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

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

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

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

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 1 resubmitted original applications received during FY 99 within 4 months of receipt, and review and act on 50 percent within 2 months of receipt.	4 months after end of FY 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 70 percent within 2 months of receipt.	4 months after end of FY 2000
7. Review and act on 90 percent of Class 2 resubmitted original applications received during FY 2000 within 6 months of receipt.	6 months after end of FY 2000

Fiscal Year 2001

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

Fiscal Year 2002

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

II. NEW MOLECULAR ENTITY (NME) PERFORMANCE GOALS

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

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

III. PROCEDURAL AND PROCESSING 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	Paperless Application	Agency to develop and update information systems to allow paperless receipt and processing of INDs,	

and Submissions	Processing	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. Only one extension is allowed for an application.

C. A resubmitted original application is a complete response to an action letter addressing all identified deficiencies.

D. Class 1 resubmitted applications are applications resubmitted after a complete response letter (or a not approvable or approvable letter) that include the following items only (or combinations of these items):

1. Final printed labeling
2. Draft labeling
3. Safety updates submitted in the same format, including tabulations, as the original safety submission with new data and changes highlighted (except when large amounts of new information including important new adverse experiences not previously reported with the product are presented in the resubmission)
4. Stability updates to support provisional or final dating periods
5. Commitments to perform Phase 4 studies, including proposals for such studies
6. Assay validation data
7. Final release testing on the last 1-2 lots used to support approval
8. A minor reanalysis of data previously submitted to the application (determined by the agency as fitting the Class 1 category)
9. Other minor clarifying information (determined by the Agency as fitting the Class 1 category)
10. Other specific items may be added later as the Agency gains experience with the scheme and will be communicated via guidance documents to industry.

E. Class 2 resubmissions are resubmissions that include any other items, including any item that would require presentation to an advisory committee.

F. A Type A Meeting is a meeting that is necessary for an otherwise stalled drug development program to proceed (a “critical path” meeting).

G. A Type B Meeting is a 1) pre-IND, 2) end of Phase 1 (for Subpart E or Subpart H or similar products) or end of Phase 2/pre-Phase 3, or 3) a pre- NDA/PLA/BLA meeting. Each requestor should usually only request 1 each of these Type B meetings for each potential application (NDA/PLA/BLA) (or combination of closely related products, i.e., same active ingredient but different dosage forms being developed concurrently).

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

APPENDIX B: List of Approved Applications

This appendix updates the detailed review histories of the NDAs and PLA/BLAs submitted and approved under PDUFA. It shows approvals of all PDUFA-related submissions that took place in FY 01 as well as FY 00 approvals of FY 00 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 96 through FY 00. The tables show the average first review, second review, and approval times. Note that times are in months, not all applications required a second review, and some required more than two reviews. The mean total approval times shown in the tables will increase in the future as additional applications are approved.

Approved Priority NDAs/BLAs

	1st Review		2nd Review			Total Approval Time
Receipt Cohort	n	FDA Review	n	Sponsor Response	FDA Review	
FY96	32	7.4	14	5.4	3.8	13.4
FY97	23	6.3	10	4.4	3.6	9.5
FY98	30	6.1	12	1.5	2.7	8.4
FY99	25	6.3	7	1.6	2.1	7.3
FY00	20	5.9	5	2.1	3.4	7.4

Approved Standard NDAs/BLAs

	1st Review		2nd Review			Total Approval Time
Receipt Cohort	n	FDA Review	n	Sponsor Response	FDA Review	
FY96	73	11.9	40	4.1	4.1	17.1
FY97	83	11.6	36	5.3	3.8	15.9
FY98	63	11.4	39	5.0	4.8	18.3
FY99	62	10.6	26	2.8	3.5	14.0
FY00	46	10.5	15	1.9	3.0	12.1

