

CENTER FOR DRUG EVALUATION AND RESEARCH

SPECIAL INTEREST TOPIC

**TITLE: 1996-1998 COHORT REPORT (CDER) AS OF
DECEMBER 31, 1997**

DATE: 10/01/95 THROUGH 12/31/97

FY 1998 COHORT

FY 1997 COHORT

CDER FIRST ACTION PERFORMANCE FOR APPLICATIONS

FY 1997 Cohort - Oct. 1, 1996 - Sept. 30, 1997

(as of December 31, 1997)

CDER

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TYPE	NO. SUBMITTED	PF	R or WF	UN	NO. FILED	NUMBER OF FIRST ACTIONS WITHIN GOAL							NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST ACTION AND NOT OVERDUE	NUMBER OF FIRST ACTIONS OVERDUE					NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST ACTION AND OVERDUE	% OF FILED SUBMISSIONS OVERDUE	
						AP	AE	NA	WD	TOTAL		AP		AE	NA	WD	TOTAL				
										NO.	PERCENT										
NEW PRODUCT APPLICATIONS <small>(initial submission)</small>	P	26	0	0	0	26	9	5	3	3	20	77%	6	0	0	0	0	0	0	0	0%
	S	104	0	2	6	96	21	8	4	2	35	36%	61	0	0	0	0	0	0	0	0%
	Total	130	0	2	6	122	30	13	7	5	55	45%	67	0	0	0	0	0	0	0	0%
RESUBMISSIONS <small>(maj. amend after AE or NA)</small>		86	0	0	0	86	58	16	3	1	78	91%	7	0	0	1	0	1	0	0	1%
EFFECTIVENESS SUPPLEMENTS <small>(initial submission)</small>	P	11	0	0	1	10	4	1	0	1	6	60%	4	0	0	0	0	0	0	0	0%
	S	144	0	2	7	135	37	13	15	6	71	53%	62	0	0	0	0	0	0	2	1%
	Total	155	0	2	8	145	41	14	15	7	77	53%	66	0	0	0	0	0	0	2	1%
MANUFACTURING SUPPLEMENTS <small>(initial submission)</small>		1268	0	5	0	1263	918	104	51	7	1080	86%	163	11	2	2	2	17	3	2%	

CDER FIRST ACTION PERFORMANCE FOR APPLICATIONS

FY 1997 Cohort - Oct. 1, 1996 - Sept. 30, 1997

(as of December 31, 1997)

ODE I

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TYPE	NO. SUBMITTED	PF	RF or WF	UN	NO. FILED	NUMBER OF FIRST ACTIONS WITHIN GOAL						NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST ACTION AND NOT OVERDUE	NUMBER OF FIRST ACTIONS OVERDUE					NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST ACTION AND OVERDUE	% OF FILED SUBMISSIONS OVERDUE		
						AP	AE	NA	WD	TOTAL			AP	AE	NA	WD	TOTAL				
										NO.	PERCENT										
NEW PRODUCT APPLICATIONS <small>(initial submission)</small>	P	7	0	0	0	7	0	2	2	2	6	86%	1	0	0	0	0	0	0	0	0%
	S	27	0	1	0	26	2	3	1	1	7	27%	19	0	0	0	0	0	0	0	0%
	Total	34	0	1	0	33	2	5	3	3	13	39%	20	0	0	0	0	0	0	0	0%
RESUBMISSIONS <small>(maj. amend after AE or NA)</small>	31	0	0	0	31	22	6	0	0	28	90%	3	0	0	0	0	0	0	0	0	0%
EFFECTIVENESS	P	3	0	0	0	3	1	0	0	1	2	67%	1	0	0	0	0	0	0	0	0%
SUPPLEMENTS <small>(initial submission)</small>	S	24	0	0	0	24	4	1	3	0	8	33%	16	0	0	0	0	0	0	0	0%
	Total	27	0	0	0	27	5	1	3	1	10	37%	17	0	0	0	0	0	0	0	0%
MANUFACTURING SUPPLEMENTS <small>(initial submission)</small>	279	0	4	0	275	228	11	10	3	252	92%	19	3	0	1	0	4	0	0	1%	

CDER FIRST ACTION PERFORMANCE FOR APPLICATIONS

FY 1997 Cohort - Oct. 1, 1996 - Sept. 30, 1997

(as of December 31, 1997)

HFD-110

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TYPE	NO. SUBMITTED	PF	RF or WF	UN	NO. FILED	NUMBER OF FIRST ACTIONS WITHIN GOAL						NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST ACTION AND NOT OVERDUE	NUMBER OF FIRST ACTIONS OVERDUE					NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST ACTION AND OVERDUE	% OF FILED SUBMISSIONS OVERDUE			
						AP	AE	NA	WD	TOTAL			AP	AE	NA	WD	TOTAL					
										NO.	PERCENT											
NEW PRODUCT APPLICATIONS <small>(initial submission)</small>	P	3	0	0	0	3	0	1	0	1	2	67%	1	0	0	0	0	0	0	0	0	0%
	S	8	0	1	0	7	0	2	0	0	2	29%	5	0	0	0	0	0	0	0	0	0%
	Total	11	0	1	0	10	0	3	0	1	4	40%	6	0	0	0	0	0	0	0	0	0%
RESUBMISSIONS <small>(maj. amend after AE or NA)</small>		11	0	0	0	11	9	2	0	0	11	100%	0	0	0	0	0	0	0	0	0	0%
EFFECTIVENESS SUPPLEMENTS <small>(initial submission)</small>	P	0	0	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0	0	0%
	S	4	0	0	0	4	0	1	1	0	2	50%	2	0	0	0	0	0	0	0	0	0%
	Total	4	0	0	0	4	0	1	1	0	2	50%	2	0	0	0	0	0	0	0	0	0%
MANUFACTURING SUPPLEMENTS <small>(initial submission)</small>		130	0	1	0	129	116	4	3	0	123	95%	4	1	0	1	0	2	0	0	0	2%

CDER FIRST ACTION PERFORMANCE FOR APPLICATIONS

FY 1997 Cohort - Oct. 1, 1996 - Sept. 30, 1997
(as of December 31, 1997)

HFD-120

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TYPE	NO. SUBMITTED	PF	RF or WF	UN	NO. FILED	NUMBER OF FIRST ACTIONS WITHIN GOAL						NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST ACTION AND NOT OVERDUE	NUMBER OF FIRST ACTIONS OVERDUE					NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST ACTION AND OVERDUE	% OF FILED SUBMISSIONS OVERDUE		
						AP	AE	NA	WD	TOTAL			AP	AE	NA	WD	TOTAL				
										NO.	PERCENT										
NEW PRODUCT APPLICATIONS <small>(initial submission)</small>	P	2	0	0	0	2	0	0	1	1	2	100%	0	0	0	0	0	0	0	0	0%
	S	13	0	0	0	13	2	1	0	0	3	23%	10	0	0	0	0	0	0	0	0%
	Total	15	0	0	0	15	2	1	1	1	5	33%	10	0	0	0	0	0	0	0	0%
RESUBMISSIONS <small>(maj. amend after AE or NA)</small>		17	0	0	0	17	12	3	0	0	15	88%	2	0	0	0	0	0	0	0	0%
EFFECTIVENESS SUPPLEMENTS <small>(initial submission)</small>	P	0	0	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0	0%
	S	15	0	0	0	15	4	0	2	0	6	40%	9	0	0	0	0	0	0	0	0%
	Total	15	0	0	0	15	4	0	2	0	6	40%	9	0	0	0	0	0	0	0	0%
MANUFACTURING SUPPLEMENTS <small>(initial submission)</small>		90	0	3	0	87	70	3	4	2	79	91%	6	2	0	0	0	2	0	0	2%

CDER FIRST ACTION PERFORMANCE FOR APPLICATIONS

FY 1997 Cohort - Oct. 1, 1996 - Sept. 30, 1997

(as of December 31, 1997)

HFD-510

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TYPE	NO. SUBMITTED	PF	RF or WF	UN	NO. FILED	NUMBER OF FIRST ACTIONS WITHIN GOAL						NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST ACTION AND NOT OVERDUE	NUMBER OF FIRST ACTIONS OVERDUE					NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST ACTION AND OVERDUE	% OF FILED SUBMISSIONS OVERDUE		
						AP	AE	NA	WD	TOTAL			AP	AE	NA	WD	TOTAL				
										NO.	PERCENT										
NEW PRODUCT APPLICATIONS <small>(initial submission)</small>	P	4	0	0	0	4	2	0	0	1	3	75%	1	0	0	0	0	0	0	0	0%
	S	5	0	0	0	5	1	0	0	0	1	20%	4	0	0	0	0	0	0	0	0%
	Total	9	0	0	0	9	3	0	0	1	4	44%	5	0	0	0	0	0	0	0	0%
RESUBMISSIONS <small>(maj. amend after AE or NA)</small>	5	0	0	0	5	3	0	0	0	3	60%	1	0	0	1	0	1	0	0	20%	
EFFECTIVENESS SUPPLEMENTS <small>(initial submission)</small>	P	0	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0	0%	
S	22	0	0	0	22	11	0	2	0	13	59%	9	0	0	0	0	0	0	0	0%	
Total	22	0	0	0	22	11	0	2	0	13	59%	9	0	0	0	0	0	0	0	0%	
MANUFACTURING SUPPLEMENTS <small>(initial submission)</small>	283	0	0	0	283	252	9	2	0	263	93%	19	0	0	0	0	0	1	0%		

