FY 1998 PERFORMANCE REPORT TO CONGRESS

for the

Prescription Drug User Fee Act of 1992

as amended by the

Food and Drug Administration Modernization Act of 1997

Food and Drug Administration
Department of Health and Human Services

Executive Summary

The Food and Drug Administration, again in FY 1998, exceeded all the performance goals specified under the Prescription Drug User Fee Act of 1992 (PDUFA). The Agency made its review decisions for drug and biological product submissions on time in almost every case last year, reviewing 100 percent of the new product applications and 99 percent of the supplements within the target review times. By historic standards, approval rates remain high and review times and total approval times remain short.

The Food and Drug Administration Modernization Act of 1997 (FDAMA) continues the progression toward quicker reviews begun under PDUFA and extends into the investigative phase of drug development with a series of new goals that take effect in FY 99. A complete listing of the FDAMA goals is contained in Appendix C of this report. The objective of the FDAMA goals is to speed up the entire drug development process, from research to approval, without compromising safety and without sacrificing the quality that Americans expect of the Agency's application review process.

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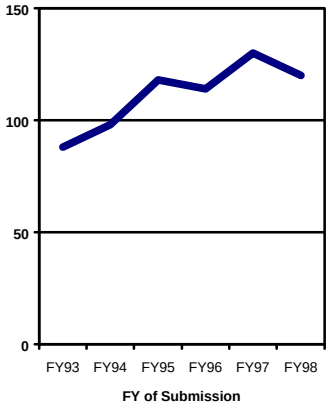
Outcomes

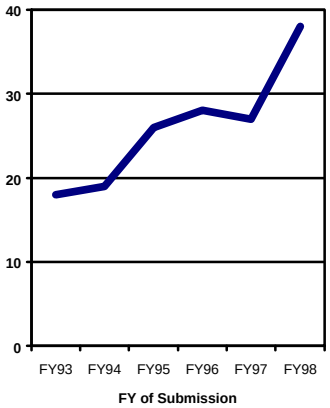
Last year's PDUFA Performance Report, which marked the end of the original Prescription Drug User Fee Act (PDUFA I[1]), reported on several important outcomes that had resulted from the Agency's meeting and exceeding its performance commitments. These included more applications filed, better applications, and quicker approvals; outcomes that result in more products reaching American consumers faster. This year, while the Agency's PDUFA II[1] goals continue their annual progression toward higher performance levels, some of the outcome measures appear to have approached their limits, and additional future gains may be small.

New Product Applications Filed



Fewer Applications Filed: Since the start of PDUFA I, annual submissions of new product applications have increased from 88 to 120, an average increase of more than 6 percent annually. Efficacy supplement receipts also increased an average of 6 percent per year, and manufacturing supplements increased 8 percent per year. FY 98 submissions, however, ran counter to this long term trend; new product submissions dropped from 130 to 120 and efficacy supplements dropped from 162 to 132. Only manufacturing supplement receipts continued to grow, increasing from 1,600 to 1,830.

Priority New Product Applications Filed

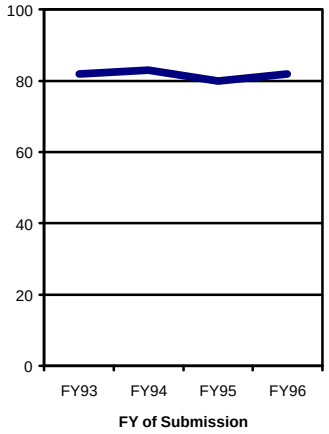


More Priority Applications: The drop in new product applications was offset somewhat by an increase in the number of priority applications. Priority applications accounted for between 20% and 25% of all applications filed each year from FY 93 through FY 97; in FY 98 they jumped to 32%. The products of priority applications represent significant therapeutic gains and are an important outcome for the consumer and the medical community.

High and Stable Approval Rates: The percentage of filed applications that ultimately are approved has increased from the less than 60 percent rate of the pre-PDUFA years[2] and now appears to have stabilized. Between 80 and 83 percent of the applications submitted from FY 93 through FY 96 have been approved. The early PDUFA cohorts are almost finished; only 3 submissions from FY 93 and 1 from FY 94 were approved in FY 98. For the later PDUFA years, FY 95 – FY 97, it appears that final approval rates will be about 85 percent.

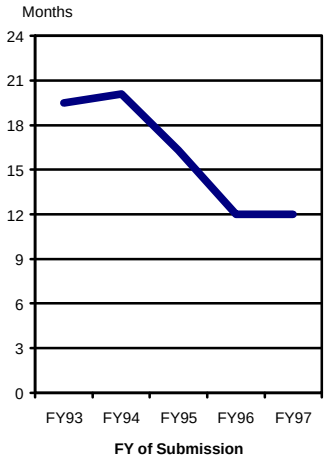
More than half of all the approval decisions are now made on the initial review cycle. This increase from the early PDUFA years, when only about 25 percent of the approvals came on the first review cycle, suggests that submission quality has improved significantly. Besides contributing to the shortened approval times, higher initial approval rates mean fewer resubmissions. In FY 96, FDA received 103 resubmissions; there were only 73 in FY 98.

Percent of Applications Approved



Quick and Steady Approval Times: The total approval times for applications submitted during the PDUFA years has leveled at a 12 month median. If 85 percent of the FY 97 submissions are approved, the median approval time will be 12 months.[3] This is the same as the median approval time for the FY 96 submissions and is an improvement over the 16.3 month median of the FY 95 submissions, the 19 to 20 month medians of the FY 93 and FY 94 submissions, and the 23 month median typical of the early 1990s[2]. Given the progression of PDUFA II review performance goals, median approval times will likely drop to 10 months in FY 2001 or FY 2002 if the current rate of first review approvals is sustained.

Median Approval Times



REPORT ON FY 1998 PDUFA GOALS

This report updates the Agency's performance on the FY 97 submissions and evaluates its performance on the FY 98 submissions and toward other PDUFA II goals. All of the FY 97 submissions (with the exception of a single NDA) have been reviewed and final performance relative to the goals can now be reported. Only a preliminary performance assessment on FY 98 submissions is possible at this time. For submission categories with a 12-month review goal, it is too early to measure review performance. For those submission categories with a review goal that is shorter than 12 months, performance on those received early in the year provides an early-indicator of final review performance.

