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 1998 Cohort - Oct. 1, 1997 - Sept. 30, 1998 (as of December 31, 1997)

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CDER

TYP	E	NO. SUBMITTED	PF	R or WF	Un	NO. FILED	NUN	ABER C WI	F FIRS THIN G	T ACTIO	NS		NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	1	MBER (OF FIRST OVERDU	T ACTIO JE	NS	NUMBER OF FILED SUBMISSIONS	% OF FILED
							АР	AE	NA	40080 Ct		PERCENT	ACTION AND	AP	AE	NA :	. WD	TOTAL	MTHOUT A FIRST ACTION AND OVERDUE	SUBMISSION OVERDUE
NEW PRODUCT	Р	10	6	0	0	4	0	0	0	0	0	0%	4	0	0	0	0	0	0	0'
APPLICATIONS (initial submission)	S	40	30	1	3	6	0	0	0	1	1	17%	5	0	0	0	0	0	0	09
(mindal southission)	Total	50	36	1	3	10	0	0	0	1	1	10%	9	0	0	0	0	0	0	09
RESUBMISSIC (maj. amend afte AE or NA)		16	0	0	0	16	7	0	1	0	8	50%	8	0	0	0	0	0	0	0%
EFFECTIVENESS	Р	1	0	0	0	1	0	0	0	0	0	0%	1	0	0	0	0	0	0	09
SUPPLEMENTS	s	27	18	1	1	7	0	0	0	0	0	0%	7	0	0	0	0	0	0	09
(initial submission)	Total	28	18	1	1	8	0	0	0	0	0	0%	8	0	0	0	0	0	0	
MANUFACTUR SUPPLEMENT (initial submission	rs	410	275	4	0	131	37	0	0	0	37	28%	94	0	0	0	0	0	0	0%

FY 1998 Cohort - Oct. 1, 1997 - Sept. 30, 1998 (as of December 31, 1997)

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ODEI

TYP	E :	NO. SUBMITTED	PF	RF or WF	UN	NO. FILED	NUI	MBER C	F FIRST	FACTIO DAL	NS		NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	NUI		F FIRST	T ACTIO	NS	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	% OF FILED
							ΑР	AE	NA .	WD	200000	TAL PERCENT	ACTION AND	АР	AE	NA	- WD	TOTAL		OVERDUE
NEW PRODUCT	Р	4	1	0	0	3	0	0	0	0	0	0%	3		0		0	0	0	0%
APPLICATIONS	S	17	12	1	1	3	0	0	0	1	1	33%	2	0	0	0	0	0	0	0%
(initial submission)	Total	21	13	1	1	6	0	0	0	1	1	17%	5	0	0	0	0	0	0	0%
RESUBMISSIC (maj. amend afte AE or NA)		5	0	0	0	5	3	0	1	0	4	80%	1	0	0	0	0	0	0	0%
EFFECTIVENESS	Р	1	0	0	0	1	0	0	0	0	0	0%	1	0	0	0	0	0	0	0%
SUPPLEMENTS	S	3	3	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
(initial submission)	Total	4	3	0	0	1	0	0	0	0	0	0%	1	0	0	0	0	0	0	0%
MANUFACTUR SUPPLEMEN' (initial submission	TS	138	93	0	0	45	24	0	0	0	24	53%	21	0	0	0	0	0	0	0%

FY 1998 Cohort - Oct. 1, 1997 - Sept. 30, 1998 (as of December 31, 1997)

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TYP	E	NO. SUBMITTED	₽ F	RF or WF	UΝ	NO. FILED	NUI		F FIRST THIN GC		18		NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	NU		F FIRST		NS	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	% OF FILED SUBMISSIONS
							AP	AE	NA	WD /	A 10 10 10 10 10 10 10 10 10 10 10 10 10	TAL PERCENT	ACTION AND NOT OVERDUE	ΑP	AE	NA"	WD	TOTAL	ACTION AND OVERDUE	OVERDUE
NEW PRODUCT	Р	1	0	0	0	1	0	0	0	0	0	0%	1	0	0		0	0	0	0%
APPLICATIONS (initial submission)	S	4	2	0	1	1	0	0	0	0	0	0%	1,	0	0	0	0	0	0	0%
(initial submission)	Total	5	2	0	1	2	0	0	0	0	0	0%	2	0	0	0	0	0	0	0%
RESUBMISSIO (maj. amend afti AE or NA)		4	0	0	0	4	2	0	1	0	3	75%	1	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%
SUPPLEMENTS	S	0	0	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
(initial submission)	Total	0	0	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
MANUFACTUR SUPPLEMEN (initial submissio	тѕ	71	51	0	0	20	16	0	0	0	16	80%	4	0	0	0	0	0	0	0%

FY 1998 Cohort - Oct. 1, 1997 - Sept. 30, 1998 (as of December 31, 1997)

HFD-120

TYP	E	NO, SUBMITTED	PF	RF or WF	UN	NO. FILED	NUI		F FIRST	ACTION	18		NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	NUI		OF FIRST		NS	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	% OF FILED
							AP	AE	NA -	WD		TAL PERCENT	ACTION AND	AP	AE .	NA .	WD	TOTAL	ACTION AND OVERDUE	SUBMISSIONS OVERDUE
NEW PRODUCT	Р	2	1	0	0	1	0	0	0	0	0	0%	1	0	0	0	0	0	0	0%
APPLICATIONS (initial submission)	s	10	7	1	0	2	0	0	0	1	1	50%	1	0	0	0	0	0	0	0%
(mida sabihisabiy	Total	12	8	1	0	3	0	0	0	1	1	33%	2	0	0	0	0	0	0	0%
RESUBMISSIC (maj. amend afte AE or NA)		0	0	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
EFFECTIVENESS	Р	0	0	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
SUPPLEMENTS	s	1	1	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
(initial submission)	Total	1	1	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
MANUFACTUR SUPPLEMEN' (initial submission	тѕ	52	33	0	0	19	7	0	0	0	7	37%	12	0	0	0	0	0	0	0%

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.: TYP	E	NO. SUBMITTED	PF	RF orWF	UN	NO. FILED	NUI	MBER O Wi	F FIRST THIN GO	ACTION	IS		NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	NUM		F FIRS	FACTIO JE	NS	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	% OF FILED
							AP	AE	NA ·	WD		TAL PERCENT	ACTION AND NOT OVERDUE	AP ,	AE	NA .	WD,	TOTAL	ACTION AND OVERDUE	OVERDUE
NEW PRODUCT	Р	1	0	0	0	1	0	0	0	0	0	0%	1	0	0	0	0	0	0	0%
APPLICATIONS (initial submission)	S	3	3	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
	Total	4	3	0	0	1	0	0	0	0	0	0%	1	0	0	0	0	0	0	0%
RESUBMISSIC (maj. amend afte AE or NA)	1.5	1	0	0	0	1	1	0	0	0	1	100%	0	0	0	0	0	0	0	0%
EFFECTIVENESS	Р	1	0	0	0	1	0	0	0	0	0	0%	1	0	0	0	0	0	0	0%
SUPPLEMENTS (initial submission)	S	2	2	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
(initial Submission)	Total	3	2	0	0	1	0	0	0	0	0	0%	1	0	0	0	0	0	0	0%
MANUFACTUR SUPPLEMEN (initial submission	тѕ	15	9	0	0	6	1	0	0	0	1	17%	5	0	0	0	0	0	0	0%

FY 1998 Cohort - Oct. 1, 1997 - Sept. 30, 1998 (as of December 31, 1997)

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ODE II

ΙΥP	E	NO. SUBMITTED	PF	R orWF	ÜN	NO. FILED	NUN		F FIRST THIN GO		18		NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	NUM		F FIRST VERDU	ACTIO	NS	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	% OF FILED
20 Species							AP	AE	NA	WD		AL PERCENT	ACTION AND NOT OVERDUE	AP	AE	NA .	WD:	TOTAL	ACTION AND	OVERDUE
NEW PRODUCT	Р	3	2	0	0	1	0	0	0	0	0	0%	1	0	0	0	0		0	0%
APPLICATIONS (initial submission)	S	7	6	0	1	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
(muai suomission)	Total	10	8	0	1	1	0	0	0	0	0	0%	1	0	0	0	0	0	0	0%
RESUBMISSIO (maj. amend afte AE or NA)	1.0	0	0	0	0	0	0	0	0	0	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%
SUPPLEMENTS	S	12	10	0	1	1	0	0	0	0	0	0%	1	0	0	0	0	0	0	0%
(initial submission)	Total	12	10	0	1	1	0	0	0	0	0	0%	1	0	0	0	0	0	0	0%
MANUFACTUR SUPPLEMEN (initial submissio	тѕ	93	53	3	0	37	3	0	0	0	3	8%	34	0	0	0	0	0	0	0%

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ТҮР	E	NO. SUBMITTED	PF	RF or:WF	UN	NO. FILED	NUI	WI.	THIN GO		NS		NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	NU	MBER O	F FIRST	ACTION	NS	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	% OF FILED
							AP.	AE	NA .	WD	, TO NO.	TAL PERCENT	ACTION AND NOT OVERDUE	AP *	ΑE	NA -	WD	TOTAL	ACTION AND OVERDUE	SUBMISSIONS OVERDUE
NEW PRODUCT	Р	1	0	0	0	1	0	0	0	0	0	0%	1	0	0	0	0	0	0	0%
APPLICATIONS (initial submission)	s -	3	3	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
	Total	4	3	0	0	1	0	0	0	0	0	0%	1	0	0	0	0	0	0	0%
RESUBMISSIC (maj. amend afte AE or NA)		0	0	0	0	0	0	0	0	0	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%
SUPPLEMENTS (initial submission)	s	4	4	0	0	0	0	0	0	0	0	0%	0	0	0	0	. 0	0	0	0%
(muda SODINSSION)	Total	4	4	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
MANUFACTUR SUPPLEMEN (initial submission	TS	23	18	0	0	5	0	0	0	0	0	0%	5	0	0	0	0	0	0	0%

CDER FIRST ACTION PERFORMANCE FOR APPLICATIONS

FY 1998 Cohort - Oct. 1, 1997 - Sept. 30, 1998 (as of December 31, 1997)

TYP	E	NO. SUBMITTED	PF	RF or WF	UN	NO. FILED	NUI		F FIRST THIN GO	ACTIO	NS		NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	NUM	MBER C	F FIRST	ACTIO IE	NS	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	% OF FILED SUBMISSIONS
							AP	AE	NA	WD	~(TAL PERCENT	ACTION AND NOT OVERDUE	AP	AE	NA	WD	TOTAL	ACTION AND OVERDUE	OVERDUE
NEW PRODUCT	Р	1	1	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
APPLICATIONS	S	1	1	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
(initial submission)	Total	2	2	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
RESUBMISSIC (maj. amend afte AE or NA)		0	0	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
EFFECTIVENESS	Р	0	0	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
SUPPLEMENTS	s	5	3	0	1	1	0	0	0	0	0	0%	1	0	0	0	0	0	0	0%
(initial submission)	Total	5	3	0	1	1	0	0	0	0	0	0%	1	0	0	0	0	0	0	0%
MANUFACTUR SUPPLEMEN (initial submission	TS	28	24	0	0	4	0	0	0	0	0	0%	4	0	0	0	0	0	0	0%

