FY 2000 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

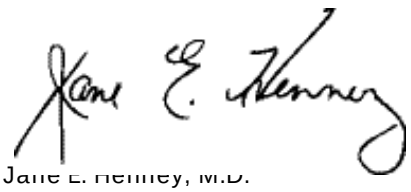
Commissioner's Report

In 1992 Congress enacted the Prescription Drug User Fee Act (PDUFA), a five-year program that provided FDA with additional resources to hire more medical and scientific reviewers to conduct premarket reviews, as well as support staff and field investigators. FDA committed, in connection with the 1992 legislation, to meet a set of review goals that would become more stringent each year. PDUFA enabled FDA to collect user fees from the industry to make achieving these goals possible. FDA was and is expected to apply the same high standards -- indeed, the gold standard for the world -- for safety and efficacy evaluation for those products that would enter the marketplace. The results of this initial experiment were reviewed in 1997. The results demonstrated clearly that, with adequate resources, FDA is capable of meeting the most demanding of performance standards. Thus, in 1997, Congress authorized PDUFA for another five years.

With this authorization came additional resources, but higher expectations for reviews, and additional goals related to FDA's responsiveness to industry during the early periods of drug development. In the first three years of PDUFA II, the Agency has met, with rare exception, all of the performance goal. We can now confidently state that these results provide evidence that we are far beyond the experimental testing phase. Nevertheless, under the sunset provisions of the Congressional authorization, further legislative action will be necessary if FDA is to maintain the authority to collect user fee revenue beyond FY 2002.

While premarket review is a critical piece in the risk assessment and management of medical products, it cannot, and should not, be seen in isolation. FDA is committed to the lifetime of the product, not just from the early stages of drug development through review and approval, but also to monitoring the products once they reach the marketplace. The post-approval areas are just as critical to assuring the safety of a product over its lifetime of use. One such area is adverse event reporting -- a process that allows us to discover previously undetected, and unexpected, adverse reactions to products after marketing. This is a key area since, prior to approval for marketing, most drugs are exposed to only a relatively small population in a controlled environment.

As we begin working with the industry, the Congress, and our stakeholders to forge PDUFA III, I want to assure the American people that FDA's overriding goal in this area is, as it has been, to bring the benefits of effective new products to the market as quickly as possible without compromising the high safety standards the American people expect.



Jane E. Henney, M.D.
Commissioner of Foods and Drugs

Table of Contents

Introduction

In 1992, Congress passed the Prescription Drug User Fee Act (PDUFA). PDUFA authorized FDA to collect fees from companies that produce 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 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 2000.

PDUFA provides FDA with additional revenue to hire more reviewers and support staff and upgrade its information technology to speed up the application review process for pharmaceutical and biological products without compromising review quality.

In consultation with industry and the Congress, FDA agreed to meet a set of review performance goals that become more stringent each year. These goals applied to the review of original new product applications, resubmissions of original applications, and supplements to approved applications. FDA met or exceeded every PDUFA I performance goal and has met or exceeded nearly every PDUFA II performance goal.

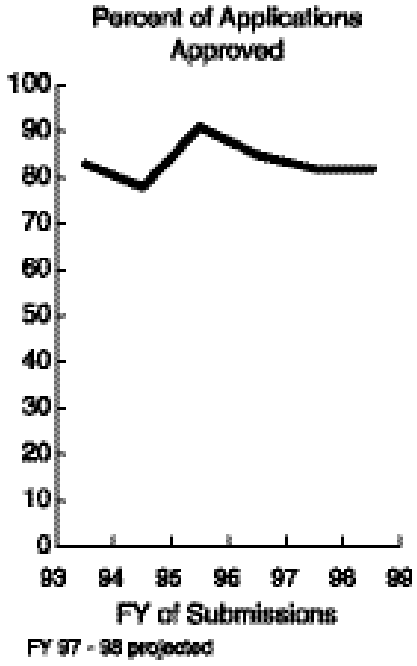
Under PDUFA II, the review goals continue to shorten. By 2002, the PDUFA II goals call for FDA to review and act on 90 percent of:

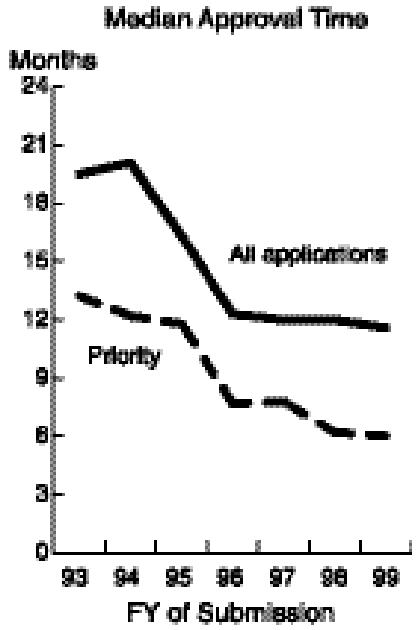
- Standard new drug and biological product applications and efficacy supplements within 10 months;
- Priority new drug and biological product applications and efficacy supplements (i.e., for products providing significant therapeutic gains) within 6 months;
- Manufacturing supplements within 6 months, and those requiring prior approval within 4 months;
- Class 1 resubmissions within 2 months, and Class 2 resubmissions within 6 months.

In addition, PDUFA II added a new set of procedural goals intended to improve FDA's responsiveness to and communication with industry sponsors during the early years of drug development. These goals specify timeframes for activities such as scheduling meetings and responding to various sponsor requests. Whereas PDUFA's original intent was to speed up the review process, PDUFA II's intent is to speed up the entire drug development process.

This report focuses on two aspects of PDUFA performance. Like previous performance reports, it measures the Agency's performance toward the agreed-upon numeric goals for reviewing and acting on submissions and responding to sponsors' pre-submission requests. In addition, it also reports on stakeholders' perceptions of PDUFA performance based on testimony from a public meeting held on September 15, 2000.

Outcomes





Previous PDUFA Performance Reports identified several important outcomes that had resulted from the Agency's meeting and exceeding its application review performance commitments. These included increasing numbers of applications filed, higher quality applications, and quicker approvals for products with the requisite data, outcomes that result in more quality products reaching American practitioners and consumers faster. In FY 2000 the Agency continued to exceed nearly all the review performance goals of PDUFA II[1] despite the goals becoming more challenging each year. Application filings and quality remain high by historic standards, and approval times continue to drop.

High Approval Rates: The percentage of filed new product applications that ultimately are approved increased from approximately 66 percent in the pre-PDUFA years[2] to roughly 80 percent for applications submitted from FY 93 through FY 95. These early PDUFA cohorts are essentially finished; only one submission from earlier than FY 96 was approved in FY 00. Approval rates currently stand at 77 percent for FY 97 applications, 69 percent for FY 98 applications, and 56 percent for FY 99 applications. The final approval rates for all of these years should be above 80 percent if present trends hold.

Compared to the approval rates for all new drug applications, there is a smaller increase in approval rates for new molecular entities (NMEs), unique new drugs that are approved for the first time by FDA. In the years before PDUFA (FY 88 to FY 92), 76 percent of the NMEs were ultimately approved. Since PDUFA, that rate has risen to approximately 81 percent.

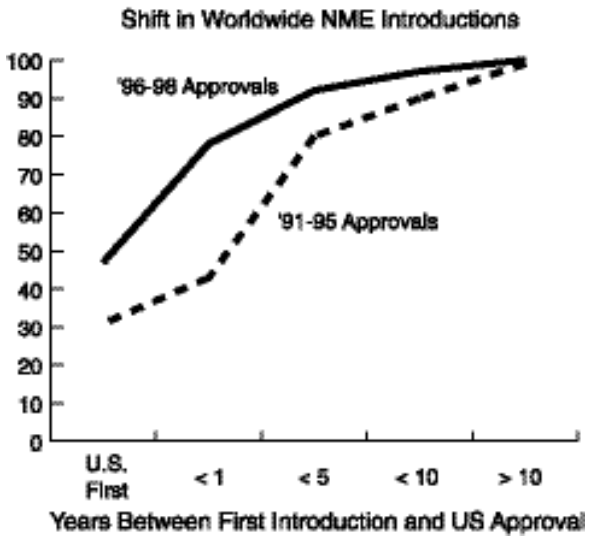
Quick Approval Times: The median total approval time for new product applications submitted in FY 99 dropped to 11.6 months . Total approval time is the time from the initial submission of a marketing application to the issuance of an approval letter for that application. It includes both FDA's review time and the time the sponsor spends answering deficiencies noted by FDA and can encompass several review 'cycles.' Given the progression

of PDUFA II review goals, median approval times may drop to 10 months in FY 01 or FY 02 if the current rate of first review cycle approvals is sustained.

Median total approval times for priority applications submitted in FY 99 was 6 months[3], less than half the median approval times for priority applications submitted in the early PDUFA years. The products of priority applications represent significant therapeutic gains and are an important outcome for the consumer and the medical community.

More NMEs Introduced in U.S. First: In the years since the passage of PDUFA, there has been a shift in the pattern of NME introductions in the world. According to information from the Tufts University Center for the Study of Drug Development presented at the PDUFA public meeting on September 15, 2000, only 43 percent of the NMEs approved in the U. S. in 1991-1995, primarily pre-PDUFA submissions, received that approval within a year of its first introduction on the world market. That percentage almost doubled to 80 percent for the NMEs approved in the U.S. from 1996-1998, primarily post-PDUFA submissions. Increasingly, American patients are receiving the benefits of important new drugs before they are available to citizens of other countries.