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

Terms and Coding Used in Tables

✓	FY 01 approval of an FY 01 submission. These were not included in earlier PDUFA performance reports and are included here for completeness.
**	Major amendment was received within 3 months of the action due date, which extended the review timeframes by 3 months.
Action Codes:	AE = Approvable AP = Approved NA = Not Approvable RL = Complete Response WD = Withdrawn

Table 1

FY 2000 Priority NDA and BLA Submissions Approved in FY 00 (✓) and FY 01

Generic Name	Sponsor	Approval Time (Months)		Review Goal Met
		Total Time	Resubmissions (if necessary)	
✓ LOPINAVIR; RITONAVIR (ORAL SOLUTION)	Abbott Labs	3.5		Y
✓ LOPINAVIR; RITONAVIR (CAPSULE)	Abbott Labs	3.5		Y
MESALAMINE	Axcan Scandipharm	4.2		Y
✓ LEVOFLOXACIN	Santen	5.6		Y
✓ UNOPROSTONE ISOPROPYL	Ciba Vision	5.6		Y
BIMATOPROST	Allergan	5.9		Y
✓ ARSENIC TRIOXIDE	Cell Therap	6.0		Y
✓ LINEZOLID (TABLET)	Pharmacia and Upjohn	6.0		Y
✓ LINEZOLID (ORAL SUSPENSION)	Pharmacia and Upjohn	6.0		Y
✓ LINEZOLID (POWDER FOR INJECTION SOLUTION)	Pharmacia and Upjohn	6.0		Y
VALGANCICLOVIR HYDROCHLORIDE	Syntex (USA) LLC	6.0		Y
CASPOFUNGIN ACETATE	Merck Res	6.0		Y
OSELTAMIVIR PHOSPHATE	Roche	6.0		Y
✓ GEMTUZUMAB OZOGAMICIN	Wyeth Ayerst Labs	6.6		Y**
✓ BEXAROTENE	Ligand	6.6	FDA First Action: 6.0 (AE) Sponsor Response: 0.0 FDA Second Action: 0.6 (AP)	Y Y
TRAVOPROST	Alcon Universal	8.3	FDA First Action: 5.5 (AE) Sponsor Response: 0.2 FDA Second Action: 2.6 (AP)	Y Y
DIDANOSINE	Bristol Myers Squibb	9.0		Y
ALEMTUZUMAB (BLA)	Millennium & ILEX Partners, LP	16.5	FDA First Action: 6.0 (RL) Sponsor Response: 1.9 FDA Second Action: 6.0 (RL) Sponsor Response: 1.0 FDA Third Action: 1.6 (AP)	Y Y Y
ABACAVIR SULFATE; LAMIVUDINE; ZIDOVUDINE	Glaxo Wellcome	10.9	FDA First Action: 5.8 (AE) Sponsor Response: 3.2 FDA Second Action: 2.0 (AP)	Y Y
ZOLEDRONIC ACID	Novartis Pharms	20.0	FDA First Action: 9.0 (AE) Sponsor Response: 5.0 FDA Second Action: 6.0 (AP)	Y** Y