CDER FIRST ACTION PERFORMANCE FOR APPLICATIONS

FY 1998 Cohort - Oct. 1, 1997 - Sept. 30, 1998 (as of December 31, 1997)

ТҮР	E	NO. SUBMITTED	PF	RF or WF	UN	NO. FILED	NU	MBER C WI	F FIRST	T ACTIO	NS		NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	NU	MBER C	F FIRST	FACTION IE	vs	NUMBER OF FILED SUBMISSIONS	% OF FILED
							AP	AE	,NA	WD		TAL PERCENT	ACTION AND	ΑP	AE	,NA	-WD-	TOTAL	MITHOUT A FIRST ACTION AND OVERDUE	SUBMISSIONS
NEW PRODUCT	Р	1	1	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
APPLICATIONS (initial submission)	S	3	2	0	1	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
	Total	4	3	0	1	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
RESUBMISSIC (maj. amend afte AE or NA)		0	0	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
EFFECTIVENESS	Р	0	0	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
SUPPLEMENTS	s	3	3	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
(initial submission)	Total	3	3	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
MANUFACTUR SUPPLEMEN (initial submission	rs	42	11	3	0	28	3	0	0	0	3	11%	25	0	0	0	0	0	0	0%

CDER FIRST ACTION PERFORMANCE FOR APPLICATIONS

FY 1998 Cohort - Oct. 1, 1997 - Sept. 30, 1998 (as of December 31, 1997)

ODE III

ТҮР	E å	NO. SUBMITTED	PF	R or WF	UN	NO. FILED	NU		F FIRST	ACTIO	NS		NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	NUI		F FIRST		NS	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	% OF FILED
							AP	AE	NA	WD	TO NO.	TAL PERCENT	ACTION AND	AP	AE	NA .	WD	TOTAL	ACTION AND OVERDUE	SUBMISSIONS OVERDUE
NEW PRODUCT	Р	0	0	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
APPLICATIONS (initial submission)	S	5	4	0	0	1	0	0	0	0	0	0%	1	0	0	0	0	0	0	0%
	Total	5	4	0	0	1	0	0	0	0	0	0%	1	0	0	0	0	0	0	0%
RESUBMISSIC (maj. amend afte AE or NA)	799	5	0	0	0	5	2	0	0	0	2	40%	3	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%
SUPPLEMENTS	S	2	1	0	0	1	0	0	0	0	0	0%	1	0	0	0	0	0	0	0%
(initial submission)	Total	2	1	0	0	1	0	0	0	0	0	0%	1	0	0	0	0	0	0	0%
MANUFACTUR SUPPLEMEN (initial submission	тѕ	52	36	1	0	15	4	0	0	0	4	27%	11	0	0	0	0	0	0	0%

CDER FIRST ACTION PERFORMANCE FOR APPLICATIONS

FY 1998 Cohort - Oct. 1, 1997 - Sept. 30, 1998 (as of December 31, 1997)

ТҮР	E	NO. SUBMITTED	PF	RF or WF	บท	NO. FILED	NUI		THIN GO		NS		NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	NUI		F FIRST	ACTIO	NS	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	% OF FILED
	Addil.						AP	AE	NA.	WD	A 8 1 (100 - 100)	TAL PERCENT	ACTION AND NOT OVERDUE	AP	AE .	NA .	WD	TOTAL		OVERDUE
NEW PRODUCT	P	0	0	0	0	0	0	0	0	0	0	0%	0		0	0	0		0	0%
APPLICATIONS (initial submission)	\$	1	0	0	0	1	0	0	0	0	0	0%	1	0	0	0	0	0	0	0%
(mixel 333)	Total	1	0	0	0	1	0	0	0	0	0	0%	1	0	0	0	0	0	0	0%
RESUBMISSIC (maj. amend afte AE or NA)		0	0	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
EFFECTIVENESS	Р	0	0	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
SUPPLEMENTS	s	0	0	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
(initial submission)	Total	0	0	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
MANUFACTUR SUPPLEMEN (initial submission	тѕ	17	10	1	0	6	1	0	0	0	1	17%	5	0	0	0	0	0	0	0%

FY 1998 Cohort - Oct. 1, 1997 - Sept. 30, 1998 (as of December 31, 1997)

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TYP	E	NO. SUBMITTED	PF	RF or WF	UN	NO. FILED	NUI	MBER O Wi	F FIRST	ACTIOI DAL	NS .		NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	NUI	MBER C	F FIRST	ACTIOI E	NS	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	% OF FILED
· · · · · · · · · · · · · · · · · · ·							AP	AE	NA	WD		TAL PERCENT		AP	AE .	NA :	WD	TOTAL	ACTION AND OVERDUE	OVERDUE
NEW PRODUCT	Р	0	0	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
APPLICATIONS (initial submission)	S.	1	1	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
(and submission)	Total	1	1	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
RESUBMISSIO (maj. amend afte AE or NA)		0	0	0	0	0	0	0	0	0	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%
SUPPLEMENTS	s	2	1	0	0	1	0	0	0	0	0	0%	1	0	0	0	0	0	0	0%
(initial submission)	Total	2	1	0	0	1	0	0	0	0	0	0%	1	0	0	0	0	0	0	0%
MANUFACTUR SUPPLEMEN (initial submission	τs	9	7	0	0	2	0	0	0	0	0	0%	2	0	0	0	0	0	0	0%

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TYP	Έ	NO. SUBMITTED	PF	RF or WF	UN	NO. FILED	NUI	MBER O Wi	F FIRST THIN GO	ACTIO	VS		NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	NUI	MBER C	F FIRST	ACTIO	NS	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	% OF FILED SUBMISSIONS
					1		AP	AE	NA	WD	- SAN COLUMN 1897	TAL PERCENT	ACTION AND NOT OVERDUE	AP-	. AE	NA:	WD.	TOTAL	ACTION AND OVERDUE	OVERDUE
NEW PRODUCT	P	0	0	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0		0%
APPLICATIONS (initial submission)	S	3	3	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
	Total	3	3	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
RESUBMISSIC (maj. amend afte AE or NA)		5	0	0	0	5	2	0	0	0	2	40%	3	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%
SUPPLEMENTS	S	0	0	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
(initial submission)	Total	0	0	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
MANUFACTUR SUPPLEMEN (initial submissio	TS	26	19	0	0	7	3	0	0	0	3	43%	4	0	0	0	0	0	0	0%

FY 1998 Cohort - Oct. 1, 1997 - Sept. 30, 1998 (as of December 31, 1997)

SEST POSSIBLE COPY

ODE IV

TYP	E :	NO. SUBMITTED	PF	R or WF	UN	NO. FILED	NUM		F FIRST	ACTION	vs		NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	NUM		F FIRST		NS	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	% OF FILED SUBMISSIONS
							AP	AE	NA	WD		TAL PERCENT	ACTION AND NOT OVERDUE	ΑP	AE	, NA	WD.	TOTAL	ACTION AND OVERDUE	OVERDUE
NEW PRODUCT	P	3	3	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
APPLICATIONS (Initial submission)	s	4	2	0	0	2	0	0	0	0	0	0%	2	0	0	0	0	0	0	0%
(Total	7	5	0	0	2	0	0	0	0	0	0%	2	0	0	0	0	0	0	0%
RESUBMISSIC (maj. amend afte AE or NA)		0	0	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
EFFECTIVENESS	Р	0	0	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
SUPPLEMENTS	s	9	3	1	0	5	0	0	0	0	0	0%	5	0	0	0	0	0	0	0%
(initial submission)	Total	9	3	1	0	5	0	0	0	0	0	0%	5	0	0	0	0	0	0	0%
MANUFACTUR SUPPLEMEN (initial submissio	TS	60	39	0	0	21	5	0	0	0	5	24%	16	0	0	0	0	0	0	0%

FY 1998 Cohort - Oct. 1, 1997 - Sept. 30, 1998 (as of December 31, 1997)

CEST POSSIBLE COPY

TYF	PE N	NO. SUBMITTED	PF	RF or WF	UN	NO. FILED	NUI	MBER O Wi	F FIRST	CACTION DAL	NS		NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	NUI		F FIRST	r actio	NS	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	% OF FILED SUBMISSIONS
	· · · · · · · · · · · · · · · · · · ·						AP.	ΑE	NA	WD	27,000,000,000,000	TAL PERCENT	ACTION AND NOT OVERDUE	AР	AE ,	, NA	. WD	TOTAL	ACTION AND OVERDUE	OVERDUE
NEW PRODUCT	Р	0	0	0	0	0	0	0	0	0	0	0%	0	0	0	. 0	0	0	0	0%
APPLICATIONS (initial submission)	S	1	0	0	0	1	0	0	0	0	0	0%	1	0	0	0	0	0	0	0%
(Total	1	0	0	0	1	0	0	0	0	0	0%	1	0	0	0	0	0	0	0%
RESUBMISSIO (maj. amend aft AE or NA)		0	0	0	0	0	.0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
EFFECTIVENESS	Р	0	0	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
SUPPLEMENTS	S	4	2	1	0	1	0	0	0	0	0	0%	1	0	0	0	0	0	0	0%
(initial submission)	Total	4	2	1	0	1	0	0	0	0	0	0%	1	0	0	0	0	0	0	0%
MANUFACTUF SUPPLEMEN (initial submission	ITS	22	14	0	0	8	4	0	0	0	4	50%	4	0	0	0	0	0	0	0%

FY 1998 Cohort - Oct. 1, 1997 - Sept. 30, 1998 (as of December 31, 1997)

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ТҮР	- (4) E	NO. SUBMITTED	PF	RF or WF	UN	NO. FILED	NUI	MBER C WI	THIN GO				NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	NUI	MBER C	F FIRST		vs .	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	% OF FILED SUBMISSIONS
ands.	2 1 en 43						AP	AE	NA	WD		TAL PERCENT		AP	AE	NA ,	WD	TOTAL	ACTION AND OVERDUE	OVERDUE
NEW PRODUCT	P	0	0	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
APPLICATIONS (initial submission)	s	2	2	0	0	0	0	0	0	0	0	0%	0	0	0	0	o	0	0	0%
	Total	2	2	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
RESUBMISSIC (maj. amend afte AE or NA)		0	0	0	0	0	0	0	0	0	0	0%	o	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%
SUPPLEMENTS (initial submission)	s	1	1	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
	Total	1	1	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
MANUFACTUR SUPPLEMEN (initial submission	TS	14	11	0	0	3	1	0	0	0	1	33%	2	0	0	0	0	0	0	0%