CDER FIRST ACTION PERFORMANCE FOR APPLICATIONS

FY 1997 Cohort - Oct. 1, 1996 - Sept. 30, 1997

(as of December 31, 1997)

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						AP	AE	NA	WD	TOTAL			AP	AE	NA	WD	TOTAL					
										NO.	PERCENT											
NEW PRODUCT APPLICATIONS (initial submission)	P	26	0	0	0	26	9	5	3	3	20	77%	6	0	0	0	0	0	0	0	0%	
	S	104	0	2	6	96	21	8	4	2	35	36%	61	0	0	0	0	0	0	0	0%	
	Total	130	0	2	6	122	30	13	7	5	55	45%	67	0	0	0	0	0	0	0	0%	
RESUBMISSIONS (maj. amend after AE or NA)	86	0	0	0	86	58	16	3	1	78	91%	7	0	0	1	0	1	0	0	0	1%	
EFFECTIVENESS SUPPLEMENTS (initial submission)	P	11	0	0	1	10	4	1	0	1	6	60%	4	0	0	0	0	0	0	0	0	0%
S	144	0	2	7	135	37	13	15	6	71	53%	62	0	0	0	0	0	0	2	1%		
	Total	155	0	2	8	145	41	14	15	7	77	53%	66	0	0	0	0	0	2	1%		
MANUFACTURING SUPPLEMENTS (initial submission)	1268	0	5	0	1263	918	104	51	7	1080	86%	163	11	2	2	2	17	3	2%			

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						AP	AE	NA	WD	TOTAL			AP	AE	NA	WD	TOTAL				
										NO.	PERCENT										
NEW PRODUCT APPLICATIONS <small>(initial submission)</small>	P	7	0	0	0	7	0	2	2	2	6	86%	1	0	0	0	0	0	0	0	0%
	S	27	0	1	0	26	2	3	1	1	7	27%	19	0	0	0	0	0	0	0	0%
	Total	34	0	1	0	33	2	5	3	3	13	39%	20	0	0	0	0	0	0	0	0%
RESUBMISSIONS <small>(maj. amend after AE or NA)</small>		31	0	0	0	31	22	6	0	0	28	90%	3	0	0	0	0	0	0	0	0%
EFFECTIVENESS SUPPLEMENTS <small>(initial submission)</small>	P	3	0	0	0	3	1	0	0	1	2	67%	1	0	0	0	0	0	0	0	0%
	S	24	0	0	0	24	4	1	3	0	8	33%	16	0	0	0	0	0	0	0	0%
	Total	27	0	0	0	27	5	1	3	1	10	37%	17	0	0	0	0	0	0	0	0%
MANUFACTURING SUPPLEMENTS <small>(initial submission)</small>		279	0	4	0	275	228	11	10	3	252	92%	19	3	0	1	0	4	0	0	1%

CDER FIRST ACTION PERFORMANCE FOR APPLICATIONS

FY 1997 Cohort - Oct. 1, 1996 - Sept. 30, 1997

(as of December 31, 1997)

HFD-110

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TYPE	NO. SUBMITTED	PF	RF or WF	UN	NO. FILED	NUMBER OF FIRST ACTIONS WITHIN GOAL						NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST ACTION AND NOT OVERDUE	NUMBER OF FIRST ACTIONS OVERDUE					NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST ACTION AND OVERDUE	% OF FILED SUBMISSIONS OVERDUE		
						AP	AE	NA	WD	TOTAL			AP	AE	NA	WD	TOTAL				
										NO.	PERCENT										
NEW PRODUCT APPLICATIONS <small>(initial submission)</small>	P	3	0	0	0	3	0	1	0	1	2	67%	1	0	0	0	0	0	0	0	0%
	S	8	0	1	0	7	0	2	0	0	2	29%	5	0	0	0	0	0	0	0	0%
	Total	11	0	1	0	10	0	3	0	1	4	40%	6	0	0	0	0	0	0	0	0%
RESUBMISSIONS <small>(maj. amend after AE or NA)</small>		11	0	0	0	11	9	2	0	0	11	100%	0	0	0	0	0	0	0	0	0%
EFFECTIVENESS SUPPLEMENTS <small>(initial submission)</small>	P	0	0	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0	0%
	S	4	0	0	0	4	0	1	1	0	2	50%	2	0	0	0	0	0	0	0	0%
	Total	4	0	0	0	4	0	1	1	0	2	50%	2	0	0	0	0	0	0	0	0%
MANUFACTURING SUPPLEMENTS <small>(initial submission)</small>		130	0	1	0	129	116	4	3	0	123	95%	4	1	0	1	0	2	0	0	2%

CDER FIRST ACTION PERFORMANCE FOR APPLICATIONS

FY 1997 Cohort - Oct. 1, 1996 - Sept. 30, 1997
(as of December 31, 1997)

HFD-120

BEST POSSIBLE COPY

TYPE	NO. SUBMITTED	PF	RF or WF	UN	NO. FILED	NUMBER OF FIRST ACTIONS WITHIN GOAL						NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST ACTION AND NOT OVERDUE	NUMBER OF FIRST ACTIONS OVERDUE					NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST ACTION AND OVERDUE	% OF FILED SUBMISSIONS OVERDUE		
						AP	AE	NA	WD	TOTAL			AP	AE	NA	WD	TOTAL				
										NO.	PERCENT										
NEW PRODUCT APPLICATIONS (initial submission)	P	2	0	0	0	2	0	0	1	1	2	100%	0	0	0	0	0	0	0	0	0%
	S	13	0	0	0	13	2	1	0	0	3	23%	10	0	0	0	0	0	0	0	0%
	Total	15	0	0	0	15	2	1	1	1	5	33%	10	0	0	0	0	0	0	0	0%
RESUBMISSIONS (maj. amend after AE or NA)	17	0	0	0	17	12	3	0	0	15	88%	2	0	0	0	0	0	0	0	0	0%
EFFECTIVENESS SUPPLEMENTS (initial submission)	P	0	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0	0	0%
SUPPLEMENTS (initial submission)	S	15	0	0	0	15	4	0	2	0	6	40%	9	0	0	0	0	0	0	0	0%
	Total	15	0	0	0	15	4	0	2	0	6	40%	9	0	0	0	0	0	0	0	0%
MANUFACTURING SUPPLEMENTS (initial submission)	90	0	3	0	87	70	3	4	2	79	91%	6	2	0	0	0	2	0	0	2%	

CDER FIRST ACTION PERFORMANCE FOR APPLICATIONS

FY 1997 Cohort - Oct. 1, 1996 - Sept. 30, 1997

(as of December 31, 1997)

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ODE II

TYPE	NO. SUBMITTED	PF	R or WF	UN	NO. FILED	NUMBER OF FIRST ACTIONS WITHIN GOAL						NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST ACTION AND NOT OVERDUE	NUMBER OF FIRST ACTIONS OVERDUE					NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST ACTION AND OVERDUE	% OF FILED SUBMISSIONS OVERDUE		
						AP	AE	NA	WD	TOTAL			AP	AE	NA	WD	TOTAL				
										NO.	PERCENT										
NEW PRODUCT APPLICATIONS <small>(initial submission)</small>	P	6	0	0	0	6	3	0	0	1	4	67%	2	0	0	0	0	0	0	0	0%
	S	27	0	0	1	26	5	1	1	1	8	31%	18	0	0	0	0	0	0	0	0%
	Total	33	0	0	1	32	8	1	1	2	12	38%	20	0	0	0	0	0	0	0	0%
RESUBMISSIONS <small>(maj. amend after AE or NA)</small>		14	0	0	0	14	9	3	0	0	12	86%	1	0	0	1	0	1	0	0	7%
EFFECTIVENESS SUPPLEMENTS <small>(initial submission)</small>	P	1	0	0	0	1	0	0	0	0	0	0%	1	0	0	0	0	0	0	0	0%
	S	51	0	2	1	48	19	0	5	1	25	52%	23	0	0	0	0	0	0	0	0%
	Total	52	0	2	1	49	19	0	5	1	25	51%	24	0	0	0	0	0	0	0	0%
MANUFACTURING SUPPLEMENTS <small>(initial submission)</small>		477	0	0	0	477	382	26	17	1	426	89%	50	0	0	0	0	0	1	0	0%

CDER FIRST ACTION PERFORMANCE FOR APPLICATIONS

FY 1997 Cohort - Oct. 1, 1996 - Sept. 30, 1997

(as of December 31, 1997)

ODE III

BEST POSSIBLE

TYPE	NO. SUBMITTED	PF	R or WF	UN	NO. FILED	NUMBER OF FIRST ACTIONS WITHIN GOAL						NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST ACTION AND NOT OVERDUE	NUMBER OF FIRST ACTIONS OVERDUE					NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST ACTION AND OVERDUE	% OF FILED SUBMISSIONS OVERDUE		
						AP	AE	NA	WD	TOTAL			AP	AE	NA	WD	TOTAL				
										NO.	PERCENT										
NEW PRODUCT APPLICATIONS <small>(initial submission)</small>	P	4	0	0	0	4	0	2	0	0	2	50%	2	0	0	0	0	0	0	0	0%
	S	10	0	0	1	9	2	1	1	0	4	44%	5	0	0	0	0	0	0	0	0%
	Total	14	0	0	1	13	2	3	1	0	6	46%	7	0	0	0	0	0	0	0	0%
RESUBMISSIONS <small>(maj. amend after AE or NA)</small>		16	0	0	0	16	11	2	2	0	15	94%	1	0	0	0	0	0	0	0	0%
EFFECTIVENESS SUPPLEMENTS <small>(initial submission)</small>	P	1	0	0	0	1	0	1	0	0	1	100%	0	0	0	0	0	0	0	0	0%
	S	20	0	0	3	17	1	2	3	1	7	41%	8	0	0	0	0	0	0	2	12%
	Total	21	0	0	3	18	1	3	3	1	8	44%	8	0	0	0	0	0	0	2	11%
MANUFACTURING SUPPLEMENTS <small>(initial submission)</small>		124	0	1	0	123	73	15	9	1	98	80%	15	4	1	1	2	8	2	8%	