This report makes some breaks from previous PDUFA reports:

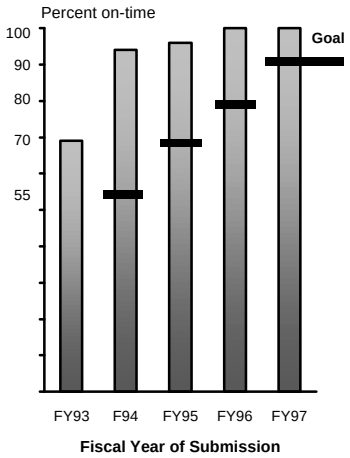
- Although many of the Agency's performance goals under PDUFA II are new and have no parallels under PDUFA I, the goals relating directly to application review seek to extend and improve on the gains made under PDUFA I. This report continues to show both current performance and past performance relative to these review goals. However, where charts in the previous reports included average Agency performance on FY 90 and FY 91 submissions as a 'pre-PDUFA' baseline for measuring improvement, this report simply tracks performance for the last five years.
- CBER is in the process of changing from counting PLAs and ELAs separately to combining them as BLAs (Biologic License Applications). 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.
- This report computes performance statistics for efficacy and manufacturing supplements submitted in FY 97 the same as it does all the other PDUFA years. The original commitment letter for PDUFA I treated supplements submitted in FY 97 differently than those submitted in other years. An explanation of the differences and the performance statistics computed using the literal methodology for FY97 supplements are shown in the endnotes.

New Product Applications

Goal --Review and act upon complete NDAs and BLAs[4]

On-time Goal	Submission Year				
	FY 97,98	FY 99	FY 00	FY 01	FY 02
Priority – 6 months	90%	90	90	90	90
Standard – 12 months	90%	90	90	90	
Standard – 10 months		30	50	70	90

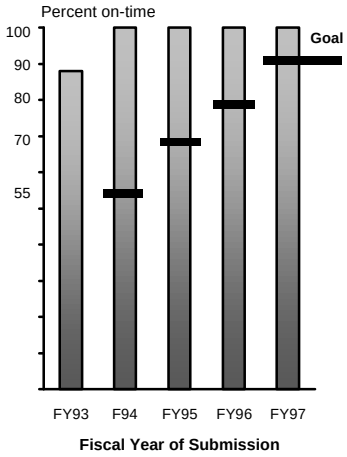
NDAs



Workload -- Original submissions filed *(Priority/Standard)*:

	FY 94	FY 95	FY 96	FY 97	FY 98[5]
• **NDAs**	90	106	105	114 *(24/90)*	108 *(30/78)*
• **BLAs**	4	12	9	16 *(3/13)*	12 *(8/4)*
• **PDUFA Total**	94	118	114	130 *(27/103)*	120 *(38/82)*
NMEs[6]					47 *(18/29)*

BLAs



Performance

FY 97 Submissions:

- As of September 30, 1998, 129 of 130 FY 97 submissions had been reviewed, all on time. The remaining submission is not yet due.
- On-time performance for both priority and standard applications will be 100 percent if the single remaining submission is reviewed on time.

FY 98 Submissions:

- As of September 30, 1998, 26 priority and 5 standard FY 98 submissions had been reviewed, all on time.
- Combined CDER/CBER early indicator performance for 25 priority (6-month goal) submissions received during the first six months of FY 98 is 100 percent on time.

NMEs and BLAs

- As of September 30, 1998, 13 FY 98 NMEs and 6 BLAs had been reviewed, all on time. All were priority submissions.

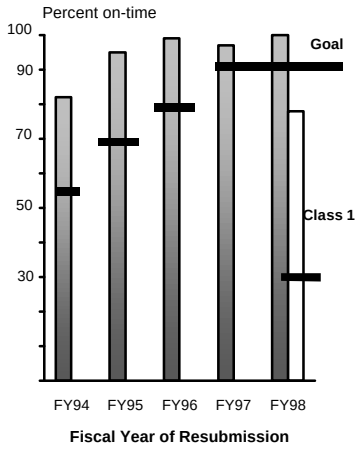
Goal -- Review and act upon resubmitted[7] NDAs and BLAs[4]

Resubmitted New Product Applications

On-time Goal		Resubmission Year					
		FY97	FY98	FY99	FY00	FY01	FY02
Class 1	6 months	90%*	90				
	4 months			90	90		
	2 months		30	50	70	90	90
Class 2	6 months	90%*	90	90	90	90	90

** Class 1 and 2 distinctions did not apply to FY 97 resubmissions. All FY97 resubmissions had a 6 month on-time goal of 90%.*

Resubmitted NDAs



Workload -- Resubmissions received [Total (Class 1)]:

	FY94	FY95	FY96	FY97	FY98
• **of Original NDAs**	24	58	89	87	54 (23)
• **of Original BLAs**	6	3	14	8	19 (14)
• **PDUFA Total**	30	61	103	95	73 (37)

Performance

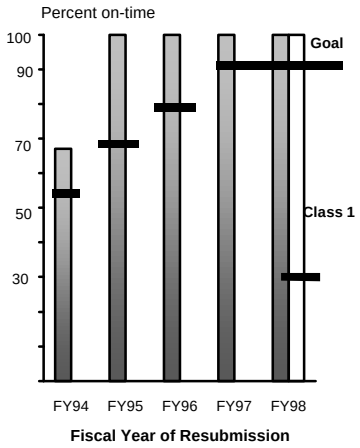
FY 97 Resubmissions:

- All 95 FY 97 resubmissions have been reviewed, 92 on time.
- Combined CDER/CBER on-time performance was 97 percent.

FY 98 Resubmissions:

- As of September 30, 1998, 22 class 1 resubmissions and 28 class 2 resubmissions had been reviewed. All reviews (100%) were completed within 6 months and 20 class 1 reviews (91%) were completed within 2 months.
- Early-indicator performance for 24 resubmissions submitted in the first 6 months of FY 98 is 100% on time (i.e., within 6-months).
- Early-indicator performance for 21 class 1 resubmissions submitted in the first 10 months of FY 98 is 81% on time (i.e., within 2 months).