FY 1998 Cohort - Oct. 1, 1997 - Sept. 30, 1998 (as of December 31, 1997)

BEST POSSIBLE COPY

TYP	E	NO. SUBMITTED	PF	R or WF	UN	NO. FILED	NÜI	MBER C WI	THIN GO		NS		NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST			F FIRST	ACTIO	NS	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	% OF FILED
							AP:	AE	NA.	WD		TAL PERCENT	ACTION AND NOT OVERDUE	AP	AE	NA .	WD	TOTAL	ACTION AND OVERDUE	OVERDUE
NEW PRODUCT	Р	3	3	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
APPLICATIONS (initial submission)	S	1	0	0	0	1	0	0	0	0	0	0%	1	0	0	0	0	0	0	0%
	Total	4	3	0	0	1	0	0	0	0	0	0%	1	0	0	0	0	0	0	0%
RESUBMISSIC (maj. amend afte AE or NA)		0	0	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
EFFECTIVENESS	Р	0	0	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
SUPPLEMENTS	S	4	0	0	. 0	4	0	0	0	0	0	0%	4	0	0	0	0	0	0	0%
(initial submi ssion)	Total	4	0	0	0	4	0	0	0	0	0	0%	4	0	0	0	0	0	0	0%
MANUFACTUR SUPPLEMEN (initial submission	TS	24	14	0	0	10	0	0	0	0	0	0%	10	0	0	0	0	0	0	0%

FY 1998 Cohort - Oct. 1, 1997 - Sept. 30, 1998 (as of December 31, 1997)

BEST POSSIBLE COPY

ТҮР	E	NO. SUBMITTED	PF	R or WF	אַע	NO, FILED	NUI	MBER C WI	F FIRST	TACTIOI DAL	NS		NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	NUI		OF FIRST OVERDU		NS	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	% OF FILED
							AP	AE	. NA	WD	************************	TAL PERCENT	ACTION AND NOT OVERDUE	AΡ	AE	NA .	WD	TOTAL	ACTION AND OVERDUE	SUBMISSION
NEW PRODUCT	Р —	3	3	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	09
APPLICATIONS (initial submission)	s 	1	0	0	0	1	0	0	0	0	0	0%	1	0	0	0	0	0	0	09
	Total	4	3	0	0	1	0	0	0	0	0	0%	1	0	0	0	0	0	0	0%
RESUBMISSIC (maj. amend afte AE or NA)		0	0	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
EFFECTIVENESS	Р	0	0	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
SUPPLEMENTS (initial submission)	S	4	0	0	0	4	0	0	0	0	0	0%	4	0	0	0	0	0	0	09
(initial southission)	Total	4	0	0	0	4	0	0	0	0	0	0%	4	0	0	0	0	0	0	0%
MANUFACTUR SUPPLEMEN (initial submission	rs	24	14	0	0	10	0	0	0	0	0	0%	10	0	0	0	0	0	0	0%

FY 1998 Cohort - Oct. 1, 1997 - Sept. 30, 1998 (as of December 31, 1997)

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ODE V

TYP	E	NO. SUBMITTED	PF	R orWF	UN	NO. FILED	NU		F FIRST THIN GO	ACTION	18		NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	NUM		F FIRST	FACTION DE	NS	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	% OF FILED
							AP	AE:	NA	WD	1,750 July 1,460 Lindbla.	TAL PERCENT	ACTION AND NOT OVERDUE	AP	, AE,	NA 🔅	. WD:	, TOTAL	ACTION AND OVERDUE	OVERDUE
NEW PRODUCT	P	0	0	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
APPLICATIONS (initial submission)	s	7	6	0	1	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
	Total	7	6	0	1	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
RESUBMISSIC (maj. amend afte AE or NA)		6	0	0	0	6	2	0	0	0	2	33%	4	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%
SUPPLEMENTS (initial submission)	S	1	1	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
(minai submission)	Total	1	1	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
MANUFACTUR SUPPLEMEN' (initial submission	rs	67	54	0	0	13	1	0	0	0	1	8%	12	0	0	0	0	0	0	0%

FY 1998 Cohort - Oct. 1, 1997 - Sept. 30, 1998 (as of December 31, 1997)

BEST POSSIBLE CO.

ТҮР	E .	NO. SUBMITTED	PF	RF or WF	UN	NO. FILED	NUI	MBER C	THIN GO				NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	NUA		F FIRST		NS	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	% OF FILED
, i							AP	AE	NA	WD	TO NO.	TAL PERCENT	ACTION AND NOT OVERDUE	AP	AE -	, NA	WD	TOTAL	ACTION AND OVERDUE	OVERDUE
NEW PRODUCT	P	0	0	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
APPLICATIONS (initial submission)	s	4	4	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
	Total	4	4	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
RESUBMISSIC (maj. amend afte AE or NA)		1	0	0	0	1	0	0	0	0	0	0%	1	0	0	0	0	0	0	0%
EFFECTIVENESS	Р	0	0	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
SUPPLEMENTS (initial submission)	S	0	0	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
(initial dubinisation)	Total	0	0	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
MANUFACTUR SUPPLEMEN (initial submission	TS	22	22	0	0	0.	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%

FY 1998 Cohort - Oct. 1, 1997 - Sept. 30, 1998 (as of December 31, 1997)

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ТҮР	:.i E .	NO. SUBMITTED	PF	RF or WF	UN	NO. FILED	NU	MBER O Wi	F FIRST THIN GO	ACTION DAL	18		NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	NUI	MBER O	F FIRST	ACTIO	vs	NUMBER OF FILED SUBMISSIONS	% OF FILED
<u>,</u>							ΑP	AE	NA	WD	5000 WHEN \$1500 TO	TAL PERCENT	ACTION AND	AP	AE	NA	WD	TOTAL	MITHOUT A FIRST ACTION AND OVERDUE	SUBMISSION: OVERDUE
NEW PRODUCT	P	0	0	0	. 0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
APPLICATIONS (initial submission)	S	3	2	0	1	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
	Total	3	2	0	1	0	0	0	0	0	0	0%	0	0	О	0	0	0	0	0%
RESUBMISSIC (maj. amend afte AE or NA)	17 4. 48	5	0	0	0	5	2	0	0	0	2	40%	3	0	0	0	0	0	0	0%
EFFECTIVENESS	Р	0	0	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
SUPPLEMENTS (initial submission)	S	1	1	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
	Total	1	1	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
MANUFACTUR SUPPLEMEN (initial submission	rs	30	21	0	0	9	1	0	0	0	1	11%	8	0	0	0	0	0	0	0%

FY 1998 Cohort - Oct. 1, 1997 - Sept. 30, 1998 (as of December 31, 1997)

BEST POSSIBLE CONT

TYF	E	NO. SUBMITTED	PF	RF or WF	UN	NO. FILED			F FIRST	ACTIO			NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST		MBER O	F FIRST VERDU		NS	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	% OF FILED SUBMISSIONS
							AP	AE	, NA	WD		TAL PERCENT	ACTION AND NOT OVERDUE	ΑP	AE	NA .	WD	TOTAL	ACTION AND OVERDUE	OVERDUE
NEW PRODUCT	Р	0	0	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
APPLICATIONS (initial submission)	S	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%
RESUBMISSIO	7.0	0	0	0	0	0	0	0	0	0	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%
SUPPLEMENTS (initial submission)	s	0	0	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
(Amous Scientissaion)	Total	0	0	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
MANUFACTUR SUPPLEMEN (Initial submission	тѕ	15	11	0	0	4	0	0	0	0	0	0%	4	0	0	0	0	0	0	0%

FY 1997 COHORT

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

CDER

ТҮР	E :	NO. SUBMITTED	PF	R or WF	UN	NO. FILED	NU	MBER C	F FIRS THIN GO	T ACTIC DAL)NS		NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	NUI		F FIRST	ractio Je	NS .	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	% OF FILED
jan kulu Kananan							AP	AE	ii: NA	WD		TAL PERCENT	ACTION AND NOT OVERDUE	AP	AE	NA	WD .	TOTAL	ACTION AND OVERDUE	OVERDUE
NEW PRODUCT	P	26	0	0	0	26	9	5	3	3	20	77%	6	0	0	0	0	0	0	0%
APPLICATIONS (initial submission)	S	104	0	2	6	96	21	8	4	2	35	36%	61	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%
RESUBMISSIC (maj. amend afte AE or NA)		86	0	0	0	86	58	16	3	1	78	91%	7	0	0	1	0	1	0	1%
EFFECTIVENESS	Р	11	0	0	1	10	4	1	0	1	6	60%	4	0	0	0	0	0	0	0%
SUPPLEMENTS (initial submission)	S	144	0	2	7	135	37	13	15	6	71	53%	62	0	0	0	0	0	2	1%
(muda submission)	Total	155	0	2	8	145	41	14	15	7	77	53%	66	0	0	0	0	0	2	1%
MANUFACTUR SUPPLEMENT (initial submission	rs	1268	0	5	0	1263	918	104	51	7	1080	86%	163	11	2	2	2	17	3	2%

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

ODE I

TYP	E ;	NO. SUBMITTED	PF.	RF or WF	UN	NO. FILED	NUN		F FIRST THIN GC		15		NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	NUN		F FIRST		NS	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	% OF FILED SUBMISSIONS
	-						AP	AE .	NA		TO NO.	AL PERCENT	ACTION AND NOT OVERDUE	AP:	AE	NA .	WD	TOTAL	ACTION AND OVERDUE	OVERDUE
NEW PRODUCT	Р	7	0	0	0	7	0	2	2	2	6	86%	1	0	0	0	0	0	0	0%
APPLICATIONS	S	27	0	1	0	26	2	3	1	1	7	27%	19	0	0	0	0	0	0	0%
(initial submission)	Total	34	0	1	0	33	2	5	3	3	13	39%	20	0	0	0	0	0	0	0%
RESUBMISSIC (maj. amend afte AE or NA)		31	0	0	0	31	22	6	0	0	28	90%	3	0	0	0	0	0	0	0%
EFFECTIVENESS	Р	3	0	0	0	3	1	0	0	1	2	67%	1	0	0	0	0	0	0	0%
SUPPLEMENTS	S	24	0	0	0	24	4	1	3	0	8	33%	16	0	0	0	0	0	0	0%
(initial submission)	Total	27	0	0	0	27	5	1	3	1	10	37%	17	0	0	0	0	0	0	0%
MANUFACTUF SUPPLEMEN (initial submission	TS	279	0	4	0	275	228	11	10	3	252	92%	19	3	0	1	0	4	0	1%