Table 2

FY 2000 Standard NDA and BLA Submissions Approved in FY 00 (✓) and FY 01

	Generic Name	Sponsor	Approval Time (Months)		Review Goal Met
			Total Time	Resubmissions (if necessary)	
	BRIMONIDINE TARTRATE	Allergan	8.5		Y
✓	CETRORELIX	Serono Inc	9.4		Y
	TOLTERODINE TARTRATE	Pharmacia and Upjohn	9.8		Y
	OXCARBAZEPINE	Novartis Pharms	9.8		Y
✓	SIROLIMUS	Wyeth Ayerst Res	9.9		Y
✓	CHORIOGONADOTROPIN ALFA	Serono Labs	9.9		Y
✓	ESTRADIOL	Novartis Pharms	9.9		Y
	GRANISETRON HYDROCHLORIDE	Roche	9.9		Y
	LEVOTHYROXINE SODIUM	Jones Pharma	9.9		Y
	FLUVASTATIN SODIUM	Novartis Pharms	9.9		Y
	GABAPENTIN	Parke Davis	9.9		Y
✓	SODIUM PHOSPHATE, DIBASIC, ANHYDROUS; SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE	Inkine	10.0		Y
✓	IBUPROFEN ; PSEUDOEPHEDRINE HYDROCHLORIDE	Mcneil Cons	10.0		Y
✓	DIVALPROEX SODIUM	Abbott Labs	10.0		Y
✓	LEVOTHYROXINE SODIUM	Jerome Stevens	10.0		Y
	LANSOPRAZOLE	Tap Pharm	10.0		Y
	ZOLMITRIPTAN	AstraZeneca Pharms	10.0		Y
	MICONAZOLE NITRATE 2%; MICONAZOLE NITRATE 4%	Personal Prods	10.0		Y
	BENZOYL PEROXIDE; ERYTHROMYCIN	Dermik Labs	10.0		Y
	CLINDAMYCIN PHOSPHATE	Target Res	10.0		Y
	DOXYCYCLINE HYCLATE	Collagenex Pharms	10.0		Y
	INFUVITE PEDIATRIC (MULTIPLE VITAMINS)	Sabex	10.1		Y
	CEFUROXIME SODIUM	B Braun	10.1		Y
	LEVONORGESTREL	Berlex Labs	10.2		Y
	TELMISARTAN; HYDROCHLOROTHIAZIDE	Boehringer Ingelheim	10.7	FDA First Action: 10.0 (AE) Sponsor Response: 0.3 FDA Second Action: 0.4 (AP)	Y Y
	METFORMIN HYDROCHLORIDE	Bristol Myers Squibb	11.0		Y
	VALSARTAN	Novartis Pharms	11.3	FDA First Action: 10.0 (AE) Sponsor Response: 0.4 FDA Second Action: 1.0 (AP)	Y Y
	FLUOXETINE HYDROCHLORIDE	Lilly	11.5	FDA First Action: 9.9 (AE) Sponsor Response: 0.3 FDA Second Action: 1.3 (AP)	Y Y
	FLUOROURACIL	Dermik Labs	12.0		Y
	METHYLPHENIDATE HYDROCHLORIDE	Celltech Pharms	12.0	FDA First Action: 10.0 (AE) Sponsor Response: 0.4 FDA Second Action: 1.6 (AP)	Y Y
	FORMOTEROL FUMARATE	Novartis Pharms	12.0		Y

Table 2 (continued)