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CDER FIRST ACTION PERFORMANCE FOR APPLICATIONS

FY 1997 Cohort - Oct. 1, 1996 - Sept. 30, 1997
(as of December 31, 1997)

HFD-170

TYPE	NO. SUBMITTED	PF	RF or WF	UN	NO. FILED	NUMBER OF FIRST ACTIONS WITHIN GOAL						NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST ACTION AND NOT OVERDUE	NUMBER OF FIRST ACTIONS OVERDUE					NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST ACTION AND OVERDUE	% OF FILED SUBMISSIONS OVERDUE		
						AP	AE	NA	WD	TOTAL			AP	AE	NA	WD	TOTAL				
										NO.	PERCENT										
NEW PRODUCT APPLICATIONS (initial submission)	P	0	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0	0%	
	S	2	0	0	0	2	0	0	1	0	1	50%	1	0	0	0	0	0	0	0	0%
	Total	2	0	0	0	2	0	0	1	0	1	50%	1	0	0	0	0	0	0	0	0%
RESUBMISSIONS (maj. amend after AE or NA)	0	0	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0	0%	
EFFECTIVENESS SUPPLEMENTS (initial submission)	P	0	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0	0%	
	S	8	0	0	2	6	0	0	0	0	0%	4	0	0	0	0	0	0	2	33%	
	Total	8	0	0	2	6	0	0	0	0	0%	4	0	0	0	0	0	0	2	33%	
MANUFACTURING SUPPLEMENTS (initial submission)	36	0	0	0	36	17	0	5	0	22	61%	5	4	0	1	2	7	2	25%		

CDER FIRST ACTION PERFORMANCE FOR APPLICATIONS

FY 1997 Cohort - Oct. 1, 1996 - Sept. 30, 1997

(as of December 31, 1997)

BEST POSSIBLE COPY

HFD-180

TYPE	NO. SUBMITTED	PF	RF or WF	UN	NO. FILED	NUMBER OF FIRST ACTIONS WITHIN GOAL						NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST ACTION AND NOT OVERDUE	NUMBER OF FIRST ACTIONS OVERDUE					NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST ACTION AND OVERDUE	% OF FILED SUBMISSIONS OVERDUE		
						AP	AE	NA	WD	TOTAL			AP	AE	NA	WD	TOTAL				
										NO.	PERCENT										
NEW PRODUCT APPLICATIONS <small>(initial submission)</small>	P	3	0	0	0	3	0	2	0	0	2	67%	1	0	0	0	0	0	0	0	0%
	S	5	0	0	0	5	0	1	0	0	1	20%	4	0	0	0	0	0	0	0	0%
	Total	8	0	0	0	8	0	3	0	0	3	38%	5	0	0	0	0	0	0	0	0%
RESUBMISSIONS <small>(maj. amend after AE or NA)</small>	12	0	0	0	12	8	1	2	0	11	92%	1	0	0	0	0	0	0	0	0	0%
EFFECTIVENESS SUPPLEMENTS <small>(initial submission)</small>	P	1	0	0	0	1	0	1	0	0	1	100%	0	0	0	0	0	0	0	0	0%
	S	10	0	0	1	9	0	2	2	1	5	56%	4	0	0	0	0	0	0	0	0%
	Total	11	0	0	1	10	0	3	2	1	6	60%	4	0	0	0	0	0	0	0	0%
MANUFACTURING SUPPLEMENTS <small>(initial submission)</small>	64	0	1	0	63	36	12	4	1	53	84%	9	0	1	0	0	1	0	0	2%	

CDER FIRST ACTION PERFORMANCE FOR APPLICATIONS

FY 1997 Cohort - Oct. 1, 1996 - Sept. 30, 1997

(as of December 31, 1997)

BEST POSSIBLE COPY

ODE V

TYPE	NO. SUBMITTED	PF	R or WF	UN	NO. FILED	NUMBER OF FIRST ACTIONS WITHIN GOAL					NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST ACTION AND NOT OVERDUE	NUMBER OF FIRST ACTIONS OVERDUE					NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST ACTION AND OVERDUE	% OF FILED SUBMISSIONS OVERDUE			
						AP	AE	NA	WD	TOTAL		AP	AE	NA	WD	TOTAL					
										NO.									PERCENT		
NEW PRODUCT APPLICATIONS <small>(initial submission)</small>	P	1	0	0	0	1	0	1	0	0	1	100%	0	0	0	0	0	0	0	0	0%
	S	20	0	0	2	18	4	3	1	0	8	44%	10	0	0	0	0	0	0	0	0%
	Total	21	0	0	2	19	4	4	1	0	9	47%	10	0	0	0	0	0	0	0	0%
RESUBMISSIONS <small>(maj. amend after AE or NA)</small>	22	0	0	0	22	14	5	1	0	20	91%	2	0	0	0	0	0	0	0	0	0%
EFFECTIVENESS SUPPLEMENTS <small>(initial submission)</small>	P	0	0	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0	0%
	S	17	0	0	1	16	2	6	1	1	10	63%	6	0	0	0	0	0	0	0	0%
	Total	17	0	0	1	16	2	6	1	1	10	63%	6	0	0	0	0	0	0	0	0%
MANUFACTURING SUPPLEMENTS <small>(initial submission)</small>	268	0	0	0	268	147	50	8	2	207	77%	56	4	1	0	0	5	0	0	0	2%

CDER FIRST ACTION PERFORMANCE FOR APPLICATIONS

FY 1997 Cohort - Oct. 1, 1996 - Sept. 30, 1997

(as of December 31, 1997)

BEST POSSIBLE COPY

HFD-540

TYPE	NO. SUBMITTED	PF	RF or WF	UN	NO. FILED	NUMBER OF FIRST ACTIONS WITHIN GOAL						NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST ACTION AND NOT OVERDUE	NUMBER OF FIRST ACTIONS OVERDUE					NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST ACTION AND OVERDUE	% OF FILED SUBMISSIONS OVERDUE		
						AP	AE	NA	WD	TOTAL			AP	AE	NA	WD	TOTAL				
										NO.	PERCENT										
NEW PRODUCT APPLICATIONS <small>(initial submission)</small>	P	1	0	0	0	1	0	1	0	0	1	100%	0	0	0	0	0	0	0	0	0%
	S	10	0	0	1	9	4	1	0	0	5	56%	4	0	0	0	0	0	0	0	0%
	Total	11	0	0	1	10	4	2	0	0	6	60%	4	0	0	0	0	0	0	0	0%
RESUBMISSIONS <small>(maj. amend after AE or NA)</small>	5	0	0	0	5	4	0	1	0	5	100%	0	0	0	0	0	0	0	0	0	0%
EFFECTIVENESS	P	0	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0	0	0%
SUPPLEMENTS <small>(initial submission)</small>	S	8	0	0	1	7	1	3	1	0	5	71%	2	0	0	0	0	0	0	0	0%
	Total	8	0	0	1	7	1	3	1	0	5	71%	2	0	0	0	0	0	0	0	0%
MANUFACTURING SUPPLEMENTS <small>(initial submission)</small>	63	0	0	0	63	46	1	2	1	50	79%	11	1	1	0	0	2	0	0	3%	

CDER FIRST ACTION PERFORMANCE FOR APPLICATIONS

FY 1997 Cohort - Oct. 1, 1996 - Sept. 30, 1997

(as of December 31, 1997)

BEST POSSIBLE COPY

HFD-550

TYPE	NO. SUBMITTED	PF	RF or WF	UN	NO. FILED	NUMBER OF FIRST ACTIONS WITHIN GOAL						NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST ACTION AND NOT OVERDUE	NUMBER OF FIRST ACTIONS OVERDUE					NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST ACTION AND OVERDUE	% OF FILED SUBMISSIONS OVERDUE		
						AP	AE	NA	WD	TOTAL			AP	AE	NA	WD	TOTAL				
										NO.	PERCENT										
NEW PRODUCT APPLICATIONS (initial submission)	P	0	0	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%	
	S	10	0	0	1	9	0	2	1	0	3	33%	6	0	0	0	0	0	0	0	0%
	Total	10	0	0	1	9	0	2	1	0	3	33%	6	0	0	0	0	0	0	0	0%
RESUBMISSIONS (maj. amend after AE or NA)	11	0	0	0	11	5	4	0	0	9	82%	2	0	0	0	0	0	0	0	0%	
EFFECTIVENESS SUPPLEMENTS (initial submission)	P	0	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0	0%	
	S	3	0	0	0	3	0	0	0	1	33%	2	0	0	0	0	0	0	0	0%	
	Total	3	0	0	0	3	0	0	0	1	33%	2	0	0	0	0	0	0	0	0%	
MANUFACTURING SUPPLEMENTS (initial submission)	158	0	0	0	158	81	38	4	0	123	78%	34	1	0	0	0	1	0	1%		

