.7% for drugs approved pre-PDUFA and 2.5% for drugs approved under PDUFA)[3]. While FDA's standards for safety have not changed under PDUFA, the total number of drug and biologic products on the U.S. market has increased substantially, and many of these products are being approved first in the U.S. As a result of this heightened awareness, the importance of rigorous post-market surveillance of recently approved products

has increased under PDUFA.

PDUFA III Commitments: New Goals and Approaches

Last year, Congress passed the Bioterrorism Act, which included an extension of PDUFA (PDUFA III) for an additional five years. By authorizing increased user-fees, the goal of PDUFA III is to bring revenue and resources back into balance with the increasing total PDUFA workload. This rebalancing, however, will take several years as FDA recruits and trains new review and support staff.

PDUFA III retains the review performance goals and the procedural and processing goals of PDUFA II essentially unchanged from their FY 2002 performance levels. It adds one new review goal, establishes several pilot efforts to further speed the review process, and for the first time authorizes FDA to expend user-fee revenue on certain post-market safety activities. Detailed information about PDUFA III, including the text of the amendments and the performance goals and procedures can be found at http://www.fda.gov/oc/pdufa/PDUFA3.html. Very briefly, the additional challenges and commitments the Agency faces under PDUFA III include:

- A new and increasingly stringent set of review performance goals for resubmitted efficacy supplements. By FY 2007 FDA will review and act upon 90 percent of Class 1 efficacy supplement resubmissions within 2 months and 90 percent of Class 2 efficacy supplement resubmissions within 6 months.
- The establishment and evaluation of two pilot programs to explore the continuous marketing application concept, which are expected to further decrease drug development and review times for Fast Track drugs and biologics. Under these pilot programs FDA will provide sponsors with earlier and more frequent feedback and interactions during the drug development phase and expand the use of rolling reviews for certain Fast Track products.
- A variety of new risk management initiatives including the submission and review of risk management plans as part of pre-NDA/BLA meetings and as part of original NDA/BLA applications. In addition, FDA will be allowed to use fee revenue for the first time for post-approval safety activities. Finally, FDA has committed to develop and publish guidances to industry on Good Risk Assessment, Good Risk Management, and Good Pharmacovigalence.
- The limited use of independent consultants, at the sponsor's request, for biotechnology clinical trial protocol review for products that represent a significant advance or address an unmet medical need.
- Several initiatives to improve FDA performance management including
    - ✓ Developing guidance on good review management principles,
    - ✓ Notifying sponsors of issues identified during the filing review,
    - ✓ Contracting with an outside consultant for a comprehensive review and analysis of the drug and biologic review process.
    - ✓ Further studies of program design, performance features, and costs, including a re-analysis of program costs under PDUFA III.

- A variety of information technology initiatives aimed at developing centralized and uniform information systems to simplify and enhance the use of electronic applications and submissions.

As the progression of performance commitments under PDUFA makes clear, continuing to speed drug development and approval while preserving and even raising FDA's high standards for safety, effectiveness, and product quality, is becoming increasingly difficult. Under PDUFA I, the Agency improved its performance by shortening review times. Under PDUFA II, the Agency continued to shorten review times and also improved its responsiveness to sponsors during the drug development phase. PDUFA III maintains the gains of the past, but commits the Agency to finding new ways to improve the entire review process, from drug development through application review and into the post-market surveillance period. Underscoring all of these commitments is the Agency's commitment to the American people – to work with application sponsors and our stakeholders to bring effective new drug products to market as quickly as possible without sacrificing the high standards for safety that practitioners and patients rely on.

Report on FY 2001 and 2002 PDUFA Goals

This report updates the Agency's review performance on the FY 2001 application submissions and evaluates its performance in reviewing FY 2002 application submissions and meeting other PDUFA II goals. All of the original applications submitted during FY 2001 have been reviewed and acted upon, and final performance data can now be reported. Only a preliminary performance assessment on applications submitted during FY 2002 is possible at this time. For submission categories with a 10-month review goal, it is too early to measure review performance. For those submission categories with a review goal that is shorter than 10 months, performance on submissions received early in the fiscal year provides an early-indicator of final review performance. Unless otherwise noted, all performance data in this section are as of September 30, 2002.

