CENTER FOR DRUG EVALUATION AND RESEARCH

SPECIAL INTEREST TOPICS

TITLE: QUANTITATIVE REPORT (OFFICE OF GENERIC DRUGS, 9/96 THROUGH 7/97)

DATE: 10/1/97

Center for Drug Evaluation and Research - Office of Generic Drugs
Quantitative Report

ORIGINAL APPLICATIONS*

	Sep-96	Oct-96	Nov-96	Dec-96	Jan-97	Feb-97	Mar-97	Apr-97	May-97	Jun-97	Jul-97	Aug-97	TOTAL	AVG LAST 12 MOS	AVG LAST 3 MOS	AVG PRIOR YEAR
--RECEIPTS--																
TOTAL ORIGINALS	20	35	31	50	26	31	25	24	16	17	32	29	336	28	26	23
AMENDMENTS	97	136	115	116	103	125	109	114	127	111	112	108	1373	114	110	102
-MAJOR	57	81	53	63	41	59	50	54	62	44	48	45	657	55	46	54
-MINOR	40	55	62	53	52	37	38	37	45	43	38	27	527	44	36	48
-FACSIMILE**	n/a	n/a	n/a	n/a	10	29	21	23	20	24	26	36	189	n/a	29	n/a
-ACTIONS-																
APPROVALS	17	20	8	18	21	16	28	37	20	23	26	22	256	21	24	18
TENTATIVE APPROVALS+	1	2	6	5	5	4	9	3	2	3	7	1	48	4	4	1
NOT APPROVABLE	39	44	32	39	57	30	38	43	47	44	62	29	504	42	45	54
FACSIMILE REQUEST**	n/a	n/a	n/a	n/a	18	22	14	14	16	20	16	12	132	n/a	16	n/a
REFUSE TO FILE	8	3	6	6	12	18	12	12	17	5	7	4	110	9	5	10
WITHDRAWALS	0	23	3	14	6	30	49	9	58	32	22	31	277	23	28	35
- OF APPROVED	0	21	2	0	4	13	39	7	53	26	20	18	203	17	21	21
- OF UNAPPROVED	0	2	1	14	2	17	10	2	5	6	2	13	74	6	7	14
--REVIEW STATUS--																
AWAITING OGD ACTION(TOTAL)***	352	397	413	455	434	451	425	396	402	391	359	356		403	369	370
AWAITING OGD ACTION (>180 DAYS)	29	30	31	53	48	70	69	88	90	82	56	65		59	68	49
AWAITING OGD ACTION (<=180DAYS)	323	367	382	402	386	381	356	308	312	309	303	291		343	301	321

* - Please see page titled "Old Counting System" for numbers represented by the old counting system as reported in prior months.

** - Facsimile policy went into effect in January of 1997

*** - In September, 1991, the Office of Generic Drugs started implementation of its Application Integrity Policy by suspending review of applications suspected of being tainted by fraud. Review status figures reported since this date exclude suspended applications. As of August 31, 1997, 0 original applications and 17 supplements were suspended.

Upon completion of validity assessments, suspended applications may be returned to active pending status.

\+ - Note: Tentative approvals are counted as approvals subsequently when approved. For example 28 of the 256 approvals for the year ending August 31, 1997 were previously reported as tentatively approved applications.

Center for Drug Evaluation and Research - Office of Generic Drugs
Quantitative Report

POST APPROVAL SUBMISSIONS TO APPLICATIONS (CHEMISTRY)

	Sep-96	Oct-96	Nov-96	Dec-96	Jan-97	Feb-97	Mar-97	Apr-97	May-97	Jun-97	Jul-97	Aug-97	TOTAL	AVG LAST 12 MOS	AVG LAST 6 MOS	AVG PRIOR YEAR
--RECEIPTS--																
ORIGINAL SUPPLEMENTS	151	220	204	96	164	95	140	160	187	164	362	218	2161	180	248	160
AMENDMENTS TO SUPPLEMENTS	133	129	149	100	171	127	127	112	117	151	242	154	1712	143	182	140
--SUPPLEMENTAL ACTIONS-																
APPROVALS	130	96	77	145	184	168	73	115	154	141	205	128	1616	135	158	163
APPROVABLE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NOT APPROVABLE	55	81	80	57	65	25	31	43	52	85	87	43	704	59	72	87
WITHDRAWALS	15	43	13	20	35	4	8	8	8	14	0	13	185	15	9	23
--REVIEW STATUS--																
SUPPLEMENTS AWAITING* OGD ACTION (TOTAL)	744	866	907	866	880	858	968	1045	1069	1030	1142	1249		969	1140	1093
SUPPLEMENTS AWAITING OGD ACTION (>180 DAYS)	76	152	114	82	61	57	75	125	135	110	47	65		92	74	138
SUPPLEMENTS AWAITING OGD ACTION (<=180 DAYS)	668	714	793	784	819	801	893	920	934	920	1095	1184		877	1066	956