CDER FIRST ACTION PERFORMANCE FOR APPLICATIONS

FY 1997 Cohort - Oct. 1, 1996 - Sept. 30, 1997

(as of December 31, 1997)

BEST POSSIBLE COPY

HFD-560

TYPE	NO. SUBMITTED	PF	RF or WF	UN	NO. FILED	NUMBER OF FIRST ACTIONS WITHIN GOAL						NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST ACTION AND NOT OVERDUE	NUMBER OF FIRST ACTIONS OVERDUE					NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST ACTION AND OVERDUE	% OF FILED SUBMISSIONS OVERDUE			
						AP	AE	NA	WD	TOTAL			AP	AE	NA	WD	TOTAL					
										NO.	PERCENT											
NEW PRODUCT APPLICATIONS (initial submission)	P	0	0	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0	0%	
	S	0	0	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0	0	0%
	Total	0	0	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0	0	0%
RESUBMISSIONS (maj. amend after AE or NA)	6	0	0	0	6	5	1	0	0	6	100%	0	0	0	0	0	0	0	0	0	0	0%
EFFECTIVENESS SUPPLEMENTS (initial submission)	P	0	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0	0	0	0%
	S	6	0	0	0	6	1	3	0	4	67%	2	0	0	0	0	0	0	0	0	0	0%
	Total	6	0	0	0	6	1	3	0	4	67%	2	0	0	0	0	0	0	0	0	0	0%
MANUFACTURING SUPPLEMENTS (initial submission)	47	0	0	0	47	20	11	2	1	34	72%	11	2	0	0	0	2	0	0	0	4%	

FY 1996 COHORT

CDER FIRST ACTION PERFORMANCE FOR APPLICATIONS

FY 1996 Cohort - Oct. 1, 1995 - Sept. 30, 1996

(as of December 31, 1997)

BEST POSSIBLE COPY

CDER

TYPE	NO. SUBMITTED	RF, UN, or WF	NO. FILED	NUMBER OF FIRST ACTIONS WITHIN GOAL					NUMBER OF FIRST ACTIONS OVERDUE					NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST ACTION AND NOT OVERDUE	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST ACTION AND OVERDUE	% OF FILED SUBMISSIONS OVERDUE
				AP	AE	NA	WD	TOTAL	AP	AE	NA	WD	TOTAL			
NEW PRODUCT APPLICATIONS (initial submission)	123	14	109	50	38	19	1	108	0	0	0	0	0	1	0	0%
RESUBMISSIONS (maj. amend after AE or NA)	89	0	89	67	16	5	0	88	0	1	0	0	1	0	0	1%
EFFECTIVENESS SUPPLEMENTS (initial submission)	118	12	106	60	32	7	4	103	0	2	0	0	2	0	1	3%
MANUFACTURING SUPPLEMENTS (initial submission)	1238	20	1218	991	60	87	32	1170	27	5	16	0	48	0	0	4%

Definitions:

1. New Applications include NDAs, PLAs, and ELAs.
2. AP = Approval; AE = Approvable; NA = Not Approvable; and WD = Withdrawn
3. Resubmission for user fee purposes is the complete response (amendment) to an Approvable or Not Approvable letter for a new product application.
4. The FY 96 first action performance goal is to review and issue a comprehensive action letter within goal on at least 80% of the new product applications, effectiveness supplements, manufacturing supplements, and resubmissions submitted (and filed) in FY 96. This means that not greater than 20% of new product applications, effectiveness supplements, manufacturing supplements, and resubmissions received (and filed) during FY 96 should be overdue.
5. Overdue, for new products and effectiveness supplements, is having not issued a comprehensive action letter within 12 months of receipt (and filing) of the application.
6. Overdue, for manufacturing supplements and resubmissions, is having not issued a comprehensive action letter within 6 months of receipt (and filing) of the application.
7. Major amendments received within 3 months of the goal date will extend the goal date by 3 months. Such extensions are included in the results charted above.
8. The number submitted includes applications received and not yet officially filed. The number filed reflects the number of applications submitted minus applications that are Refused to File (RF), found UNacceptable for filing (UN), or Withdrawn before Filing (WF), which are reflected in the RF, UN, or WF column.

CDER FIRST ACTION PERFORMANCE FOR APPLICATIONS

FY 1996 Cohort - Oct. 1, 1995 - Sept. 30, 1996

(as of December 31, 1997)

BEST POSSIBLE COPY

ODE I

TYPE	NO. SUBMITTED	RF, UN, or WF	NO. FILED	NUMBER OF FIRST ACTIONS WITHIN GOAL					NUMBER OF FIRST ACTIONS OVERDUE					NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST ACTION AND NOT OVERDUE	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST ACTION AND OVERDUE	% OF FILED SUBMISSIONS OVERDUE	
				AP	AE	NA	WD	TOTAL	AP	AE	NA	WD	TOTAL				
NEW PRODUCT APPLICATIONS (initial submission)	35	3	32	8	20	4	0	32	0	0	0	0	0	0	0	0	0%
RESUBMISSIONS (maj. amend after AE or NA)	25	0	25	20	3	2	0	25	0	0	0	0	0	0	0	0	0%
EFFECTIVENESS SUPPLEMENTS (initial submission)	17	2	15	3	7	4	1	15	0	0	0	0	0	0	0	0	0%
MANUFACTURING SUPPLEMENTS (initial submission)	300	3	297	268	12	12	4	296	1	0	0	0	1	0	0	0	0%

Definitions:

1. New Applications include NDAs, PLAs, and ELAs.
2. AP = Approval; AE = Approvable; NA = Not Approvable; and WD = Withdrawn
3. Resubmission for user fee purposes is the complete response (amendment) to an Approvable or Not Approvable letter for a new product application.
4. The FY 96 first action performance goal is to review and issue a comprehensive action letter within goal on at least 80% of the new product applications, effectiveness supplements, manufacturing supplements, and resubmissions submitted (and filed) in FY 96. This means that not greater than 20% of new product applications, effectiveness supplements, manufacturing supplements, and resubmissions received (and filed) during FY 96 should be overdue.
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6. Overdue, for manufacturing supplements and resubmissions, is having not issued a comprehensive action letter within 6 months of receipt (and filing) of the application.
7. Major amendments received within 3 months of the goal date will extend the goal date by 3 months. Such extensions are included in the results charted above.
8. The number submitted includes applications received and not yet officially filed. The number filed reflects the number of applications submitted minus applications that are Refused to File (RF), found UNacceptable for filing (UN), or Withdrawn before Filing (WF), which are reflected in the RF, UN, or WF column.

CDER FIRST ACTION PERFORMANCE FOR APPLICATIONS

FY 1996 Cohort - Oct. 1, 1995 - Sept. 30, 1996

(as of December 31, 1997)

HFD-110

BEST POSSIBLE COPY

TYPE	NO. SUBMITTED	RF, UN, or WF	NO. FILED	NUMBER OF FIRST ACTIONS WITHIN GOAL					NUMBER OF FIRST ACTIONS OVERDUE					NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST ACTION AND NOT OVERDUE	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST ACTION AND OVERDUE	% OF FILED SUBMISSIONS OVERDUE
				AP	AE	NA	WD	TOTAL	AP	AE	NA	WD	TOTAL			
NEW PRODUCT APPLICATIONS (initial submission)	9	0	9	2	5	2	0	9	0	0	0	0	0	0	0	0%
RESUBMISSIONS (maj. amend after AE or NA)	10	0	10	6	2	2	0	10	0	0	0	0	0	0	0	0%
EFFECTIVENESS SUPPLEMENTS (initial submission)	5	0	5	0	3	1	1	5	0	0	0	0	0	0	0	0%
MANUFACTURING SUPPLEMENTS (initial submission)	163	3	160	141	10	6	3	160	0	0	0	0	0	0	0	0%

Definitions:

1. New Applications include NDAs, PLAs, and ELAs.
2. AP = Approval; AE = Approvable; NA = Not Approvable; and WD = Withdrawn
3. Resubmission for user fee purposes is the complete response (amendment) to an Approvable or Not Approvable letter for a new product application.
4. The FY 96 first action performance goal is to review and issue a comprehensive action letter within goal on at least 80% of the new product applications, effectiveness supplements, manufacturing supplements, and resubmissions submitted (and filed) in FY 96. This means that not greater than 20% of new product applications, effectiveness supplements, manufacturing supplements, and resubmissions received (and filed) during FY 96 should be overdue.
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6. Overdue, for manufacturing supplements and resubmissions, is having not issued a comprehensive action letter within 6 months of receipt (and filing) of the application.
7. Major amendments received within 3 months of the goal date will extend the goal date by 3 months. Such extensions are included in the results charted above.
8. The number submitted includes applications received and not yet officially filed. The number filed reflects the number of applications submitted minus applications that are Refused to File (RF), found UNacceptable for filing (UN), or Withdrawn before Filing (WF), which are reflected in the RF, UN, or WF column.