This important benefit, however, brings with it a need for increased surveillance. Although the Agency's high standards for safety and efficacy have not changed under PDUFA, the pre-market approval process cannot detect all possible future safety issues. Once a new drug is approved, safety issues sometimes arise simply because of its much wider use. Historically, about 3 to 4 percent of the NMEs approved in the world have eventually been withdrawn from the market for safety reasons. Because more of these products are now marketed in the U.S. first, FDA recognizes that it must be increasingly vigilant in its post-market surveillance efforts.



Report on PDUFA Goals

This report updates the Agency's review performance on the FY 99 application submissions and evaluates its performance in reviewing FY 00 application submissions and meeting other PDUFA II goals. All but two of the FY 99 submissions have been reviewed and acted upon, and final performance elative to the goals can now be reported. Only a preliminary performance assessment on FY 00 submissions is possible at this time. For submission categories with a 10- or 12-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, 2000.

FDA's Center for Biologics Evaluation and Research (CBER) is in the process of changing 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 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 remains constant. For standard applications, the review-time goals drop over the five-year period. For applications filed in FY 98, the goal was to review 90 percent in 12 months; for FY 02 applications, the goal is to review 90 percent in 10 months. For standard applications filed in FY 2000, the goal was to review 90 percent in 12 months and 50 percent in 10 months.

Goals		On-Time Performance by Submission Year				
		FY 98	FY 99	**FY00**	FY 01	FY 02
Priority	6 months	90% on time	90%	**90%**	90%	90%
Standard	12 months 10 months	90%	90% 30%	**90%** **50%**	90% 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 00 submissions assumes that all submissions received in the last two months of FY 00 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 96	FY 97	FY 98	FY 99	FY 00[4]
• **NDAs**	106	117 (25/92)	109 (30/79)	121 (30/91)	121 (27/94)
• **BLAs**	9	16 (3/13)	12 (8/4)	6 (1/5)	13 (4/9)
• **PDUFA Total**	115	133 (28/105)	121 (38/83)	127 (31/96)	134 (31/103)
NMEs[5]			42 (19/23)	41 (16/25)	35 (17/18)

Performance

FY 99 Submissions

For FY 99 applications, FDA met the 6-month review goal for priority submissions and the 12-month goal for standard submissions in every case. Two standard applications submitted late in FY 99 are still pending but have not exceeded the 12-month goal[6]. Sixty-eight percent of all standard applications and 60 percent of the NMEs and BLAs were reviewed and acted upon within 10 months, exceeding the 30 percent review goal in both cases.

FY 99 Submissions			Reviewed and acted upon	Number on Time	Percent on Time
Priority	6 month goal	All Applications	31	31	100
		NMEs & BLAs	17	17	100
Standard	12 month goal	All Applications	94*	94	100*
		NMEs & BLAs	30	30	100
	10 month goal	All Applications	94	64	68
		NMEs & BLAs	30	18	60

**Two standard submissions still pending but not late*

FY 00 Submissions

While it is too early to report meaningful review performance statistics for standard applications submitted in FY 00, all priority applications that have been reviewed have met the 6 month review goal.

FY 00 Submissions			Reviewed and acted upon	Number on Time	Percent on Time
Priority	6 month goal	All Applications	18	18	100
		NMEs & BLAs	9	9	100
Standard	12 month goal	All Applications	Too early to report meaningful review performance statistics. Sixteen standard applications have been reviewed and acted upon, all within 10 months.		
		NMEs & BLAs			
	10 month goal	All Applications			
		NMEs & BLAs			

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 its original application's year of submission. The definitions of Class 1 and Class 2 resubmissions can be found at the end of Appendix B.

Goals		On-Time Performance by Submission Year				
		FY 98	FY 99	**FY00**	FY 01	FY 02
Class 1	6 months 4 months 6 months	90% on time 30%	90% 50%	**90%** **70%**	90%	90%
Class 2	6 months	90%	90%	**90%**	90%	90%

Workload -- Resubmissions received (Total (Class 1/Class 2))

	FY 96	FY 97	FY 98	FY 99	FY 00
• **of original NDAs**	84	82	50 *(19/31)*	63 *(17/46)*	77 *(26/51)*
• **of original BLAs**	14	8	21 *(5/16)*	14 *(2/12)*	9 *(1/8)*
• **PDUFA Total**	98	90	71 *(24/47)*	77 *(19/58)*	86 *(27/59)*

Performance

FY 99 Submissions

All 19 Class 1 resubmissions received in FY 99 were reviewed and acted upon within 2 months, and all 58 Class 2 resubmissions were reviewed and acted upon within 6 months. Review performance on both classes of FY 99 resubmissions exceeded the PDUFA review goals.

FY 99 Resubmissions		Reviewed and acted upon	Number on Time	Percent on Time
Class 1	4 months	19	19	100
	2 months		19	100
Class 2	6 months	58	58	100

FY 00 Submissions

As of September 30, 2000, 23 FY 00 Class 1 resubmissions had been reviewed and acted upon. All 23 met the 4-month review goal, and all but one met the 2-month goal. With only 4 Class 1 resubmissions still pending, review performance on FY 00 Class 1 resubmissions will exceed the review goals.

All but one of the Class 2 resubmissions that have been reviewed and acted upon have met the 6 month goal. While too many are still pending to make a final performance determination, current on-time performance stands at 97 percent.

FY 00 Resubmissions		Reviewed and acted upon	Number on Time	Percent on Time
Class 1	4 months	23	23	100
	2 months		22	96
Class 2	6 months	30	29	97

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 remains constant. For standard efficac supplements, the review-time goals drop over the five-year period. For FY 98 submissions, the goal was to review 90 percent in 12 months; for FY 02 submissions, the goal is to review 90 percent in 10 months. For standard efficacy supplements received in FY 2000, the goal was to review 90 percent in 12 months and 50 percent in 10 months.

Goals		On-Time Performance by Submission Year				
		FY 98	FY 99	**FY00**	FY 01	FY 02
Priority	6 months	90% on time	90%	**90%**	90%	90%
Standard	12 months 10 months	90%	90% 30%	**90%** **50%**	90% 70%	90%

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

	FY 96	FY 97	FY 98	FY 99	FY 00[4]
• **to NDAs**	103	146 *(10/136)*	126 *(10/116)*	135 *(15/120)*	173 *(16/157)*
• **to BLAs**	8	15 *(3/12)*	10 *(1/9)*	10 *(2/8)*	11 *(2/9)*
• **PDUFA Total**	111	161 *(13/148)*	136 *(11/125)*	145 *(17/128)*	184 (18/166)

Efficacy Supplements

Performance

FY 99 Submissions

Fifteen of the seventeen priority efficacy supplements submitted in FY 99 were reviewed and acted upon within the 6 month review goal. The on-time rate of 88 percent narrowly missed the 90 percent on-time goal.

All of the standard efficacy supplements were reviewed and acted upon within 12 months and 86 percent were reviewed within 10 months. This performance exceeds the FY 99 goals of 90 percent and 30 percent respectively.

FY 99 Submissions		Reviewed and acted upon	Number on Time	Percent on Time
Priority	6 months	17	15	88
Standard	12 months	128	128	100
	10 months		110	86

FY 00 Submissions

Fifteen of the eighteen priority efficacy supplements submitted in FY 00 have been reviewed and acted upon. All have met the 6-month review goal. Only 33 of the 166 standard efficacy supplements have been reviewed, but all of these have met the 10-month goal.

FY 00 Submissions		Reviewed and acted upon	Number on Time	Percent on Time
Priority	6 months	15	15	100
Standard	12 months	33	33	100
	10 months		33	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 do not change over the five years of PDUFA II. For manufacturing supplements that do require FDA's approval, the goal times decrease from 6 months for FY 98 submissions to 4 months for FY 02 submissions.

Goals		On-Time Performance by Submission Year				
		FY 98	FY 99	**FY00**	FY 01	FY 02
Prior approval not required	6 months	90% on time	90%	**90%**	90%	90%
Prior approval required	6 months 4 months	90%	90% 30%	**90%** **50%**	90% 70%	90%

Workload -- Manufacturing supplements filed (Total/Prior Approval Required):

	FY 96	FY 97	FY 98	FY 99	FY 00[4]
• **to NDAs**	1,218	1,262	1,463	1,459 *(900)*	1,446 *(708)*
• **to BLAs**	261	338	371	477 *(259)*	569 *(244)*
• **PDUFA Total**	1,479	1,600	1,834	1,936 *(1,159)*	2,015 *(952)*

Manufacturing Supplements

Performance

FY 99 Submissions

Ninety-eight percent of the manufacturing supplements that did not require prior FDA approval submitted in FY 99 were reviewed within 6 months. That level of performance exceeded the 90 percent on-time review goal.

Ninety-eight percent of the manufacturing supplements that required prior FDA approval submitted in FY 99 also were reviewed within 6 months. Seventy-six percent of these were reviewed within 4 months. That level of performance exceeded FY 99's goals of 90 percent and 30 percent respectively.