FDA's Center for Biologics Evaluation and Research (CBER) has changed from counting Product License Applications (PLAs) and Establishment License Applications (ELAs) separately to combining them as Biologic License Applications (BLAs). This report shows CBER's workload and performance on PLAs and BLAs only (i.e., Product Applications). To simplify notation, it uses BLA as a generic term for both BLAs and PLAs. Original and resubmitted ELAs have been dropped, both from workload counts and performance measurements. These new counts are reflected in the workload and performance data for the PDUFA I years, so trends into PDUFA II are consistent.

Original New Product Applications

Goal --Review and act upon complete original NDAs and BLAs

The table below summarizes the annually decreasing review-time goals for original New Drug Applications (NDAs) and BLAs under PDUFA II. Over the five-year period, the goal of reviewing 90 percent of priority applications in six months remained constant. For standard applications, the review-time goals dropped over the five-year period. For applications filed in FY 1998, the goal was to review 90 percent in 12 months; for FY 2002 applications, the goal is to review 90 percent in 10 months. The statute allows three additional months for review of original NDA and BLA submissions that involve major amendments received within the last three months of their usual review intervals.

Goals		On-Time Performance by Submission Year				
		FY 98	FY 99	FY 00	FY 01	**FY 02**
Priority	6 months	90% on time	90%	90%	90%	**90%**
Standard	12 months	90%	90%	90%	90%	
	10 months		30%	50%	70%	**90%**

Workload

The following table shows the number of original NDAs and BLAs filed in each of the last five years. The count of FY 2002 submissions assumes that all submissions received in the last two months of FY 2002 are filed. When FDA files a submission, it is deemed "complete" by PDUFA definition. FDA makes a filing decision within 60 days of an original application's receipt. All calculations of PDUFA review times are made, however, from the original receipt date of the filed application.

Original submissions filed *(Priority/Standard)*:

	FY 98	FY 99	FY 00	FY 01	FY 02[4]
• **NDAs**	109 *(30/79)*	121 *(30/91)*	121 *(29/92)*	*96 (10/86)*	100 *(9/91)*
• **BLAs**	12 *(8/4)*	6 *(1/5)*	13 *(4/9)*	8 *(3/5)*	9 *(3/6)*
• **PDUFA Total**	121 *(38/83)*	127 *(31/96)*	134 *(33/101)*	*104 (13/91)*	109 *(12/97)*
NMEs[5]	*42 (19/23)*	41 *(16/25)*	*32 (17/15)*	*34 (8/26)*	*23 (7/16)*

Original New Product Applications

Performance

FY 2001 Submissions

FDA met the goal of reviewing and acting upon priority applications within 6 months for all thirteen priority NDAs and BLAs filed in FY 2001. FDA also met the 12-month goal for standard submissions for 89 of the 91 standard submissions reviewed (98% on time). Ninety percent of all standard applications and 81 percent of the NMEs and BLAs were reviewed and acted upon within 10 months, exceeding the 70 percent review goal in both cases.

FY 01 Submissions			Reviewed and acted upon	Number on time	Percent on time
Priority	6 month goal	All Applications	13	13	100
		NMEs & BLAs	11	11	100
Standard	12 month goal	All Applications	91	89	98*
		NMEs & BLAs	31	29	94*
	10 month goal	All Applications	91	82	90
		NMEs & BLAs	31	25	81

** Because receipt of a major amendment extended the 10-month goal to 13 months, the two standard applications (both NMEs) that did not meet the 12-month goal met the extended 10-month goal.*

FY 2002 Submissions

While it is too early to report meaningful review performance statistics for applications submitted in FY 2002, all priority applications that have been reviewed have met the 6-month review goal, and all standard applications that have been reviewed have met the 10-month review goal. No applications are late.

FY 02 Submissions			Reviewed and acted upon	Number on time	Percent on time
Priority	6 month goal	All Applications	4	4	100
		NMEs & BLAs	4	4	100
Standard	10 month goal	All Applications	16	16	100
		NMEs & BLAs	7	7	100

Resubmitted New Product Applications

Goal -- Review and act upon resubmitted NDAs and BLAs.