CDER FIRST ACTION PERFORMANCE FOR APPLICATIONS

FY 1996 Cohort - Oct. 1, 1995 - Sept. 30, 1996

(as of December 31, 1997)

BEST POSSIBLE COPY

HFD-120

TYPE	NO. SUBMITTED	RF, UN, or WF	NO. FILED	NUMBER OF FIRST ACTIONS WITHIN GOAL					NUMBER OF FIRST ACTIONS OVERDUE					NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST ACTION AND NOT OVERDUE	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST ACTION AND OVERDUE	% OF FILED SUBMISSIONS OVERDUE
				AP	AE	NA	WD	TOTAL	AP	AE	NA	WD	TOTAL			
NEW PRODUCT APPLICATIONS (initial submission)	16	1	15	0	14	1	0	15	0	0	0	0	0	0	0	0%
RESUBMISSIONS (maj. amend after AE or NA)	9	0	9	9	0	0	0	9	0	0	0	0	0	0	0	0%
EFFECTIVENESS SUPPLEMENTS (initial submission)	7	0	7	1	4	2	0	7	0	0	0	0	0	0	0	0%
MANUFACTURING SUPPLEMENTS (initial submission)	106	0	106	101	1	3	1	106	0	0	0	0	0	0	0	0%

Definitions:

1. New Applications include NDAs, PLAs, and ELAs.
2. AP = Approval; AE = Approvable; NA = Not Approvable; and WD = Withdrawn
3. Resubmission for user fee purposes is the complete response (amendment) to an Approvable or Not Approvable letter for a new product application.
4. The FY 96 first action performance goal is to review and issue a comprehensive action letter within goal on at least 80% of the new product applications, effectiveness supplements, manufacturing supplements, and resubmissions submitted (and filed) in FY 96. This means that not greater than 20% of new product applications, effectiveness supplements, manufacturing supplements, and resubmissions received (and filed) during FY 96 should be overdue.
5. Overdue, for new products and effectiveness supplements, is having not issued a comprehensive action letter within 12 months of receipt (and filing) of the application.
6. Overdue, for manufacturing supplements and resubmissions, is having not issued a comprehensive action letter within 6 months of receipt (and filing) of the application.
7. Major amendments received within 3 months of the goal date will extend the goal date by 3 months. Such extensions are included in the results charted above.
8. The number submitted includes applications received and not yet officially filed. The number filed reflects the number of applications submitted minus applications that are Refused to File (RF), found UNacceptable for filing (UN), or Withdrawn before Filing (WF), which are reflected in the RF, UN, or WF column.

CDER FIRST ACTION PERFORMANCE FOR APPLICATIONS

FY 1996 Cohort - Oct. 1, 1995 - Sept. 30, 1996

(as of December 31, 1997)

BEST POSSIBLE COPY

HFD-150

TYPE	NO. SUBMITTED	RF, UN, or WF	NO. FILED	NUMBER OF FIRST ACTIONS WITHIN GOAL					NUMBER OF FIRST ACTIONS OVERDUE					NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST ACTION AND NOT OVERDUE	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST ACTION AND OVERDUE	% OF FILED SUBMISSIONS OVERDUE
				AP	AE	NA	WD	TOTAL	AP	AE	NA	WD	TOTAL			
NEW PRODUCT APPLICATIONS (initial submission)	10	2	8	6	1	1	0	8	0	0	0	0	0	0	0	0%
RESUBMISSIONS (maj. amend after AE or NA)	6	0	6	5	1	0	0	6	0	0	0	0	0	0	0	0%
EFFECTIVENESS SUPPLEMENTS (initial submission)	5	2	3	2	0	1	0	3	0	0	0	0	0	0	0	0%
MANUFACTURING SUPPLEMENTS (initial submission)	31	0	31	26	1	3	0	30	1	0	0	0	1	0	0	3%

Definitions:

1. New Applications include NDAs, PLAs, and ELAs.
2. AP = Approval; AE = Approvable; NA = Not Approvable; and WD = Withdrawn
3. Resubmission for user fee purposes is the complete response (amendment) to an Approvable or Not Approvable letter for a new product application.
4. The FY 96 first action performance goal is to review and issue a comprehensive action letter within goal on at least 80% of the new product applications, effectiveness supplements, manufacturing supplements, and resubmissions submitted (and filed) in FY 96. This means that not greater than 20% of new product applications, effectiveness supplements, manufacturing supplements, and resubmissions received (and filed) during FY 96 should be overdue.
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7. Major amendments received within 3 months of the goal date will extend the goal date by 3 months. Such extensions are included in the results charted above.
8. The number submitted includes applications received and not yet officially filed. The number filed reflects the number of applications submitted minus applications that are Refused to File (RF), found UNacceptable for filing (UN), or Withdrawn before Filing (WF), which are reflected in the RF, UN, or WF column.

CDER FIRST ACTION PERFORMANCE FOR APPLICATIONS

FY 1996 Cohort - Oct. 1, 1995 - Sept. 30, 1996

(as of December 31, 1997)

BEST POSSIBLE COPY

ODE II

TYPE	NO. SUBMITTED	RF, UN, or WF	NO. FILED	NUMBER OF FIRST ACTIONS WITHIN GOAL					NUMBER OF FIRST ACTIONS OVERDUE					NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST ACTION AND NOT OVERDUE	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST ACTION AND OVERDUE	% OF FILED SUBMISSIONS OVERDUE
				AP	AE	NA	WD	TOTAL	AP	AE	NA	WD	TOTAL			
NEW PRODUCT APPLICATIONS (initial submission)	33	5	28	19	6	3	0	28	0	0	0	0	0	0	0	0%
RESUBMISSIONS (maj. amend after AE or NA)	18	0	18	16	1	1	0	18	0	0	0	0	0	0	0	0%
EFFECTIVENESS SUPPLEMENTS (initial submission)	20	2	18	14	2	1	1	18	0	0	0	0	0	0	0	0%
MANUFACTURING SUPPLEMENTS (initial submission)	420	12	408	337	4	36	16	393	9	0	6	0	15	0	0	4%

Definitions:

1. New Applications include NDAs, PLAs, and ELAs.
2. AP = Approval; AE = Approvable; NA = Not Approvable; and WD = Withdrawn
3. Resubmission for user fee purposes is the complete response (amendment) to an Approvable or Not Approvable letter for a new product application.
4. The FY 96 first action performance goal is to review and issue a comprehensive action letter within goal on at least 80% of the new product applications, effectiveness supplements, manufacturing supplements, and resubmissions submitted (and filed) in FY 96. This means that not greater than 20% of new product applications, effectiveness supplements, manufacturing supplements, and resubmissions received (and filed) during FY 96 should be overdue.
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7. Major amendments received within 3 months of the goal date will extend the goal date by 3 months. Such extensions are included in the results charted above.
8. The number submitted includes applications received and not yet officially filed. The number filed reflects the number of applications submitted minus applications that are Refused to File (RF), found UNacceptable for filing (UN), or Withdrawn before Filing (WF), which are reflected in the RF, UN, or WF column.

CDER FIRST ACTION PERFORMANCE FOR APPLICATIONS

FY 1996 Cohort - Oct. 1, 1995 - Sept. 30, 1996

(as of December 31, 1997)

BEST POSSIBLE COPY

HFD-510

TYPE	NO. SUBMITTED	RF, UN, or WF	NO. FILED	NUMBER OF FIRST ACTIONS WITHIN GOAL					NUMBER OF FIRST ACTIONS OVERDUE					NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST ACTION AND NOT OVERDUE	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST ACTION AND OVERDUE	% OF FILED SUBMISSIONS OVERDUE	
				AP	AE	NA	WD	TOTAL	AP	AE	NA	WD	TOTAL				
NEW PRODUCT APPLICATIONS (initial submission)	12	2	10	9	1	0	0	10	0	0	0	0	0	0	0	0	0%
RESUBMISSIONS (maj. amend after AE or NA)	4	0	4	3	0	1	0	4	0	0	0	0	0	0	0	0	0%
EFFECTIVENESS SUPPLEMENTS (initial submission)	7	0	7	6	0	1	0	7	0	0	0	0	0	0	0	0	0%
MANUFACTURING SUPPLEMENTS (initial submission)	255	3	252	212	1	23	13	249	3	0	0	0	3	0	0	0	1%

Definitions:

1. New Applications include NDAs, PLAs, and ELAs.
2. AP = Approval; AE = Approvable; NA = Not Approvable; and WD = Withdrawn
3. Resubmission for user fee purposes is the complete response (amendment) to an Approvable or Not Approvable letter for a new product application.
4. The FY 96 first action performance goal is to review and issue a comprehensive action letter within goal on at least 80% of the new product applications, effectiveness supplements, manufacturing supplements, and resubmissions submitted (and filed) in FY 96. This means that not greater than 20% of new product applications, effectiveness supplements, manufacturing supplements, and resubmissions received (and filed) during FY 96 should be overdue.
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7. Major amendments received within 3 months of the goal date will extend the goal date by 3 months. Such extensions are included in the results charted above.
8. The number submitted includes applications received and not yet officially filed. The number filed reflects the number of applications submitted minus applications that are Refused to File (RF), found UNacceptable for filing (UN), or Withdrawn before Filing (WF), which are reflected in the RF, UN, or WF column.