FY 99 Submissions		Reviewed and acted upon	Number on Time	Percent on Time
Prior approval not required	6 months	777	759	98
Prior approval required	6 months	1159	1141	98
	4 months		887	76

FY 00 Submissions

As of September 30, 2000, almost 59 percent of the manufacturing supplements that do not require prior approval, and 64 percent of those that do require prior approval had been reviewed. Ninety-nine percent of both categories of manufacturing supplements had been reviewed within 6 months, and 82 percent of those requiring prior approval had been reviewed within 4 months. Although it is too early to make a final determination with only 61 percent of the submissions reviewed, performance in all categories is well above the FY 00 review goals.

FY 00 Submissions		Reviewed and acted upon	Number on Time	Percent on Time
Prior approval not required	6 months	625	620	99
Prior approval required	6 months	610	605	99
	4 months		503	82

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 B. This section reports on actions on items that occurred in FY 00.

Meeting Management:

- Meeting Requests: Notify requestor of formal meeting in writing within14 days of request.
- Scheduling Meetings: Schedule meetings within goal date or within 14 days of requested date if longer than 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.
- 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[7]	Pending Within Goal[8]	% On Time[9]
On-time Goal							**80%**
Meeting Requests		CBER	283	277	6	0	
		CDER	900	768	108	24	
		Combined	1183	1045	114	24	**90%**
Scheduling Meetings	Type A	CBER	16	13	1	2	
		CDER	33	24	6	3	
	Type B	CBER	189	157	10	22	
		CDER	416	304	99	13	
	Type C	CBER	61	51	1	9	
		CDER	406	379	19	8	
	All	CBER	266	221	12	33	
		CDER	855	707	124	24	
		Combined	1121	928	136	57	**87%**
Meeting Minutes		CBER	201	168	11	22	
		CDER	808	417	150	241	
		Combined	1009	585	161	263	**78%**

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[7]	Pending Within Goal[8]	% On Time[9]
On-time Goal					**90%**
CBER	89	79	2	8	
CDER	44	38	5	1	
Combined	133	117	7	9	**94%**

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

	Total	Met Goal	Missed Goal[7]	Pending Within Goal[8]	% On Time[9]
On-time Goal					**80%**
CBER	0	0	0	0	
CDER	13	13	0	0	
Combined	13	13	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[7]	Pending Within Goal[8]	% On Time[9]
On-time Goal					**70%**
CBER	0	0	0	0	
CDER	128	107	3	18	
Combined	128	107	3	18	**97%**

Notes

[1] This report uses the terms PDUFA I and PDUFA II to distinguish between the original Prescription Drug User Fee Act of 1992 and the Act as reauthorized and amended by the Food and Drug Administration Modernization Act of 1997 (FDAMA) respectively. Where no distinction is needed or where the reference is obvious, the term PDUFA is used.

[2] Previous PDUFA Performance Reports mentioned a pre-PDUFA approval rate of less than 60 percent. The source for this information was the United States General Accounting Office [FDA Drug Approval: Review Time Has Decreased in Recent Years (GAO/PEMD-96-1), October 1995]. Since 1995, additional NDAs from pre-PDUFA submission cohorts have been approved. A recent analysis by the Center for Drug Evaluation and Research now puts the pre-PDUFA approval rate at approximately 66 percent.

[3] Although the last approvals for FY 99 submissions (as well as for earlier years) have not yet occurred, the median statistic can be estimated from approvals to date and estimates of the percent of submissions that will ultimately be approved.

[4] The count of FY 00 submissions assumes that all submissions received in the last two months of FY 00 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 re-designated as non-NMEs. In FY 00, CDER designated 36 filings as NMEs initially (17 priority, 19 standard). Only 35 of these are 'discrete' (17 priority, 18 standard).

[6] 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.

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

[8] 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.

[9] Actions pending were excluded from the calculation.

APPENDIX A: FDA and Stakeholders Public Meeting

Executive Summary

On September 15, 2000 FDA held a public meeting to hear the views of interested stakeholders about the user fee program established by the Prescription Drug User Fee Act (PDUFA). The 1997 reauthorization of PDUFA is set to expire at the end of FY 2002, and FDA is now considering what features it should advocate in proposing new or amended provisions to the legislation.

PDUFA authorizes FDA to collect fees from companies that produce certain human drug and biological products. The collected fees are intended to supplement FDA's human drug review appropriation, so the Agency can hire more reviewers and support staff, and upgrade its information technology to speed up the application review process for human drugs and biological products, without compromising review quality. In exchange for the fees, FDA agreed to certain human drug review performance goals designed to speed the review process. By law, PDUFA fees can only be used for specific costs related to the review of human drug and biological products, as defined in the PDUFA. No PDUFA user fees are assessed for generic drugs, most over-the-counter drugs, blood products, foods, cosmetics, medical devices or animal drugs.

The purpose of the public meeting was for FDA to hear stakeholders' views on particular features of the current PDUFA program, such as faster drug reviews and negotiate performance goals; their general views on having FDA collect user fees to support a regulatory function; and their opinions on having user fees apply to other FDA oversight activities in addition to the review of human drug products.

The full-day public meeting included presentations by members of four different panels of stakeholders. The panels respectively represented: patient advocacy groups, consumer protection groups, regulated industry groups, and health professional groups and academic researchers.

General Findings

Presentations by members of the different panels of stakeholders at the meeting made clear that there is a wide diversity of views about the PDUFA program, which has been in operation since it was first authorized in late 1992. The meeting was helpful in enabling FDA to hear the range of current opinion and the scope of issues to be addressed, and to provide key stakeholders the opportunity to hear one another's views.

Among the stakeholders who spoke at the public meeting, there were a few areas of general agreement. These views concerned:

FDA's underlying ability to perform

- It was generally agreed that with adequate resources, FDA can meet targeted performance goals as agreed under PDUFA. It would be preferable, however, that these funds be provided by Congressional appropriations.

- There was general agreement about FDA's need for increased funding for many activities that PDUFA does not currently fund. Most stakeholders considered that FDA does not receive adequate funding for many oversight activities that are not supplemented by PDUFA fees, but are critical to the Agency's mission to promote and protect patient and consumer health.

In addition, there were a number of areas in which the stakeholder panels expressed divergent views about the PDUFA program. These views concerned:

User fees as an appropriate mechanism to fund FDA

- The industries currently involved in the PDUFA program expressed strong support for the continuation of user fees, but a number of the representatives from patient and consumer advocacy groups did not support continuation of user fees as an FDA funding mechanism.

- The patient and consumer organizations expressed concern about the perception and potential for conflict of interest and inordinate industry influence created by user fees, and were concerned that funding FDA through user fees may undercut Congressional support for additional FDA appropriations, especially for safety programs not funded by user fees.

The setting of performance goals for FDA drug review

- Representatives from industry, the American Medical Association, and one patient advocacy group, expressed strong support for the PDUFA performance goals, currently negotiated between FDA and the regulated industry. These groups maintained that setting specific goals is critical to achieving accountability and predictability, and research findings presented by some panelists showed that FDA has exceeded those goals.

- The consumer protection groups and other patient advocacy groups were not critical of most of the goals themselves, but were critical of the current approach to setting performance goals, citing the lack of consumer and patient representation in that

process. This was viewed as giving priority to industry rather than consumers, with a resulting perceived emphasis on time goals rather than safety goals, and designation of priority status for all "new" drugs, without sufficient regard to their real therapeutic significance (even though this is not the case in reality.)

User fee funding for FDA's other product safety responsibilities

- Representatives from the drug industry, some consumer and patient advocacy groups, and the American Medical Association, did not support the extension of user fee funding to other aspects of product safety assurance, in addition to the review of new drug applications. Other aspects of product safety, including FDA surveillance for adverse effects after a drug's approval, were considered a public health function, and therefore not appropriate for user fee funding.

- A number of the consumer protection and patient advocacy groups, the American Pharmaceutical Association, and health care payer and provider representatives attending the meeting supported the allocation of user fee funds to other FDA safety functions. The most often-cited areas for coverage by user fees were FDA monitoring of safety after drug approval (i.e., post-market surveillance) and FDA oversight of direct-to-consumer (DTC) advertising.

Aside from the question of how other responsibilities should be funded, some stakeholders also expressed concern about unintended impacts of the PDUFA program on funding for other FDA programs. The technical requirements and funding triggers specified as part of the current user fee program, coupled with modest increases in FDA appropriations over the past few years, have worked to shift a larger share of total FDA resources to pre-market drug and biologic review, and reduced funds available for many other vital programs. Some considered this phenomenon to be further evidence of the problems with user fees, while others identified this as evidence of the need for more aggressive efforts to obtain increased Congressional appropriations for FDA.

As a follow-up to the public meeting, FDA is now in the process of further reviewing the comments provided by stakeholders, both at the meeting and submitted in writing. The five sections that follow provide an overview of key issues identified in the presentations within each of the five panels in the public meeting. The panels are as follows: FDA, Patient Advocacy Groups, Consumer Protection Groups, Industry Groups, and Health Professional Groups and Academic Researchers. The complete written statements submitted by participants can be obtained through the FDA website, at http://www.fda.gov/oc/pdufa2/meeting2000.html.

Panel I - Key Points from Presentations by FDA

The FDA panel included the Commissioner, the Senior Associate Commissioner, the Director of the Center for Drug Evaluation and Research, and the Director of the Center for Biologics Evaluation and Research. Key observations made by the Agency panel included the following.