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

HFD-110

TYP	E	NO. SUBMITTED	PF	RF or WF	UN	NO. FILED	NUI	MBER C WI	F FIRS	ACTIO	NS	Neri in oppid	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	NUI	MBER C	F FIRST	ACTIO	NS	NUMBER OF FILED SUBMISSIONS	% OF FILED
							AΡ	AE	NA	WD		TAL PERCENT	ACTION AND	AP ·	AE *	NA:	WD	TOTAL	WITHOUT A FIRST ACTION AND OVERDUE	SUBMISSIONS OVERDUE
NEW PRODUCT	Р	3	0	0	0	3	0	1	0	1	2	67%	1	0	0	0	0	0	0	0%
APPLICATIONS (initial submission)	S	8	0	1	0	7	0	2	0	0	2	29%	5	0	0	0	0	0	0	0%
(minar submission)	Total	11	0	1	0	10	0	3	0	1	4	40%	6	0	0	0	0	0	0	0%
RESUBMISSIC (maj. amend afte AE or NA)	:	11	0	0	0	11	9	2	0	0	11	100%	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%
SUPPLEMENTS	s	4	0	0	0	4	0	1	1	0	2	50%	2	0	0	0	0	0	0	0%
(initial submission)	Total	4	0	0	0	4	0	1	1	0	2	50%	2	0	0	0	0	0	0	0%
MANUFACTUR SUPPLEMEN (initial submission	TS	130	0	1	0	129	116	4	3	0	123	95%	4	1	0	1	0	2	0	2%

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

HFD-120

TYP	E . :	NO. SUBMITTED	PF	RF or WF	UN	NO. FILED	NUi	MBER C WI	F FIRST	ACTIO	NS		NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	NUN	MBER C	F FIRST	ACTIO	NS	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	% OF FILED
							AP	AE	NA	WD	NO.	TAL PERCENT	ACTION AND NOT OVERDUE	AP	ΑE	NA :	WD	TOTAL	ACTION AND	OVERDUE
NEW PRODUCT	Р	2	0	0	0	2	0	0	1	1	2	100%	0	0	0	0	0	0	0	0%
APPLICATIONS (initial submission)	s	13	0	0	0	13	2	1	0	0	3	23%	10	0	0	0	0	0	0	0%
(made 335/m33/01)	Total	15	0	0	0	15	2	1	1	1	5	33%	10	0	0	0	0	0	0	0%
RESUBMISSIO (maj. amend afto AE or NA)		17	0	0	0	17	12	3	0	0	15	88%	2	0	0	0	0	0	0	0%
EFFECTIVENESS	Р	0	0	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
SUPPLEMENTS	S	15	0	0	0	15	4	0	2	0	6	40%	9	0	0	0	0	0	0	0%
(initial submission)	Total	15	0	0	0	15	4	0	2	0	6	40%	9	0	0	0	0	0	0	0%
MANUFACTUR SUPPLEMEN (initial submission	TS	90	0	3	0	87	70	3	4	2	79	91%	6	2	0	0	0	2	0	2%

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



TYP	E	NO. SUBMITTED	PF	RF or WF	UN	NO. FILED	NU	MBER (F FIRS	TACTIO DAL			NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	NUI	MBER C	F FIRST	FACTIO IE	NS	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	% OF FILED
							AP	AE	NA :	WD		TAL PERCENT	ACTION AND NOT OVERDUE	AP	AE	NA .	WD	TOTAL		OVERDUE
NEW PRODUCT	Р	2	0	0	0	2	0	1	1	0	2	100%	0	0	0	0	0	0	0	0%
APPLICATIONS (initial submission)	S	6	0	0	0	6	0	0	1	1	2	33%	4	0	0	0	0	0	0	0%
(Total	8	0	0	0	8	0	1	2	1	4	50%	4	0	0	0	0	0	0	0%
RESUBMISSIC (maj. amend afte AE or NA)	_	3	0	0	0	3	τ-	1	0	0	2	67%	1	0	0	0	0	0	0	0%
EFFECTIVENESS	Р	3	0	0	0	3	1	0	0	1	2	67%	1	0	0	0	0	0	0	0%
SUPPLEMENTS (initial submission)	S	5	0	0	0	5	0	0	0	0	0	0%	5	0	0	0	0	0	0	0%
(muai submission)	Total	8	0	0	0	8	1	0	0	1	2	25%	6	0	0	0	0	0	0	0%
MANUFACTUR SUPPLEMEN' (initial submission	тѕ	59	0	0	0	59	42	4	3	1	50	85%	9	0	0	0	0	0	0	0%

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

BEST POSSIBLE COPY

ODE II

TYP	E .	NO. SUBMITTED	PF	R or WF	UN	NO. FILED	NUI		F FIRST	CACTION DAL	NS	Es elega	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	NUI		F FIRST	ACTION E	vs	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	% OF FILED SUBMISSION
							AP	AE	NA			TAL PERCENT	ACTION AND NOT OVERDUE	AP*	AE	NA .		TOTAL	ACTION AND OVERDUE	OVERDUE
NEW PRODUCT	Р	6	0	0	0	6	3	0	0	1	4	67%	2	0	0	0	0	0	0	0%
APPLICATIONS (initial submission)	s	27	0	0	1	26	5	1	1	1	8	31%	18	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%
RESUBMISSIO (maj. amend afte AE or NA)		14	0	0	0	14:	9	3	0	0	12	86%	1	0	0	1	0	1	0	7%
EFFECTIVENESS	Р	1	0	0	0	1	0	0	0	0	0	0%	1	0	0	0	0	0	0	0%
SUPPLEMENTS (initial submission)	s	51	0	2	1	48	19	0	5	1	25	52%	23	0	0	0	0	0	0	0%
(initial submission)	Total	52	0	2	1	49	19	0	5	1	25	51%	24	0	0	0	0	0	0	0%
MANUFACTUR SUPPLEMEN (initial submission	TS	477	0	0	0	477	382	26	17	1	426	89%	50	0	0	0	0	0	1	0%

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

HFD-510

TYP	E	NO. SUBMITTED	PF	RF or WF	UN	NO. FILED	NUI	MBER C	F FIRST THIN GO				NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	NU	MBER (F FIRST	ACTIO	NS	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	% OF FILED SUBMISSIONS
	į						AP	AE	NA	WD	C. Chengony arcyc	TAL PERCENT	ACTION AND NOT OVERDUE	ΑP	AE	NA .	WD	TOTAL	ACTION AND OVERDUE	OVERDUE
NEW PRODUCT	Р	4	0	0	0	4	2	0	0	1	3	75%	1	0	0	0	0	0		0%
APPLICATIONS (initial submission)	s	5	0	0	0	5	1	0	0	0	1	20%	4	0	0	0	0	0	0	0%
(made substitution)	Total	9	0	0	0	9	3	0	0	1	4	44%	5	0	0	0	0	0	0	0%
RESUBMISSIC (maj. amend afte AE or NA)		5	0	0	0	5	3	0	0	0	3	60%	1	0	0	1	0	1	0	20%
EFFECTIVENESS	Р	0	0	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
SUPPLEMENTS	S	22	0	0	0	22	11	0	2	0	13	59%	9	0	0	0	0	0	0	0%
(initial submission)	Total	22	0	0	0	22	11	. 0	2	0	13	59%	9	0	0	0	0	0	0	0%
MANUFACTUR SUPPLEMEN (initial submissio	TS	283	0	0	0	283	252	9	2	0	263	93%	19	0	0	0	0	0	1	0%

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

HFD-570

BEST POSSIBLE CONT

ТҮР	E	NO. SUBMITTED	PF	RF or WF	UN	NO. FILED	NU	MBER C Wi	F FIRS THIN GO	FACTIO DAL	NS		NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	NÚI	MBER O	F FIRST	ACTIO E	NS	NUMBER OF FILED SUBMISSIONS	% OF FILED
							AP	AE	NA	WD	2.000	TAL PERCENT	ACTION AND	ΑР	AE	NA .	WD	TOTAL	MTHOUT A FIRST ACTION AND OVERDUE	SUBMISSION: OVERDUE
NEW PRODUCT	Р	1	0	0	0	1	0	0	0	0	0	0%	1	0	0	0	0	0	0	0%
APPLICATIONS (initial submission)	S	11	0	0	1	10	3	1	1	0	5	50%	5	0	0	0	0	0	0	0%
(maar susmission)	Total	12	0	0	1	11	3	1	1	0	5	45%	6	0	0	0	0	0	0	0%
RESUBMISSIC (maj. amend afte AE or NA)		4	0	0	0	4.	2	2	0	0	4	100%	0	0	0	0	0	0	0	0%
EFFECTIVENESS	Р	0	0	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
SUPPLEMENTS	s	19	0	1	0	18	7	0	3	1	11	61%	7	0	0	0	0	0	0	0%
(initial submission)	Total	19	0	1	0	18	7	0	3	1	11	61%	7	0	0	0	0	0	0	0%
MANUFACTUR SUPPLEMEN (initial submission	тѕ	64	0	0	0	64	38	15	6	0	59	92%	5	0	0	0	0	0	0	0%

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

BEST POSSIBLE COPY

CDER

TYP	E	NO. SUBMITTED	PF	R or WF	UN	NO. FILED	NUI	MBER C WI	F FIRST	CACTIO DAL			NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	i	MBER O	F FIRST	LACTIO	NS	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	% OF FILED SUBMISSIONS
							AP	ΑE	NA .	WD	·	TAL PERCENT	ACTION AND NOT OVERDUE	ΑP	AE	NA :	WD	TOTAL	ACTION AND OVERDUE	OVERDUE
NEW PRODUCT	Р	26	0	0	0	26	9	5	3	3	20	77%	6.	0	0	0	0	0	0	0%
APPLICATIONS (initial submission)	s	104	0	2	6	96	21	8	4	2	35	36%	61	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%
RESUBMISSIC (maj. amend afte AE or NA)		86	0	0	0	86	58	16	3	1	78	91%	7	0	0	1	0	1	0	1%
EFFECTIVENESS	P	11	0	0	1	10	4	1	0	1	6	60%	4	0	0	0	0	0	0	0%
SUPPLEMENTS (initial submission)	S	144	0	2	7	135	37	13	15	6	71	53%	62	0	0	0	0	0	2	1%
(muai submission)	Total	155	0	2	8	145	41	14	15	7	77	53%	66	0	0	0	0	0	2	1%
MANUFACTUR SUPPLEMENT (initial submission	гs	1268	0	5	0	1263	918	104	51	7	1080	86%	163	11	2	2	2	17	3	2%