* - In September, 1991, the Office of Generic Drugs started implementation of its Application Integrity Policy by suspending review of applications suspected of being tainted by fraud. Review status figures reported since this date exclude suspended applications. As of August 31, 1997, 0 original applications and 17 supplements were suspended. Upon completion of validity assessments, suspended applications may be returned to active pending status.

Center for Drug Evaluation and Research - Office of Generic Drugs
Quantitative Report

POST APPROVAL SUBMISSIONS TO APPLICATIONS (LABELING)

	Sep-96	Oct-96	Nov-96	Dec-96	Jan-97	Feb-97	Mar-97	Apr-97	May-97	Jun-97	Jul-97	Aug-97	TOTAL	AVG LAST 12 MOS	AVG LAST 24 MOS	AVG PRIOR YEAR
--RECEIPTS--																
ORIGINAL SUPPLEMENTS	35	48	76	122	80	46	52	39	50	45	44	53	690	58	47	49
AMENDMENTS TO SUPPLEMENTS	73	61	73	54	68	56	49	56	67	56	46	35	694	58	46	52
--SUPPLEMENTAL ACTIONS--																
APPROVALS	49	55	38	46	63	56	35	60	41	48	63	36	590	49	49	59
APPROVABLE	4	14	10	19	22	16	5	21	5	3	28	4	151	13	12	19
NOT APPROVABLE	2	12	4	7	9	6	6	7	6	7	81	6	153	13	31	13
WITHDRAWALS	8	9	2	0	2	3	4	3	0	2	7	2	42	4	4	7
--REVIEW STATUS--																
SUPPLEMENTS AWAITING OGD ACTION (TOTAL)	313	305	361	447	430	411	414	391	425	414	303	358		381	358	553
SUPPLEMENTS AWAITING OGD ACTION (>180 DAYS)	134	136	139	136	121	123	123	128	142	205	134	162		140	167	230
SUPPLEMENTS AWAITING OGD ACTION (<=180 DAYS)	179	169	222	311	309	288	291	263	283	209	169	196		241	191	323

- In September, 1991, the Office of Generic Drugs started implementation of its Application Integrity Policy by suspending review of applications suspected of being tainted by fraud. Review atus figures reported since this date exclude suspended applications. As of August 31, 1997, 0 original applications and 17 supplements were suspended. Upon completion of validity assessments, spended applications may be returned to active pending status.

Center for Drug Evaluation and Research - Office of Generic Drugs
Quantitative Report