Program strengths

PDUFA has been successful in achieving the original goals of eliminating backlogs of drug and biologic product marketing applications, decreasing review times of drug and biologic marketing applications, and reducing the total time to drug approval. The program has benefited patients, who have received faster access to new therapies and increased options for treatment. Industry has also benefited from a process that is faster, more predictable, accountable and open, and provides more consistent access to FDA advice and input. Finally, user fees have improved the resources available for reviewers and support staff, for pre-approval inspectors, for computer staff and computer system upgrades.

Challenges

The PDUFA program has also presented challenges. PDUFA covers only a limited part of a drug's "life cycle" by focusing only on marketing application review, without support for drug safety after approval, including surveillance of suspected adverse drug reactions, standard setting and product safety research, drug advertising regulation, or Good Manufacturing Practice surveillance. In addition, the workload and volume of review deadlines can create a "sweatshop" mentality among reviewers, with little time or resources available to continue their own research to keep current with their field of expertise. Review staff turnover has been an ongoing concern.

Finally, PDUFA statutory triggers and fee structure limit FDA's flexibility to allocate its resources to address emerging safety risks quickly. These risks may involve any of a wide range of products and problems not covered by user fees - e.g., blood products, vaccine safety, adverse drug reactions, medication errors, and counterfeit drug products. In particular,

- The authority to collect user fees also requires that FDA annually spend at least as much as its 1997 appropriation for drug review work, adjusted for inflation. This effectively earmarks a large portion of FDA's appropriation for only drug review work.

- User fee funding is somewhat unpredictable. The total funds from application fees[1] are driven by the number of applications received, and this determines the amount of fees that can be collected from the other two sources. This is because the statute requires that FDA collect one-third of all user fees from application fees, one-third from marketed product fees and one-third from establishment fees.

Panel II - Key Points from Presentations by Patient Advocacy Groups

The panel of patient advocacy groups included the National Organization for Rare Disorders, the Kidney Cancer Association, the National Health Council and a patient representative. Key points made by members of this panel included the following.

Several of the panelists considered the current PDUFA program to benefit industry primarily, and not patients, particularly with the current approach to priority assignments for new drug applications. It was recommended that FDA give first priority to speedy reviews for new drugs for currently untreatable and serious chronic diseases (which FDA already does), and lower priority to lifestyle drugs and me-too drugs. In addition, FDA should include consumer and patient representatives in establishing priorities. Most members of this panel also considered the current PDUFA performance goals were overly time-focused and did not give FDA sufficient latitude with review deadlines to assure quality.

While recognizing that PDUFA user fees were originally intended to supplement resources for drug approvals, some on the panel cited the chronic underfunding of other areas, e.g. post-market safety surveillance, as a rationale for extending user fee coverage to these areas. This extension would be in keeping with FDA's role as a consumer protection agency, not a new drug review agency. But several panelists cited the mechanism of user fees as problematic, because with increased user fees, Congress might shift financial responsibility for public safety to the private sector-- having the regulated pay for activities of the regulator. Most of the panelists viewed this as creating an inherent conflict of interest.

One panelist stated that FDA provides a lot of unfunded assista including FDA development of regulatory guidance and other standards documents, cited as leveling the industry playing field; FDA advice on whether a product in development is showing promise-- which he credited with saving industry millions of dollars in misdirected

[1] The amounts FDA can collect per application are pre-specified in the statue.

research; FDA time spent providing guidance through the clinical phase that is not compensated in the NDA review, making FDA a partner in the research and development without a share of financial returns; and the liability protection that FDA oversight provides to industry.

All members of the panel expressed concern about the lack of adequate funding for FDA review of, and follow-up on, adverse events after approval. One panel member observed that NIH is at the front end of the pipeline, and given large appropriations to do research to find new advances in medicine, but FDA is at the other end of that pipeline, making sure that the products developed are safe for patients, with no corresponding increase in its appropriations.

One of the members of this panel considered that PDUFA has been a success for patients and industry, offering a model for what can be done when government and industry work together. This panelist considered that clear goals have worked well in PDUFA II, and the goals have been an important factor in improving performance. The only downside to PDUFA has been the lack of overall appropriations from Congress on an annual basis, but the panelist maintained that policymakers need to fix this through appropriations, not PDUFA fees which are only meant to supplement FDA's appropriation. According to this panelist, PDUFA fees are were not meant to cover activities beyond pre-market review, such as post-market surveillance.

Panel III - Key Points from Presentations by Consumer Protection Groups

The panel of consumer protection groups included the National Women's Health Network, Public Citizen, the National Consumer League and the Center for Medical Consumers. Members of this panel were generally concerned about the potential conflict of interest that could be created by user fees and "industry-set" performance goals. Most thought that consumers and patients needed a larger role in setting goals. All expressed concerns about providing adequate funding for FDA safety oversight. Key points made by members of this panel included the following.

One panelist considered that PDUFA has blurred the lines defining conflict of interest, and that FDA should get more funding without strings attached. To achieve this, it was recommended that FDA be fully funded through Congressional appropriations. Another panelist also expressed concern that PDUFA creates a perception and problem of conflict of interest, and that having statutory responsibilities funded by private user fees inherently creates the risk of a conflict. In addition, this panelist viewed PDUFA as providing a lever that allows industry to periodically renegotiate the whole scheme of consumer protection in the Federal Food, Drug, and Cosmetic Act.

One of the panelists, who opposed PDUFA reauthorization, observed that the user fees--authorized in FDAMA -_ provide funding only for new drug review, yet FDAMA also gave FDA other unfunded mandates. These and other areas of FDA responsibility were considered to be chronically underfunded by Congress. These underfunded areas were identified as including post-market safety surveillance, oversight of direct-to-consumer (DTC) advertising and FDA inspections of imported products. Other panel members expressed similar concerns about the growing inadequacy of funds available for non-PDUFA programs, e.g., food inspections. One panelist considered the lack of resources to put FDA at risk of losing the confidence of Americans.

Members of this panel thought that PDUFA performance goals should be set by consumers rather than by industry. Current review timelines were considered to be enforced by industry, putting FDA funding at risk. This was described as creating "PDUFA compression," in which industry has learned to game the review system, withholding data from FDA until the last minute and not allowing sufficient time for careful review. This panelist remarked that the public needed to put the drug review clock in the hands of an independent FDA.

The pre-market focus of PDUFA was also considered shortsighted. One panel member remarked that while Congress and industry have focused PDUFA on drug review, adverse drug reactions among patients are on the increase, driven by increases in drug utilization, increases in the use of dietary supplements in combination with drugs, and the growth of the self-care movement in our country. These safety issues also need to be addressed.

To further align performance goals with the best interests of patients and consumers, members of this panel also recommended development of a review prioritization system that gives highest priority to drugs for treatment of serious conditions and rare disorders with no treatment available (which already exists). One of the panelists also recommended that if PDUFA were reauthorized it should be amended to remove the potential for conflict of interest, including disassociating any fees from performance goals, and consulting with consumers when setting performance goals.

Panel IV - Key Points from Presentations by Industry Groups

The panel of industry groups included representatives of manufacturers of brand-name, generic and biological products, including the Biotechnology Industry Organization, Procter and Gamble Pharmaceuticals (for the Pharmaceutical Research and Manufacturers of America), Teva Pharmaceuticals USA (for the Generic Pharmaceutical Association), and the National Association of Pharmaceutical Manufacturers.

Brand Drug and Biotech Industries

All of the panelists considered the current PDUFA program to be a success. As one panelist described it, PDUFA has realized all of its goals: new medicines have been developed more quickly and predictably, and an FDA information infrastructure is now in place to support review. This panelist considered that without PDUFA, patients would have had to wait longer for new medicines, and that FDA's system for new drug approval is much better than the European counterparts.

While pointing to the improved speed of the drug review process, industry panelists considered that FDA's review process is as stringent as ever, and that industry's relationship with FDA is not a partnership. One of the panelists asserted that while US citizens may be skeptical about government in general, they trust FDA and European regulatory agencies do not enjoy this level of public trust.

Most of the members of this panel thought user fees should only be applied to new product reviews. According to one of the panelists, PDUFA was intended to enhance only one aspect of FDA work -- new product reviews -- and in exchange for performance goals. The fees were intended to provide supplemental funding for review, not for approvals. User fees are appropriate for industry product review because that is not a public health function that should be supported by tax revenues.

Nonetheless, one member of the industry panel stated that because of flat federal appropriations over the past several years, the true operating budget of the FDA has shrunk dramatically and done so just as biotech companies are coming online with a "virtual tsunami" of new treatments for formerly intractable diseases, many diseases suffered by the Medicare population. Some of the panelists considered it critical that Congress fully fund all other aspects of FDA work, and that FDA needed assurance of adequate resources in order to attract and retain the brightest talent.

Panelists from the industries already participating in PDUFA had suggestions for improvements to be included in reauthorization. These included: further requirements for more predictable and timely reviews, FDA written agreements to protocol specifications, further action on FDA guidelines for health economic information and continuation of the extension of the pediatric exclusivity provided in FDAMA.

Generic Drug Industry

Panelists representing the generic drug industry considered PDUFA to be a success for brand-name and biologics manufacturers. One of these panelists recommended that FDA propose a generic drug user fee program, as a way to address the current delays

in generic review cited by the panelist. Under the proposed program, collected user fees would be in addition to, not a replacement for, appropriated funds. The collected user fees for generic drugs should only be used for hiring review staff and supporting review information systems for generic products. The proposal would also feature a 6-month review process and performance goals to enforce time frames.