CDER FIRST ACTION PERFORMANCE FOR APPLICATIONS

FY 1996 Cohort - Oct. 1, 1995 - Sept. 30, 1996

(as of December 31, 1997)

BEST POSSIBLE COPY

HFD-570

TYPE	NO. SUBMITTED	RF, UN, or WF	NO. FILED	NUMBER OF FIRST ACTIONS WITHIN GOAL					NUMBER OF FIRST ACTIONS OVERDUE					NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST ACTION AND NOT OVERDUE	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST ACTION AND OVERDUE	% OF FILED SUBMISSIONS OVERDUE
				AP	AE	NA	WD	TOTAL	AP	AE	NA	WD	TOTAL			
NEW PRODUCT APPLICATIONS (initial submission)	7	1	6	3	2	1	0	6	0	0	0	0	0	0	0	0%
RESUBMISSIONS (maj. amend after AE or NA)	9	0	9	8	1	0	0	9	0	0	0	0	0	0	0	0%
EFFECTIVENESS SUPPLEMENTS (initial submission)	6	0	6	3	2	0	1	6	0	0	0	0	0	0	0	0%
MANUFACTURING SUPPLEMENTS (initial submission)	61	6	55	40	3	9	2	54	1	0	0	0	1	0	0	2%

Definitions:

1. New Applications include NDAs, PLAs, and ELAs.
2. AP = Approval; AE = Approvable; NA = Not Approvable; and WD = Withdrawn
3. Resubmission for user fee purposes is the complete response (amendment) to an Approvable or Not Approvable letter for a new product application.
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6. Overdue, for manufacturing supplements and resubmissions, is having not issued a comprehensive action letter within 6 months of receipt (and filing) of the application.
7. Major amendments received within 3 months of the goal date will extend the goal date by 3 months. Such extensions are included in the results charted above.
8. The number submitted includes applications received and not yet officially filed. The number filed reflects the number of applications submitted minus applications that are Refused to File (RF), found UNacceptable for filing (UN), or Withdrawn before Filing (WF), which are reflected in the RF, UN, or WF column.

CDER FIRST ACTION PERFORMANCE FOR APPLICATIONS

FY 1996 Cohort - Oct. 1, 1995 - Sept. 30, 1996

(as of December 31, 1997)

BEST POSSIBLE COPY

HFD-580

TYPE	NO. SUBMITTED	RF, UN, or WF	NO. FILED	NUMBER OF FIRST ACTIONS WITHIN GOAL					NUMBER OF FIRST ACTIONS OVERDUE					NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST ACTION AND NOT OVERDUE	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST ACTION AND OVERDUE	% OF FILED SUBMISSIONS OVERDUE	
				AP	AE	NA	WD	TOTAL	AP	AE	NA	WD	TOTAL				
NEW PRODUCT APPLICATIONS (initial submission)	14	2	12	7	3	2	0	12	0	0	0	0	0	0	0	0	0%
RESUBMISSIONS (maj. amend after AE or NA)	5	0	5	5	0	0	0	5	0	0	0	0	0	0	0	0	0%
EFFECTIVENESS SUPPLEMENTS (initial submission)	7	2	5	5	0	0	0	5	0	0	0	0	0	0	0	0	0%
MANUFACTURING SUPPLEMENTS (initial submission)	104	3	101	85	0	4	1	90	5	0	6	0	11	0	0	11%	

Definitions:

1. New Applications include NDAs, PLAs, and ELAs.
2. AP = Approval; AE = Approvable; NA = Not Approvable; and WD = Withdrawn
3. Resubmission for user fee purposes is the complete response (amendment) to an Approvable or Not Approvable letter for a new product application.
4. The FY 96 first action performance goal is to review and issue a comprehensive action letter within goal on at least 80% of the new product applications, effectiveness supplements, manufacturing supplements, and resubmissions submitted (and filed) in FY 96. This means that not greater than 20% of new product applications, effectiveness supplements, manufacturing supplements, and resubmissions received (and filed) during FY 96 should be overdue.
5. Overdue, for new products and effectiveness supplements, is having not issued a comprehensive action letter within 12 months of receipt (and filing) of the application.
6. Overdue, for manufacturing supplements and resubmissions, is having not issued a comprehensive action letter within 6 months of receipt (and filing) of the application.
7. Major amendments received within 3 months of the goal date will extend the goal date by 3 months. Such extensions are included in the results charted above.
8. The number submitted includes applications received and not yet officially filed. The number filed reflects the number of applications submitted minus applications that are Refused to File (RF), found UNacceptable for filing (UN), or Withdrawn before Filing (WF), which are reflected in the RF, UN, or WF column.

CDER FIRST ACTION PERFORMANCE FOR APPLICATIONS
FY 1996 Cohort - Oct. 1, 1995 - Sept. 30, 1996
(as of December 31, 1997)

ODE III

BEST POSSIBLE COPY

TYPE	NO. SUBMITTED	RF, UN, or WF	NO. FILED	NUMBER OF FIRST ACTIONS WITHIN GOAL					NUMBER OF FIRST ACTIONS OVERDUE					NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST ACTION AND NOT OVERDUE	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST ACTION AND OVERDUE	% OF FILED SUBMISSIONS OVERDUE
				AP	AE	NA	WD	TOTAL	AP	AE	NA	WD	TOTAL			
NEW PRODUCT APPLICATIONS (initial submission)	19	3	16	2	7	5	1	15	0	0	0	0	0	1	0	0%
RESUBMISSIONS (maj. amend after AE or NA)	10	0	10	6	4	0	0	10	0	0	0	0	0	0	0	0%
EFFECTIVENESS SUPPLEMENTS (initial submission)	18	1	17	6	7	1	1	15	0	2	0	0	2	0	0	12%
MANUFACTURING SUPPLEMENTS (initial submission)	160	4	156	98	20	21	5	144	6	0	6	0	12	0	0	8%

Definitions:

- New Applications include NDAs, PLAs, and ELAs.
- AP = Approval; AE = Approvable; NA = Not Approvable; and WD = Withdrawn
- Resubmission for user fee purposes is the complete response (amendment) to an Approvable or Not Approvable letter for a new product application.
- The FY 96 first action performance goal is to review and issue a comprehensive action letter within goal on at least 80% of the new product applications, effectiveness supplements, manufacturing supplements, and resubmissions submitted (and filed) in FY 96. This means that not greater than 20% of new product applications, effectiveness supplements, manufacturing supplements, and resubmissions received (and filed) during FY 96 should be overdue.
- Overdue, for new products and effectiveness supplements, is having not issued a comprehensive action letter within 12 months of receipt (and filing) of the application.
- Overdue, for manufacturing supplements and resubmissions, is having not issued a comprehensive action letter within 6 months of receipt (and filing) of the application.
- Major amendments received within 3 months of the goal date will extend the goal date by 3 months. Such extensions are included in the results charted above.
- The number submitted includes applications received and not yet officially filed. The number filed reflects the number of applications submitted minus applications that are Refused to File (RF), found UNacceptable for filing (UN), or Withdrawn before Filing (WF), which are reflected in the RF, UN, or WF column.

CDER FIRST ACTION PERFORMANCE FOR APPLICATIONS

FY 1996 Cohort - Oct. 1, 1995 - Sept. 30, 1996

(as of December 31, 1997)

BEST POSSIBLE COPY

HFD-160

TYPE	NO. SUBMITTED	RF, UN, or WF	NO. FILED	NUMBER OF FIRST ACTIONS WITHIN GOAL					NUMBER OF FIRST ACTIONS OVERDUE					NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST ACTION AND NOT OVERDUE	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST ACTION AND OVERDUE	% OF FILED SUBMISSIONS OVERDUE
				AP	AE	NA	WD	TOTAL	AP	AE	NA	WD	TOTAL			
NEW PRODUCT APPLICATIONS (initial submission)	5	0	5	0	2	2	0	4	0	0	0	0	0	1	0	0%
RESUBMISSIONS (maj. amend after AE or NA)	3	0	3	3	0	0	0	3	0	0	0	0	0	0	0	0%
EFFECTIVENESS SUPPLEMENTS (initial submission)	2	0	2	1	1	0	0	2	0	0	0	0	0	0	0	0%
MANUFACTURING SUPPLEMENTS (initial submission)	23	0	23	13	5	2	3	23	0	0	0	0	0	0	0	0%

Definitions:

1. New Applications include NDAs, PLAs, and ELAs.
2. AP = Approval; AE = Approvable; NA = Not Approvable; and WD = Withdrawn
3. Resubmission for user fee purposes is the complete response (amendment) to an Approvable or Not Approvable letter for a new product application.
4. The FY 96 first action performance goal is to review and issue a comprehensive action letter within goal on at least 80% of the new product applications, effectiveness supplements, manufacturing supplements, and resubmissions submitted (and filed) in FY 96. This means that not greater than 20% of new product applications, effectiveness supplements, manufacturing supplements, and resubmissions received (and filed) during FY 96 should be overdue.
5. Overdue, for new products and effectiveness supplements, is having not issued a comprehensive action letter within 12 months of receipt (and filing) of the application.
6. Overdue, for manufacturing supplements and resubmissions, is having not issued a comprehensive action letter within 6 months of receipt (and filing) of the application.
7. Major amendments received within 3 months of the goal date will extend the goal date by 3 months. Such extensions are included in the results charted above.
8. The number submitted includes applications received and not yet officially filed. The number filed reflects the number of applications submitted minus applications that are Refused to File (RF), found UNacceptable for filing (UN), or Withdrawn before Filing (WF), which are reflected in the RF, UN, or WF column.