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

BEST POSSIBLE COPY

ODE I

TYP	Έ	NO. SUBMITTED	PF	RF or WF	UN	NO. FILED	NUI	MBER C WI	F FIRST	ACTIO DAL	NS		NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	NUI	MBER C	F FIRST	ACTIO	NS	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	% OF FILED
							AP	AE	NA :	. WD √	-	TAL PERCENT	ACTION AND NOT OVERDUE	AP	AE -	NA.	WD.	TOTAL	ACTION AND OVERDUE	OVERDUE
NEW PRODUCT	P	7	0	0	0	7	0	2	2	2	6	86%	1	0	0	0	0	0	0	0%
APPLICATIONS (initial submission)	S	27	0	1	0	26	2	3	1	1	7	27%	19	О	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%
RESUBMISSIC (maj. amend after AE or NA)		31	0	0	0	31	22	6	0	0	28	90%	3	0	0	0	0	0	0	0%
EFFECTIVENESS	Р	3	0	0	0	3	1	0	0	1	2	67%	1	0	0	0	0	0	0	0%
SUPPLEMENTS (initial submission)	S	24	0	0	0	24	4	1	3	0	8	33%	16	0	0	0	0	0	0	0%
(ilidal subhission)	Total	27	0	0	0	27	5	1	3	1	10	37%	17	0	0	0	0	0	0	0%
MANUFACTUR SUPPLEMEN (initial submission	тѕ	279	0	4	0	275	228	11	10	3	252	92%	19	3	0	1	0	4	0	1%

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

BEST POSSIBLE COPY

ТҮР	E	NO. SUBMITTED	PF	RF or WF	UN	NO. FILED	NUI	MBER O WI	F FIRST THIN GO	ACTIO AL	NS		NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	NUI	MBER O	F FIRST		NS	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	% OF FILED SUBMISSIONS
							AP	. AE	NA	WD		TAL PERCENT	ACTION AND NOT OVERDUE	AP.	AE .	NA 4	WD .	TOTAL	ACTION AND OVERDUE	OVERDUE
NEW PRODUCT	P	3	0	0	0	3	0	1	0	1	2	67%	1	0	0	0	0	0	0	0%
APPLICATIONS (initial submission)	S	8	0	1	0	7	0	2	0	0	2	29%	5	0	0	0	0	0	0	0%
(#### 345)##34011	Total	11	0	1	0	10	0	3	0	1	4	40%	6	0	0	0	0	0	0	0%
RESUBMISSIC (maj. amend afte AE or NA)		11	0	0	0	11	9	2	0	0	11	100%	0	0	0	0	0	0	0	0%
EFFECTIVENESS	Р	0	0	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
SUPPLEMENTS (initial submission)	S	4	0	0	0	4	0	1	1	0	2	50%	2	0	0	0	0	0	0	0%
(initial submission)	Total	4	0	0	0	4	0	1	1	0	2	50%	2	0	0	0	0	0	0	0%
MANUFACTUR SUPPLEMEN (initial submission	тѕ	130	0	1	0	129	116	4	3	0	123	95%	4	1	0	1	0	2	0	2%

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

HFD-120

ТҮР	E	NO. SUBMITTED	PF	RF or WF	UN	NO. FILED	NUI	MBER C WI	F FIRST	CACTIO DAL	NS		NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	NU	MBER C	F FIRST	FACTION IE	NS	NUMBER OF FILED SUBMISSIONS	% OF FILED
							AP	ΑE	NA	WD		TAL PERCENT	ACTION AND NOT OVERDUE	ΑP	AE	NA.	WD	TOTAL	WITHOUT A FIRST ACTION AND OVERDUE	SUBMISSIONS OVERDUE
NEW PRODUCT	Р	2	0	0	0	2	0	0	1	1	2	100%	0	0	0	0	0	0	0	0%
APPLICATIONS (initial submission)	S	13	0	0	0	13	2	1	0	0	3	23%	10	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%
RESUBMISSIO (maj. amend afte AE or NA)		17	0	0	0	17	12	3	0	0	15	88%	2	0	0	0	0	0	0	0%
EFFECTIVENESS	Ρ	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%
(madi submission)	Total	15	0	0	0	15	4	0	2	0	6	40%	9	0	0	0	0	0	0	0%
MANUFACTUR SUPPLEMEN (initial submission	тѕ	90	0	3	0	87	70	3	4	2	79	91%	6	2	0	0	0	2	0	2%

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

HFD-150

TYP	PE .	NO. SUBMITTED	PF	RF or WF	UN	NO. FILED	NUI	MBER C WI	F FIRST	CACTION DAL	NS		NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST		MBER C	F FIRST OVERDU	FACTIOI IE	NS	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	% OF FILED
							AP	AE	NA -	WD		TAL PERCEN	ACTION AND NOT OVERDUE	APa	ΑE	NA .	WD .	TOTAL	and the second section of the section of the second section of the section of the second section of the section of th	OVERDUE
NEW PRODUCT	Р	2	0	0	0	2	0	1	1	0	2	100%	0	0		I	0	0	0	0%
APPLICATIONS (initial submission)	s	6	0	0	0	6	0	0	1	1	2	33%	4	0	0	0	0	0	0	0%
	Total	8	0	0	0	8	0	1	2	1	4	50%	4	0	0	0	0	0	0	0%
RESUBMISSIC (maj. amend afte AE or NA)		3	0	0	0	3	1	1	0	0	2	67%	1	0	0	0	0	0	0	0%
EFFECTIVENESS	Р	3	0	0	0	3	1	0	0	1	2	67%	1	0	0	0	0	0	0	0%
SUPPLEMENTS	S	5	0	0	0	5	0	0	0	0	0	0%	5	0	0	0	0	0	0	0%
(initial submission)	Total	8	0	0	0	8	1	0	0	1	2	25%	6	0	0	0	0	0	0	0%
MANUFACTUR SUPPLEMEN (initial submissio	TS	59	0	0	0	59	42	4	3	1	50	85%	9	0	0	0	0	0	0	0%

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

BEST POSSIBLE COPY

ODE II

TYP	PE ,	NO, SUBMITTED	PF	R or WF	UN	NO. FILED	NUI		F FIRST				NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	NUA		F FIRST VERDU		NS	NUMBER OF FILED SUBMISSIONS	% OF FILED
	·						AP	AE	NA	WD	NO.	TAL PERCENT	ACTION AND NOT OVERDUE	ΑP	AE	NA.	WD.	TOTAL	MITHOUT A FIRST ACTION AND OVERDUE	SUBMISSIONS OVERDUE
NEW PRODUCT	Р	6	0	0	0	6	3	0	0	1	4	67%	2	0	0	0	0	0	0	0%
APPLICATIONS (initial submission)	S	27	0	0	1	26	5	1	1	1	8	31%	18	0	0	0	0	0	0	0%
(andar submission)	Total	33	0	0	1	32	8	1	1	2	12	38%	20	0	0	0	0	0	0	0%
RESUBMISSI((maj. amend afte AE or NA)		14	0	0	0	14	9	3	0	0	12	86%	1	0	0	1	0	1	0	7%
EFFECTIVENESS	Р	1	0	0	0	1	0	0	0	0	0	0%	1	0	0	0	0	0	0	0%
SUPPLEMENTS	s	51	0	2	1	48	19	0	5	1	25	52%	23	0	0	0	0	0	0	0%
(initial submission)	Total	52	0	2	1	49	19	0	5	1	25	51%	24	0	0	0	0	0	0	0%
MANUFACTUR SUPPLEMEN (initial submission	тѕ	477	0	0	0	477	382	26	17	1	426	89%	50	0	0	0	0	0	1	0%

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

BEST POSSIBLE COPT

TYP	E	NO. SUBMITTED	PF	RF or WF	UN	NO. FILED	NUI		F FIRST THIN GO		NS		NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	NUN		F FIRST	ACTIO	NS	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	% OF FILED SUBMISSIONS
					5 4 4		AP	AE	NA	WD	COLORS SAN CONT.	TAL PERCENT	ACTION AND NOT OVERDUE	AP	AE	NA .	WD	TOTAL	ACTION AND OVERDUE	OVERDUE
NEW PRODUCT	Р	4	0	0	0	4	2	0	0	1	3	75%	1	0	0	0	0	0	0	0%
APPLICATIONS (initial submission)	s	5	0	0	0	5	1	0	0	0	1	20%	4	0	0	0	0	0	0	0%
(mada submission)	Total	9	0	0	0	9	3	0	0	1	4	44%	5.	0	0	0	0	0	0	0%
RESUBMISSIO (maj. amend afte AE or NA)		5	0	0	0	5	3	0	0	0	3	60%	1	0	0	1	0	1	0	20%
EFFECTIVENESS	Р	0	0	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
SUPPLEMENTS	s	22	0	0	0	22	11	0	2	0	13	59%	9	0	0	0	0	0	0	0%
(initial submission)	Total	22	0	0	0	22	11	0	2	0	13	59%	9	0	0	0	0	0	0	0%
MANUFACTUR SUPPLEMEN (initial submission	TS .	283	0	0	0	283	252	9	2	0	263	93%	19	0	0	0	0	0	1	0%

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

HFD-570

TYP	Ε	NO. SUBMITTED	PF	RF or WF	UN	NO. FILED	NU	MBER C WI	F FIRS THIN G	FACTIO DAL	NS		NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	NU	MBER C	F FIRST	r actioi IE	NS	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	% OF FILED
							AΡ	AE	NA .	WD		TAL PERCENT	ACTION AND NOT OVERDUE	AP	ΑE	NA.	, WD	TOTAL	ACTION AND OVERDUE	SUBMISSIONS OVERDUE
NEW PRODUCT	P	1	0	0	0	1	0	0	0	0	0	0%	1	0	0		0	0	0	0%
APPLICATIONS (initial submission)	S	11	0	0	1	10	3	1	1	0	5	50%	5	0	0	0	0	0	0	0%
(minual submission)	Total	12	0	0	1	11	3	1	1	0	5	45%	6	0	0	0	0	0	0	0%
RESUBMISSIC (maj. amend afte AE or NA)		4	0	0	0	4	2	2	0	0	4	100%	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%
SUPPLEMENTS	S	19	0	1	0	18	7	0	3	1	11	61%	7	0	0	0	0	0	0	0%
(initial submission)	Total	19	0	1	0	18	7	0	3	1	11	61%	7	0	0	0	0	0	0	0%
MANUFACTUR SUPPLEMEN (initial submission	TS	64	0	0	0	64	38	15	6	0	59	92%	5	0	0	0	0	0	0	0%

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

BEST POSSIBLE COPY

TYP		NO. SUBMITTED	PF	RF or WF	UN	NO. FILED	NUI	MBER C WI	F FIRST	CACTIO DAL	NS		NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	NU		OF FIRS	T ACTIO	NS	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	% OF FILED SUBMISSIONS
	1		**************************************				АР	ΑE	NA	WD	000000000000000000000000000000000000000	TAL PERCENT	ACTION AND NOT OVERDUE	AP	AE	- NA	WD	TOTAL	ACTION AND OVERDUE	OVERDUE
NEW PRODUCT	Р	1	0	0	0	1	1	0	0	0	1	100%	0	0	0	0	0	0	0	0%
APPLICATIONS	S	11	0	0	0	11	1	0	0	1	2	18%	9	0	0	0	0	0	0	0%
(initial submission)	Total	12	0	0	0	12	2	0	0	1	3	25%	9	0	0	0	0	0	0	0%
RESUBMISSION (maj. amend afte		5	0	0	0	5	4	1	0	0	5	100%	0	0	0	0	0	0	0	0%
EFFECTIVENESS	P	1	0	0	0	1	0	0	0	0	0	0%	1	0	0	0	0	0	0	0%
SUPPLEMENTS	S	10	0	1	1	8	1	0	0	0	1	13%	7	0	0	0	0	0	0	0%
(initial submission)	Total	11	0	1	1	9	1	0	0	0	1	11%	8	0	0	0	0	0	0	0%
MANUFACTUR SUPPLEMEN (initial submissio	TS	130	0	0	0	130	92	2	9	1	104	80%	26	0	0	0	0	0	0	0%