A resubmission is a firm's response after an FDA action of "approvable," "not approvable," or "complete response" on an application. The applicable performance goal for a resubmission is determined by the year in which the resubmission itself is received, rather than the year in which the original application was submitted. The definitions of Class 1 and Class 2 resubmissions can be found at the end of Appendix A.

Goals		On-Time Performance by Resubmission Year				
		FY 98	FY 99	FY 00	FY 01	**FY 02**
Class 1	6 months	90% on time				
	4 months		90%	90%		
	2 months	30%	50%	70%	90%	**90%**
Class 2	6 months	90%	90%	90%	90%	**90%**

Workload -- Resubmissions received (*Class 1/Class 2*):

	FY 98	FY 99	FY 00	FY 01	FY 02
• **of Original NDAs**	50 *(19/31)*	63 *(17/46)*	80 *(25/55)*	62 *(25/37)*	62 *(26/36)*
• **of Original BLAs**	21 *(5/16)*	14 *(2/12)*	9 *(1/8)*	16 *(6/10)*	15 *(2/13)*
• **PDUFA Total**	71 *(24/47)*	77 *(19/58)*	89 *(26/63)*	78 *(31/47)*	77 *(28/49)*

Resubmitted New Product Applications

Performance

FY 2001 Resubmissions

Twenty-eight of the 31 Class 1 resubmissions received in FY 2001 were reviewed and acted upon within 2 months, and all 47 of the Class 2 resubmissions were reviewed and acted upon within 6 months. Review performance on both classes of FY 2001 resubmissions met or exceeded the 90 percent on-time PDUFA review goals.

FY 01 Resubmissions		Reviewed and acted upon	Number on time	Percent on time
Class 1	2 months	31	28	90
Class 2	6 months	47	47	100

FY 2002 Resubmissions

As of September 30, 2002, 21 FY 2002 Class 1 resubmissions and 27 Class 2 resubmissions had been reviewed and acted upon. All had met their respective review goals. With 7 Class 1 and 22 Class 2 resubmissions still pending and not overdue, it is too early to make a final performance determination, but current on-time performance for both classes of resubmissions exceeds the goals.

FY 02 Resubmissions		Reviewed and acted upon	Number on time	Percent on time
Class 1	2 months	21	21	100
Class 2	6 months	27	27	100

Efficacy Supplements

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

The table below summarizes the annually decreasing review-time goals for efficacy supplements to NDAs and BLAs under PDUFA II. Review goals for efficacy supplements follow the same progression as the review goals for original NDAs and BLAs. Over the five-year period, the goal of reviewing 90 percent of priority efficacy supplements in six months remained constant. For standard efficacy supplements, the review-time goals dropped over the five-year period. For FY 1998 submissions, the goal was to review 90 percent in 12 months; for FY 2002 submissions, the goal was to review 90 percent in 10 months.

Goals		On-Time Performance by Submission Year				
		FY 98	FY 99	FY 00	FY 01	**FY 02**
Priority	6 months	90% on time	90%	90%	90%	**90%**
Standard	12 months	90%	90%	90%	90%	
	10 months		30%	50%	70%	**90%**

Workload -- Efficacy supplements filed *(Priority / Standard)*:

	FY 98	**FY 99**	**FY 00**	**FY 01**	**FY 02**[4]
• **to NDAs**	126 *(10/116)*	135 *(15/120)*	175 *(18/157)*	154 *(7/147)*	158 *(29/129)*
• **to BLAs**	10 *(1/9)*	10 (2/8)	12 *(2/10)*	16 *(2/14)*	10 *(3/7)*
• **PDUFA total**	136 *(11/125)*	145 *(17/128)*	187 *(20/167)*	170 *(9/161)*	168 *(32/136)*

Efficacy Supplements

Performance

FY 2001 Submissions

Eight of the 9 priority efficacy supplements submitted in FY 2001 were reviewed and acted upon within the 6-month review goal. On-time performance was 89 percent, which is slightly below the 90 percent goal.