Generic Name	Sponsor	Approval Time (Months)		Review Goal Met
		Total Time	Resubmissions (if necessary)	
TRIPTORELIN PAMOATE	Debio Recherche	12.0		Y
MINOCYCLINE HYDROCHLORIDE	Orapharma	12.0		Y
NATEGLINIDE	Novartis Pharms	12.2		N
MIRTAZAPINE	Organon Inc	12.5	FDA First Action: 10.0 (AE) Sponsor Response: 0.5 FDA Second Action: 1.9 (AP)	Y Y
PEGINTERFERON ALFA-2B (BLA)	Schering Corporation	12.9	FDA First Action: 10.7 (RL) Sponsor Response: 0.5 FDA Second Action: 1.7 (AP)	Y2 Y
LOPERAMIDE HYDROCHLORIDE; SIMETHICONE	Mcneil Cons	13.0		Y**
ESOMEPRAZOLE MAGNESIUM	AstraZeneca	14.6	FDA First Action: 10.0 (AE) Sponsor Response: 0.5 FDA Second Action: 1.9 (AE) Sponsor Response: 0.2 FDA Third Action: 2.0 (AP)	Y Y Y
ALMOTRIPTAN MALATE	Pharmacia and Upjohn	16.6	FDA First Action: 12.0 (AE) Sponsor Response: 2.5 FDA Second Action: 2.0 (AP)	Y Y
GALANTAMINE HYDROBROMIDE (ORAL SOLUTION)	Janssen	16.6	FDA First Action: 9.9 (AE) Sponsor Response: 4.8 FDA Second Action: 1.8 (AP)	Y Y
ACETAMINOPHEN; CLEMASTINE FUMARATE; PSEUDOPHEDRINE HYDROCHLORIDE	Novartis Cons	16.8	FDA First Action: 9.9 (AE) Sponsor Response: 1.2 FDA Second Action: 5.7 (AP)	Y Y
ATROPINE SULFATE	Abbott Labs	18.6	FDA First Action: 12.0 (AE) Sponsor Response: 3.5 FDA Second Action: 3.2 (AP)	Y N
CETIRIZINE HYDROCHLORIDE; PSEUDOEPHEDRINE HYDROCHLORIDE	Pfizer	18.7	FDA First Action: 12.0 (AE) Sponsor Response: 0.9 FDA Second Action: 5.9 (AP)	Y Y
CEFDITOREN PIVOXIL	Tap Pharm	20.0	FDA First Action: 10.0 (AE) Sponsor Response: 4.1 FDA Second Action: 5.9 (AP)	Y Y
DARBEPOETIN ALFA (BLA)	Amgen, Inc.	20.6	FDA First Action: 13.6 (RL) Sponsor Response: 3.0 FDA Second Action: 4.0 (AP)	Y** Y

2 CBER put out a Federal Register notice in June 2000 stating that it would not accept licensing submissions while its new tracking system was being installed. Due dates of any pending applications were extended for the duration of this moratorium.

Generic Name	Sponsor	Approval Time (Months)		Review Goal Met
		Total Time	Resubmissions (if necessary)	
FENOFIBRATE	Abbott Labs	21.8	FDA First Action: 10.0 (AE) Sponsor Response: 5.7 FDA Second Action: 6.0 (AP)	Y Y

Table 3

FY 1999 Standard NDA and BLA Submissions Approved in FY 01

Generic Name	Sponsor	Approval Time (Months)		Review Goal Met
		Total Time	Resubmissions (if necessary)	
BUSPIRONE HYDROCHLORIDE	Bristol Myers Squibb	14.9	FDA First Action: 10.0 (AE) Sponsor Response: 3.0 FDA Second Action: 1.9 (AP)	Y Y
TACROLIMUS	Fujisawa Hlthcare	15.0		Y**
IRON SUCROSE	Luitpold Pharms	15.0		Y**
GALANTAMINE HYDROBROMIDE (TABLET)	Janssen Res Fdn	17.0	FDA First Action: 10.0 (AE) Sponsor Response: 1.1 FDA Second Action: 6.0 (AP)	Y Y
DESOGESTREL; ETHINYL ESTRADIOL	Organon Inc	19.5	FDA First Action: 10.0 (AE) Sponsor Response: 7.5 FDA Second Action: 2.0 (AP)	Y Y
CALCIUM ACETATE	Braintree Labs	22.0	FDA First Action: 10.0 (AE) Sponsor Response: 6.0 FDA Second Action: 6.0 (AP)	Y Y
CHLORHEXIDINE GLUCONATE; ETHYL ALCOHOL	3M Hlth (US)	23.4	FDA First Action: 12.0 (NA) Sponsor Response: 8.1 FDA Second Action: 3.4 (AP)	Y Y
ACETAMINOPHEN ; TRAMADOL HYDROCHLORIDE	RW Johnson	23.5	FDA First Action: 10.0 (AE) Sponsor Response: 4.5 FDA Second Action: 6.0 (AE) Sponsor Response: 1.0 FDA Third Action: 2.0 (AP)	Y Y Y
BOTULINUM TOXIN TYPE B (BLA)	Elan Pharmaceuticals	23.6	FDA First Action: 10.0 (RL) Sponsor Response: 4.7 FDA Second Action: 6.7 (RL) Sponsor Response: 0.2 FDA Third Action: 2.0 (AP)	Y Y[1] Y
DICLOFENAC SODIUM	Bioglan Pharma PLC	23.8	FDA First Action: 12.0 (NA) Sponsor Response: 3.1 FDA Second Action: 5.8 (AE) Sponsor Response: 0.9 FDA Third Action: 2.0 (AP)	Y Y Y
DROSPIRENONE ; ETHINYL ESTRADIOL	Berlex Labs	23.8	FDA First Action: 10.0 (AE) Sponsor Response: 1.8 FDA Second Action: 2.0 (AE) Sponsor Response: 4.1 FDA Third Action: 5.9 (AP)	Y Y Y
SULFAMETHOXAZOLE; TRIMETHOPRIM; PHENAZOPYRIDINE HYDROCHLORIDE	Able Labs	24.7	FDA First Action: 15.0 (NA) Sponsor Response: 8.1 FDA Second Action: 1.6 (AP)	Y** Y