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

ODE III

BEST POSSIBLE OF

TYF	PΕ	NO. SUBMITTED	PF	R or WF	UN	NO. FILED	NU		F FIRS	CACTIO DAL	NS		NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	NUI		F FIRST		NS	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	% OF FILED
						and the second	AP.	AE	NA	.WD	100 100 2000	TAL PERCENT	ACTION AND	AP	AE	NA .	WD.	TOTAL	ACTION AND OVERDUE	SUBMISSIONS OVERDUE
NEW PRODUCT	P	4	0	0	0	4	0	2	0	0	2	50%	2	0	0	0	0	0	0	0%
APPLICATIONS (initial submission)	S	10	0	0	1	9	2	1	1	0	4	44%	5	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%
RESUBMISSIO (maj. amend aft AE or NA)	-	16	0	0	0	16	11	2	2	0	15	94%	1	0	0	0	0	0	0	0%
EFFECTIVENESS	Р	1	0	0	0	1	0	1	0	0	1	100%	0	0	0	0	0	0	0	0%
SUPPLEMENTS	s	20	0	0	3	17	1	2	3	1	7	41%	8	0	0	0	0	0	2	12%
(initial submission)	Total	21	0	0	3	18	1	3	3	1	8	44%	8	0	0	0	0	0	2	11%
MANUFACTUR SUPPLEMEN (initial submission	тѕ	124	0	1	0	123	73	15	9	1	98	80%	15	4	1	1	2	8	2	8%

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

HFD-160

TYP	E	NO. SUBMITTED	PF	RF or WF	UN	NO. FILED	NU	MBER C WI	F FIRST	T ACTIOI DAL	NS		NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	NUI		F FIRST	LACTIO	NS	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	% OF FILED SUBMISSIONS
							AP	AE	NA	WD		TAL PERCENT	ACTION AND NOT OVERDUE	AP	AE	. NA	WD	TOTAL	ACTION AND OVERDUE	OVERDUE
NEW PRODUCT	P	1	0	0	0	1	0	0	0	0	0	0%	1	0	0	0	0	0	0	0%
APPLICATIONS (initial submission)	s	3	0	0	1	2	2	0	0	0	2	100%	0	0	0	0	0	0	0	0%
(maas submission)	Total	4	0	0	1	3	2	0	0	0	2	67%	1	0	0	0	0	0	0	0%
RESUBMISSIC (maj. amend afte AE or NA)		4	0	0	0	4	3	1	0	0	4	100%	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%
SUPPLEMENTS	S	2	0	0	0	2	1	0	1	0	2	100%	0	0	0	0	0	0	0	0%
(initial submission)	Total	2	0	0	0	2	1	0	1	0	2	100%	0	0	0	0	0	0	0	0%
MANUFACTUR SUPPLEMEN (initial submission	TS	24	0	0	0	24	20	3	0	0	23	96%	1.	0	0	0	0	0	0	0%

CDER FIRST ACTION PERFORMANCE FOR APPLICATIONS
FY 1997 Cohort - Oct. 1, 1996 - Sent. 30, 1997

(as of December 31, 1997)

TYF	PΕ	NO. SUBMITTED	PF	RF or WF	UN	NO. FILED	NU	MBER C	F FIRST	TACTIO DAL	NS		NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	NUN		F FIRST		NS	NUMBER OF FILED SUBMISSIONS	% OF FILED
							AP	AE	NA .	WD		TAL PERCENT	ACTION AND	AP	AE !	NA ,	WD	TOTAL	WITHOUT A FIRST ACTION AND OVERDUE	SUBMISSION OVERDUE
NEW PRODUCT	Р	0	0	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
APPLICATIONS (initial submission)	s 	2	0	0	0	2	0	0	1	0	1	50%	1	0	0	0	0	0	0	09
	Total	2	0	0	0	2	0	0	1	0	1	50%	1	0	0	0	0	0	0	0%
RESUBMISSIO (maj. amend afte AE or NA)		0	0	0	0	0	0	0	0	0	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%
SUPPLEMENTS (initial submission)	s	8	0	0	2	6	0	0	0	0	0	0%	4	0	0	0	0	0	2	33%
(initial submission)	Total	8	0	0	2	6	0	0	0	0	0	0%	4	0	0	0	0	0	2	33%
MANUFACTUR SUPPLEMEN (initial submission	TS :	36	0	0	0	36	17	0	5	0	22	61%	5	4	0	1	2	7	2	25%

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

BEST POSSIBLE CONT

TYP	E	NO. SUBMITTED	PF	RF or WF	UN	NO. FILED	NU	MBER C	F FIRST	ACTION DAL	NS		NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	NUI		F FIRST	ACTION E	vs	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	% OF FILED
	:	a yang Malika. Pagahara					AP	AE	NA NA	WD	A 20 20 20 90 00 00 00 00 00 00 00 00 00 00 00 00	TAL PERCENT	ACTION AND NOT OVERDUE	AP	AE	NA .	WD	TOTAL		OVERDUE
NEW PRODUCT	P	3	0	0	0	3	0	2	0	0	2	67%	1	0	0	0	0	0	0	0%
APPLICATIONS (initial submission)	S .	5	0	0	0	5	0	1	0	0	1	20%	4	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%
RESUBMISSIO (maj. amend afte AE or NA)		12	0	0	0	12	8	1	2	0	11	92%	1	0	0		0	0	0	0%
EFFECTIVENESS	Р	1	0	0	0	1	0	1	0	0	1	100%	0	0	0	0	0	0	0	0%
SUPPLEMENTS (initial submission)	S	10	0	0	1	9	0	2	2	1	5	56%	4	0	0	0	0	0	0	0%
(initial Scottission)	Total	11	0	0	1	10	0	3	2	1	6	60%	4	0	0	0	0	0	0	0%
MANUFACTUR SUPPLEMEN (initial submission	тѕ	64	0	1	0	63	36	12	4	1	53	84%	9	0	1	0	0	1	0	2%

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

ODE IV

TYP	E	NO. SUBMITTED	PF	R or WF	UN	NO FILED	NU	MBER C	F FIRST	ACTIO DAL	NS		NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	NUN	ABER C	F FIRST VERDU	ACTION	NS	NUMBER OF FILED SUBMISSIONS	% OF FILED
							AP	AE	NA *	WD		TAL PERCENT	ACTION AND NOT OVERDUE	AP	AE	NA ·	WD	TOTAL	WITHOUT A FIRST ACTION AND OVERDUE	SUBMISSION: OVERDUE
NEW PRODUCT	Р	8	0	0	0	8	6	0	1	0	7	88%	1	0	0	0	0	0	0	0%
APPLICATIONS (initial submission)	S	20	0	1	2	17	8	0	0	0	8	47%	9	0	0	0	0	0	0	0%
,	Total	28	0	1	2	25	14	0	1	0	15	60%	10	0	0	0	0	0	0	0%
RESUBMISSIC (maj. amend afte AE or NA)		3	0	0	0	3	2	0	0	1	3	100%	0	0	0	0	0	0	0	0%
EFFECTIVENESS	Φ	6	0	0	1	5	3	0	0	0	3	60%	2	0	0	0	0	0	0	0%
SUPPLEMENTS (initial submission)	\$ 	32	0	0	2	30	11	4	3	3	21	70%	9	0	0	0	0	0	0	0%
(muai suomassion)	Total	38	0	0	3	35	14	4	3	3	24	69%	11	0	0	0	0	0	0	0%
MANUFACTURI SUPPLEMENT (initial submission	rs	120	0	0	0	120	88	2	7	0	97	81%	23	0	0	0	0	0	0	0%

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

HFD-520

TYP	E	NO. SUBMITTED	PF	RF or WF	UN	NO. FILED	NUI	MBER O WI	F FIRS THIN G	T ACTIO	NS		NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	NUI	MBER C	F FIRS	LACTIO JE	NS	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	% OF FILED
							AP	AE	NA	WD	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	TAL PERCENT	ACTION AND NOT OVERDUE	AP .	AE	NA .	WD.,	TOTAL	ACTION AND OVERDUE	OVERDUE
NEW PRODUCT	Р	2	0	0	0	2	1	0	0	0	1	50%	1	0	0	0	0	0	0	0%
APPLICATIONS (initial submission)	S	9	0	0	1	8	3	0	0	0	3	38%	5	0	0	0	0	0	0	0%
	Total	11	0	0	1	10	4	0	0	0	4	40%	6	0	0	0	0	0	0	0%
RESUBMISSIO (maj. amend afte AE or NA)		0	0	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
EFFECTIVENESS	Р	0	0	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
SUPPLEMENTS (initial submission)	s 	14	0	0	0	14	4	4	2	1	11	79%	3	0	0	0	0	0	0	0%
,	Total	14	0	0	0	14	4	4	2	1	11	79%	3	0	0	0	0	0	0	0%
MANUFACTUR SUPPLEMEN' (initial submission	rs	50	0	0	0	50	39	2	•5	0	46	92%	4	0	0	0	0	0	0	0%

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

HFD-530

TYP	E	NO. SUBMITTED	PF	RF or WF	UN	NO. FILED	NU	MBER C	OF FIRST	T ACTIO DAL	NS		NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	NUI	MBER (F FIRST	ACTIO	NS	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	% OF FILED
	· · · · · ·						AP	AE	NA .	WD	11 Mars 17 5 C	TAL PERCENT	ACTION AND NOT OVERDUE	AP	ΑE	NA	WD	TOTAL	ACTION AND OVERDUE	SUBMISSION: OVERDUE
NEW PRODUCT	P	5	0	0	0	5	4	0	1	0	5	100%	0	0	0	0	0	4.40000-6-5	0	0%
APPLICATIONS (initial submission)	S	1	0	0	0	1	0	0	0	0	0	0%	1	0	0	0	0	0	0	0%
(**************************************	Total	6	0	0	0	6	4	0	1	0	5	83%	1	0	0	0	0	0	0	0%
RESUBMISSIO		0	0	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
EFFECTIVENESS	Р	4	0	0	0	4	3	0	0	0	3	75%	1	0	0	0	0	0	0	0%
SUPPLEMENTS (initial submission)	s	10	0	0	1	9	3	0	1	1	5	56%	4	0	0	0	0	0	0	0%
(**************************************	Total	14	0	0	1	13	6	0	1	1	8	62%	5	0	0	0	0	0	0	0%
MANUFACTUR SUPPLEMEN	тѕ	45	0	0	0	45	33	0	0	0	33	73%	12	0	0	0	0	0	0	0%