ORIGINAL APPLICATIONS - OLD COUNTING SYSTEM

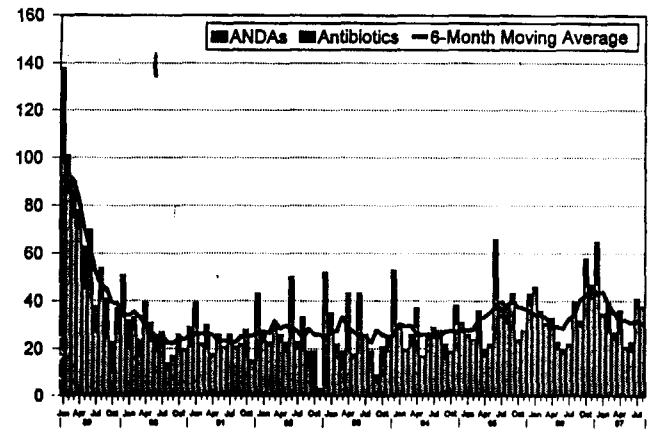
	Sep-96	Oct-96	Nov-96	Dec-96	Jan-97	Feb-97	Mar-97	Apr-97	May-97	Jun-97	Jul-97	Aug-97	TOTAL	AVG LAST 12 MOS	AVG LAST 3 MOS	AVG PRIOR YEAR
--RECEIPTS--																
TOTAL ORIGINALS	32	58	47	65	35	39	27	36	21	23	41	38	462	39	34	32
AMENDMENTS	97	136	115	116	103	125	109	114	127	111	112	108	1373	114	110	102
-MAJOR	57	81	53	63	41	59	50	54	62	44	48	45	657	55	46	54
-MINOR	40	55	62	53	52	37	38	37	45	43	38	27	527	44	36	48
-FACSIMILE*	n/a	n/a	n/a	n/a	10	29	21	23	28	24	26	36	189	n/a	29	n/a
-ACTIONS-																
APPROVALS	23	30	17	31	31	22	41	53	32	36	40	36	392	33	37	28
TENTATIVE APPROVALS+	2	2	11	6	8	9	15	4	5	8	15	1	86	7	8	2
NOT APPROVABLE	62	72	51	63	77	42	59	53	73	63	82	42	739	62	62	84
FACSIMILE REQUEST*	n/a	n/a	n/a	n/a	18	22	14	14	16	20	16	12	132	n/a	16	n/a
REFUSE TO FILE	10	3	6	6	16	22	16	13	22	5	10	4	133	11	6	15
WITHDRAWALS	0	24	3	14	6	32	53	9	59	33	25	37	295	25	32	37
- OF APPROVED	0	21	2	0	4	13	39	7	53	26	20	18	203	17	21	21
- OF UNAPPROVED	0	3	1	14	2	19	14	2	6	7	5	19	92	8	10	16
--REVIEW STATUS--																
AWAITING OGD ACTION(TOTAL)**	527	605	616	671	659	679	636	607	597	567	522	518		600	536	562
AWAITING OGD ACTION (>180 DAYS)	46	46	43	62	61	101	104	143	154	143	103	115		93	120	69
AWAITING OGD ACTION (<=180DAYS)	481	559	573	609	598	578	532	464	443	424	419	403		507	415	488

* - Facsimile policy went into effect in January of 1997

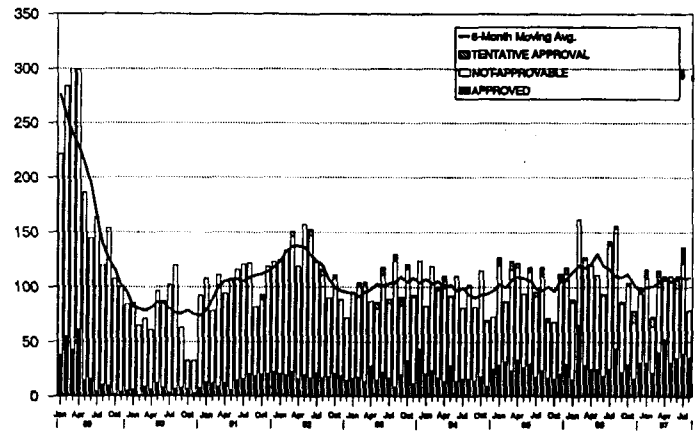
** - In September, 1991, the Office of Generic Drugs started implementation of its Application Integrity Policy by suspending review of applications suspected of being tainted by fraud. Review status figures reported since this date exclude suspended applications. As of August 31, 1997, 0 original applications and 17 supplements were suspended. Upon completion of validity assessments, suspended applications may be returned to active pending status.

\+ - Note: Tentative approvals are counted as approvals subsequently when approved. For example 28 of the 392 approvals for the year ending August 31, 1997 were previously reported as tentatively approved applications .

