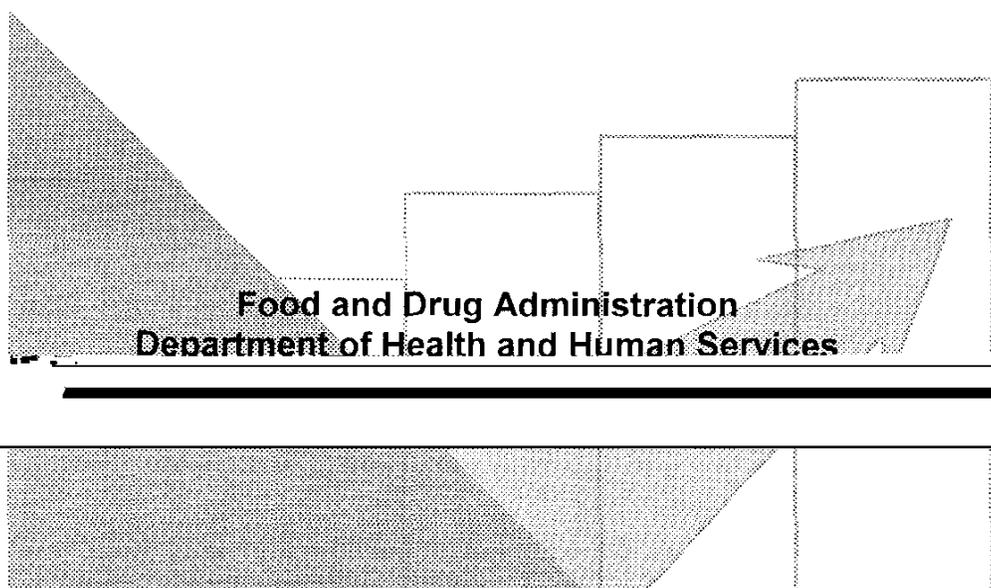


FOURTH ANNUAL PERFORMANCE REPORT

Prescription Drug User Fee Act of 1992

Fiscal Year 1996 Report to Congress

December 1, 1996



Food and Drug Administration
Department of Health and Human Services

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PURPOSE

The Prescription Drug User Fee Act of 1992 (PDUFA), 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. These revenues were directed by section 102(3) of this Act toward accomplishment of goals identified in the letters of September 14 and 21, 1992 from the Commissioner of Food and Drugs to the Chairman of the Energy and Commerce Committee of the House of Representatives and the Chairman of the Labor and Human Resources Committee of the Senate (as set forth at 138 Congressional Record H9099-H9100: daily edition of September 22, 1992).

Section 104 of the Act 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 1996. It reports on progress toward four FY 96 submission review goals, and updates performance on the FY 95 submission goals.

REPORT ON FY 1996 PDUFA GOALS

Twenty-nine performance-based goals constitute the management framework for PDUFA. These goals, listed by fiscal year in Appendix A, span the five-year term of the statute. Collectively, they direct management efforts toward three broad priorities: eliminating overdue backlogs, building excellence into the review process, and achieving measurable, high performance.

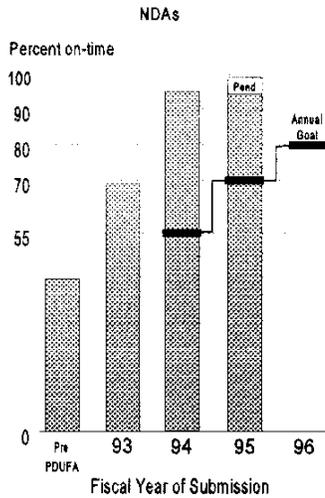
Eighteen of the goals have been reported in previous years' performance reports. Four goals remain for FY 96 and seven for FY 97. The FY 96 goals specify review performance targets for the submissions received subject to PDUFA during FY 96. Final review performance results on submissions received during a fiscal year cannot be determined fully at the end of that fiscal year. The review goals for original NDAs, PLAs, and ELAs and for efficacy supplements specify a 12-month review period¹. For most FY 96 submissions, the 12-month review period obviously has not yet occurred. In contrast, nearly all of the FY 95 submissions have been reviewed, and Agency performance on those submissions can now be evaluated.

This report uses the FY 90 and FY 91 submissions as a pre-PDUFA baseline for evaluating longer term changes. The baseline omits FY 92 because some PDUFA measures extend into the last month of FY 92, and the processing of most FY 92 submissions benefited from post-PDUFA process improvements. Some CBER pre-PDUFA comparisons are not possible due to the imprecise distinction between an original biologic application and its resubmission before PDUFA.

Goal 1 Review and act upon complete NDA, PLA and ELA submissions within 12 months of submission date:

FY 94 Submissions: 55 percent on-time
 FY 95 Submissions: 70 percent on-time
 FY 96 Submissions: 80 percent on-time

CDER ON-TIME REVIEW PERFORMANCE



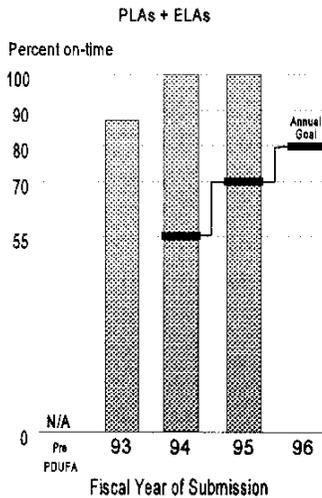
Original NDAs, PLAs, and ELAs Filed:

	FY93 ²	FY94	FY95	FY 96 ³
• NDAs	81	90	106	116
• PLAs+ELAs	7+8	4+5	12+7	9+6
• PDUFA Total	96	99	125	131

Performance on FY 95 submissions:

- Combined CDER/CBER on-time performance is currently 95 percent. Could reach 99 percent if 5 pending submissions are reviewed within time frame
- Performance exceeds FY95's 70 percent goal
- Proportion of submissions reviewed on-time more than doubles the pre-PDUFA performance level of 42 percent
- Only one submission has failed to meet the performance goal -- an NDA that was three days late

CBER ON-TIME REVIEW PERFORMANCE



Performance on FY 96 submissions:

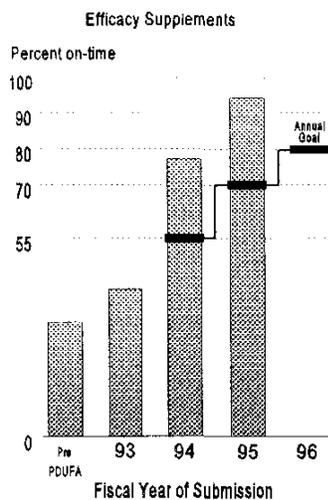
- On-time review performance will exceed the PDUFA standard of 80 percent based on year-to-year performance trends
- Final review performance assessment will occur on December 31, 1997
- As of October 1, 1996, 16 percent of applications had been acted upon (all within goal)