All of the standard efficacy supplements were reviewed and acted upon within 12 months and 91 percent were reviewed within 10 months. This performance exceeds the FY 2001 goals of 90 percent and 70 percent respectively.

FY 01 Submissions		Reviewed and acted upon	Number on time	Percent on time
Priority	6 months	9	8	89
Standard	12 months	161	161	100
	10 months		149	93

FY 2002 Submissions

While it is too early to report meaningful review performance statistics for efficacy supplements submitted in FY 2002, all priority efficacy supplements that have been reviewed have met the 6-month review goal and all standard efficacy supplements that have been reviewed have met the 10-month review goal. No efficacy supplements are late.

FY 02 Submissions		Reviewed and acted upon	Number on time	Percent on time
Priority	6 months	13	13	100
Standard	10 months	29	29	100

Manufacturing Supplements

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

The review performance goals for manufacturing supplements that do not require FDA approval before the changes they specify can be enacted did not change over the five years of PDUFA II. For manufacturing supplements that do require FDA's approval before the changes can be enacted, the goal times decreased from 6 months for FY 1998 submissions to 4 months for FY 2002 submissions.

Goals		On-Time Performance by Submission Year				
		FY 98	FY 99	FY 00	FY 01	**FY 02**
Prior approval not required	6 months	90% on time	90%	90%	90%	**90%**
Prior approval required	6 months	90%	90%	90%	90%	
	4 months		30%	50%	70%	**90%**

Workload -- Manufacturing supplements filed *(Prior Approval / No Prior Approval)*:

	FY 98	FY 99	FY 00	FY 01	FY 02[4]
• **to NDAs**	1,463	1,459 *(900/559)*	1,438 *(684/754)*	1,474 *(579/895)*	1,753 *(622/1,131)*
• **to BLAs**	371	477 *(259/218)*	587 *(239/348)*	591 *(185/406)*	717 *(217/500)*
• **PDUFA total**	1,834	1,936 *(1,159/777)*	2,025 *(923/1,102)*	2,065 *(764/1,301)*	2,470 *(839/1,631)*

Manufacturing Supplements

Performance:

FY 2001 Submissions

Ninety-seven percent of the manufacturing supplements submitted in FY 2001 that did not require prior FDA approval were reviewed within 6 months. That level of performance exceeded the 90 percent on-time review goal.

Ninety-seven percent of the manufacturing supplements submitted in FY 2002 that required prior FDA approval also were reviewed within 6 months. Eighty-six percent of these were reviewed within 4 months. That level of performance exceeded FY 2001's goals of 90 percent and 70 percent respectively.

FY 01 Submissions		Reviewed and acted upon	Number on time	Percent on time
Prior approval not required	6 months	1301	1260	97
Prior approval required	6 months	764	744	97
	4 months		657	86

FY 2002 Submissions

As of September 30, 2002, almost 53 percent of the manufacturing supplements that do not require prior approval, and over 70 percent of those that do require prior approval had been reviewed. Ninety-eight percent those not requiring prior approval had been reviewed within the 6-month goal, and 95 percent of those that do require prior approval had been reviewed within the 4-month goal. Although it is too early to make a final determination with only 58 percent of the submissions reviewed, performance in both categories is well above the FY 2002 review goals.

FY 02 Submissions		Reviewed and acted upon	Number on time	Percent on time
Prior approval not required	6 months	857	843	98
Prior approval required	4 months	585	556	95

Procedural and Processing Goals

This section reports on a number of PDUFA II goals that had no precedent under PDUFA I. These goals relate to the IND phase of drug development and some aspects of the infrastructure of drug review. A detailed description of the goals, the annual performance targets, and definitions of terms can be found in Appendix A. This section reports on actions on items that occurred in FY 2002.

Meeting Management:

- **Meeting Requests:** Notify requestor of formal meeting in writing within 14 days of request.
- **Scheduling Meetings:** Schedule meetings within goal date (within 30 days of receipt of request for Type A meetings, 60 days for Type B meetings, and 75 days for Type C meetings). If the requested date for any of these types of meetings is greater than 30, 60, or 75 days, as appropriate, from the date the request is received by the Agency, the meeting date should be within 14 days of the requested date.
- **Meeting Minutes:** Agency prepared minutes, clearly outlining agreements, disagreements, issues for further discussion and action times will be available to sponsor within 30 calendar days of meeting.