Original ANDAs and AADAs Received

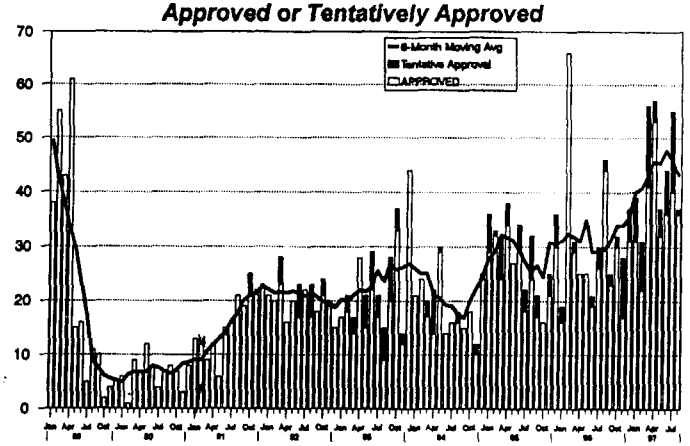


Actions on ANDAs/AADAs



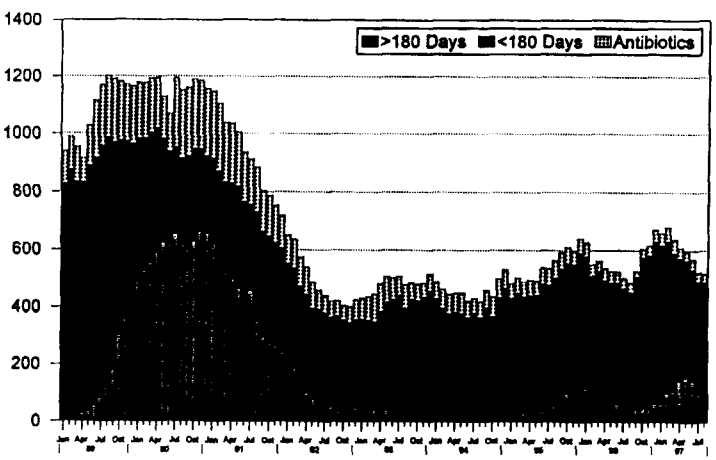
NOTE: TENTATIVE APPROVALS ARE APPLICATIONS THAT HAVE BEEN APPROVED BY THE OFFICE PENDING PATENT EXPIRATION. TENTATIVE APPROVALS ARE COUNTED AS APPROVALS SUBSEQUENTLY WHEN APPROVED.

Original ANDAs/AADAs Approved or Tentatively Approved

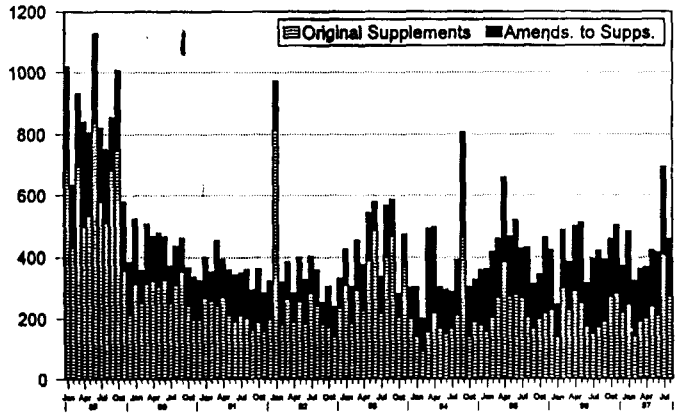


NOTE: TENTATIVE APPROVALS ARE APPLICATIONS THAT HAVE BEEN APPROVED BY THE OFFICE PENDING PATENT EXPIRATION. TENTATIVE APPROVALS ARE COUNTED AS APPROVALS SUBSEQUENTLY WHEN APPROVED. FOR EXAMPLE 44 OF 68 APPROVALS FOR FEBRUARY 1998 WERE PREVIOUSLY TENTATIVELY APPROVED. THE LARGE NUMBER OF APPROVALS RESULTED FROM A DRUG COMING OFF PATENT IN FEBRUARY.