Goal 2 Review and act upon efficacy supplements⁴

to NDAs and PLAs within 12 months of submission date:

FY 94 Submissions: 55 percent on-time
 FY 95 Submissions: 70 percent on-time
 FY 96 Submissions: 80 percent on-time

CDER ON-TIME REVIEW PERFORMANCE



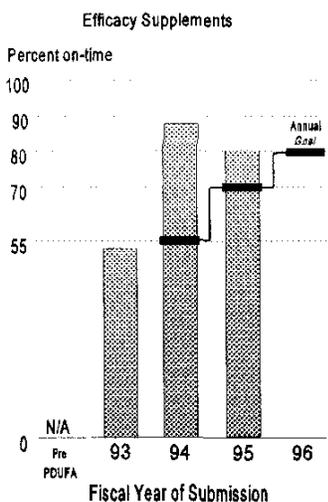
Efficacy Supplements Filed:

	FY93 ²	FY94	FY95	FY96 ³
● to NDAs	92	86	77	101
● to PLAs	8	6	10	8
● PDUFA Total	100	92	87	109

Performance on FY 95 submissions:

- Combined CDER/CBER on-time performance is 93 percent
- Performance exceeds FY95's 70 percent goal
- Proportion of submissions reviewed within a 12-month time frame nearly triples the pre-PDUFA performance level of 33 percent
- Combined CDER/CBER performance improves over FY93's 42 percent on-time rate (no goal in effect) and FY94's 77 percent rate

CBER ON-TIME REVIEW PERFORMANCE



Performance on FY 96 submissions:

- On-time review performance will exceed the PDUFA performance standard of 80 percent based on year-to-year performance trends
- Final review performance assessment will occur on September 30, 1997
- As of October 1, 1996, 20 percent of submissions had been acted upon (all within goal)

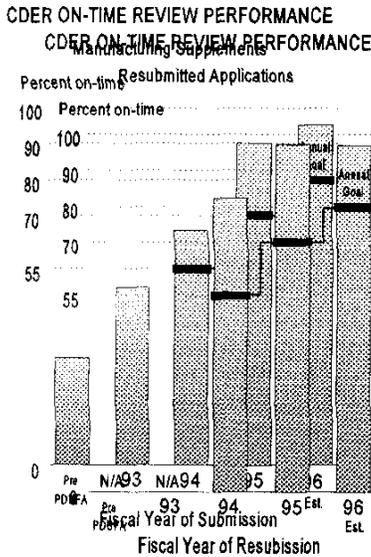
Goal 3 Review and act upon manufacturing supplements to NDAs, PLAs and ELAs

within 6 months of submission date:

FY 94 Submissions: 55 percent on-time
 FY 95 Submissions: 70 percent on-time
 FY 96 Submissions: 80 percent on-time

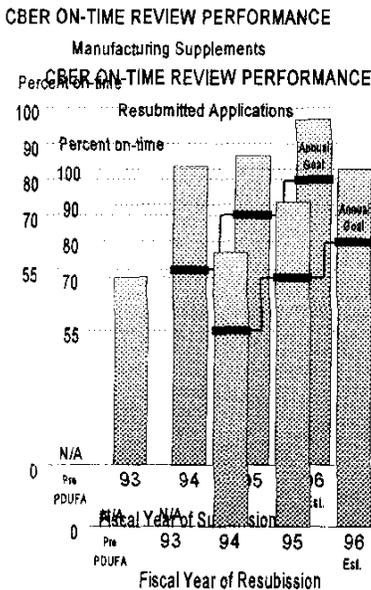
Manufacturing Supplements Filed:

	FY93 ²	FY94	FY95	FY96 ³
• to NDAs	1,045	872	1,251	1,232
• to PLAs, ELAs	203	186	268	262
• PDUFA Total	1,248	1,058	1,519	1,494



Performance on FY 95 submissions:

- Combined CDER/CBER on-time performance is 89 percent
- Performance exceeds FY 95's 70 percent goal
- Combined CDER/CBER performance improves over FY 93's 51 percent on-time rate (no goal in effect) and FY 94's 69 percent rate



Performance on FY 96 submissions:

- FY96 bars in charts depict on-time performance on supplements received during first half of FY 96. Since review goal is 6 months, this is an early indicator of final FY 96 performance
- Combined CDER/CBER on-time performance through first 6 months is 96 percent
- Final on-time performance projected to exceed FY 96's 80 percent goal
- Combined CDER/CBER projected performance improves over FY95's 89 percent on-time rate
- Final review performance assessment will occur on March 31, 1997

Goal 4: Review and act upon resubmitted⁵ NDAs, PLAs and ELAs within 6 months of resubmission date:

FY 94 Resubmissions: 55 percent on-time
FY 95 Resubmissions: 70 percent on-time
FY 96 Resubmissions: 80 percent on-time

Resubmissions Received:

	FY93	FY94	FY95	FY96
● of Original NDAs	2	24	58	89
● of Original PLAs, ELAs	1	13	11	18
● PDUFA Total	3	37	71	106

Performance on FY 95 resubmissions:

- Combined CDER/CBER on-time performance is 96 percent
- Performance exceeds FY 95's 70 percent goal
- Combined CDER/CBER performance improves over FY 94's 81 percent on-time rate

Performance on FY 96 resubmissions:

- FY96 bars in charts depict on-time performance on resubmissions received during first half of FY 96. Since review goal is 6 months, this is an early indicator of final FY 96 performance
- Combined CDER/CBER on-time performance through first 6 months is 98 percent
- Final on-time performance projected to exceed FY 96's 80 percent goal
- Combined CDER/CBER projected performance improves over FY95's 89 percent on-time rate
- Final review performance assessment will occur on March 31, 1997

DISCUSSION OF PERFORMANCE DURING FY96

As the fourth year of PDUFA ends, its success is apparent. The cumulative effects of additional human and financial resources, the use of project management methodology to guide the review process and monitor the increasing workload, the elimination of the backlogs, and the increased emphasis on timeliness as a performance measure, are resulting in significantly improved Agency and industry performance, predictability, and accountability. In FY 96, FDA approved a record 131 NDAs and PLAs -- a substantial increase over the 84 in FY 95 and the 67 in FY 94.

The record number of approvals is but one sign of an improved working relationship between sponsors and the Agency. PDUFA has resulted in better applications which can be accepted immediately and reviewed more quickly. Ultimately, new products get on the market faster. These changes can be documented by empirical evidence.

Better Initial Submissions: A key measure of submission quality is the "Refuse to File" rate. As of October 1, 1996, only 6 NDAs/PLAs/ELAs submitted in FY 96 had been refused. These numbers compare with nine RTFs total for the FY 95 submissions, and are much lower than the 25 RTFs for the FY 94 submissions and 34 for FY 93. Because so few initial submissions are refused, more applications are going directly into the review process.