CDER FIRST ACTION PERFORMANCE FOR APPLICATIONS

FY 1996 Cohort - Oct. 1, 1995 - Sept. 30, 1996

(as of December 31, 1997)

BEST POSSIBLE COPY

HFD-170

TYPE	NO. SUBMITTED	RF, UN, or WF	NO. FILED	NUMBER OF FIRST ACTIONS WITHIN GOAL					NUMBER OF FIRST ACTIONS OVERDUE					NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST ACTION AND NOT OVERDUE	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST ACTION AND OVERDUE	% OF FILED SUBMISSIONS OVERDUE
				AP	AE	NA	WD	TOTAL	AP	AE	NA	WD	TOTAL			
NEW PRODUCT APPLICATIONS (initial submission)	3	1	2	2	0	0	0	2	0	0	0	0	0	0	0	0%
RESUBMISSIONS (maj. amend after AE or NA)	1	0	1	1	0	0	0	1	0	0	0	0	0	0	0	0%
EFFECTIVENESS SUPPLEMENTS (initial submission)	6	1	5	1	1	0	1	3	0	2	0	0	2	0	0	40%
MANUFACTURING SUPPLEMENTS (initial submission)	56	1	55	36	0	5	2	43	6	0	6	0	12	0	0	22%

Definitions:

1. New Applications include NDAs, PLAs, and ELAs.
2. AP = Approval; AE = Approvable; NA = Not Approvable; and WD = Withdrawn
3. Resubmission for user fee purposes is the complete response (amendment) to an Approvable or Not Approvable letter for a new product application.
4. The FY 96 first action performance goal is to review and issue a comprehensive action letter within goal on at least 80% of the new product applications, effectiveness supplements, manufacturing supplements, and resubmissions submitted (and filed) in FY 96. This means that not greater than 20% of new product applications, effectiveness supplements, manufacturing supplements, and resubmissions received (and filed) during FY 96 should be overdue.
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8. The number submitted includes applications received and not yet officially filed. The number filed reflects the number of applications submitted minus applications that are Refused to File (RF), found UNacceptable for filing (UN), or Withdrawn before Filing (WF), which are reflected in the RF, UN, or WF column.

CDER FIRST ACTION PERFORMANCE FOR APPLICATIONS

FY 1996 Cohort - Oct. 1, 1995 - Sept. 30, 1996

(as of December 31, 1997)

BEST POSSIBLE COPY

HFD-180

TYPE	NO. SUBMITTED	RF, UN, or WF	NO. FILED	NUMBER OF FIRST ACTIONS WITHIN GOAL					NUMBER OF FIRST ACTIONS OVERDUE					NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST ACTION AND NOT OVERDUE	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST ACTION AND OVERDUE	% OF FILED SUBMISSIONS OVERDUE	
				AP	AE	NA	WD	TOTAL	AP	AE	NA	WD	TOTAL				
NEW PRODUCT APPLICATIONS (initial submission)	11	2	9	0	5	3	1	9	0	0	0	0	0	0	0	0	0%
RESUBMISSIONS (maj. amend after AE or NA)	6	0	6	2	4	0	0	6	0	0	0	0	0	0	0	0	0%
EFFECTIVENESS SUPPLEMENTS (initial submission)	10	0	10	4	5	1	0	10	0	0	0	0	0	0	0	0	0%
MANUFACTURING SUPPLEMENTS (initial submission)	81	3	78	49	15	14	0	78	0	0	0	0	0	0	0	0	0%

Definitions:

1. New Applications include NDAs, PLAs, and ELAs.
2. AP = Approval; AE = Approvable; NA = Not Approvable; and WD = Withdrawn
3. Resubmission for user fee purposes is the complete response (amendment) to an Approvable or Not Approvable letter for a new product application.
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8. The number submitted includes applications received and not yet officially filed. The number filed reflects the number of applications submitted minus applications that are Refused to File (RF), found UNacceptable for filing (UN), or Withdrawn before Filing (WF), which are reflected in the RF, UN, or WF column.

CDER FIRST ACTION PERFORMANCE FOR APPLICATIONS

FY 1996 Cohort - Oct. 1, 1995 - Sept. 30, 1996

(as of December 31, 1997)

BEST POSSIBLE COPY

ODE IV

TYPE	NO. SUBMITTED	RF, UN, or WF	NO. FILED	NUMBER OF FIRST ACTIONS WITHIN GOAL					NUMBER OF FIRST ACTIONS OVERDUE					NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST ACTION AND NOT OVERDUE	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST ACTION AND OVERDUE	% OF FILED SUBMISSIONS OVERDUE
				AP	AE	NA	WD	TOTAL	AP	AE	NA	WD	TOTAL			
NEW PRODUCT APPLICATIONS (initial submission)	20	1	19	18	1	0	0	19	0	0	0	0	0	0	0	0%
RESUBMISSIONS (maj. amend after AE or NA)	8	0	8	7	1	0	0	8	0	0	0	0	0	0	0	0%
EFFECTIVENESS SUPPLEMENTS (initial submission)	41	6	35	24	9	1	1	35	0	0	0	0	0	0	0	0%
MANUFACTURING SUPPLEMENTS (initial submission)	108	0	108	96	1	6	3	106	2	0	0	0	2	0	0	2%

Definitions:

1. New Applications include NDAs, PLAs, and ELAs.
2. AP = Approval; AE = Approvable; NA = Not Approvable; and WD = Withdrawn
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8. The number submitted includes applications received and not yet officially filed. The number filed reflects the number of applications submitted minus applications that are Refused to File (RF), found UNacceptable for filing (UN), or Withdrawn before Filing (WF), which are reflected in the RF, UN, or WF column.

CDER FIRST ACTION PERFORMANCE FOR APPLICATIONS

FY 1996 Cohort - Oct. 1, 1995 - Sept. 30, 1996

(as of December 31, 1997)

BEST POSSIBLE COPY

HFD-520

TYPE	NO. SUBMITTED	RF, UN, or WF	NO. FILED	NUMBER OF FIRST ACTIONS WITHIN GOAL					NUMBER OF FIRST ACTIONS OVERDUE					NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST ACTION AND NOT OVERDUE	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST ACTION AND OVERDUE	% OF FILED SUBMISSIONS OVERDUE
				AP	AE	NA	WD	TOTAL	AP	AE	NA	WD	TOTAL			
NEW PRODUCT APPLICATIONS (initial submission)	3	1	2	2	0	0	0	2	0	0	0	0	0	0	0	0%
RESUBMISSIONS (maj. amend after AE or NA)	5	0	5	4	1	0	0	5	0	0	0	0	0	0	0	0%
EFFECTIVENESS SUPPLEMENTS (initial submission)	8	1	7	7	0	0	0	7	0	0	0	0	0	0	0	0%
MANUFACTURING SUPPLEMENTS (initial submission)	54	0	54	43	1	6	2	52	2	0	0	0	2	0	0	4%

Definitions:

1. New Applications include NDAs, PLAs, and ELAs.
2. AP = Approval; AE = Approvable; NA = Not Approvable; and WD = Withdrawn
3. Resubmission for user fee purposes is the complete response (amendment) to an Approvable or Not Approvable letter for a new product application.
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8. The number submitted includes applications received and not yet officially filed. The number filed reflects the number of applications submitted minus applications that are Refused to File (RF), found UNacceptable for filing (UN), or Withdrawn before Filing (WF), which are reflected in the RF, UN, or WF column.

CDER FIRST ACTION PERFORMANCE FOR APPLICATIONS

FY 1996 Cohort - Oct. 1, 1995 - Sept. 30, 1996

(as of December 31, 1997)

BEST POSSIBLE COP

HFD-530

TYPE	NO. SUBMITTED	RF, UN, or WF	NO. FILED	NUMBER OF FIRST ACTIONS WITHIN GOAL					NUMBER OF FIRST ACTIONS OVERDUE					NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST ACTION AND NOT OVERDUE	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST ACTION AND OVERDUE	% OF FILED SUBMISSIONS OVERDUE
				AP	AE	NA	WD	TOTAL	AP	AE	NA	WD	TOTAL			
NEW PRODUCT APPLICATIONS (initial submission)	8	0	8	8	0	0	0	8	0	0	0	0	0	0	0	0%
RESUBMISSIONS (maj. amend after AE or NA)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0%
EFFECTIVENESS SUPPLEMENTS (initial submission)	13	1	12	7	5	0	0	12	0	0	0	0	0	0	0	0%
MANUFACTURING SUPPLEMENTS (initial submission)	22	0	22	22	0	0	0	22	0	0	0	0	0	0	0	0%

Definitions:

1. New Applications include NDAs, PLAs, and ELAs.
2. AP = Approval; AE = Approvable; NA = Not Approvable; and WD = Withdrawn
3. Resubmission for user fee purposes is the complete response (amendment) to an Approvable or Not Approvable letter for a new product application.
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7. Major amendments received within 3 months of the goal date will extend the goal date by 3 months. Such extensions are included in the results charted above.
8. The number submitted includes applications received and not yet officially filed. The number filed reflects the number of applications submitted minus applications that are Refused to File (RF), found UNacceptable for filing (UN), or Withdrawn before Filing (WF), which are reflected in the RF, UN, or WF column.