Generic Name	Sponsor	Approval Time (Months)		Review Goal Met
		Total Time	Resubmissions (if necessary)	
DIGOXIN IMMUNE FAB (OVINE) (BLA)	Protherics Inc.	24.9	FDA First Action: 13.6 (RL) Sponsor Response: 5.3 FDA Second Action: 6.0 (AP)	Y** Y
HEPATITIS A INACTIVATED & HEPATITIS B (RECOMBINANT) VACCINE (BLA)	SmithKline Beecham Biologicals	27.3	FDA First Action: 9.9 (RL) Sponsor Response: 2.0 FDA Second Action: 5.8 (RL) Sponsor Response: 3.5 FDA Third Action: 6.0 (AP)	Y Y Y
PERFLUTREN	Dupont Pharms	31.7	FDA First Action: 10.0 (AE) Sponsor Response: 4.0 FDA Second Action: 5.9 (AE) Sponsor Response: 5.9 FDA Third Action: 6.0 (AP)	Y Y Y

Table 4

FY 1998 Standard NDA and BLA Submissions Approved in FY 01

Generic Name	Sponsor	Approval Time (Months)		Review Goal Met
		Total Time	Resubmissions (if necessary)	
BENZOYL PEROXIDE; CLINDAMYCIN PHOSPHATE	Dermik Labs	17.43	FDA First Action: 11.7 (NA) Sponsor Response: 15.0 FDA Second Action: 5.7 (AP)	Y Y
NESIRITIDE	Scios	19.04	FDA First Action: 12.0 (NA) Sponsor Response: 20.5 FDA Second Action: 5.8 (AE) Sponsor Response: 0.9 FDA Third Action: 0.3 (AP)	Y Y Y
ALBUTEROL SULFATE (INHALATION AEROSOL)	Glaxo	21.55	FDA First Action: 12.0 (AE) Sponsor Response: 12.1 FDA Second Action: 6.0 (AE) Sponsor Response: 0.1 FDA Third Action: 3.4 (AP)	Y Y N
AMOXICILLIN; CLAVULANATE POTASSIUM	GlaxoSmithkline	26.36	FDA First Action: 11.8 (NA) Sponsor Response: 17.4 FDA Second Action: 6.0 (AE) Sponsor Response: 2.6 FDA Third Action: 6.0 (AP)	Y Y Y
CROTALIDAE POLYVALENT IMMUNE FAB (OVINE) (BLA)	Protherics Inc.	29.1	FDA First Action: 12.0 (RL) Sponsor Response: 2.6 FDA Second Action: 6.0 (RL) Sponsor Response: 3.2 FDA Third Action: 5.4 (AP)	Y Y Y
CALCIUM CARBONATE; FAMOTIDINE; MAGNESIUM HYDROXIDE	Merck Res	31.9	FDA First Action: 12.0 (NA) Sponsor Response: 10.0 FDA Second Action: 6.0 (AE) Sponsor Response: 1.4 FDA Third Action: 2.4 (AP)	Y Y Y

3 The total approval time for this NDA was adjusted because a manufacturing facility was not available. The time period from 4/1/99 to 6/30/00 was excluded while the facility was being rebuilt.