Higher Rates of Positive First Actions: The proportion of first reviews that result in positive (i.e., "Approved" or "Approvable") decisions is another measure of submission quality and another key factor in achieving timely approvals. For original NDAs, PLAs, and ELAs submitted in FY 95, this measure rose to a 67 percent rate which is a substantial increase over the 48 percent rate experienced only one year ago (FY 94). As a result, comparatively few eventually approved applications go through time-consuming major revisions in response to "Not Approvable" decisions by FDA.

Faster Action on Resubmissions: Sponsor response times to initial decisions (other than "Approved") and Agency decisions following the resubmissions continue to accelerate. In response to initial FDA decisions on FY 95 submissions, sponsors resubmitted NDA and PLA applications to the Agency in an average of 1.2 months. The Agency reviewed these resubmissions and issued action letters in an average of 2.2 months after resubmission. For

FY 95 submissions, total elapsed time from initial decision to approval averaged 3.4 months which is less than half the 8.4 months experienced on resubmissions of FY 94 applications. Further details on resubmission performance are provided in Appendix B.

Increasing Approval Rates: Another indication of improved submission quality is the increase in the percentage of submissions that are ultimately approved. For the years immediately preceding PDUFA, roughly 56 percent of the original submissions were approved.⁶ To date, 55 percent of the FY 95 submissions (65 NDAs and PLAs) have been approved and another 18 percent (20) are “approvable” or “pending” following an initial “approvable” decision. The final approval rate for the FY 95 submissions will approach 80 percent. The final approval rates for the FY 94 and FY 93 submissions are also high by historical standards and should reach 75 percent.

Quicker Approval Times: The ultimate approval times for applications submitted during the PDUFA years continue to decline from the 23 month median typical of the early 1990's.⁷

Submission Year	FY 93	FY 94	FY 95
Median Months to Approval	19.0	18.5	15.0

Progress on Priority Applications: Beginning with the FY 97 submissions, 90 percent of the priority NDAs, PLAs, and ELAs must be reviewed and acted upon within six months. Even though there was no separate goal for priority applications submitted prior to FY 97, some progress is already evident. In the first half of FY 96, FDA received 18 priority applications. Ten of these (56 percent) were reviewed within 6 months. This is an improvement over the 33 percent rate for priority applications received in FY 95 and the 37 percent rate for FY 94's receipts, but it is still well below the 90 percent goal that is in effect for the FY 97 submissions.

Notes:

1. The PDUFA agreements allow for one 3-month extension of the review time if there is a major amendment to an original NDA, PLA, or ELA submission in month 10, 11, or 12 of the first review cycle. A submission that was received in late FY 95 that received such a major amendment could have as its PDUFA review goal a date in December 1996. This extension is not allowed for efficacy supplements, manufacturing supplements, or resubmissions.
2. FY 93 was a 13-month fiscal year including September 1992. Calculations of annual changes in workload extrapolate counts downward to a 12-month year.
3. The count of FY 96 submissions assumes that all submissions received in the last two months of FY 96 are filed. When FDA files a submission, it is deemed "complete" by PDUFA definition. FDA determines the "fileability" of an application within 60 days of its original receipt. All calculations of PDUFA review times are made, however, from the original receipt date of the filed application.
4. The term "supplement" applies to both drug and biologic submissions. It includes the former term of "amendments" to biologic submissions.
5. A resubmission is a firm's response after an FDA action of "approvable" or "not approvable" 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.
6. Source: United States General Accounting Office, FDA Drug Approval: Review Time Has Decreased in Recent Years (GAO/PEMD-96-1), October 1995.
7. The calculation of the ultimate median approval times for the PDUFA years is based upon final approval rates of 75 % for FY 93 and FY 94 submissions and 80 % for FY 95. Although the last approvals for these submission years have not yet occurred, the median statistic can be computed from approvals to date.

APPENDIX A: 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 (1) 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:

<u>INTERIM GOALS BY FISCAL YEAR</u>	<u>TIMING OF MEASUREMENT</u>	<u>MEASUREMENT DATE¹</u>
<u>INTERIM GOALS OF FY 93</u>		
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
<u>INTERIM GOALS OF FY 94</u>		
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 90 percent of complete PLAs, ELAs and NDAs for priority applications within 6 months after submission date.	6 months after end of FY 97	Mar. 31, 1998
2. Review 90 percent of complete PLAs, ELAs and NDAs for standard applications within 12 months after submission date.	12 months after end of FY 97	Sept. 30, 1998
3. Review 90 percent of priority supplements to PLAs, ELAs, and NDAs within 6 months after submission date.	6 months after end of FY 97	Mar. 31, 1998
4. Review 90 percent of standard supplements to PLAs, ELAs and NDAs that require review of clinical data (efficacy supplements) within 12 months after submission.	12 months after end of FY 97	Sept. 30, 1998
5. Review 90 percent of supplements to PLAs, ELAs and NDAs 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 90 percent of complete applications resubmitted following receipt of a non-approval letter 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 B: APPROVAL HISTORY OF FY 93, FY 94, AND FY 95 SUBMISSIONS

This appendix presents the NDA and PLA approvals for the FY 93, FY 94, and FY 95 submissions. Approvals are listed in order of total approval time, by submission year and priority designation:

- Table 1: FY 93 priority submissions
- Table 2: FY 93 standard submissions
- Table 3: FY 94 priority submissions
- Table 4: FY 94 standard submissions
- Table 5: FY 95 priority submissions
- Table 6: FY 95 standard submissions

The following tables show summary statistics detailing the average review, response, and approval times for those applications. Times are in months. Not all applications require a second review. The mean total approval times for the FY 94 and FY 95 submissions should increase in the future as additional applications are approved.

Approved Priority NDAs/PLAs

Submission Year	First Review		Second Review			Total Approval Time
	n	FDA Review (months)	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	15	8.5	4	1.3	0.3	9.0

Approved Standard NDAs/PLAs

Submission	First Review		Second Review			Total Approval
	n	FDA (months)	n	Sponsor	FDA	
FY93	51	14.8	34	3.6	4.5	21.7
FY94	47	12.3	32	3.5	3.8	18.4
FY95	48	12.1	19	1.1	2.6	13.6

TERMS AND CODING USED IN TABLES

√ FY 96 approvals

* May not appear to add to total due to rounding.