CDER FIRST ACTION PERFORMANCE FOR APPLICATIONS

FY 1996 Cohort - Oct. 1, 1995 - Sept. 30, 1996

(as of December 31, 1997)

BEST POSSIBLE COPY

HFD-590

TYPE	NO. SUBMITTED	RF, UN, or WF	NO. FILED	NUMBER OF FIRST ACTIONS WITHIN GOAL					NUMBER OF FIRST ACTIONS OVERDUE					NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST ACTION AND NOT OVERDUE	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST ACTION AND OVERDUE	% OF FILED SUBMISSIONS OVERDUE
				AP	AE	NA	WD	TOTAL	AP	AE	NA	WD	TOTAL			
NEW PRODUCT APPLICATIONS (initial submission)	9	0	9	8	1	0	0	9	0	0	0	0	0	0	0	0%
RESUBMISSIONS (maj. amend after AE or NA)	3	0	3	3	0	0	0	3	0	0	0	0	0	0	0	0%
EFFECTIVENESS SUPPLEMENTS (initial submission)	20	4	16	10	4	1	1	16	0	0	0	0	0	0	0	0%
MANUFACTURING SUPPLEMENTS (initial submission)	32	0	32	31	0	0	1	32	0	0	0	0	0	0	0	0%

Definitions:

1. New Applications include NDAs, PLAs, and ELAs.
2. AP = Approval; AE = Approvable; NA = Not Approvable; and WD = Withdrawn
3. Resubmission for user fee purposes is the complete response (amendment) to an Approvable or Not Approvable letter for a new product application.
4. The FY 96 first action performance goal is to review and issue a comprehensive action letter within goal on at least 80% of the new product applications, effectiveness supplements, manufacturing supplements, and resubmissions submitted (and filed) in FY 96. This means that not greater than 20% of new product applications, effectiveness supplements, manufacturing supplements, and resubmissions received (and filed) during FY 96 should be overdue.
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8. The number submitted includes applications received and not yet officially filed. The number filed reflects the number of applications submitted minus applications that are Refused to File (RF), found UNacceptable for filing (UN), or Withdrawn before Filing (WF), which are reflected in the RF, UN, or WF column.

CDER FIRST ACTION PERFORMANCE FOR APPLICATIONS

FY 1996 Cohort - Oct. 1, 1995 - Sept. 30, 1996

(as of December 31, 1997)

BEST POSSIBLE COPY

ODE V

TYPE	NO. SUBMITTED	RF, UN, or WF	NO. FILED	NUMBER OF FIRST ACTIONS WITHIN GOAL					NUMBER OF FIRST ACTIONS OVERDUE					NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST ACTION AND NOT OVERDUE	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST ACTION AND OVERDUE	% OF FILED SUBMISSIONS OVERDUE
				AP	AE	NA	WD	TOTAL	AP	AE	NA	WD	TOTAL			
NEW PRODUCT APPLICATIONS (initial submission)	16	2	14	3	4	7	0	14	0	0	0	0	0	0	0	0%
RESUBMISSIONS (maj. amend after AE or NA)	28	0	28	18	7	2	0	27	0	1	0	0	1	0	0	4%
EFFECTIVENESS SUPPLEMENTS (initial submission)	22	1	21	13	7	0	0	20	0	0	0	0	0	0	1	5%
MANUFACTURING SUPPLEMENTS (initial submission)	250	1	249	192	23	12	4	231	9	5	4	0	18	0	0	7%

Definitions:

1. New Applications include NDAs, PLAs, and ELAs.
2. AP = Approval; AE = Approvable; NA = Not Approvable; and WD = Withdrawn
3. Resubmission for user fee purposes is the complete response (amendment) to an Approvable or Not Approvable letter for a new product application.
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8. The number submitted includes applications received and not yet officially filed. The number filed reflects the number of applications submitted minus applications that are Refused to File (RF), found UNacceptable for filing (UN), or Withdrawn before Filing (WF), which are reflected in the RF, UN, or WF column.

CDER FIRST ACTION PERFORMANCE FOR APPLICATIONS
FY 1996 Cohort - Oct. 1, 1995 - Sept. 30, 1996
(as of December 31, 1997)

BEST POSSIBLE COPY

HFD-540

TYPE	NO. SUBMITTED	RF, UN, or WF	NO. FILED	NUMBER OF FIRST ACTIONS WITHIN GOAL					NUMBER OF FIRST ACTIONS OVERDUE					NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST ACTION AND NOT OVERDUE	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST ACTION AND OVERDUE	% OF FILED SUBMISSIONS OVERDUE
				AP	AE	NA	WD	TOTAL	AP	AE	NA	WD	TOTAL			
NEW PRODUCT APPLICATIONS (initial submission)	7	1	6	2	1	3	0	6	0	0	0	0	0	0	0	0%
RESUBMISSIONS (maj. amend after AE or NA)	15	0	15	9	4	2	0	15	0	0	0	0	0	0	0	0%
EFFECTIVENESS SUPPLEMENTS (initial submission)	11	0	11	8	3	0	0	11	0	0	0	0	0	0	0	0%
MANUFACTURING SUPPLEMENTS (initial submission)	54	0	54	43	3	1	1	48	4	2	0	0	6	0	0	11%

Definitions:

1. New Applications include NDAs, PLAs, and ELAs.
2. AP = Approval; AE = Approvable; NA = Not Approvable; and WD = Withdrawn
3. Resubmission for user fee purposes is the complete response (amendment) to an Approvable or Not Approvable letter for a new product application.
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CDER FIRST ACTION PERFORMANCE FOR APPLICATIONS

FY 1996 Cohort - Oct. 1, 1995 - Sept. 30, 1996

(as of December 31, 1997)

BEST POSSIBLE COPY

HFD-550

TYPE	NO. SUBMITTED	RF, UN, or WF	NO. FILED	NUMBER OF FIRST ACTIONS WITHIN GOAL					NUMBER OF FIRST ACTIONS OVERDUE					NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST ACTION AND NOT OVERDUE	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST ACTION AND OVERDUE	% OF FILED SUBMISSIONS OVERDUE
				AP	AE	NA	WD	TOTAL	AP	AE	NA	WD	TOTAL			
NEW PRODUCT APPLICATIONS (initial submission)	9	1	8	1	3	4	0	8	0	0	0	0	0	0	0	0%
RESUBMISSIONS (maj. amend after AE or NA)	5	0	5	3	1	0	0	4	0	1	0	0	1	0	0	20%
EFFECTIVENESS SUPPLEMENTS (initial submission)	6	0	6	3	2	0	0	5	0	0	0	0	0	0	1	17%
MANUFACTURING SUPPLEMENTS (initial submission)	145	1	144	115	16	6	3	140	1	3	0	0	4	0	0	3%

Definitions:

1. New Applications include NDAs, PLAs, and ELAs.
2. AP = Approval; AE = Approvable; NA = Not Approvable; and WD = Withdrawn
3. Resubmission for user fee purposes is the complete response (amendment) to an Approvable or Not Approvable letter for a new product application.
4. The FY 96 first action performance goal is to review and issue a comprehensive action letter within goal on at least 80% of the new product applications, effectiveness supplements, manufacturing supplements, and resubmissions submitted (and filed) in FY 96. This means that not greater than 20% of new product applications, effectiveness supplements, manufacturing supplements, and resubmissions received (and filed) during FY 96 should be overdue.
5. Overdue, for new products and effectiveness supplements, is having not issued a comprehensive action letter within 12 months of receipt (and filing) of the application.
6. Overdue, for manufacturing supplements and resubmissions, is having not issued a comprehensive action letter within 6 months of receipt (and filing) of the application.
7. Major amendments received within 3 months of the goal date will extend the goal date by 3 months. Such extensions are included in the results charted above.
8. The number submitted includes applications received and not yet officially filed. The number filed reflects the number of applications submitted minus applications that are Refused to File (RF), found UNacceptable for filing (UN), or Withdrawn before Filing (WF), which are reflected in the RF, UN, or WF column.

CDER FIRST ACTION PERFORMANCE FOR APPLICATIONS

FY 1996 Cohort - Oct. 1, 1995 - Sept. 30, 1996

(as of December 31, 1997)

BEST POSSIBLE COPY

HFD-560

TYPE	NO. SUBMITTED	RF, UN, or WF	NO. FILED	NUMBER OF FIRST ACTIONS WITHIN GOAL					NUMBER OF FIRST ACTIONS OVERDUE					NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST ACTION AND NOT OVERDUE	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST ACTION AND OVERDUE	% OF FILED SUBMISSIONS OVERDUE
				AP	AE	NA	WD	TOTAL	AP	AE	NA	WD	TOTAL			
NEW PRODUCT APPLICATIONS <i>(initial submission)</i>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0%
RESUBMISSIONS <i>(maj. amend after AE or NA)</i>	8	0	8	6	2	0	0	8	0	0	0	0	0	0	0	0%
EFFECTIVENESS SUPPLEMENTS <i>(initial submission)</i>	5	1	4	2	2	0	0	4	0	0	0	0	0	0	0	0%
MANUFACTURING SUPPLEMENTS <i>(initial submission)</i>	51	0	51	34	4	5	0	43	4	0	4	0	8	0	0	16%

Definitions:

1. New Applications include NDAs, PLAs, and ELAs.
2. AP = Approval; AE = Approvable; NA = Not Approvable; and WD = Withdrawn
3. Resubmission for user fee purposes is the complete response (amendment) to an Approvable or Not Approvable letter for a new product application.
4. The FY 96 first action performance goal is to review and issue a comprehensive action letter within goal on at least 80% of the new product applications, effectiveness supplements, manufacturing supplements, and resubmissions submitted (and filed) in FY 96. This means that not greater than 20% of new product applications, effectiveness supplements, manufacturing supplements, and resubmissions received (and filed) during FY 96 should be overdue.
5. Overdue, for new products and effectiveness supplements, is having not issued a comprehensive action letter within 12 months of receipt (and filing) of the application.
6. Overdue, for manufacturing supplements and resubmissions, is having not issued a comprehensive action letter within 6 months of receipt (and filing) of the application.
7. Major amendments received within 3 months of the goal date will extend the goal date by 3 months. Such extensions are included in the results charted above.
8. The number submitted includes applications received and not yet officially filed. The number filed reflects the number of applications submitted minus applications that are Refused to File (RF), found UNacceptable for filing (UN), or Withdrawn before Filing (WF), which are reflected in the RF, UN, or WF column.