Resubmitted BLAs

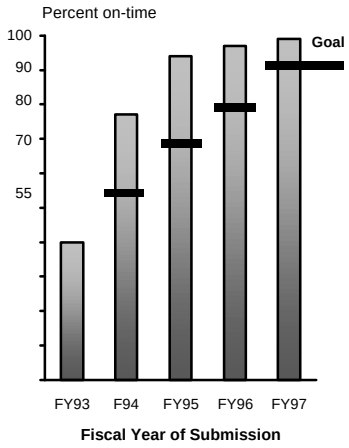


Efficacy Supplements

Goal -- Review and act upon complete efficacy supplements to NDAs and BLAs[4]

On-time Goal		Submission Year				
		FY 97[8]-98	FY 99	FY 00	FY 01	FY 02
Priority	6 months	90%	90	90	90	90
Standard	12 months	90%	90	90	90	
	10 months		30	50	70	90

NDA Efficacy Supplements



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

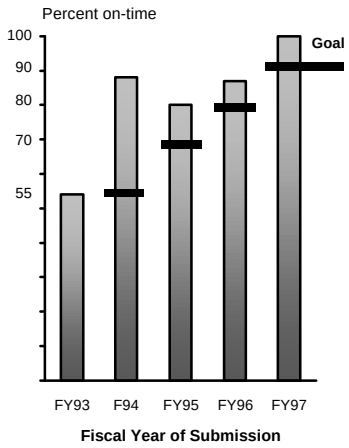
	FY 94	FY 95	FY 96	FY 97	FY 98[5]
• **to NDAs**	86	77	106	147 *(10/137)*	122 *(6/116)*
• **to BLAs**	6	10	8	15 *(3/12)*	10 *(1/9)*
• **PDUFA total**	92	87	114	162 *(13/149)*	132 *(7/125)*

Performance

FY 97 Submissions:

- All 162 FY 97 efficacy supplements have been reviewed, 160 on time.
- All priority efficacy supplements were reviewed on time.
- Combined CDER/CBER on-time performance was 99 percent.

BLA Efficacy Supplements



FY 98 Submissions:

- As of September 30, 1998, 2 priority and 21 standard FY 98 efficacy supplements had been reviewed, all on time.
- Combined CDER/CBER early-indicator performance for 2 priority efficacy supplements (6-month goal) received during the first six months of FY 98 is 100 percent on time.

Manufacturing Supplements

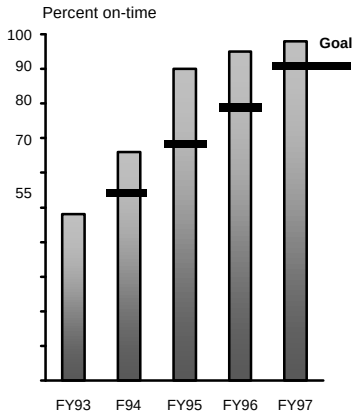
Goal -- Review and act upon complete manufacturing supplements to NDAs and BLAs[4]

On-time Goal		Submission Year				
		FY 97[8],98	FY99	FY00	FY01	FY02
Prior approval not required	6 months	90%	90	90	90	90
Prior approval required	6 months	90%	90	90	90	
	4 months		30	50	70	90

Workload -- Manufacturing supplements filed:

	FY 94	FY 95	FY 96	FY 97	FY 98[5]
• **to NDAs**	871	1,249	1,218	1,262	1,460
• **to BLAs**	186	273	261	338	370
• **PDUFA total**	1,057	1,522	1,479	1,600	1,830

NDA Manufacturing Supplements

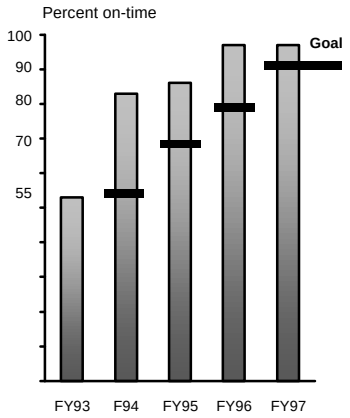


Performance:

FY 97 Submissions:

- All 1,600 FY 97 manufacturing supplements have been reviewed, 1,577 on time.
- Combined CDER/CBER on-time performance was 99 percent.

BLA Manufacturing Supplements



FY 98 Submissions:

- As of September 30, 1998, 1,157 FY 98 manufacturing supplements had been reviewed, 1,146 on time.
- Combined CDER/CBER early-indicator performance for 914 manufacturing supplements received during the first six months of FY 98 is 98 percent on time.

Processing and Procedural 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 more detailed description of the goals, the annual performance targets, and definitions of terms can be found in Appendix C. With the exception of the "clinical holds" goal, none of these goals had performance targets for FY 98.

Meeting Management:

- **Meeting Requests:**
- **Scheduling Meetings:**
- **Meeting Minutes:**

Clinical Holds:

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

		Submission Year				
		FY98[9]	FY99	FY00	FY01	FY02
On-time Goal		**75%**	**90**	**90**	**90**	**90**
Sponsor's Complete Responses		42				
FDA Actions	Within Goal	34				
	Overdue	8				
% On time		**81%**				

Major Dispute Resolution:

Special Protocol Question Assessment and Agreement:

Electronic Applications and Submissions:

Simplification of Action Letters:

Sponsor Notification of Deficiencies in Applications:

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 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] Source: United States General Accounting Office, FDA Drug Approval: Review Time Has Decreased in Recent Years (GAO/PEMD-96-1), October 1995

[3] Although the last approvals for FY 97 submissions (as well as for earlier years) have not yet occurred, the median statistic can be computed from approvals to date and estimates of the percent of submissions that will ultimately be approved.

[4] CBER's workload counts and performance statistics in PDUFA I Performance Reports included original and resubmitted ELAs. CBER is in the process of changing from counting PLAs and ELAs separately to combining them as BLAs (Biologic License Applications). This report shows CBER's workload and performance on PLAs and BLAs only (i.e., Product Applications) and, for notational simplicity, refers to both as BLAs. Original and resubmitted ELAs have been dropped, both from workload counts and performance measurements.