The other panelist from the generic drug industry agreed that ANDA reviews have been delayed, and questioned whether the lack of FDA resources for these reviews could be attributed to a PDUFA diversion of center resources from non-PDUFA programs. But he also raised the question of whether a generic drug user fee program would result in faster time to market for generic drugs.

According to this panelist, provisions in Hatch-Waxman that protect brand exclusivity, other patent extensions granted by Congress, and the FDAMA pediatric exclusivity provision have had more of a role in the delay in a generic drug's time to market.

Panel V - Key Points from Presentations by Health Professional Groups and Academic Researchers

The panel of health professional groups and academic researchers included representatives of the American Medical Association, the American Pharmaceutical Association, Tufts Center for the Study of Drug Development and the Centre for Medicines Research International. Key points made by members of this panel are summarized below.

Health Professionals

The panelists representing health professionals shared the opinion that PDUFA has been successful in speeding the review of new drug applications, however their overall assessments of PDUFA's impact differed. One of the panelists recommended that PDUFA be reauthorized in FY2002, with user fees tied to performance goals negotiated with industry. He further recommended that user fees be used to cover [only] new drug reviews, and that Congress should fully fund all other FDA activities.

The other health professional panelist considered that PDUFA/FDAMA has had both positive and negative effects. While PDUFA has resulted in faster reviews--which can be done safely-- FDA review and approval of new products does not guarantee that these products are risk-free. Health professionals and the public can't assume that new products will never be withdrawn. At the same time, physicians are increasingly time-pressured and many are not reading the literature on new products, nor reading the black box information and, often, are not safely prescribing and monitoring the use of new

products, as required in the labeling. This panelist cited the need for additional funding for FDA post-market surveillance, describing the current reporting as insufficient and FDA's current system as insufficient and underfunded. He also suggested that pharmacists need to participate in the "phase 4" process of monitoring a drug after approval.

Coupled with faster approvals, one of the health care panelists cited increased drug promotion and related drug utilization as cause for concern. The panelist was concerned that direct-to-consumer (DTC) advertising was creating an attitude of casualness toward prescription drug use, causing decreased vigilance and fostering a growing lack of respect for the fact that medicines are risky. He cited the need to assure that information for consumers is complete, comprehensible and understandable. The panelist thought that increased FDA oversight was needed.

Given these safety challenges--that have increased with faster drug approvals-- this panelist thought that PDUFA fees should be extended to fund post-market surveillance and added oversight of DTC advertising. At the same time, the panelist urged a balance between user fees and appropriations--industry should share the costs, but there should be a cap on the percentage of total costs that will be covered by user fees.

Academic Researchers

The panelists who were academic researchers studying drug review processes both presented findings from their respective studies of PDUFA program performance. One of the panelists presented the results of an analysis of FDA drug review times for FY 1993 through FY 1998, showing that FDA has steadily reduced the amount of time required for NDA review, for both time to first action and total review time. His analysis found that reductions have been achieved for both standard and priority reviews, in keeping with respective goals. Examination of product withdrawals over the same period showed that the rate of withdrawals had not increased over this time.

The other academic research panelist presented findings from a study comparing the performance of FDA with other regulatory authorities in several other developed countries. He considered that PDUFA has helped to make the U.S. number one in the introduction of new drugs onto the market, e.g., when compared to other markets in Europe and Asia, by contributing to one of the three basic drivers: 1) a strong and efficient FDA, 2) freedom of pricing in the US, and 3) having the largest world market for drugs. FDA was found to have provisions for virtually every aspect of review transparency considered in an international survey of regulatory authorities. The panelist concluded by stating that compared to regulatory authorities in other developed countries, FDA has appropriate systems to assure quality in review, greater staff resources for review than anywhere else, and performance goals that work to make FDA a leader in time-for-review. Based on this, other countries might consider FDA the benchmark for performance.

Comments from the Floor--Consumers and Health Care Organizations

In addition to the comments from invited speakers, FDA heard from other stakeholders who attended the public meeting. These included representatives of Blue Cross/ Blue Shield of America, the Consumer Federation and the United Auto Workers. These speakers were generally concerned about the need for more FDA oversight of DTC advertising and post-market safety surveillance. One of these speakers recommended that FDA require that drug companies track the use and post-market safety of fast-track drugs, citing an increase in adverse drug reactions since PDUFA. It was recommended that FDA also develop criteria for the kind of information that should be provided for consumers in DTC advertisements. Although all of these commenters supported increased FDA funding for these activities, some preferred funding through Congressional appropriations, rather than through user fees. Those who preferred appropriations did not want to increase FDA dependence on user fees, citing a potential for draining resources from other activities, and concerns about the dominant role they consider that industry has played in the past in setting FDA's performance goals in exchange for user fees.

Next Steps

FDA has been gratified by the response to its request for stakeholder input on the PDUFA program. The Agency has received important feedback and suggestions for improvement that will be invaluable in helping identify issues and priorities in future discussions and negotiations.

APPENDIX B: PDUFA Performance Goals, FY 1998 - FY 2002

The following list presents by fiscal year the performance measures set forth in the letters referenced in the Food and Drug Administration Modernization Act of 1997. The following chart lists the goals by fiscal year with appropriate goal measurement dates:

I. FIVE-YEAR REVIEW PERFORMANCE GOALS	MEASUREMENT DATE
Fiscal Year 1998	
1. Review and act on 90 percent of standard original NDAs and PLA/BLAs filed during FY 98 within 12 months of receipt.[1]	12 months after end of FY 1998
2. Review and act on 90 percent of priority original NDAs and PLA/BLAs filed during FY 98 within 6 months of receipt.[1]	6 months after end of FY 1998
3. Review and act on 90 percent of standard efficacy supplements filed during FY 98 within 12 months of receipt.	12 months after end of FY 1998
4. Review and act on 90 percent of priority efficacy supplements filed during FY 98 within 6 months of receipt.	6 months after end of FY 1998
5. Review and act on 90 percent of manufacturing supplements filed during FY 98 within 6 months of receipt.	6 months after end of FY 1998
6. Review and act on 90 percent of resubmitted original applications received during FY 98 within 6 months of receipt, and review and act on 30 percent of Class 1 resubmitted original applications within 2 months of receipt.	6 months after end of FY 1998

[1] The goal letter allows three additional months for review of original NDA, PLA, or BLA submissions that involve major amendments within the last three months of their usual review interval. In these cases, the measurement dates shown in this Appendix move forward by 3 months.

APPENDIX B: PDUFA Performance Goals, FY 1998 - FY 2002

Fiscal Year 1999

1. Review and act on 90 percent of standard original NDAs and PLA/BLAs filed during FY 99 within 12 months of receipt and review and act on 30 percent within 10 months of receipt.[1]	12 months after end of FY 1999
2. Review and act on 90 percent of priority original NDAs and PLA/BLAs filed during FY 99 within 6 months of receipt.[1]	6 months after end of FY 1999
3. Review and act on 90 percent of standard efficacy supplements filed during FY 99 within 12 months of receipt and review and act on 30 percent within 10 months of receipt.	12 months after end of FY 1999
4. Review and act on 90 percent of priority efficacy supplements filed during FY 99 within 6 months of receipt.	6 months after end of FY 1999
5. Review and act on 90 percent of manufacturing supplements filed during FY 99 within 6 months of receipt and review and act on 30 percent of manufacturing supplements requiring prior approval within 4 months of receipt.	6 months after end of FY 1999
6. Review and act on 90 percent of Class 1 resubmitted original applications received during FY 99 within 4 months of receipt, and review and act on 50 percent within 2 months of receipt.	4 months after end of FY 1999
7. Review and act on 90 percent of Class 2 resubmitted original applications received during FY 99 within 6 months of receipt.	6 months after end of FY 1999

Fiscal Year 2000

1. Review and act on 90 percent of standard original NDAs and PLA/BLAs filed during FY 2000 within 12 months of receipt and review and act on 50 percent within 10 months of receipt.[1]	12 months after end of FY 2000
2. Review and act on 90 percent of priority original NDAs and PLA/BLAs filed during FY 2000 within 6 months of receipt.[1]	6 months after end of FY 2000
3. Review and act on 90 percent of standard efficacy supplements filed during FY 2000 within 12 months of receipt and review and act on 50 percent within 10 months of receipt.	12 months after end of FY 1999
4. Review and act on 90 percent of priority efficacy supplements filed during FY 2000 within 6 months of receipt.	6 months after end of FY 2000
5. Review and act on 90 percent of manufacturing supplements filed during FY 2000 within 6 months of receipt and review and act on 50 percent of manufacturing supplements requiring prior approval within 4 months of receipt.	6 months after end of FY 2000
6. Review and act on 90 percent of Class 1 resubmitted original applications received during FY 2000 within 4 months of receipt, and review and act on 70 percent within 2 months of receipt.	4 months after end of FY 2000
7. Review and act on 90 percent of Class 2 resubmitted original applications received during FY 2000 within 6 months of receipt.	6 months after end of FY 2000