4 The time period from 4/27/99 to 1/10/01 was excluded from the total approval time while the sponsor designed and conducted new clinical trials.

5 The time period from 7/1/99 to 7/3/00 was excluded from the total approval time while the sponsor submitted new manufacturing and methods needed for approval.

6 The time period from 10/26/98 to 4/6/00 was excluded from the total approval time. The sponsor submitted new clinical data to support the indication.

Generic Name	Sponsor	Approval Time (Months)		Review Goal Met
		Total Time	Resubmissions (if necessary)	
PANTOPRAZOLE SODIUM	Wyeth Ayerst Labs	32.1	FDA First Action: 12.0 (AE) Sponsor Response: 1.4 FDA Second Action: 5.8 (AE) Sponsor Response: 2.2 FDA Third Action: 6.0 (AE) Sponsor Response: 2.7 FDA Fourth Action: 1.9 (AP)	Y Y Y Y
ALBUTEROL SULFATE; IPRATROPIUM BROMIDE	Dey Labs	33.8	FDA First Action: 12.0 (AE) Sponsor Response: 6.2 FDA Second Action: 6.0 (AE) Sponsor Response: 3.6 FDA Third Action: 6.0 (AP)	Y Y Y
BIVALIRUDIN	The Medicines Company	35.8	FDA First Action: 10.8 (NA) Sponsor Response: 5.3 FDA Second Action: 6.0 (AE) Sponsor Response: 0.5 FDA Third Action: 6.0 (AE) Sponsor Response: 2.2 FDA Fourth Action: 5.0 (AP)	Y Y Y Y
ALBUTEROL SULFATE (INHALATION SOLUTION)	Dey Labs	37.1	FDA First Action: 12.0 (AE) Sponsor Response: 8.3 FDA Second Action: 6.0 (AE) Sponsor Response: 4.8 FDA Third Action: 6.0 (AP)	Y Y Y

Table 5

FY 1997 Standard NDA and BLA Submissions Approved in FY 01

Generic Name	Sponsor	Approval Time (Months)		Review Goal Met
		Total Time	Resubmissions (if necessary)	
ESTRADIOL CYPIONATE; MEDROXYPROGESTERONE	Pharmacia and Upjohn	24.07	FDA First Action: 12.0 (NA) Sponsor Response: 6.7 FDA Second Action: 6.0 (AE) Sponsor Response: 5.8 FDA Third Action: 6.0 (AP)	Y Y Y
FORMOTEROL FUMARATE	Novartis Pharms	24.08	FDA First Action: 12.0 (AE) Sponsor Response: 17.0 FDA Second Action: 6.0 (AE) Sponsor Response: 2.8 FDA Third Action: 6.0 (AP)	Y Y Y
ZIPRASIDONE HYDROCHLORIDE	Pfizer Cent Res	46.7	FDA First Action: 15.0 (NA) Sponsor Response: 20.8 FDA Second Action: 6.0 (AE) Sponsor Response: 1.5 FDA Third Action: 3.5 (AP)	Y** Y Y

7 The total approval time for this NDA was adjusted. The application did not contain adequate data collection for safety and efficacy assessments. The time period from 9/25/98 to 4/14/99 was excluded. FDA also requested further clinical trials to determine added benefits of this combination product. The time period from 10/15/99 to 4/7/00 was excluded.

8 The total approval time for this NDA was adjusted because the application did not contain adequate stability data meeting agency standards. A follow-up stability submission did not address all the packaging and storage conditions. The time periods from 6/26/98 to 11/24/99 and 5/24/00 to 8/18/00 were excluded while new stability studies were being performed.

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

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