[5] The count of FY 98 submissions assumes that all submissions received in the last two months of FY 98 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.

[6] 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 98, CDER designated 53 filings as NMEs initially (21 priority, 32 standard). Only 47 of these are 'discrete' (18 priority, 29 standard).

[7] 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. This explains the relatively low number of resubmissions in the early PDUFA years.

[8] Performance goals for supplements submitted from FY 93 to FY 2002 were written in terms of Efficacy Supplements and Manufacturing Supplements except for FY 97. The goals for FY 97 were written in terms of priority supplements (which had 6-month goals), standard supplements with clinical data (12-months), and standard supplements without clinical data (6-months). Since some efficacy supplements do not contain clinical data and some manufacturing supplements contain clinical data, FY 97 supplement performance, if strictly interpreted, does not correspond exactly with any other PDUFA years. The statistics in the body of this report ignore this anomaly and measure FY 97 supplement performance in terms of efficacy supplements (priority and standard) and manufacturing supplements. Here, however, are the strictly interpreted performance figures for FY 97:

- Priority Supplements (13 Efficacy, 5 Manufacturing), 100% on-time
- Standard Supplements with Clinical Data (137 Efficacy, 1 Manufacturing), 99% on-time
- Standard Supplements without Clinical Data (12 Efficacy, 1594 Manufacturing), 98% on-time

[9] FDA did not begin tracking performance on responses to clinical holds until March 1, 1998.

APPENDIX A: PURPOSE

The Prescription Drug User Fee Act of 1992, Public Law 102-571, authorized revenues from fees paid by the pharmaceutical industry to expedite review by the Food and Drug Administration (FDA) of human drug applications. The Food and Drug Administration Modernization Act of 1997 (FDAMA), Public Law 105-115, extended this authorization until FY 2002. Along with the extension of revenues, the FDA agreed to meet increasingly stringent review time frames and other procedural performance goals.

FDAMA 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 1998.

APPENDIX B: PDUFA PERFORMANCE GOALS, FY 1993 - FY 1997

The following list presents by fiscal year the performance measures set forth in the letters referenced in Section 102(3) of the PDUFA. In those letters, the timing of a number of the goals was conditional either (l) on the date (July 2, 1993) upon which a supplemental appropriation was enacted to permit FDA to collect PDUFA user fees, or (2) a specific performance interval (e.g., 6 or 12 months after submission). The following chart lists the 29 goals by fiscal year with appropriate goal measurement dates:

INTERIM GOALS BY FISCAL YEAR	TIMING OF MEASUREMENT	MEASUREMENT DATE[1]
INTERIM GOALS OF FY 93		
1. Establish an industry/FDA working group upon initiation of the user fee program.	Supplemental appropriation date	July 2, 1993
2. Initiate a pilot computer-assisted PLA review (CAPLAR) program during FY 93.	End of FY 93	Sept. 30, 1993
INTERIM GOALS OF FY 94		
1. Review and act upon 55 percent of complete NDA and PLA/ELA submissions received during FY 94 within 12 months after submission date.	12 months after end of FY 94	Sept. 30, 1995
2. Review and act upon 55 percent of efficacy supplements[2] received during FY 94 within 12 months after submission date.	12 months after end of FY 94	Sept. 30, 1995
3. Review and act upon 55 percent of manufacturing supplements[2] received during FY 94 within 6 months after submission date.	6 months after end of FY 94	Mar. 31, 1995
4. Review and act upon 55 percent of resubmitted applications received during FY 94 within 6 months after the resubmission date.	6 months after end of FY 94	Mar. 31, 1995
5. Implement performance tracking and monthly monitoring of CBER performance within 6 months of initial user fee payments.	6 months after 7/2/93	Jan. 2, 1994
6. Implement project management methodology for all NDA reviews within 12 months of the initiation of user fee payments.	12 months after 7/2/93	July 2, 1994

INTERIM GOALS OF FY 95

1.	Review and act upon 70 percent of complete NDA and PLA/ELA submissions received during FY 95 within 12 months after submission date.	12 months after end of FY 95	Sept. 30, 1996
2.	Review and act upon 70 percent of efficacy supplements received during FY 95 within 12 months after submission date.	12 months after end of FY 95	Sept. 30, 1996
3.	Review and act upon 70 percent of manufacturing supplements received during FY 95 within 6 months after submission date.	6 months after end of FY 95	Mar. 31, 1996
4.	Review and act upon 70 percent of resubmitted applications received during FY 95 within 6 months after the resubmission date.	6 months after end of FY 95	Mar. 31, 1996
5.	Recruit and bring on board 50 percent of FDA incremental review staff by first quarter of FY 95.	3 months after end of FY 94	Dec. 31, 1994
6.	Implement project management methodology for all PLA/ELA reviews within 18 months of user fee payments.	18 months after 7/2/93	Jan. 2, 1995
7.	Eliminate overdue backlogs of efficacy and manufacturing supplements to NDAs within 18 months of initiation of user fee payments.	18 months after 7/2/93	Jan. 2, 1995
8.	Eliminate overdue backlog of NDAs within 24 months of initiation of user fees.	24 months after 7/2/93	July 2, 1995
9.	Eliminate overdue backlog of PLAs, ELAs, and PLA/ELA supplements within 24 months of initiation of user fees.	24 months after 7/2/93	July 2, 1995
10.	Adopt uniform computer assisted NDA standards during FY 95.	End of FY 95	Sept. 30, 1995

INTERIM GOALS OF FY 96

1.	Review and act upon 80 percent of complete NDA and PLA/ELA submissions received during FY 96 within 12 months after submission date.	12 months after end of FY 96	Sept. 30, 1997
2.	Review and act upon 80 percent of efficacy supplements received during FY 96 within 12 months after submission date.	12 months after end of FY 96	Sept. 30, 1997
3.	Review and act upon 80 percent of manufacturing supplements received during FY 96 within 6 months after submission date.	6 months after end of FY 96	Mar. 31, 1997
4.	Review and act upon 80 percent of resubmitted applications received during FY 96 within 6 months after the resubmission date.	6 months after end of FY 96	Mar. 31, 1997