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

Action Codes: NA = Not Approvable
AE = Approvable
AP = Approval

Table 1
Priority NDA and PLA Approvals—FY 93 Submissions
(Approvals from September 1, 1992—September 30, 1996)

Generic Name	Sponsor	Approval Time (Months)		Review Goal Met
		Total Time*	Resubmissions (if necessary)	
LEVOMETHADYL ACETATE HCL	Biodevelopment	0.6		Y
FENTANYL CITRATE	Anesta	4.3		Y
TACROLIMUS Injectable	Fujisawa USA	8.1		Y
TACROLIMUS Capsules	Fujisawa USA	8.4		Y
DORNASE ALFA (PLA)	Genentech, Inc.	9.0		Y
IMIGLUCERASE	Genzyme	12.1		N
APROTININ	Miles Pharmaceutical	13.2	FDA 1st Action: 7.2 (AE) Sponsor Response: 5.5 FDA 2nd Action: 0.5 (AP)	Y Y
METFORMIN HYDROCHLORIDE	Bristol Myers Squibb	15.0		Y**
VINORELBINE TARTRATE	Burroughs Wellcome	15.9	FDA 1st Action: 14.9 (AE) Sponsor Response: 0.3 FDA 2nd Action: 0.7 (AP)	Y** Y
FLUDEOXYGLUCOSE F-18	Downstate Clinical	19.0		N
MILRINONE LACTATE	Sterling Winthrop	19.3	FDA 1st Action: 3.6 (NA) Sponsor Response: 7.1 FDA 2nd Action: 1.2 (AE) Sponsor Response: 1.8 FDA 3rd Action: 5.5 (AP)	Y Y Y
RHO(D) IMMUNE GLOBULIN INTRAVENOUS (HUMAN) (PLA)	Rh Pharmaceuticals Inc.	21.7	FDA 1st Action: 13.8 (NA) Sponsor Response: 1.1 FDA 2nd Action: 6.8 (AP)	N N
√ DAUNORUBICIN CITRATE	Nexstar	37.5	FDA 1st Action: 11.2 (NA) Sponsor Response: 11.4 FDA 2nd Action: 6.0 (AE) Sponsor Response: 3.0 FDA 3rd Action: 6.0 (AP)	Y Y Y

Table 2
Standard NDA and PLA Approvals—FY 93 Submissions
(Approvals from September 1, 1992—September 30, 1996)

Generic Name	Sponsor	Approval Time (Months)		Review Goal Met
		Total Time*	Resubmissions (if necessary)	
DESOGESTREL/ETHINYL ESTRADIOL	Johnson RW	2.2		Y
SOMATROPIN, BIOSYNTHETIC	Genentech, Inc.	4.2		Y
DOBUTAMINE HYDROCHLORIDE	Baxter Healthcare	6.9	FDA 1st Action: 3.2 (NA) Sponsor Response: 3.1 FDA 2nd Action: 0.6 (AP)	Y Y
ROCURONIUM BROMIDE	Organon	8.6	FDA 1st Action: 6.4 (AE) Sponsor Response: 1.0 FDA 2nd Action: 1.2 (AP)	Y Y
TRIMETREXATE	U.S. Bioscience	10.5		Y
CLOTRIMAZOLE	Miles Pharmaceutical	10.4	FDA 1st Action: 7.3 (AE) Sponsor Response: 0.6 FDA 2nd Action: 2.4 (AP)	Y Y
TIMOLOL MALEATE	Merck	10.9	FDA 1st Action: 6.5 (AE) Sponsor Response: 1.1 FDA 2nd Action: 3.3 (AP)	Y Y
DESMOPRESSIN ACETATE	Rhone Poulenc Rorer	11.5		Y
FAMCICLOVIR	SmithKline Beecham	12.0		Y
ISONIAZID/PYRAZINAMIDE/ RIFAMPIN	Marion Merrell	12.4		N
NAPROXEN SODIUM	Hamilton	12.8		N
BUDESONIDE	Astra	13.5	FDA 1st Action: 11.5 (AE) Sponsor Response: 0.4 FDA 2nd Action: 1.5 (AP)	Y Y
CLARITHROMYCIN	Abbott Labs	13.7		Y**
IBUPROFEN Chewable tablets	McNeil	14.4		N
ESTRADIOL TRANSDERMAL SYSTEM	3M Pharm.	14.7		Y**
MENOTROPINS (FSH; LH) LUTEINIZING HORMONE	Organon	14.9		Y**
GLIPIZIDE EXTENDED RELEASE	Pfizer	15.8		N**
CLOBETASOL PROPIONATE Gel	Glaxo	16.4	FDA 1st Action: 12.0 (AE) Sponsor Response: 0.7 FDA 2nd Action: 3.7 (AP)	Y Y

Table 2, Continued

Generic Name	Sponsor	Approval Time (Months)		Review Goal Met
		Total Time*	Resubmissions (if necessary)	
ISRADIPINE	Sandoz Pharmaceutical	17.0	FDA 1st Action: 12.0 (AE) Sponsor Response: 0.2 FDA 2nd Action: 4.8 (AP)	Y Y
TERAZOSIN HYDROCHLORIDE	Abbott	17.6	FDA 1st Action: 12.9 (AE) Sponsor Response: 0.3 FDA 2nd Action: 4.4 (AP)	N Y
CLOBETASOL PROPIONATE Cream	Glaxo	17.8	FDA 1st Action: 12.0 (AE) Sponsor Response: 0.6 FDA 2nd Action: 5.2 (AP)	Y Y
IBUPROFEN 200 mg capsules	Sandoz	18.7		N
FLUTICASONE PROPIONATE	Glaxo	18.8	FDA 1st Action: 16.8 (AE) Sponsor Response: 1.4 FDA 2nd Action: 0.6 (AP)	N Y
INDIUM IN-111 PENTETREOTIDE KIT	Mallinckrodt	19.3		N**
GRANISETRON HYDROCHLORIDE	SmithKline Beecham	19.5	FDA 1st Action: 7.1 (NA) Sponsor Response: 1.3 FDA 2nd Action: 5.7 (AE) Sponsor Response: 0.6 FDA 3rd Action: 4.9 (AP)	Y Y Y
AMLODIPINE BESYLATE/ BENZAEPRIIL HYDROCHLORIDE	Ciba Geigy	20.1	FDA 1st Action: 13.0 (AE) Sponsor Response: 3.9 FDA 2nd Action: 3.2 (AP)	Y** Y
MAGNESIUM SULFATE	Abbott	20.1	FDA 1st Action: 6.9 (NA) Sponsor Response: 5.8 FDA 2nd Action: 7.4 (AP)	Y N
VARICELLA VIRUS VACCINE LIVE (PLA)	Merck & Co., Inc.	22.0	FDA 1st Action: 11.5 (NA) Sponsor Response: 1.5 FDA 2nd Action: 9.0 (AP)	Y N
ESTRADIOL	Ciba Geigy	22.1	FDA 1st Action: 15.0 (AE) Sponsor Response: 5.5 FDA 2nd Action: 1.7 (AP)	Y** Y
NISOLDIPINE	Zeneca	22.1	FDA 1st Action: 11.8 (NA) Sponsor Response: 4.3 FDA 2nd Action: 6.0 (AP)	Y Y
IOPAMIDOL	Bracco Dxs	22.3	FDA 1st Action: 12.5 (NA) Sponsor Response: 3.9 FDA 2nd Action: 5.9 (AP)	N Y
DALTEPARIN SODIUM	Pharmacia	23.7	FDA 1st Action: 12.4 (AE) Sponsor Response: 9.0 FDA 2nd Action: 2.3 (AP)	Y** Y