Fiscal Year 2001	
1. Review and act on 90 percent of standard original NDAs and PLA/BLAs filed during FY 2001 within 12 months of receipt and review and act on 70 percent within 10 months of receipt.[1]	12 months after end of FY 2001
2. Review and act on 90 percent of priority original NDAs and PLA/BLAs filed during FY 2001 within 6 months of receipt.[1]	6 months after end of FY 2001
3. Review and act on 90 percent of standard efficacy supplements filed during FY 2001 within 12 months of receipt and review and act on 70 percent within 10 months of receipt.	12 months after end of FY 2001
4. Review and act on 90 percent of priority efficacy supplements filed during FY 2001 within 6 months of receipt.	6 months after end of FY 2001
5. Review and act on 90 percent of manufacturing supplements filed during FY 2001 within 6 months of receipt and review and act on 70 percent of manufacturing supplements requiring prior approval within 4 months of receipt.	6 months after end of FY 2001
6. Review and act on 90 percent of Class 1 resubmitted original applications received during FY 2001 within 2 months of receipt.	2 months after end of FY 2001
7. Review and act on 90 percent of Class 2 resubmitted original applications received during FY 2001 within 6 months of receipt.	6 months after end of FY 2001

Fiscal Year 2002	
1. Review and act on 90 percent of standard original NDAs and PLA/BLAs filed during FY 2002 within 10 months of receipt.[1]	10 months after end of FY 2002
2. Review and act on 90 percent of priority original NDAs and PLA/BLAs filed during FY 2002 within 6 months of receipt.[1]	6 months after end of FY 2002
3. Review and act on 90 percent of standard efficacy supplements filed during FY 2002 within 10 months of receipt.	10 months after end of FY 2002
4. Review and act on 90 percent of priority efficacy supplements filed during FY 2002 within 6 months of receipt.	6 months after end of FY 2002
5. Review and act on 90 percent of manufacturing supplements filed during FY 2002 within 6 months of receipt and review and act on 90 percent of manufacturing supplements requiring prior approval within 4 months of receipt.	6 months after end of FY 2002
6. Review and act on 90 percent of Class 1 resubmitted original applications received during FY 2002 within 2 months of receipt.	2 months after end of FY 2002
7. Review and act on 90 percent of Class 2 resubmitted original applications received during FY 2002 within 6 months of receipt.	6 months after end of FY 2002

II. NEW MOLECULAR ENTITY (NME) PERFORMANCE GOALS

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

III. PROCEDURAL AND PROCESSING GOAL

Performance Area	Agency Activity	Performance Goal	Performance Level
Meeting Management	Meeting Requests -- Notify requestor of formal meeting in writing (date, time, place, and participants)	within 14 days of receipt of request	FY 1999 requests -- 70% on time FY 2000 -- 80% on time FY 2001 and on -- 90% on time
	Scheduling Meetings -- Schedule meetings within goal date or within 14 days of requested date if longer than goal date.	Type A Meetings within 30 days of receipt of request Type B Meetings within 60 days of receipt of request Type C Meetings within 75 days of receipt of request	FY 1999 requests -- 70% on time FY 2000 -- 80% on time FY 2001 and on -- 90% on time
	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	FY 1999 meetings -- 70% on time FY 2000 -- 80% on time FY 2001 and on -- 90% on time
Clinical Holds	Response to sponsor's complete response to a clinical hold	within 30 days of receipt of sponsor's response	FY 1998 -- 75% on time FY 1999 and on -- 90% on time
Major Dispute Resolution	Response to sponsor's appeal of decision	within 30 days of receipt of sponsor's appeal	FY 1999 -- 70% on time FY 2000 -- 80 % on time FY 2001 and on -- 90% on time
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	FY 1999 -- 60% on time FY 2000 -- 70% on time FY 2001 -- 80% on time FY 2002 -- 90% on time
Electronic Applications and Submissions	Paperless Application Processing	Agency to develop and update information systems to allow paperless receipt and processing of INDs, human drug applications, and related submissions by end of FY 2002.	
Additional Procedures	Simplification of Action Letters	Centers to amend regulations and processes to provide for issuance of 'Approval' (AP) or 'Complete Response' (CR) action letters.	
	Sponsor Notification of Deficiencies in Applications	Centers to notify sponsors of deficiencies via 'information request' (IR) when each discipline has finished its initial review.	

APPENDIX B: PDUFA Performance Goals, FY 1998 - FY 2002

Definitions of Terms:

A. The term "review and act on" is understood to mean 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. A major amendment to an original application submitted within three months of the goal date extends the goal date by three months. Only one extension is allowed for an application.

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/PLA/BLA meeting. Each requestor should usually only request 1 each of these Type B meetings for each potential application (NDA/PLA/BLA) (or combination of closely related products, i.e., same active ingredient but different dosage forms being developed con currently).

H. A Type C Meeting is any other type of meeting.

APPENDIX C: List of Approved Applications

This appendix updates the detailed review histories of the NDAs and PLA/BLAs submitted and approved under PDUFA. It shows approvals of all PDUFA-related submissions that took place in FY 00 as well as FY 99 approvals of FY 99 submissions. Earlier PDUFA approvals were listed in previous performance reports.

The following two tables summarize the review histories for all approved applications submitted from FY 95 through FY 99. The tables show the average first review, second review, and approval times. Note that times are in months, not all applications required a second review, and some required more than two reviews. The mean total approval times shown in the tables will increase in the future as additional applications are approved.

Approved Priority NDAs/BLAs

	1st Review		2nd Review			Total Approval Time
Receipt Cohort	N	FDA Review	N	Sponsor Response	FDA Review	
FY95	21	8.7	10	6.0	3.3	13.2
FY96	31	7.4	13	2.6	3.7	11.6
FY97	23	6.3	10	4.4	3.6	9.5
FY98	31	6.1	12	1.5	2.7	8.1
FY99	25	6.3	7	1.6	2.1	7.3

Approved Standard NDAs/BLAs

	1st Review		2nd Review			Total Approval Time
Receipt Cohort	N	FDA Review	N	Sponsor Response	FDA Review	
FY95	83	12.2	53	2.8	4.2	17.8
FY96	73	11.9	40	4.1	4.1	17.0
FY97	80	11.5	33	4.4	3.6	14.8
FY98	53	11.3	29	3.3	4.5	16.3
FY99	46	10.4	11	1.0	2.2	11.2

The remainder of this appendix shows the individual review histories. 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 99 can be found in the appendices of the earlier PDUFA Performance Reports which are available at http://www.fda.gov.

APPENDIX C: List of Approved Applications

Terms and Coding Used In Tables

✓ FY 99 approval of an FY 99 submission. These were not included in earlier PDUFA performance reports and are included here for completeness.

** Major amendment was received within 3 months of the action due date, which extended the review timeframes by 3 months.

Action Codes:

AE = Approvable
AP = Approved
NA = Not Approvable
RL = Complete Response
WD = Withdrawn

APPENDIX C: List of Approved Applications

Table 1
FY 1999 Priority NDA and BLA Submissions Approved in FY 99 (✓) and FY 00

Generic Name	Sponsor	Approval Time (Months)		Review Goal Met
		Total Time	Resubmissions (if necessary)	
✓ AMPRENAVIR (ORAL SOLUTION)	Glaxo Wellcome	4.2		Y
SOMATROPIN - RDNA ORIGIN (SUSPENSION FOR INJECTION)	Genentech	5.8		Y
✓ CYTARABINE	Skyepharma	5.9		Y
✓ ROFECOXIB (ORAL SUSPENSION)	Merck Res	5.9		Y
✓ ROFECOXIB (TABLET)	Merck Res	5.9		Y
✓ KETOTIFEN FUMARATE	Ciba Vision	5.9		Y
✓ LEVONORGESTREL	Womens Capital	5.9		Y
OSELTAMIVIR PHOSPHATE	Roche	6.0		Y
LEVOBETAXOLOL HYDROCHLORIDE	Alcon	6.0		Y
✓ GANIRELIX ACETATE	Organon Inc	6.0		Y
✓ ROSIGLITAZONE MALEATE	SKB Pharms	6.0		Y
✓ PIOGLITAZONE HYDROCHLORIDE	Takeda Pharms	6.0		Y
✓ AMPRENAVIR (CAPSULE)	Glaxo Wellcome	6.0		Y
✓ PEMIROLAST POTASSIUM	Santen	6.0		Y
BEXAROTENE	Ligand	6.2	FDA First Action: 6.0 (AE) Sponsor Response: 0.1 FDA Second Action: 0.1 (AP)	Y Y
NITRIC OXIDE	INO	6.9 [1]	FDA First Action: 5.8 (AE) Sponsor Response: 0.7 FDA Second Action: 0.5 (AP)	Y Y
ALOSETRON HYDROCHLORIDE	Glaxo Wellcome	7.4		Y
VERTEPORFIN	QLT	7.9	FDA First Action: 5.9 (AE) Sponsor Response: 0.4 FDA Second Action: 1.6 (AP)	Y Y
NEDOCROMIL SODIUM	Allergan	8.2	FDA First Action: 6.0 (AE) Sponsor Response: 0.5 FDA Second Action: 1.8 (AP)	Y Y
PNEUMOCOCCAL 7-VALENT CONJUGATE VACCINE (DIPHTHERIA CRM197 PROTEIN) (BLA)	Lederle Laboratories Division American Cyanamid Company	8.5	FDA First Action: 5.9 (RL) Sponsor Response: 0.7 FDA Second Action: 1.9 (AP)	Y Y
✓ ZANAMIVIR	Glaxo Wellcome	8.9		Y
✓ SIROLIMUS	Wyeth Ayerst Labs	9.0		Y
✓ EPIRUBICIN HYDROCHLORIDE	Pharmacia and Upjohn	9.0		Y
ASPIRIN/DIPYRIDAMOLE	Boehringer Pharms	11.2	FDA First Action: 6.0 (AE) Sponsor Response: 2.3 FDA Second Action: 3.0 (AP)	Y Y
ATOVAQUONE/PROGUANIL HYDROCHLORIDE	Glaxo Wellcome	18.5	FDA First Action: 6.0 (AE) Sponsor Response: 6.7 FDA Second Action: 5.8 (AP)	Y Y

[1] This application was originally submitted on 6/16/97 and was withdrawn on 9/17/97 because of insufficient data. It was resubmitted on 5/26/99. This date was used to calculate the total approval time.