FIVE YEAR GOALS OF FY 97

1.	Review and act upon 90 percent of complete NDA and PLA/ELA submissions for priority applications received during FY 97 within 6 months after submission date.	6 months after end of FY 97	Mar. 31, 1998
2.	Review and act upon 90 percent of complete NDA and PLA/ELA submissions for standard applications received during FY 97 within 12 months after submission date.	12 months after end of FY 97	Sept. 30, 1998
3.	Review and act upon 90 percent of priority supplements received during FY 97 within 6 months after submission date.	6 months after end of FY 97	Mar. 31, 1998
4.	Review and act upon 90 percent of standard supplements received during FY 97 that require review of clinical data (e.g., efficacy supplements) within 12 months after submission.	12 months after end of FY 97	Sept. 30, 1998
5.	Review and act upon 90 percent of supplements received during FY 97 that do not require review of clinical data (e.g., manufacturing supplements) within 6 months after submission date.	6 months after end of FY 97	Mar. 31, 1998
6.	Review and act upon 90 percent of resubmitted applications received during FY 97 within 6 months after the resubmission date.	6 months after end of FY 97	Mar. 31, 1998
7.	Total review staff increment recruited and on board by end of FY 97.	End of FY 97	Sept. 30, 1997

NOTES

1 The statute allows three additional months for review of original NDA, PLA, or ELA submissions that involve major amendments within the last three months of their usual 6- or 12-month review intervals. In these cases, the measurement dates shown in this Appendix move forward by 3 months.

2 The term “supplement” applies to both drug and biologic submissions. It includes “amendments” to biologic submissions.

APPENDIX C: 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 statute 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 intervals. In these cases, the measurement dates shown in this Appendix move forward by 3 months.

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 99
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 99
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 99
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 99
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 99
6.	Review and act on 90 percent of Class 1resubmitted 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 99
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 99

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 2000
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 50 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 1resubmitted original applications received during FY 2001 within 4 months of receipt, and review and act on 70 percent within 2 months of receipt.	4 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]	12 months after end of FY 2001
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 2001
3.	Review and act on 90 percent of standard efficacy supplements filed during FY 2002 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 90 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 1resubmitted original applications received during FY 2001within 2 months of receipt.	4 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

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 GOALS

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 FY2001 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 FY2001 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 FY2001 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.	

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.

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 concurrently).

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

APPENDIX D: LIST OF APPROVED APPLICATIONS

This appendix updates the detailed review histories of the NDAs and BLAs submitted and approved under PDUFA. It shows approvals of FY 93 through FY 97 submissions that took place this year as well as FY 97 approvals of FY 97 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 93 through FY 97. 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 for the FY 96 and FY 97 submissions will increase in the future as additional applications are approved.

Approved Priority NDAs/BLAs

	1st Review		2nd Review			Total Approval Time
Submission Year	n	FDA Review	n	Sponsor Response	FDA Review	
FY93	13	9.8	5	5.1	3.0	14.2
FY94	13	9.8	8	1.6	3.4	12.9
FY95	21	8.7	10	6.0	3.3	13.2
FY96	30	7.3	12	3.0	3.5	11.3
FY97	20	6.2	7	1.7	3.2	7.9

Approved Standard NDAs/BLAs

	1st Review		2nd Review			Total Approval Time
Submission Year	n	FDA Review	n	Sponsor Response	FDA Review	
FY93	59	15.0	42	5.5	4.7	25.7
FY94	65	12.7	50	5.3	4.4	22.9
FY95	82	12.2	52	2.8	4.2	17.3
FY96	66	11.9	33	2.5	3.7	15.1
FY97	59	11.4	12	1.4	2.6	12.4

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 98 can be found in the appendices of the earlier PDUFA Performance Reports which are available at http://www.fda.gov/ope/reports.html.

TERMS AND CODING USED IN TABLES

✓	FY 97 approval of an FY 97 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.
†	Tentative Approval
	Action Codes: NA = Not Approvable AE = Approvable AP = Approval RL = Complete Response

Table 1
FY 97 Priority NDA and BLA Submissions Approved in FY 97 (✓) and FY 98

	Generic Name	Sponsor	Approval Time (Months)		Review Goal Met
			Total Time	Resubmissions (if necessary)	
✓	NELFINAVIR MESYLATE	Agouron	2.6		Y
✓	NELFINAVIR MESYLATE (PEDIATRIC)	Agouron	2.6		Y
✓	LAMIVUDINE/ZIDOVUDINE	Glaxo Wellcome	3.9		Y
	TOBRAMYCIN	Pathogenesis	5.4		Y
	REPAGLINIDE	Novo Nordisk Pharm	5.7		Y
	SAQUINAVIR	Roche	5.9		Y
	SILDENAFIL CITRATE	Pfizer-Agri	5.9		Y
	DACLIZUMAB (BLA)	Hoffmann-LaRoche, Inc.	6.0		Y
✓	PROGESTERONE	Columbia Res Labs	6.0		Y
	RALOXIFENE HYDROCHLORIDE	Lilly	6.0		Y
	CLOPIDOGREL BISULFATE	Sanofi Pharms	6.7	FDA First Action: 6.0 (AE) Sponsor Response: 0.2 FDA Second Action: 0.5 (AP)	Y Y
	RITUXIMAB FORMULATED BULK (BLA)	IDEC Pharmaceuticals Corporation	8.7	FDA First Action: 5.7 (NA) Sponsor Response: 1.6 FDA Second Action: 1.4 (AP)	Y Y
✓	PACLITAXEL	Baker Norton	8.8		Y†
	GLUCAGON HYDROCHLORIDE RECOMBINANT	Novo Nordisk Pharm	8.9		Y
✓	AMPHOTERICIN B LIPOSOME	Fujisawa USA	8.9		Y
	RITUXIMAB (BLA)	Genentech, Inc.	8.9	FDA First Action: 6.0 (NA) Sponsor Response: 1.0 FDA Second Action: 2.0 (AP)	Y Y
	SACROSIDASE	Orphan Medcl	11.1	FDA First Action: 6.0 (AE) Sponsor Response: 1.3 FDA Second Action: 3.8 (AP)	Y Y
	TECHNETIUM TC 99M APTICIDE	Diatide	12.8	FDA First Action: 6.0 (AE) Sponsor Response: 0.8 FDA Second Action: 6.0 (AP)	Y Y
	LEPIRUDIN	Hoechst Marion Rssl	14.1	FDA First Action: 8.3 (AE) Sponsor Response: 2.5 FDA Second Action: 3.4 (AP)	Y Y
	THALIDOMIDE	Celgene	18.8	FDA First Action: 9.0 (AE) Sponsor Response: 4.3 FDA Second Action: 5.6 (AP)	Y Y