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

HFD-590

ТҮР	E	NO. SUBMITTED	PF	R or WF	UN	NO. FILED	NU	MBER C	F FIRST	TACTIO DAL	NS		NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST		MBER C	F FIRST	r actio JE	NS	NUMBER OF FILED SUBMISSIONS	% OF FILED
							. AP	AE	NA #	WD	-	PERCENT	ACTION AND	AP	ΑE	NA	WD	TOTAL	WITHOUT A FIRST ACTION AND OVERDUE	SUBMISSION
NEW PRODUCT	Р	1	0	0	0	1	1	0	0	0	1	100%	0	0	0	0	0	0	0	09
APPLICATIONS (initial submission)	S	10	0	1	1	8	5	0	0	0	5	63%	3	0	0	0	0	0	0	09
,	Total	11	0	1	1	9	6	0	0	0	6	67%	3	0	0	0	0	0	0	0%
RESUBMISSIC (maj. amend afte AE or NA)	- 1	3	0	0	0	3	2	0	0	1	3	100%	0.	0	0	0	0	0	0	0%
EFFECTIVENESS	P	2	0	0	1	1	0	0	0	0	0	0%	1	0	0	0	0	0	0	0%
SUPPLEMENTS (initial submission)	s 	8	0	0	1	7	4	0	0	1	5	71%	2	0	0	0	0	0	0	0%
(**************************************	Total	10	0	0	2	8	4	0	0	1	5	71%	3	0	0	0	0	0	0	0%
MANUFACTURI SUPPLEMENT (initial submission	rs	25	0	0	0	25	16	0	2	0	18	72%	7	0	0	0	0	0	0	0%

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

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TYP	E	NO. SUBMITTED	PF	R or WF	UN	NO. FILED	ŅUI	MBER C WI	F FIRST	ACTIO	NS		NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	NUI		F FIRST	FACTIO	NS	NUMBER OF FILED SUBMISSIONS	% OF FILED
							AP	AE	NA	WD	1000000	TAL PERCENT	ACTION AND NOT OVERDUE	AΡ	AE	NA	WD	TOTAL	WITHOUT A FIRST ACTION AND OVERDUE	SUBMISSION
NEW PRODUCT	Р	1	0	0	0	1	0	1	0	0	1	100%	0	0	0	0	0	0	0	0%
APPLICATIONS (initial submission)	S	20	0	0	2	18	4	3	1	0	8	44%	10	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%
RESUBMISSIO (maj. amend afte AE or NA)		22	0	0	0	22	14	5	1	0	20	91%	2	0	0	0	0	0	0	0%
EFFECTIVENESS	Р	0	0	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
SUPPLEMENTS (initial submission)	S	17	0	0	1	16	2	6	1	1	10	63%	6	0	0	0	0	0	0	0%
(midal submission)	Total	17	0	0	1	16	2	6	1	1	10	63%	6	0	0	0	0	0	0	0%
MANUFACTUR SUPPLEMEN' (initial submission	rs	268	0	0	0	268	147	50	8	2	207	77%	56	4	1	0	0	5	0	2%

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

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TYP	E	NO. SUBMITTED	PF	RF or WF	UN	NO. FILED	NU	MBER C	F FIRST	CACTIO DAL	NS		NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	NUI	MBER C	F FIRST OVERDU	ACTIOI E	VS	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	% OF FILED
							AP	AE	NA	WD		PERCENT	ACTION AND NOT OVERDUE	AP	AE.	NA **	:WD	TOTAL	ACTION AND OVERDUE	SUBMISSION OVERDUE
NEW PRODUCT	Р —	1	0	0	0	1	0	1	0	0	1	100%	0	0	0	0	0	0	0	0%
APPLICATIONS (initial submission)	\$	10	0	0	1	9	4	1	0	0	5	56%	4	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%
RESUBMISSIO (maj. amend afte AE or NA)		5	0	0	0	5	4	0	1	0	5	100%	0	0	0	0	0	0	0	0%
EFFECTIVENESS	Р	0	0	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
SUPPLEMENTS	s	8	0	0	1	7	1	3	1	0	5	71%	2	0	0	0	0	0	0	0%
(initial submission)	Total	8	0	0	1	7	1	3	1	0	5	71%	2	0	0	0	0	0	0	0%
MANUFACTUR SUPPLEMEN* (initial submission	rs	63	0	0	0	63	46	1	2	1	50	79%	11	1	1	0	0	2	0	3%

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

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TYF	PΕ	NO. SUBMITTED	.PF	RF. or WF	UN	NO FILED	NU	MBER C WI	F FIRS THIN G	T ACTIO	NS		NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	NUI	MBER O	F FIRST	ACTION	NS	NUMBER OF FILED SUBMISSIONS	% OF FILED
							AP	AE	NA	WD	A	PERCENT	ACTION AND NOT OVERDUE	AP	ΑĒ	I NA	WD	TOTAL	MTHOUT A FIRST ACTION AND OVERDUE	SUBMISSION OVERDUE
NEW PRODUCT	Р	0	0	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
APPLICATIONS (initial submission)	S	10	0	0	1	9	0	2	1	0	3	33%	6	0	0	0	0	0	0	0%
(maai submission)	Total	10	0	0	1	9	0	2	1	0	3	33%	6	0	0	0	0	0	0	09
RESUBMISSIC (ma), amend afte AE or NA)		11	0	0	0	11	5	4	0	0	9	82%	2	0	0	0	0	0	0	0%
EFFECTIVENESS	Р	0	0	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
SUPPLEMENTS	S	3	0	0	0	3	0	0	0	1	1	33%	2	0	0	0	0	0	0	
(initial submission)	Total	3	0	0	0	3	0	0	0	1	1	33%	2	0	0	0	0	0	0	0%
MANUFACTUR SUPPLEMEN* (initial submission	rs	158	0	0	0	158	81	38	4	0	123	78%	34	1	0	0	0	1	0	1%

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

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TYP	E	NO. SUBMITTED	PF	RF or WF	UN	NO. FILED	NU		F FIRS THIN G	T ACTIO OAL	NS		NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	NU		F FIRS	FACTION	vs	NUMBER OF FILED SUBMISSIONS	% OF FILED
							AP*	AE	NA .	WD	Same College	TAL PERCENT	ACTION AND	AP	AE	NA .	WD	TOTAL	WITHOUT A FIRST ACTION AND OVERDUE	SUBMISSION
NEW PRODUCT	P	0	0	0	0	0	0	0	0	0	0	0%	0	0		0	0	0	0	0%
APPLICATIONS (initial submission)	S	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%
RESUBMISSIC (maj. amend afte AE or NA)	_	6	0	0	0	6	5	1	0	0	6	100%	0.	0	0	0	0	0	0	0%
EFFECTIVENESS	Р	0	0	0	0	0	0	0	0	0	0	0%	0	0	0	0	0	0	0	0%
SUPPLEMENTS	s	6	0	0	0	6	1	3	0	0	4	67%	2	0	0	0	0	0	0	0%
(initial submission)	Total	6	0	0	0	6	1	3	0	0	4	67%	2	0	0	0	0	0	0	0%
MANUFACTUR SUPPLEMEN (initial submission	rs	47	0	0	0	47	20	11	2	1	34	72%	11	2	0	0	0	2	0	4%

FY 1996 COHORT

FY 1996 Cohort - Oct. 1, 1995 - Sept. 30, 1996 (as of December 31, 1997)

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TYPE	NO. SUBMITTED	RF, UN, or WF	NO. FILED	NUI	MBER C Wi	F FIRS	T ACTIO	ONS	NU	MBER C	OF FIRS	T ACTIC		SUBMISSIONS	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	% OF FILED SUBMISSIONS
				AP	AE	NA	WD	TOTAL	AΡ	AE		WD	TOTAL		ACTION AND OVERDUE	OVERDUE
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%

- 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.

FY 1996 Cohort - Oct. 1, 1995 - Sept. 30, 1996 (as of December 31, 1997)

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TYPE	NO. SUBMITTED	RE, UN, or WE	NO. FILED	NUN		F FIRS /ITHIN C		ONS	NU		OF FIRS)NS	SUBMISSIONS	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	% OF FILED
				AP	AE	NA	Š	TOTAL	AΡ	AE	NA.	WD	TOTAL	ACTION AND	ACTION AND OVERDUE	OVERDUE
NEW PRODUCT APPLICATIONS (initial submission)	35	3	32	8	20	4	0	32	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%
EFFECTIVENESS SUPPLEMENTS (initial submission)	17	2	15	3	7	4	1	15	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%

- 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.

FY 1996 Cohort - Oct. 1, 1995 - Sept. 30, 1996 (as of December 31, 1997)

HFD-110

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TYPE	NO. SUBMITTED	RF, UN, or WF	NO. FILED	NU	MBER (VITHIN (ONS	NUI		OF FIRS		ONS	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	SUBMISSIONS	% OF FILED SUBMISSIONS
				AP	ΑĘ	, NA	WD:	TOTAL	AP .	ΑE		WD	TOTAL	ACTION AND	ACTION AND OVERDUE	OVERDUE
NEW PRODUCT													-	NOT OVERDOE	OVERBOE	
APPLICATIONS (initial submission)	9	0	9	2	5	2	0	9	0	0	0	0	o	О	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%

- 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.

FY 1996 Cohort - Oct. 1, 1995 - Sept. 30, 1996 (as of December 31, 1997)

HFD-120

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								. –								
TYPE	NO. SUBMITTED	RF, UN, or WF	NO. FILED			ITHIN G	OAL	ons	NUI	MBER (OF FIRS	T ACTIC	ns	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	% OF FILED SUBMISSION
	* 1 14 14 14 14 14 14 14 14 14 14 14 14 1			AP	AE:	NA .	WD*	TOTAL	ΑP	AE	NA:	WD	TOTAL	ACTION AND NOT OVERDUE	ACTION AND OVERDUE	OVERDUE
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%

- 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.

FY 1996 Cohort - Oct. 1, 1995 - Sept. 30, 1996 (as of December 31, 1997)

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HFD-150

																
TYPE	NO. SUBMITTED	RF, UN, or WF	NO. FILED	NU	MBER C WI	F FIRS THIN GO	T ACTIC DAL	NS	וטא	MBER O	F FIRS)NS	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	% OF FILE
NEW PROPILE				AP	AE	NA .	WD	TOTAL	AP.	AE	NA	WDi	TOTAL		ACTION AND OVERDUE	SUBMISSION OVERDUE
NEW PRODUCT APPLICATIONS (initial submission)	10	2	8	6	1	1	0	8	0	0	0	0	0	0	0	09
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	09
MANUFACTURING SUPPLEMENTS (initial submission)	31	0	31	26	1	3	0	30	1	0	0	0	1	0	0	39

- 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.