APPENDIX C: List of Approved Applications

Table 2
FY 1999 Standard NDA and BLA Submissions Approved in FY 99 (✓) and FY 00

Generic Name	Sponsor	Approval Time (Months)		Review Goal Met
		Total Time	Resubmissions (if necessary)	
QUINAPRIL HYDROCHLORIDE/ HYDROCHLOROTHIAZIDE	Parke Davis	7.9 [2]	FDA First Action: 6.9 (AE) Sponsor Response: 0.3 FDA Second Action: 0.6 (AP)	Y Y
C13-UREA	Metabolic Solutions	9.0		Y
AZELASTINE HYDROCHLORIDE	Asta Medica (US)	9.6		Y
CLOTRIMAZOLE	Taro Pharms (US)	9.9		Y
SEVELAMER HYDROCHLORIDE	Geltex	9.9		Y
COLESEVELAM HYDROCHLORIDE (CAPSULE)	Sankyo Pharma Inc	9.9		Y
COLESEVELAM HYDROCHLORIDE (TABLET)	Sankyo Pharma Inc	9.9		Y
LEVETIRACETAM	UCB Pharma	9.9		Y
ESTRADIOL/NORGESTIMATE	RW Johnson	9.9		Y
ETHINYL ESTRADIOL/NORETHINDRONE ACETATE	Parke Davis	9.9		Y
TENECTEPLASE (BLA)	Genentech, Inc.	10.0		Y
✓ MENOTROPINS/LUTEINIZING HORMONE	Ferring Pharms	10.0		Y
✓ CLINDAMYCIN PHOSPHATE	Pharmacia and Upjohn	10.0		Y
EXEMESTANE	Pharmacia and Upjohn	10.0		Y
NAPROXEN SODIUM/PSEU DOEPHEDRINE HYDROCHLORID	Bayer Cons	10.0		Y
GABAPENTIN	Parke Davis	10.0		Y
EFLORNITHINE HYDROCHLORIDE	Westwood Squibb	10.0		Y
✓ ESTRADIOL	RW Johnson	10.0		Y
TESTOSTERONE	Unimed Pharms	10.0		Y
LEUPROLIDE ACETATE	Alza	10.0		Y
CALCIUM CHLORIDE	Abbott Labs	10.0		Y
METFORMIN HYDROCHLORIDE /GLYBURIDE	Bristol Myers Squibb	10.0		Y
CLARITHROMYCIN	Abbott Labs	10.0		Y
NITROGLYCERIN	Parke Davis	10.9	FDA First Action: 9.7 (AE) Sponsor Response: 0.6 FDA Second Action: 0.7 (AP)	Y Y
CEFAZOLIN SODIUM	B Braun	11.1		Y

[2] This application was submitted on 2/14/90 and withdrawn on 10/27/92. It was resubmitted on 5/3/99. This date was used to calculate the total approval time.

APPENDIX C: List of Approved Applications

Generic Name	Sponsor	Approval Time (Months)		Review Goal Met
		Total Time	Resubmissions (if necessary)	
CANDESARTAN CILEXETIL / HYDROCHLOROTHIAZIDE	AstraZeneca	11.3	FDA First Action: 9.7 (AE) Sponsor Response: 0.7 FDA Second Action: 0.9 (AP)	Y Y
GATIFLOXACIN (TABLET)	Bristol Myers Squibb	11.6		Y
GATIFLOXACIN (INJECTION)	Bristol Myers Squibb	11.6		Y
DILTIAZEM HYDROCHLORIDE	Biovail Labs	11.6	FDA First Action: 10.0 (AE) Sponsor Response: 0.9 FDA Second Action: 0.8 (AP)	Y Y
SOMATROPIN - RDNA ORIGIN (SOLUTION FOR INJECTION)	Novo Nordisk Pharm	11.7		Y
INSULIN GLARGINE	Aventis Pharms	11.9		Y
CICLOPIROX	Aventis Pharms	12.0		Y
DEXMEDETOMIDINE	Abbott Labs	12.0		Y
INSULIN LISPRO 25% /INSULIN LISPRO PROTAMINE 75%	Lilly	12.0		Y
INSULIN LISPRO 50% /INSULIN LISPRO PROTAMINE 50%	Lilly	12.0		Y
MOXIFLOXACIN HYDROCHLORIDE	Bayer	12.0		Y
TRETINOIN	Johnson and Johnson	12.0		Y
TAZAROTENE	Allergan	12.0		Y
DOXERCALCIFEROL	Bone Care	12.0		Y
METHYLPHENIDATE HYDROCHLORIDE	Alza	12.5	FDA First Action: 10.0 AE) Sponsor Response: .6 FDA Second Action: 1.9 (AP)	Y Y
TINZAPARIN SODIUM	Dupont Pharma	12.5	FDA First Action: 10.0 (AE) Sponsor Response: 0.6 FDA Second Action: 1.9 (AP)	Y Y
OLANZAPINE	Lilly	13.2	FDA First Action: 9.7 (AE) Sponsor Response: 1.2 FDA Second Action: 2.3 (AP)	Y Y
CITALOPRAM HYDROBROMIDE	Forest Labs	13.6	FDA First Action: 10.0 (AE) Sponsor Response: 2.0 FDA Second Action: 1.7 (AP)	Y Y
MELOXICAM	Boehringer Pharms	15.9	FDA First Action: 12.0 (AE) Sponsor Response: 2.0 FDA Second Action: 1.9 (AP)	Y Y
SALMETEROL XINAFOATE /FLUTICASONE PROPIONATE	Glaxo Wellcome	17.0	FDA First Action: 10.1 (AE) Sponsor Response: 1.0 FDA Second Action: 6.0 (AP)	Y Y
RIVASTIGMINETARTRATE (ORAL SOLUTION)	Novartis Pharms	17.1	FDA First Action: 9.6 (AE) Sponsor Response: 1.4 FDA Second Action: 6.0 (AP)	Y Y

APPENDIX C: List of Approved Applications

Table 3
FY 1998 Priority NDA and BLA Submissions Approved in FY 00

Generic Name	Sponsor	Approval Time (Months)		Review Goal Met
		Total Time	Resubmissions (if necessary)	
BUDESONID (SUSPENSION FOR INHALATION)	AstraZeneca Pharms	26.6[3]	FDA First Action: 6.0 (AE) Sponsor Response: 2.7 FDA Second Action: 6.0 (AE) Sponsor Response: 12.0 FDA Third Action: 5.9 (AP)	Y Y Y

[3] The total approval time for this NDA was adjusted. The firm encountered a problem with the container when the product was shipped. Six months were excluded from the total approval time while the firm resolved the problem.

APPENDIX C: List of Approved Applications

Table 4
FY 1998 Standard NDA and BLA Submissions Approved in FY 00

Generic Name	Sponsor	Approval Time (Months)		Review Goal Met
		Total Time	Resubmissions (if necessary)	
OXCARBAZEPINE	Novartis Pharms	15.6	FDA First Action: 12.0 (AE) Sponsor Response: 1.7 FDA Second Action: 1.9 (AP)	Y Y
PROCHLORPERAZINE MALEATE	SKB Pharms	15.6 [4]	FDA First Action: 4.6 (NA) Sponsor Response: 2.4 FDA Second Action: 5.8 (NA) Sponsor Response: 2.5 FDA Third Action: 1.8 (AE) Sponsor Response: 1.7 FDA Fourth Action: 5.3 (AP)	Y Y Y Y
CEVIMELINE HYDROCHLORIDE	Snowbrand	16.5	FDA First Action: 12.0 (AE) Sponsor Response: 2.5 FDA Second Action: 2.0 (AP)	Y Y
AMINOLEVULINIC ACID HYDROCHLORIDE	DUSA	17.1	FDA First Action: 11.9 (AE) Sponsor Response: 3.3 FDA Second Action: 2.0 (AP)	Y Y
PIPERONYL BUTOXIDE /PYRETHRINS	Pfizer	17.9	FDA First Action: 9.9 (AE) Sponsor Response: 2.0 FDA Second Action: 6.0 (AP)	Y Y
GADOPENTETATE DIMEGLUMINE	Berlex Labs	18.4	FDA First Action: 11.9 (AE) Sponsor Response: 0.6 FDA Second Action: 1.9 (AE) Sponsor Response: 0.1 FDA Third Action: 3.9 (AP)	Y Y Y
DOFETILIDE	Pfizer	18.8	FDA First Action: 11.9 (AE) Sponsor Response: 6.2 FDA Second Action: 0.7 (AP)	Y Y
PANTOPRAZOLE SODIUM	Wyeth Ayerst Labs	19.1	FDA First Action: 12.0 (AE) Sponsor Response: 1.1 FDA Second Action: 6.0 (AP)	Y Y
FEXOFENADINE HYDROCHLORIDE	Aventis Pharms	19.3	FDA First Action: 12.0 (AE) Sponsor Response: 1.4 FDA Second Action: 6.0 (AP)	Y Y
SERTRALINE HYDROCHLORIDE	Pfizer Pharms	19.7	FDA First Action: 12.0 (AE) Sponsor Response: 1.7 FDA Second Action: 6.0 (AP)	Y Y
INSULIN ASPART (RDNA ORIGIN)	Novo Nordisk Pharm	20.7	FDA First Action: 12.0 (AE) Sponsor Response: 2.7 FDA Second Action: 6.0 (AP)	Y Y
GADOVERSETAMIDE (GLASS VIAL)	Mallinckrodt	21.2	FDA First Action: 9.7 (NA) Sponsor Response: 5.5 FDA Second Action: 6.0 (AP)	Y Y