Table 2
FY 97 Standard NDA and BLA Submissions Approved in FY 97 (✓) and FY 98

	Generic Name	Sponsor	Approval Time (Months)		Review Goal Met
			Total Time	Resubmissions (if necessary)	
	AMOXICILLIN/CLARITHROMYCIN/ LANSOPRAZOLE	Tap Holdings	4.3		Y
	METRONIDAZOLE (TABLET)	Searle	5.9		Y
	MINOXIDIL	Pharmacia And Upjohn	8.5		Y
✓	DILTIAZEM HYDROCHLORIDE	Hoechst Marion Rssl	8.5	FDA First Action: 6.0 (AE) Sponsor Response: 1.9 FDA Second Action: 0.7 (AP)	Y Y
✓	IODIXANOL	Nycomed	9.2		Y
	DORZOLAMIDE HYDROCHLORIDE/ TIMOLOL MALEATE	Merck Res	9.4		Y
	CEFDINIR (ORAL SUSPENSION)	Parke Davis	11.1		Y
	OPRELVEKIN (BLA)	Genetics Institute, Inc.	11.1		Y
	VALSARTAN/ HYDROCHLOROTHIAZIDE	Novartis Pharms	11.2	FDA First Action: 10.7 (AE) Sponsor Response: 0.2 FDA Second Action: 0.3 (AP)	Y Y
	MYCOPHENOLATE MOFETIL HYDROCHLORIDE	Roche Bioscience	11.3		Y
	TROVAFLOXACIN MESYLATE	Pfizer Cent Res	11.6		Y
	ALATROFLOXACIN MESYLATE	Pfizer Cent Res	11.6		Y
	FEXOFENADINE HYDROCHLORIDE/ PSEUDOEPHEDRINE HYDROCHLORIDE	Hoechst Marion Rssl	11.7		Y
	DESOGESTREL / ETHINYL ESTRADIOL	Organon	11.7		Y
✓	METRONIDAZOLE CREAM	Dermik Labs	11.8		Y
	TESTOSTERONE	Alza	11.8		Y
	BECAPLERMIN CONCENTRATE (BLA, BULK)	Chiron Corporation	11.9		Y
	RISEDRONATE SODIUM	Procter Gamble Pharm	11.8		Y
	AMOXICILLIN	SKB Pharms	11.9		Y
	ESTRADIOL	Fournier Res	11.9		Y
	GREPAFLOXACIN HYDROCHLORIDE	Glaxo Wellcome	11.9		Y
	FOMEPIZOLE	Orphan Medcl	11.9		Y
	OFLOXACIN	Daiichi Pharm	11.9		Y
	TERBINAFINE HYDROCHLORIDE	Novartis Pharms	12.0		Y
	ZOLMITRIPTAN	Zeneca	12.0		Y
	FINASTERIDE	Merck Res	12.0		Y

Table 2 (continued)

Generic Name	Sponsor	Approval Time (Months)		Review Goal Met
		Total Time	Resubmissions (if necessary)	
ACETAMINOPHEN/ ASPIRIN/ CAFFEINE	Bristol Myers	12.0		Y
CLONAZEPAM	Roche	12.0		Y
MICONAZOLE NITRATE	Advanced Care Prods	12.0		Y
MONTELUKAST SODIUM (TABLETS)	Merck Res	12.0		Y
MONTELUKAST SODIUM (CHEWABLE TABLETS)	Merck Res	12.0		Y
AMINO ACID	Baxter Hlthcare	12.0		Y
RIZATRIPTAN BENZOATE (TABLETS)	Merck	12.0		Y
RIZATRIPTAN BENZOATE (DISINTEGRATING DISC)	Merck	12.0		Y
ETOPOSIDE PHOSPHATE	Bristol Myers Squibb	12.0		Y
MUPIROCIN CALCIUM	SKB Pharms	12.0		Y
NEDOCROMIL SODIUM	Rhone Poulenc Rorer	12.0		Y
MOMETASONE FUROATE MONOHYDRATE	Schering Plough	12.0		Y
TOLTERODINE TARTRATE	Pharmacia And Upjohn	12.0		Y
CIPROFLOXACIN HYDROCHLORIDE/ HYDROCORTISONE	Bayer	12.0		Y
TERBINAFINE	Novartis Pharms	12.0		Y
ESTRADIOL/NORETHINDRONE ACETATE	Rhone Poulenc Rorer	12.0		Y
PIPERACILLIN SODIUM/ TAZOBACTAM SODIUM	Lederle Piperacillin	12.0		Y
BECAPLERMIN (BLA)	OMJ Pharmaceuticals, Inc.	12.0		Y
LEVONORGESTREL / ETHINYL ESTRADIOL	Berlex Labs	13.0		Y
LOTEPREDNOL ETABONATE 0.2%	Pharmos	13.1		Y
CANDESARTAN CILEXETIL	Astra Pharms	13.2	FDA First Action: 11.9 (AE) Sponsor Response: 0.8 FDA Second Action: 0.4(AP)	Y Y
IBUPROFEN	Whitehall Robins	13.6	FDA First Action: 5.8 (AE) Sponsor Response: 1.8 FDA Second Action: 6.0(AP)	Y Y
BRINZOLAMIDE	Alcon	14.1	FDA First Action: 10.2 (AE) Sponsor Response: 0.4 FDA Second Action: 3.5 (AP)	Y Y
CITALOPRAM HYDROBROMIDE	Forest Labs	14.2	FDA First Action: 12.0 (AE) Sponsor Response: 0.5 FDA Second Action: 1.7 (AP)	Y Y
NARATRIPTAN HYDROCHLORIDE	Glaxo Wellcome	14.2		Y