			Total	Met Goal	Missed Goal[6]	Pending Within Goal[7]	% On Time[8]
On-time Goal							**90%**
Meeting Requests		CBER	414	399	14	1	
		CDER	1075	949	107	19	
		Combined	1489	1348	121	20	**92%**
Scheduling Meetings	Type A	CBER	16	14	1	1	
		CDER	35	24	10	1	
	Type B	CBER	245	199	8	38	
		CDER	402	281	112	9	
	Type C	CBER	113	98	5	10	
		CDER	582	549	25	8	
	All	CBER	374	311	14	49	
		CDER	1019	854	147	18	
		Combined	1393	1165	161	67	**88%**
Meeting Minutes		CBER	291	250	14	27	
		CDER	971	434	209	328	
		Combined	1262	684	223	355	**75%**

Procedural and Processing Goals

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

	Total	Met Goal	Missed Goal[6]	Pending Within Goal[7]	% On Time[8]
On-time Goal					**90%**
CBER	122	112	3	7	
CDER	52	31	18	3	
Combined	174	143	21	10	**87%**

Major Dispute Resolution: Respond to sponsor's appeal of decision within 30 days of receipt

	Total	Met Goal	Missed Goal[6]	Pending Within Goal[7]	% On Time[8]
On-time Goal					**90%**
CBER	4	4	0	0	
CDER	8	8	0	0	
Combined	12	12	0	0	**100%**

Special Protocol Question Assessment and Agreement: Respond to sponsor's request for evaluation of protocol design within 45 days of receipt

	Total	Met Goal	Missed Goal[6]	Pending Within Goal[7]	% On Time[8]
On-time Goal					**90%**
CBER	3	2	0	1	
CDER	245	196	23	26	
Combined	248	198	23	27	**90%**

Notes:

[1] Total approval time is the time from the initial submission of an original application to the issuance of an approval letter for that application. It includes both FDA's review time and the time the sponsor spends answering deficiencies noted by FDA, and can encompass several review "cycles." Not all applications receive approval letters.

[2] United States General Accounting Office, Food and Drug Administration: Effect of User Fees on Drug Approval Times, Withdrawals, and Other Agency Activities (GAO-02-958), September 2002.

[3] Food and Drug Administration. *CDER 2001 Report to the Nation: Improving Public Health Through Human Drugs. Rockville, Maryland, 2002* (p. 33). Available on the Internet at:

- PDF – http://www.fda.gov/cder/reports/rtn/2001/rtn2001.pdf
- HTML – http://www.fda.gov/cder/reports/rtn/2001/rtn2001.htm.

The PDUFA figure has changed from 2.7% to 2.5% with the approval of additional NMEs this year with no additional safety based withdrawals.

[4] The count of FY 2002 submissions assumes that all submissions received in the last two months of FY 2002 are filed. When FDA files a submission, it is deemed "complete" by PDUFA definition. FDA makes a filing decision within 60 days of an original application's receipt. All calculations of PDUFA review times are made, however, from the original receipt date of the filed application.

[5] The term NME in this report refers exclusively to NMEs that are NDAs. For FDAMA purposes, BLAs are considered to be equivalent to NMEs; however, workload and performance statistics for BLAs are reported separately. The counts of NMEs in the workload table are of 'discrete,' filed NMEs. CDER often receives multiple submissions for the same new molecular entity, for different dosage forms for example. All are initially designated as NMEs, but, when the first of the multiples is approved, the others are redesignated as non-NMEs. In FY 2002, CDER designated 25 filings as NMEs initially (8 priority, 17 standard). Only 23 of these are 'discrete' (7 priority, 16 standard).

[6] Includes those with late actions and those still pending whose goal date has passed and which have not had actions.

[7] Includes actions that are pending within goal, as well as those whose goal date has passed, but whose action status is deemed incomplete because the database had not been updated to reflect the action in time for this report.

[8] Actions pending and within goal were excluded from the calculation.