[4] The total approval time for this NDA was adjusted. The firm first submitted this application as a supplement when it should have been submitted as an NDA. The time period from 10/1/97 to 6/18/98 was excluded from the total approval time.

Table 4 (Continued)

Generic Name	Sponsor	Approval Time (Months)		Review Goal Met
		Total Time	Resubmissions (if necessary)	
GADOVERSETAMIDE (PLASTIC SYRINGE)	Mallinckrodt	21.2	FDA First Action: 9.7 (NA) Sponsor Response: 5.5 FDA Second Action: 6.0 (AP)	Y Y
GADOVERSETAMIDE (PHARMACY BULK PACK)	Mallinckrodt	21.2	FDA First Action: 9.7 (NA) Sponsor Response: 5.5 FDA Second Action: 6.0 (AP)	Y Y
ENTACAPONE	Orion	21.5	FDA First Action: 11.9 (AE) Sponsor Response: 3.6 FDA Second Action: 6.0 (AP)	Y Y
OXYCODONE HYDROCHLORIDE	Roxane	23.0	FDA First Action: 11.8 (AE) Sponsor Response: 5.2 FDA Second Action: 6.0 (AP)	Y Y
MEQUINOL / TRETINOIN	Bristol Myers Squibb	23.3	FDA First Action: 15.0 (AE) Sponsor Response: 7.6 FDA Second Action: 0.8 (AP)	Y** Y
ARTICAINE HYDROCHLORIDE / EPINEPHRINE	Deproco	24.2	FDA First Action: 10.0 (AE) Sponsor Response: 1.3 FDA Second Action: 1.9 (AE) Sponsor Response: 8.9 FDA Third Action: 2.0 (AP)	Y Y Y
ANTIHEMOPHILIC FACTOR (RECOMBINANT) (BLA)	Genetics Institute, Inc.	25.1	FDA First Action: 11.9 (RL) Sponsor Response: 4.2 FDA Second Action: 9.0 (AP)	Y N
BECLOMETHASONE DIPROPIONATE	3M Pharms	28.2	FDA First Action: 12.0 (AE) Sponsor Response: 3.2 FDA Second Action: 6.0 (AE) Sponsor Response: 0.4 FDA Third Action: 6.5 (AP)	Y Y N
FLUTICASONE PROPIONATE	Glaxo	30.0	FDA First Action: 12.0 (AE) Sponsor Response: 2.3 FDA Second Action: 6.0 (AE) Sponsor Response: 3.7 FDA Third Action: 6.0 (AP)	Y Y Y
DOCOSANOL	Avanir	31.1	FDA First Action: 12.0 (NA) Sponsor Response: 11.4 FDA Second Action: 5.9 (AE) Sponsor Response: 1.8 FDA Third Action: 0.0 (AP)	Y Y Y

APPENDIX C: List of Approved Applications

Table 5
FY 1997 Standard NDA and BLA Submissions Approved in FY 00

Generic Name	Sponsor	Approval Time (Months)		Review Goal Met
		Total Time	Resubmissions (if necessary)	
CHLORHEXIDINE GLUCONATE/ISOPROPYL ALCOHOL	Medi-Flex Hospital Product	18.0[5]	FDA First Action: 12.0 (NA) Sponsor Response: 22.8 FDA Second Action: 6.0 (AP)	Y Y
ZONISAMIDE	Dainippon Pharm	24.0 [6]	FDA First Action: 12.0 (AE) Sponsor Response: 9.4 FDA Second Action: 6.0 (AE) Sponsor Response: 3.0 FDA Third Action: 6.0 (AP)	Y Y Y
BALSALAZIDE DISODIUM	Salix	30.8 [7]	FDA First Action: 11.7 (AE) Sponsor Response: 15.3 FDA Second Action: 6.0 (AE) Sponsor Response: 2.0 FDA Third Action: 1.8 (AP)	Y Y Y
ADAPALENE	Galderma Labs LP	34.3	FDA First Action: 11.7 (NA) Sponsor Response: 14.0 FDA Second Action: 6.0 (AE) Sponsor Response: 0.9 FDA Third Action: 1.7 (AP)	Y Y Y
ARGATROBAN	Texas Biotech	34.5	FDA First Action: 8.7 (NA) Sponsor Response: 15.3 FDA Second Action: 6.1 (AE) Sponsor Response: 2.5 FDA Third Action: 1.9 (AP)	Y Y Y
RIVASTIGMINE TARTRATE (CAPSULE)	Novartis Pharms	36.5	FDA First Action: 15.0 (NA) Sponsor Response: 4.2 FDA Second Action: 6.0 (AE) Sponsor Response: 5.3 FDA Third Action: 6.0 (AP)	Y** Y Y

[5] The total approval time for this NDA was adjusted. The firm submitted new studies supporting a new indication. The time period from 2/20/98 to 1/14/00 was excluded from the total approval time.

[6] The total approval time for this NDA was adjusted because of insufficient safety and efficacy data. The time period from 3/19/98 to 3/30/99 was excluded from the total approval time.

[7] The total approval time for this NDA was adjusted. The firm submitted two pivotal studies using an active comparator that was not approved in the U.S. At FDA's request, the firm undertook additional evaluations to characterize the unapproved comparator. The time period from 3/24/99 to 9/24/99 was excluded from the total approval time.

Table 6
FY 1996 Priority NDA and BLA Submissions Approved in FY 00

Generic Name	Sponsor	Approval Time (Months)		Review Goal Met
		Total Time	Resubmissions (if necessary)	
MIFEPRISTONE	Population Council	18.0 [8]	FDA First Action: 6.0 (AE) Sponsor Response: 35.0 FDA Second Action: 6.0 (AE) Sponsor Response: 1.4 FDA Third Action: 6.0 (AP)	Y Y Y

[8] The total approval time for this NDA was adjusted. The time period from 9/18/96 to 8/19/99 was excluded from the total approval time because the sponsor had to find a new manufacturer, the final study report for the US clinical trial was completed and submitted late in the review, and stability issues had to be addressed before the sponsor could resubmit the application for review. The time period from 2/18/00 to 3/31/00 was excluded from the total approval time while the sponsor prepared for a facilities reinspection.

APPENDIX C: List of Approved Applications

Table 7
FY 1996 Standard NDA and BLA Submissions Approved in FY 00

Generic Name	Sponsor	Approval Time (Months)		Review Goal Met
		Total Time	Resubmissions (if necessary)	
PORACTANT ALFA	Dey Labs	32.0 [9]	FDA First Action: 12.0 (NA) Sponsor Response: 8.0 FDA Second Action: 6.0 (AE) Sponsor Response: 8.5 FDA Third Action: 6.0 (AP)	Y Y Y
BUDESONIDE (NASAL SPRAY)	AstraZeneca	38.1	FDA First Action: 15.0 (AE) Sponsor Response: 4.1 FDA Second Action: 6.0 (AE) Sponsor Response: 3.7 FDA Third Action: 6.0 (AE) Sponsor Response: 1.0 FDA Third Action: 2.4 (AP)	Y** Y Y Y
TRIPTORELIN	Debio Recherche	47.7	FDA First Action: 12.0 (NA) Sponsor Response: 29.7 FDA Second Action: 6.0 (AP)	Y Y

Table 8
FY 1995 Standard NDA and BLA Submissions Approved in FY 00

Generic Name	Sponsor	Approval Time (Months)		Review Goal Met
		Total Time	Resubmissions (if necessary)	
BCG Live (BLA)	BioChem Vaccines, Inc.	58.6	FDA First Action: 11.9 (NA) Sponsor Response: 3.5 FDA Second Action: 5.3 (NA) Sponsor Response: 1.6 FDA Third Action: 5.9 (NA) Sponsor Response: 3.3 FDA Fourth Action: 5.9 (RL) Sponsor Response: 15.4 FDA Fifth Action: 5.8 (AP)	Y Y Y Y Y

[9] The total approval time for this NDA was adjusted. The time period until an acceptable inspection was received (9/3/98 to 5/19/99) was excluded from the total approval time.

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 (HFP-1)
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
Phone: 301-827-5292
FAX: 301-594-6777

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