Table 2 (continued)

Generic Name	Sponsor	Approval Time (Months)		Review Goal Met
		Total Time	Resubmissions (if necessary)	
EPROSARTAN MESYLATE	SKB Pharms	14.4	FDA First Action: 12.0 (AE) Sponsor Response: 0.9 FDA Second Action: 1.5 (AP)	Y Y
ALBUMIN HUMAN	Molecular Biosystems	14.5		Y2
PARICALCITOL	Abbott Labs	15.0		Y
DICLOFENAC SODIUM	Alcon	16.3	FDA First Action: 7.2 (NA) Sponsor Response: 1.4 FDA Second Action: 3.8 (AE) Sponsor Response: 1.0 FDA Third Action: 1.6 (AE) Sponsor Response: 0.5 FDA Fourth Action: 0.9 (AP)	Y Y Y Y
CHLORHEXIDINE GLUCONATE	Perio Prods (ls)	16.8	FDA First Action: 11.2 (AE) Sponsor Response: 0.7 FDA Second Action: 4.9 (AP)	Y Y
DOXYCYCLINE HYCLATE (PERIODONTAL DRUG DELIVERY SYSTEM)	Atrix	16.9	FDA First Action: 12.0 (AE) Sponsor Response: 3.0 FDA Second Action: 1.9 (AP)	Y Y
ROTAVIRUS VACCINE, LIVE, ORAL, TETRAVALENT (BLA)	Wyeth Laboratories, Inc.	19.0	FDA First Action: 14.9 (RL) Sponsor Response: 1.9 FDA Second Action: 2.2 (AP)	Y** Y
FAMOTIDINE (10 MG)	Merck Res	21.2	FDA First Action: 12.0 (AE) Sponsor Response: 1.6 FDA Second Action: 5.9 (AE) Sponsor Response: 0.6 FDA Third Action: 1.0 (AP)	Y Y Y

[2] Review extension granted due to court ordered hold

Table 3
FY 93 through FY 96 Priority NDA and BLA Submissions Approved in FY 98

Sub-mission Year	Generic Name	Sponsor	Approval Time (Months)		Review Goal Met
			Total Time	Resubmissions (if necessary)	
FY 95	TALC	Bryan	12.3[3]	FDA First Action: 11.8 (AE) Sponsor Response: 8.6 FDA Second Action: 6.0 (AE) Sponsor Response: 0.7 FDA Third Action: 1.2 (AP)	Y Y Y
FY 95	DIPHTHERIA & TETANUS TOXOIDS & ACELLULAR PERTUSSIS VACCINE ADSORBED (BLA)	North American Vaccine, Inc.	34.0	FDA First Action: 7.2 (NA) Sponsor Response: 12.7 FDA Second Action: 5.5 (NA) Sponsor Response: 8.3 FDA Third Action: 0.4 (AP)	Y Y Y
FY 96	URSODIOL	Axcan Pharma (US)	20.5	FDA First Action: 11.9 (AE) Sponsor Response: 3.2 FDA Second Action: 5.4 (AP)	Y Y
FY 96	EPTIFIBATIDE	Cor	25.5	FDA First Action: 11.6 (NA) Sponsor Response: 6.4 FDA Second Action: 6.0 (AE) Sponsor Response: 1.4 FDA Third Action: 0.2 (AP)	Y Y Y
FY 96	DIPHTHERIA TOXOID CONCENTRATE (BLA, BULK)	Statens Serum Institut	34.0	FDA First Action: 9.8 (NA) Sponsor Response: 2.2 FDA Second Action: 5.6 (NA) Sponsor Response: 2.0 FDA Third Action: 5.9 (NA) Sponsor Response: 4.2 FDA Fourth Action: 4.4 (AP)	Y Y Y Y
FY 96	TETANUS TOXOID CONCENTRATE (BLA, BULK)	Statens Serum Institut	34.0	FDA First Action: 9.8 (NA) Sponsor Response: 1.8 FDA Second Action: 5.9 (NA) Sponsor Response: 2.0 FDA Third Action: 5.9 (NA) Sponsor Response: 0.5 FDA Fourth Action: 5.8 (RL) Sponsor Response: 1.9 FDA Fifth Action: 0.4 (AP)	Y Y Y Y Y

[3] Adjusted Approval Time – The sponsor had to find a new manufacturer and submit new manufacturing and control data. This time (16.0 months) was excluded from the approval time calculation.

Table 4
FY 93 through FY 96 Standard NDA and BLA Submissions Approved in FY 98

Sub-mission Year	Generic Name	Sponsor	Approval Time (Months)		Review Goal Met
			Total Time	Resubmissions (if necessary)	
FY 93	KETOCONAZOLE	J And J	57.8	FDA First Action: 38.8 (AE) Sponsor Response: 8.1 FDA Second Action: 6.0 (AE) Sponsor Response: 4.2 FDA Third Action: 0.7 (AP)	N Y Y
FY 93	CIPROFLOXACIN HYDROCHLORIDE	Alcon	58.2	FDA First Action: 11.8 (NA) Sponsor Response: 37.3 FDA Second Action: 6.0 (AE) Sponsor Response: 2.7 FDA Third Action: 0.5 (AP)	Y Y Y
FY 93	POOLED PLASMA, SOLVENT DETERGENT TREATED (BLA)	V. I. Technologies, Inc.	62.2	FDA First Action: 9.6 (NA) Sponsor Response: 6.8 FDA Second Action: 8.5 (NA) Sponsor Response: 14.9 FDA Third Action: 6.0 (NA) Sponsor Response: 3.9 FDA Fourth Action: 6.0 (NA) Sponsor Response: 5.8 FDA Fifth Action: 0.7 (AP)	Y N Y Y Y
FY 94	TRETINOIN	Penederm	33.6	FDA First Action: 12.0 (NA) Sponsor Response: 9.3 FDA Second Action: 5.7 (NA) Sponsor Response: 0.6 FDA Third Action: 6.0 (AP)	Y Y Y†
FY 95	LOTEPREDNOL ETABONATE 0.5%	Pharmos	12.04	FDA First Action: 12.4 (NA) Sponsor Response: 11.0 FDA Second Action: 5.8 (AE) Sponsor Response: 3.3 FDA Third Action: 2.9 (AP)	N Y Y
FY 95	CALFACTANT	Ony	21.2	FDA First Action: 11.8 (AE) Sponsor Response: 3.5 FDA Second Action: 5.9 (AP)	Y Y†
FY 95	MANGAFODIPIR TRISODIUM	Nycomed	26.4	FDA First Action: 11.9 (AE) Sponsor Response: 1.5 FDA Second Action: 6.0 (AE) Sponsor Response: 1.1 FDA Third Action: 5.8 (AP)	Y Y Y
FY 95	SIBUTRAMINE HYDROCHLORIDE	Knoll Pharm	27.5	FDA First Action: 15.0 (AE) Sponsor Response: 6.4 FDA Second Action: 6.0 (AP)	Y Y
FY 95	LIDOCAINE / PRILOCAINE	Astra Pharms	30.7	FDA First Action: 12.8 (NA) Sponsor Response: 4.4 FDA Second Action: 13.5 (AP)	N N