Table 2, Continued

Generic Name	Sponsor	Approval Time (Months)		Review Goal Met
		Total Time*	Resubmissions (if necessary)	
√ IPRATROPIUM BROMIDE	Boehringer Ingelheim	24.2	FDA 1st Action: 11.6 (NA) Sponsor Response: 2.6 FDA 2nd Action: 6.0 (AE) Sponsor Response: 0.6 FDA 3rd Action: 3.4 (AP)	Y Y Y
FAMOTIDINE	Merck	24.9	FDA 1st Action: 24.5 (AE) Sponsor Response: 0.2 FDA 2nd Action: 0.1 (AP)	N** Y
√ IPRATROPIUM BROMIDE	Boehringer Ingelheim	25.3	FDA 1st Action: 11.4 (NA) Sponsor Response: 4.0 FDA 2nd Action: 6.0 (AE) Sponsor Response: 0.6 FDA 3rd Action: 3.4 (AP)	Y Y Y
DIRITHROMYCIN	Lilly	25.7	FDA 1st Action: 15.0 (AE) Sponsor Response: 7.0 FDA 2nd Action: 3.7 (AP)	Y** Y
MOEXIPRIL HYDROCHLORIDE	SPKU	28.0	FDA 1st Action: 17.0 (AE) Sponsor Response: 9.9 FDA 2nd Action: 1.1 (AP)	N Y
METRONIDAZOLE	Searle	28.6	FDA 1st Action: 12.0 (AE) Sponsor Response: 10.8 FDA 2nd Action: 5.8 (AP)	Y** Y
CARVEDILOL	Smithkline Beecham	29.5		N
√ NICOTINE SPRAY, METERED NASAL	Pharmacia	31.6	FDA 1st Action: 15.0 (AE) Sponsor Response: 10.6 FDA 2nd Action: 6.0 (AP)	Y** Y
CALCITONIN-SALMON	Sandoz	32.1	FDA 1st Action: 25.9 (AE) Sponsor Response: 1.2 FDA 2nd Action: 5.0 (AP)	N Y
√ TECHNETIUM TC-99M TETROFOSMIN KIT	Medi Physics	32.1	FDA 1st Action: 25.2 (AE) Sponsor Response: 1.3 FDA 2nd Action: 5.6 (AP)	N Y
CALCIUM MUPIROCIN	Smithkline Beecham	32.6	FDA 1st Action: 14.9 (AE) Sponsor Response: 3.8 FDA 2nd Action: 6.0 (AE) Sponsor Response: 3.1 FDA 3rd Action: 4.8 (AP)	Y** Y Y
√ ADAPALENE	Galderma	34.4		N

Table 2, Continued

Generic Name	Sponsor	Approval Time (Months)		Review Goal Met
		Total Time*	Resubmissions (if necessary)	
✓ RESPIRATORY SYNCYTIAL VIRUS IMMUNE GLOBULIN INTRAVENOUS (HUMAN) (PLA)	Massachusetts Public Health Biologic Laboratories	35.0	FDA 1st Action: 35.0 (NA) Sponsor Response: 1.0 FDA 2nd Action: 6.5 (NA) Sponsor Response: 17.9 FDA 3rd Action: 4.2 (AP)	Y N Y
✓ DEXFENFLURAMINE HYDROCHLORIDE	Interneuron	35.2	FDA 1st Action: 20.8 (NA) Sponsor Response: 2.9 FDA 2nd Action: 11.5 (AP)	N N
✓ IMMU-4 BULK (PLA)	Charles River Division of Wilmington Partners, L.P.	35.2	FDA 1st Action: 9.6 (NA) Sponsor Response: 10.9 FDA 2nd Action: 5.9 (NA) Sponsor Response: 3.6 FDA 3rd Action: 3.6 (AE) Sponsor Response: .5	Y Y Y Y
✓ IOXILAN	Cook Imaging	36.5	FDA 1st Action: 24.8 (NA) Sponsor Response: 5.7 FDA 2nd Action: 6.0 (AP)	N Y
✓ IODIXANOL	Nycomed	36.6	FDA 1st Action: 30.1 (AE) Sponsor Response: 0.5 FDA 2nd Action: 6.0 (AP)	N Y
✓ ADAPALENE	Galderma	38.2		N
✓ CETIRIZINE HYDROCHLORIDE	Pfizer	44.4	FDA 1st Action: 32.2 (AE) Sponsor Response: 6.2 FDA 2nd Action: 6.0 (AP)	N Y

Table 3
Priority NDA and PLA Approvals—FY 94 Submissions
(Approvals from October 1, 1993—September 30, 1996)

Generic Name	Sponsor	Approval Time (Months)		Review Goal Met
		Total Time*	Resubmissions (if necessary)	
ATOVAQUONE	Burroughs Wellcome	5.8		Y
GANCICLOVIR	Syntex	5.8		Y
STAVUDINE	Bristol Myers Squibb	5.9		Y
RIMEXOLONE	Alcon	7.0		Y
CYSTEAMINE BITARTRATE	Mylan	8.7	FDA 1st Action: 8.2 (AE) Sponsor Response: 0.4 FDA 2nd Action: 0.2 (AP)	Y Y
DORZOLAMIDE HYDROCHLORIDE	Merck	12.0		Y
ABCIXIMAB (PLA)	Centocor B.V.	12.2	FDA 1st Action: 6.0 (NA) Sponsor Response: 1.7 FDA 2nd Action: 4.5 (AP)	Y Y
√ DOXORUBICIN HYDROCHLORIDE	Sequus Phamaceuticals	14.3	FDA 1st Action: 12.0 (AE) Sponsor Response: 0.6 FDA 2nd Action: 1.7 (AP)	Y Y
√ TRETINOIN	Roche	15.9	FDA 1st Action: 12.0 (AE) Sponsor Response: 0.6 FDA 2nd Action: 3.3 (AP)	Y Y
ALPROSTADIL	UpJohn	16.7	FDA 1st Action: 11.9 (NA) Sponsor Response: 0.4 FDA 2nd Action: 4.4 (AP)	Y Y
EPOPROSTENOL SODIUM	Burroughs Wellcome	18.7	FDA 1st Action: 14.3(AE) Sponsor Response: 2.6 FDA 2nd Action: 1.8 (AP)	Y** Y
√ DOCETAXEL	Rhone Poulenc	21.6	FDA 1st Action: 15.0 (AE) Sponsor Response: 1.2 FDA 2nd Action: 5.3 (AP)	Y** Y
√ BENTOQUATAM	Enviroderm	22.9	FDA 1st Action: 12.0 (NA) Sponsor Response: 5.0 FDA 2nd Action: 6.0 (AP)	Y Y