FY 1996 Cohort - Oct. 1, 1995 - Sept. 30, 1996 (as of December 31, 1997)

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ODE II

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TYPE	NO. SUBMITTED	RF, UN, or WF	NO. FILED	NU	MBER C WI	OF FIRS THIN G	T ACTIO	NS	NUI		F FIRS)NS	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	% OF FILED
				AP	AE	NA	. WD	TOTAL	ΑP	AE	NA	WD	TOTAL	ACTION AND NOT OVERDUE	ACTION AND OVERDUE	OVERDUE
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%

- 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.

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	NUI		OF FIRS THIN GO		ONS	NUI		OF FIRS			NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	% OF FILED
	-			AP	AE	NA	WD	TOTAL	АР	AE	NA -	WD	TOTAL	ACTION AND NOT OVERDUE	ACTION AND OVERDUE	OVERDUE
NEW PRODUCT APPLICATIONS (initial submission)	12	2	10	9	1	0	0	10	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%
EFFECTIVENESS SUPPLEMENTS (initial submission)	7	0	7	6	0	1	0	7	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	1%

- 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.

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	NUN	IBER C	F FIRST	T ACTIO DAL	NS	NUM	IBER OI	F FIRST VERDU	ACTIO E	NS	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	NUMBER OF FILED SUBMISSIONS	% OF FILED
				AP	AE	NA	WD.	TOTAL	АР	AE	NA .	WD	TOTAL		ACTION AND OVERDUE	OVERDUE
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	29

- 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.

FY 1996 Cohort - Oct. 1, 1995 - Sept. 30, 1996 (as of December 31, 1997)

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HFD-580

T,Y,PE	NO. SUBMITTED	RF, UN,	NO. FILED	NUI		OF FIRS THIN G	T ACTIC OAL)NS	NUi		F FIRST			NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	% OF FILED
				AP	AE	NA	WD	TOTAL	AP	AE	NA	WD	TO 100 TO	ACTION AND NOT OVERDUE	ACTION AND OVERDUE	OVERDUE
NEW PRODUCT APPLICATIONS (initial submission)	14	2	12	7	3	2	0	12	0	o	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%
EFFECTIVENESS SUPPLEMENTS (initial submission)	7	2	5	5	0	0	0	5	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%

- 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.

FY 1996 Cohort - Oct. 1, 1995 - Sept. 30, 1996 (as of December 31, 1997)

ODE III

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TYPE	NO. SUBMITTED	RF, UN, or WF	NO. FILED	NUI	MBER C	F FIRS THIN G		ONS	NUN	MBER C	F FIRS	FACTIO IE	NS	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	SUBMISSIONS	% OF FILED
NEW PROPUST				AP	AE	NA	WD:	TOTAL	AP	ΑE	NA .	WD	TOTAL	ACTION AND NOT OVERDUE	ACTION AND OVERDUE	SUBMISSIONS OVERDUE
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%

- 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.

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	NUI	MBER C Wi	F FIRS THIN G	T ACTIC OAL	ONS	NUI	MBER C	OF FIRS	T ACTIC	NS	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	SUBMISSIONS	% OF FILED
NEW PROPUSE				AP	AĘ "	NA .	WD	TOTAL	AP	AE	NA	WD	TOTAL	ACTION AND NOT OVERDUE	ACTION AND OVERDUE	SUBMISSION
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%

- 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.

FY 1996 Cohort - Oct. 1, 1995 - Sept. 30, 1996 (as of December 31, 1997)

HFD-170

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TYPE	NO. SUBMITTED	RF, UN, or WF	NO. FILED	NUI	UBER C WI	F FIRS THIN GO	T ACTIO)NS	NUN		F FIRS	T ACTIC	NS	SUBMISSIONS	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	% OF FILED
				AP	ΑE	NA	ŴΦ	TOTAL	ΑP	AE	NA	WD	TOTAL	ACTION AND NOT OVERDUE	ACTION AND OVERDUE	OVERDUE
NEW PRODUCT									ĺ							
APPLICATIONS (initial submission)	3	1	2	2	0	0	0	2	0	0	0	0	0	О	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%

- 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.

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	NUI	MBER C Wi	F FIRST		ONS	NUM	MBER O	F FIRST VERDU	FACTIC IE)NS	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	% OF FILED
NEW PROPUST			·	AP	AE	NA	WD	TOTAL	AP	AE	NA	WD↑	TOTAL	ACTION AND NOT OVERDUE	ACTION AND OVERDUE	OVERDUE
NEW PRODUCT APPLICATIONS (initial submission)	11	2	9	0	5	3	1	9	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%
EFFECTIVENESS SUPPLEMENTS (initial submission)	10	0	10	4	5	1	0	10	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%

- 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.

FY 1996 Cohort - Oct. 1, 1995 - Sept. 30, 1996 (as of December 31, 1997)

ODE IV

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TYPE	NO. SUBMITTED	RF, UN, or WF	NO. FILED	NUI	MBER C WI	OF FIRS THIN G	T ACTIO	ONS	NUI		F FIRS	T ACTIC JE	ONS	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	% OF FILED
				AP	AE	NA	WD	TOTAL	АР	AE	NA	WD	TOTAL	ACTION AND NOT OVERDUE	ACTION AND OVERDUE	SUBMISSIONS OVERDUE
NEW PRODUCT									***************************************		er en entre en en men deuer de	and the second of the second of				
APPLICATIONS (initial submission)	20	1	19	18	1	0	0	19	0	0	0	0	0	0	О	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	О	0	0%
MANUFACTURING																
SUPPLEMENTS (initial submission)	108	0	108	96	1	6	3	106	2	0	0	0	2	О	0	2%

- 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.

FY 1996 Cohort - Oct. 1, 1995 - Sept. 30, 1996 (as of December 31, 1997)

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HFD-520

TYPE	NO. SUBMITTED	RF, UN, or WF	NO. FILED	NUI	MBER C	F FIRS	T ACTIC DAL)NS	NUi	MBER C	F FIRS	T ACTIC	NS	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	% OF FILED SUBMISSION
MEMOROR				AP	AE .	NA	WD	TOTAL	AP	ΑĒ	NA	WD:	TOTAL	ACTION AND NOT OVERDUE	ACTION AND OVERDUE	OVERDUE
NEW PRODUCT APPLICATIONS (initial submission)	3	1	2	2	0	0	0	2	0	0	0	0	0	0	0	09
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	09
MANUFACTURING SUPPLEMENTS (initial submission)	54	0	54	43	1	6	2	52	2	0	0	0	2	0	0	4%

- 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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FY 1996 Cohort - Oct. 1, 1995 - Sept. 30, 1996 (as of December 31, 1997)

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HFD-530

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TYPE	NO. SUBMITTED	RF, UN, or WF	NO. FILED	NUI	MBER C Wi	F FIRS THIN GO	T ACTIC DAL	ONS	NUN	MBER O	F FIRS VERDL	T ACTIO JE	NS	SUBMISSIONS	NUMBER OF FILED SUBMISSIONS	% OF FILE
				AP	AE	NA .	WD,	TOTAL	AP	AE	NA	, WD	TOTAL	d	ACTION AND OVERDUE	SUBMISSION OVERDUE
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

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FY 1996 Cohort - Oct. 1, 1995 - Sept. 30, 1996 (as of December 31, 1997)

HFD-590

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TYPE	NO. SUBMITTED	RF, UN, or WF	NO. FILED	NÜ	MBER C WI	OF FIRS THIN GO	T ACTIC	DNS	NUI		F FIRS		ons	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	SUBMISSIONS	% OF FILED
				АР	AE .	NA	WD	TOTAL	ΑP	ΑE	NA	WD	TOTAL	ACTION AND NOT OVERDUE	ACTION AND OVERDUE	SUBMISSIONS OVERDUE
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%

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FY 1996 Cohort - Oct. 1, 1995 - Sept. 30, 1996 (as of December 31, 1997)

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TYPE	NO. SUBMITTED	RF, UN, or WF	NO. FILED	NUI	MBER C	F FIRS THIN GO	F ACTIO	ONS	NUI		OF FIRS		NS	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST	SUBMISSIONS	% OF FILED
				AP	AE	NA .	WD	TOTAL	ΑP	AE.	NA	WD	TOTAL	ACTION AND NOT OVERDUE	ACTION AND OVERDUE	OVERDUE
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%

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FY 1996 Cohort - Oct. 1, 1995 - Sept. 30, 1996 (as of December 31, 1997)

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HFD-540

TYPE	NO. SUBMITTED	RF, UN, or WF	NO. FILED	NUI	MBER C Wi	F FIRS THIN GO	T ACTIC DAL	ONS	NUI	MBER C	F FIRS	T ACTIO JE	NS	SUBMISSIONS	NUMBER OF FILED SUBMISSIONS WITHOUT A FIRST ACTION AND OVERDUE	% OF FILED SUBMISSIONS OVERDUE
				AP	AE	NA ;	WD	TOTAL	АР	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	09
MANUFACTURING SUPPLEMENTS (initial submission)	54	0	54	43	3	1	1	48	4	2	0	0	6	0	0	119

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FY 1996 Cohort - Oct. 1, 1995 - Sept. 30, 1996 (as of December 31, 1997)

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HFD-550

TYPE	NO. SUBMITTED	RF, UN, or WF	NO. FILED	NUI	MBER O	F FIRST	FACTIC DAL	NS	NUN	MBER O	F FIRS	T ACTIC)NS	NUMBER OF FILED NUMBER OF FILED SUBMISSIONS SUBMISSIONS WITHOUT A FIRST ACTION AND ACTION AND NOT OVERDUE OVERDUE	% OF FILED	
				AP	AE.	NA .	WD.	TOTAL	AP ,	AE	NA.	WD	TOTAL			SUBMISSIONS OVERDUE
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%

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FY 1996 Cohort - Oct. 1, 1995 - Sept. 30, 1996 (as of December 31, 1997)

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TYPE NEW PRODUCT	NO. SUBMITTED	RF, UN, or WF	NO. FILED	NUMBER OF FIRST ACTIONS WITHIN GOAL							F FIRS	T ACTIO	NS	SUBMISSIONS	NUMBER OF FILED SUBMISSIONS	% OF FILED
				AP	AE.	NA	WD .	TOTAL	AP .	AE	NA	WD	TOTAL	WITHOUT A FIRST ACTION AND NOT OVERDUE	MTHOUT A FIRST ACTION AND OVERDUE	SUBMISSIONS OVERDUE
APPLICATIONS (initial submission)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	09
RESUBMISSIONS (maj. amend after AE or NA)	8	0	8	6	2	0	0	8	0	0	0	0	0	0	0	0%
EFFECTIVENESS SUPPLEMENTS (initial submission)	5	1	4	2	2	0	0	4	0	0	0	0	0	0	0	09
MANUFACTURING SUPPLEMENTS (initial submission)	51	0	51	34	4	5	0	43	4	0	4	0	8	0	0	169

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