[4] Adjusted Approval Time – New clinical data supporting a new indication were received 23.4 months after the original receipt date. This new date was used to calculate the total approval time. First action time is based on the original receipt date.

Table 4 (continued)

Sub-mission Year	Generic Name	Sponsor	Approval Time (Months)		Review Goal Met
			Total Time	Resubmissions (if necessary)	
FY 95	FLUTICASONE PROPIONATE	Glaxo Wellcome	34.3	FDA First Action: 12.0 (NA) Sponsor Response: 10.3 FDA Second Action: 5.7 (AE) Sponsor Response: 0.3 FDA Third Action: 6.0 (AP)	Y Y Y
FY 96	CISAPRIDE MONOHYDRATE	Janssen	14.0	FDA First Action: 12.0 (AE) Sponsor Response: 1.8 FDA Second Action: 0.2 (AP)	Y Y
FY 96	ALPROSTADIL	Pharmacia And Upjohn	15.0		Y
FY 96	CEFDINIR (CAPSULE)	Parke Davis	15.0		Y
FY 96	KETORALAC TROMETHAMINE	Syntex USA	15.2	FDA First Action: 6.0 (NA) Sponsor Response: 1.7 FDA Second Action: 6.0 (AE) Sponsor Response: 0.4 FDA Third Action: 1.1 (AP)	Y Y Y
FY 96	INTERFERON ALFACON-1 (BLA)	Amgen, Inc.	16.7	FDA First Action: 12.0 (AE) Sponsor Response: 1.1 FDA Second Action: 4.7 (AP)	Y Y
FY 96	VENLAFAXINE HYDROCHLORIDE	Wyeth Ayerst Labs	17.2	FDA First Action: 11.5 (AE) Sponsor Response: 1.4 FDA Second Action: 4.2 (AP)	Y Y
FY 96	SODIUM CHLORIDE / POTASSIUM CHLORIDE / CALCIUM CHLORIDE / MAGNESIUM CHLORIDE / SODIUM ACETATE / SODIUM CITRATE	Alcon	18.0	FDA First Action: 6.7 (AE) Sponsor Response: 4.7 FDA Second Action: 2.7 (AE) Sponsor Response: 1.1 FDA Third Action: 2.8 (AP)	Y Y Y
FY 96	RANITIDINE HYDROCHLORIDE	Glaxo Wellcome	19.4	FDA First Action: 11.7 (AE) Sponsor Response: 1.6 FDA Second Action: 6.0 (AP)	Y Y
FY 96	TOLCAPONE	Roche	19.8	FDA First Action: 12.0 (AE) Sponsor Response: 1.8 FDA Second Action: 6.0 (AP)	Y Y
FY 96	EMEDASTINE DIFUMARATE	Alcon	21.1	FDA First Action: 10.7 (AE) Sponsor Response: 8.4 FDA Second Action: 2.1 (AP)	Y Y
FY 96	FAMOTIDINE (20 MG/40 MG)	Merck Res	21.8	FDA First Action: 11.9 (NA) Sponsor Response: 3.9 FDA Second Action: 6.0 (AP)	Y Y
FY 96	FERRIC AMMONIUM CITRATE	Oncomembrane	22.9	FDA First Action: 12.0 (AE) Sponsor Response: 4.9 FDA Second Action: 6.0 (AP)	Y Y
FY 96	LAMOTRIGINE	Glaxo Wellcome	23.2	FDA First Action: 14.5 (AE) Sponsor Response: 2.7 FDA Second Action: 6.0 (AP)	Y** Y
FY 96	MANGANESE CHLORIDE TETRAHYDRATE	Bracco Dxs	23.9	FDA First Action: 11.9 (AE) Sponsor Response: 6.3 FDA Second Action: 5.8 (AP)	Y Y

Table 4 (continued)

Sub-mission Year	Generic Name	Sponsor	Approval Time (Months)		Review Goal Met
			Total Time	Resubmissions (if necessary)	
FY 96	DICLOFENAC SODIUM/MISOPROSTOL	Searle	24.0	FDA First Action: 15.0 (NA) Sponsor Response: 1.4 FDA Second Action: 4.3 (AE) Sponsor Response: 0.9 FDA Third Action: 2.3 (AP)	Y** Y Y
FY 96	DOXYCYCLINE HYCLATE (CAPSULES)	Collagenex	25.0	FDA First Action: 11.9 (NA) Sponsor Response: 7.1 FDA Second Action: 6.0 (AP)	Y Y
FY 96	DAUNORUBICIN HYDROCHLORIDE	Bedford Labs	26.4	FDA First Action: 11.8 (AE) Sponsor Response: 8.5 FDA Second Action: 6.0 (AP)	Y Y

This report was prepared by FDA's Office of Planning and Evaluation in collaboration with the Center for Biologics Evaluation and Research (CBER) and the Center for Drug Evaluation and Research (CDER). For information on obtaining additional copies contact:

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