Table 4
Standard NDA and PLA Approvals—FY 94 Submissions
(Approvals from October 1, 1993—September 30, 1996)

Generic Name	Sponsor	Approval Time (Months)		Review Goal Met
		Total Time*	Resubmissions (if necessary)	
SEVOFLURANE	Abbott	10.9		Y
PLAGUE VACCINE (PLA)	Greer Laboratories, Inc.	11.5	FDA 1st Action: 2.3 (NA) Sponsor Response: 1.2	Y
			FDA 2nd Action: 2.9 (NA) Sponsor Response: 2.4	Y
			FDA 3rd Action: 2.7 (AP)	Y
CYCLOSPORINE MICROEMULSION Solution	Sandoz	11.6		Y
CYCLOSPORINE MICROEMULSION Capsules	Sandoz	11.6		Y
NALMEFENE HYDROCHLORIDE	Ohmeda	11.6		Y
METRONIDAZOLE	Galderma	11.7		Y
IBUPROFEN Oral drops	McNeil	11.8		Y
NAPROXEN	Syntex	11.9		Y
ACARBOSE	Bayer	12.0		Y
ESTROGENS, CONJUGATED/ MEDROXYPROGESTERONE ACETATE	Wyeth Ayerst Labs	12.0		Y
IBUPROFEN 100 mg tablets	McNeil	12.0		Y
MAGNESIUM SULFATE	Abbott	12.0		Y
TESTOSTERONE TRANSDERMAL	Theratech	12.0		Y**
VALACYCLOVIR HCL	Burroughs Wellcome	12.0		Y
√ BICALUTAMIDE	Zeneca Pharm. Group	12.7	FDA 1st Action: 12.0 (AE) Sponsor Response: 0.2	Y
			FDA 2nd Action: 0.5 (AP)	Y
TIMOLOL HEMIHYDRATE OPHTHALMIC	Leiras	13.4	FDA 1st Action: 10.4 (NA) Sponsor Response: 1.2	Y**
			FDA 2nd Action: 1.9 (AP)	Y
√ KETOPROFEN	Bayer Cons	14.6	FDA 1st Action: 12.0 (AE) Sponsor Response: 2.6	
			FDA 2nd Action: 0.0 (AP)	
DINOPROSTONE VAGINAL INSERT	Controlled Ther	15.0		Y**
√ GLIMEPIRIDE	Hoechst Roussel	15.0		Y**

Table 4, Continued

Generic Name	Sponsor	Approval Time (Months)		Review Goal Met
		Total Time*	Resubmissions (if necessary)	
TRAMADOL HYDROCHLORIDE	Johnson RW	15.5	FDA 1st Action: 15.0 (AE) Sponsor Response: 0.2 FDA 2nd Action: 0.2 (AP)	Y** Y
ONDANSETRON HCL DIHYDRATE	Glaxo	15.8	FDA 1st Action: 6.6 (NA) Sponsor Response: 1.4 FDA 2nd Action: 4.9 (AE) Sponsor Response: 2.6 FDA 3rd Action: 0.4 (AP)	Y Y Y
LOSARTAN POTASSIUM HYDROCHLOROTHIAZIDE	Merck	16.3	FDA 1st Action: 14.9 (AE) Sponsor Response: 1.3 FDA 2nd Action: 0.1 (AP)	Y** Y
LOSARTAN POTASSIUM/ HYDROCHLOROTHIAZIDE	Merck	16.6	FDA 1st Action: 15.0 (AE) Sponsor Response: 1.6 FDA 2nd Action: 0.1 (AP)	Y** Y
LANSOPRAZOLE	Tap Holdings	17.8	FDA 1st Action: 15.0 (AE) Sponsor Response: 1.9 FDA 2nd Action: 0.9 (AP)	Y** Y
AZELAIC ACID	Allergan	18.5	FDA 1st Action: 12.0 (NA) Sponsor Response: 0.4 FDA 2nd Action: 6.0 (AP)	Y Y
√ TRANDOLAPRIL	Knoll Pharmaceuticals	18.9	FDA 1st Action: 11.9 (AE) Sponsor Response: 5.7 FDA 2nd Action: 1.3 (AP)	Y Y
AMIODARONE HYDROCHLORIDE	Wyeth Ayerst	19.2	FDA 1st Action: 13.5 (AE) Sponsor Response: 0.8 FDA 2nd Action: 1.6 (AE) Sponsor Response: 0.7 FDA 3rd Action: 2.6 (AP)	Y** Y Y
√ PHENIRAMINE MALEATE NAPHAZOLINE HYDROCHLORIDE	Akorn	19.8	FDA 1st Action: 6.7 (NA) Sponsor Response: 6.4 FDA 2nd Action: 6.0 (NA) Sponsor Response: 0.2 FDA 3rd Action: 0.4 (AP)	Y Y Y
√ CROMOLYN SODIUM	Medeva Pharms	20.1	FDA 1st Action: 3.0 (AE) Sponsor Response: 8.1 FDA 2nd Action: 3.9 (AE) Sponsor Response: 1.4 FDA 3rd Action: 3.7 (AP)	Y Y Y
√ PORFIMER SODIUM	QLT	20.5	FDA 1st Action: 15.0 (AE) Sponsor Response: 4.8 FDA 2nd Action: 0.7 (AP)	Y** Y
√ NAPROXEN SODIUM	Elan	20.7	FDA 1st Action: 15.0 (NA) Sponsor Response: 5.0 FDA 2nd Action: 0.8 (AP)	Y** Y

Table 4, Continued

Generic Name	Sponsor	Approval Time (Months)		Review Goal Met
		Total Time*	Resubmissions (if necessary)	
√ KETOPROFEN	Whitehall Robins	21.3	FDA 1st Action: 11.8 (WD) Sponsor Response: 2.7 FDA 2nd Action: 4.2 (AE) Sponsor Response: 2.3 FDA 3rd Action: 0.3 (AP)	Y Y Y
√ ESTRADIOL	Pharmacia and Upjohn	21.9	FDA 1st Action: 15.0 (AE) Sponsor Response: 1.2 FDA 2nd Action: 5.7 (AP)	Y** Y
CISAPRIDE	Janssen	22.5	FDA 1st Action: 9.2 (NA) Sponsor Response: 2.6 FDA 2nd Action: 7.5 (AE) Sponsor Response: 2.5 FDA 3rd Action: 0.6 (AP)	Y N Y
√ ETOPOSIDE PHOSPHATE	Bristol Myers Squibb	22.7	FDA 1st Action: 15.0 (AE) Sponsor Response: 1.8 FDA 2nd Action: 5.9 (AP)	Y** Y
√ TRIAMCINOLONE ACETONIDE	Rhone Poulenc Rorer	22.7	FDA 1st Action: 15.0 (AE) Sponsor Response: 1.7 FDA 2nd Action: 6.0 (AP)	Y** Y
√ DICLOFENAC SODIUM	Geigy Pharmaceuticals	22.9	FDA 1st Action: 15.0 (NA) Sponsor Response: 2.1 FDA 2nd Action: 5.8 (AP)	Y** Y
√ AZITHROMYCIN DIHYDRATE	Pfizer	23.7	FDA 1st Action: 15.0(AE) Sponsor Response: 3.2 FDA 2nd Action: 5.6 (AP)	Y Y
√ BUTOCONAZOLE NITRATE	Syntex Labs	24.0	FDA 1st Action: 13.5 (NA) Sponsor Response: 6.9 FDA 2nd Action: 3.6 (AP)	N Y
√ IPRATROPIUM BROMIDE	Boehringer Ingelheim	24.2	FDA 1st Action: 11.6 (NA) Sponsor Response: 2.6 FDA 2nd Action: 6.0 (AE) Sponsor Response: 0.6 FDA 3rd Action: 3.4 (AP)	Y Y Y
√ BECLOMETHASONE DIPROPIONATE MONOHYDRATE	Schering	26.9	FDA 1st Action: 12.0 (AE) Sponsor Response: 1.4 FDA 2nd Action: 6.0 (AE) Sponsor Response: 1.6 FDA 3rd Action: 6.0 (AP)	Y Y Y
√ LORATADINE/ PSEUDOEPHEDRINE SULFATE	Schering	28.2	FDA 1st Action: 12.0 (NA) Sponsor Response: 10.3 FDA 2nd Action: 6.0 (AP)	Y Y

Table 4, Continued

Generic Name	Sponsor	Approval Time (Months)		Review Goal Met
		Total Time*	Resubmissions (if necessary)	
√ NOFETUMOMAB (PLA)	Dr. Karl Thomae GmbH	28.7	FDA 1st Action: 8.9 (NA) Sponsor Response: 3.2 FDA 2nd Action: 5.6 (NA) Sponsor Response: 1.3 FDA 3rd Action: 5.9 (NA) Sponsor Response: 2.4 FDA 4th Action: 1.3 (AP)	Y Y Y Y
√ AZITHROMYCIN DIHYDRATE	Pfizer	29.0	FDA 1st Action: 11.9 (AE) Sponsor Response: 9.2 FDA 2nd Action: 6.0 (AE) Sponsor Response: 1.0 FDA 3rd Action: 0.9 (AP)	Y Y Y
√ NILUTAMIDE	Roussel Uclaf	30.5	FDA 1st Action: 12.0 (AE) Sponsor Response: 5.5 FDA 2nd Action: 6.0 (AE) Sponsor Response: 0.9 FDA 3rd Action: 6.0 (AP)	Y Y Y
√ MEROPENEM	Zeneca Pharmaceutical Group	30.7	FDA 1st Action: 12.0 (NA) Sponsor Response: 12.8 FDA 2nd Action: 5.9 (AP)	Y Y
√ FERUMOXIDES	Adv Magnetics	30.7	FDA 1st Action: 23.8 (AE) Sponsor Response: 2.0 FDA 2nd Action: 4.9 (AP)	Y Y

Table 5
Priority NDA and PLA Approvals—FY 95 Submissions
(Approvals from October 1, 1994—September 30, 1996)

Generic Name	Sponsor	Approval Time (Months)		Review Goal Met
		Total Time*	Resubmissions (if necessary)	
✓ SAQUINAVIR MESYLATE	Roche	3.2		Y
✓ LAMIVUDINE TABLETS	Glaxo Wellcome	4.4		Y
✓ LAMIVUDINE SOLUTION (oral)	Glaxo Wellcome	4.4		Y
✓ RILUZOLE	Rhone Poulenc	5.5	FDA 1st Action: 4.8 (AE) Sponsor Response: 0.4 FDA 2nd Action: 0.3 (AP)	Y Y
MYCOPHENOLATE MOFETIL	Syntex	5.7		Y
✓ AMPHOTERICIN B	Liposome	5.9		Y
ALENDRONATE SODIUM	Merck	6.0		Y
✓ GANCICLOVIR STERILE INTRAVITREAL IMPLANT	Chiron Vision	7.8		Y
✓ COMPTROPIN	Corning Laboratories	11.4		Y
mycostatin 5 mg				
✓ LATANOPROST	Pharmacia and Upjohn	11.7		Y
✓ INTERFERON BETA-1A (PLA)	Biogen, Inc.	11.8		Y
✓ IMCIROMAB PENTETATE (PLA)	Centocor B.V.	11.9		Y
✓ SODIUM PHENYL BUTYRATE POWDER	Ucyclyd	14.4	FDA 1st Action: 12.0 (AE) Sponsor Response: 2.2 FDA 2nd Action: 0.2 (AP)	Y Y
✓ SODIUM PHENYL BUTYRATE TABLETS	Ucyclyd	14.8	FDA 1st Action: 12.0 (AE) Sponsor Response: 2.2 FDA 2nd Action: 0.7 (AP)	Y Y
✓ GEMCITABINE HYDROCHLORIDE	Lilly	15.4	FDA 1st Action: 15.0 (AE) Sponsor Response: 0.4 FDA 2nd Action: 0.1 (AP)	Y** Y

Table 6, Continued

Table 6
Standard NDA and PLA Approvals—FY 95 Submissions
(Approvals from October 1, 1994—September 30, 1996)

Generic Name	Sponsor	Approval Time (Months)		Review Goal Met
		Total Time*	Resubmissions (if necessary)	
CMV HIGH TITER FRACTION II+III PASTE (PLA)	Baxter Healthcare Corporation	0.3		Y
✓ IOHEXOL	Nycomed	5.5		Y
✓ SELEGILINE HYDROCHLORIDE	Somerset Pharmaceuticals	8.7		Y
✓ ANASTROZOLE	Zeneca Pharmaceuticals	9.0		Y
DOPAMINE HYDROCHLORIDE IN 5% DEXTROSE INJECTION	Abbott	9.4		Y
✓ REMIFENTANIL HYDROCHLORIDE	Glaxo Wellcome	9.9		Y
✓ AMOXICILLIN/CLAVULANATE POTASSIUM POWDER FOR ORAL SOLUTION	SmithKline Beecham	10.4		Y
✓ LIDOCAINE HYDROCHLORIDE / EPINEPHRINE	lomed	10.9		Y
✓ NIMBEX INJECTABLE 2 MG/ML 10 MG/ML	Glaxo Wellcome	11.3		Y
✓ ZIDOVUDINE	Glaxo Wellcome	11.4		Y
✓ OXYCODONE HYDROCHLORIDE	Purdue Frederick	11.5		Y
✓ LIDOCAINE	Noven Pharmaceuticals	11.7		Y
✓ MORPHINE SULFATE CAPSULES	Faulding Pharmaceuticals (US)	11.8		Y
✓ FEXOFENADINE HYDROCHLORIDE	Hoechst Marion Roussel	11.8		Y
✓ MORPHINE SULFATE Injectable	Mallinckrodt	11.9		Y
✓ RSV HIGH TITER FRACTION II+III PASTE (PLA)	Baxter Healthcare Corporation	11.9		Y
✓ LEUPROLIDE ACETATE	Tap Holdings	12.0		Y
✓ ESTROGENS CONJUGATED/ MEDROXYPROGESTERONE ACETATE	Wyeth Ayerst Laboratories	12.0		Y
✓ LEVONORGESTREL	Wyeth Ayerst Laboratories	12.0		Y

Table 6, Continued

Generic Name	Sponsor	Approval Time (Months)		Review Goal Met
		Total Time*	Resubmissions (if necessary)	
✓ SOYBEAN OIL	Pharmacia and Upjohn	12.0		Y
✓ BRIMONIDINE TARTRATE	Allergan	12.0		Y
✓ RISPERIDONE	Janssen	12.3	FDA 1st Action: 11.6 (AE) Sponsor Response: 0.1 FDA 2nd Action: 0.6 (AP)	Y Y
✓ OLANZAPINE	Lilly	12.3	FDA 1st Action: 11.3 (AE) Sponsor Response: 0.6 FDA 2nd Action: 0.4 (AP)	Y Y
✓ PROCAINAMIDE HYDROCHLORIDE	Parke Davis	13.3	FDA 1st Action: 11.7 (AE) Sponsor Response: 0.1 FDA 2nd Action: 1.4 (AP)	Y Y
✓ VERAPAMIL HYDROCHLORIDE	Searle	13.3	FDA 1st Action: 12.0 (AE) Sponsor Response: 1.1 FDA 2nd Action: 0.2 (AP)	Y Y
✓ SOMATROPIN (RDNA ORIGIN)	Genentech Inc.	13.5	FDA 1st Action: 12.0 (NA) Sponsor Response: 0.3 FDA 2nd Action: 1.2 (AP)	Y Y
✓ IBUPROFEN	McNeil Consumer Products	13.6	FDA 1st Action: 12.0 (AE) Sponsor Response: 0.7 FDA 2nd Action: 0.9 (AP)	Y Y
✓ IBUTILIDE FUMARATE	Pharmacia and Upjohn	14.0		Y**
✓ RANITIDINE HYDROCHLORIDE	Glaxo Wellcome	14.0	FDA 1st Action: 12.2 (AE) Sponsor Response: 0.3 FDA 2nd Action: 1.5 (AP)	Y** Y
✓ BISMUTH SUBSALICYLATE/ METRONIDAZOLE/ TETRACYCLINE HYDROCHLORIDE	Procter and Gamble	14.4	FDA 1st Action: 12.0 (AE) Sponsor Response: 2.1 FDA 2nd Action: 0.3 (AP)	Y Y
✓ FLUTICASONE PROPIONATE	Glaxo Wellcome (US)	14.9		Y**
✓ GOSERELIN ACETATE	Zeneca (UK)	14.9		Y**
✓ CLEMASTINE FUMARATE/ PHENYLPROPANOLAMINE HYDROCHLORIDE	Sandoz Pharmaceuticals	15.0		Y**
✓ HEPATITIS A VACCINE INACTIVATED (PLA)	Merck & Co., Inc.	15.0		Y**
✓ INSULIN LISPRO	Lilly	15.0		Y**
✓ ALBUTEROL SULFATE	3M Pharmaceuticals	15.0		Y**
✓ ZAFIRLUKAST	Zeneca	15.0		Y**

Table 6, Continued

Generic Name	Sponsor	Approval Time (Months)		Review Goal Met
		Total Time*	Resubmissions (if necessary)	
✓ AMOXICILLIN/CLAVULANATE POTASSIUM TABLETS	SKB Pharmaceuticals	15.6	FDA 1st Action: 11.9 (NA) Sponsor Response: 0.4 FDA 2nd Action: 3.3 (AP)	Y Y
✓ UREA, C-13	Meretek	16.3	FDA 1st Action: 12.0 (NA) Sponsor Response: 1.7 FDA 2nd Action: 2.6 (AP)	Y Y
✓ MIRTAZAPINE	Organon	16.5	FDA 1st Action: 11.9 (AE) Sponsor Response: 1.7 FDA 2nd Action: 2.9 (AP)	Y Y
✓ NIZATIDINE	Whitehall Robins	16.6	FDA 1st Action: 11.3 (AE) Sponsor Response: 0.7 FDA 2nd Action: 4.6 (AP)	Y Y
✓ FOSPHENYTOIN SODIUM	Parke Davis	17.4	FDA 1st Action: 12.0 (AE) Sponsor Response: 1.7 FDA 2nd Action: 3.7 (AP)	Y Y
✓ TERBINAFINE HYDROCHLORIDE	Sandoz	17.6	FDA 1st Action: 12.0 (AE) Sponsor Response: 0.7 FDA 2nd Action: 4.9 (AP)	Y Y
✓ ROPIVACAINE HYDROCHLORIDE MONOHYDRATE	Astra USA	17.9	FDA 1st Action: 15.0 (AE) Sponsor Response: 1.0 FDA 2nd Action: 2.0 (AP)	Y** Y
✓ CALCIPOTRIENE	Bristol Myers Squibb	18.8	FDA 1st Action: 12.0 (AE) Sponsor Response: 0.8 FDA 2nd Action: 6.0 (AP)	Y Y
✓ RANITIDINE BISMUTH CITRATE	Glaxo Wellcome	19.3	FDA 1st Action: 15.0 (AE) Sponsor Response: 2.9 FDA 2nd Action: 1.4 (AP)	Y** Y
✓ ESTRADIOL FILM CONTROLLED RELEASE	Menorest	21.5	FDA 1st Action: 12.0 (NA) Sponsor Response: 3.5 FDA 2nd Action: 6.0 (AP)	Y Y
✓ AMMONIUM LACTATE	Bristol Myers	22.4	FDA 1st Action: 15.0 (AE) Sponsor Response: 1.4 FDA 2nd Action: 6.0 (AP)	Y** Y