ANDAs and AADAs Pending Per Month

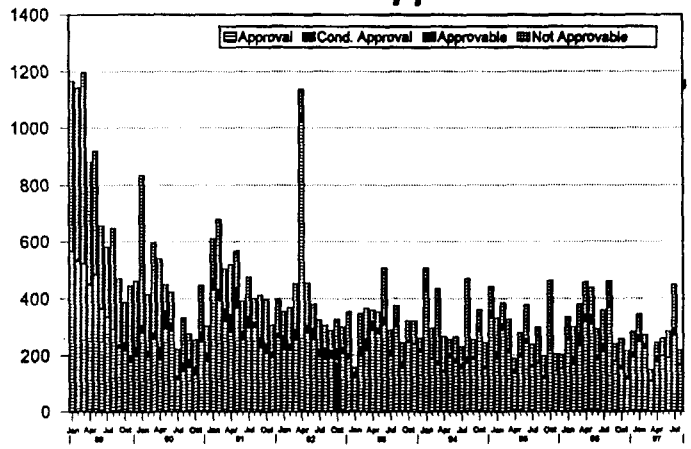


Supplements and Amendments (to Supplements) Received



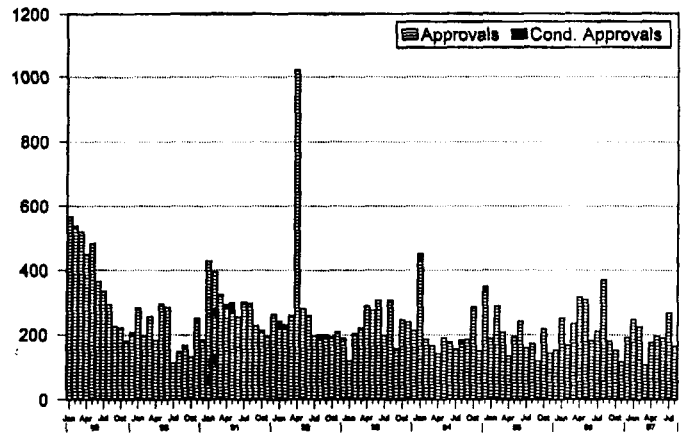
These figures include global supplements. For example one firm submitted 755 supplements in January 1992.

Actions on Supplements



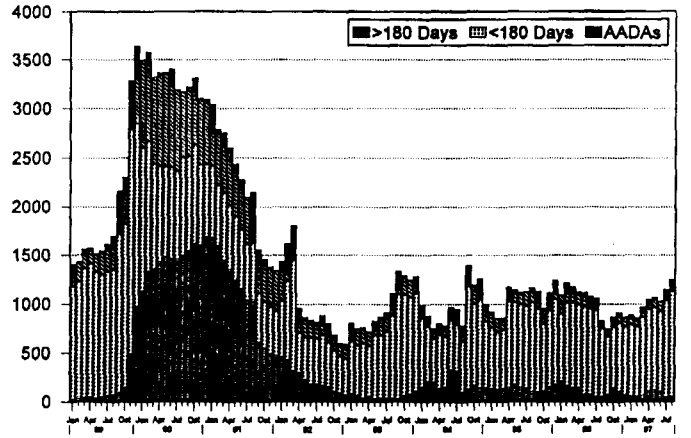
These figures include global supplements. For example one firm submitted 755 supplements in January 1992. These were approved in April 1992.

Supplements Approved



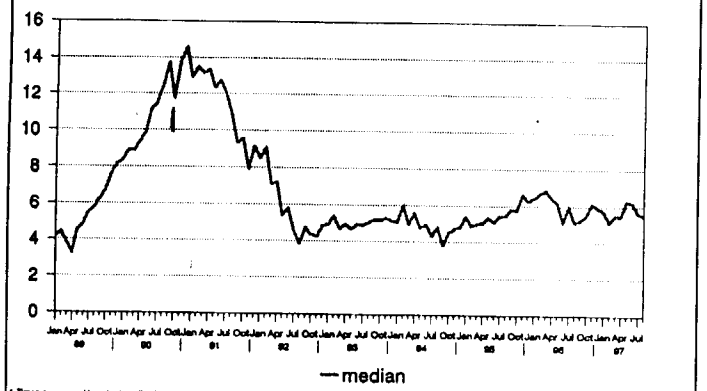
These figures include global supplements. For example one firm submitted 755 supplements in January 1992. These were approved in April 1992.

Supplements Awaiting OGD Action



Please note that abrupt changes in the level of pending supplements (e.g. the increase in September 1994) are the result of global submissions to all applications held by a single firm. Changes other than these will be explained separately.

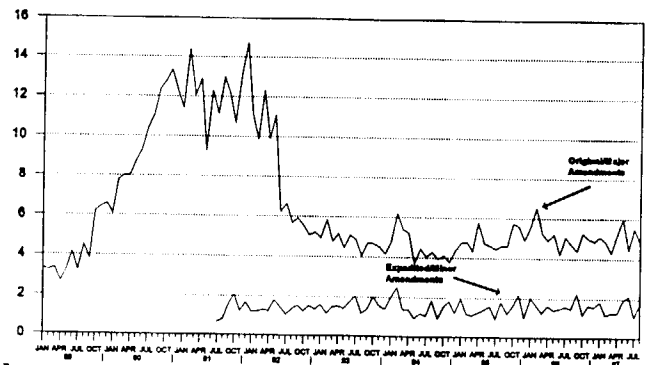
Median ANDA Review Cycle (Months)



1-Times correspond to actual applications received. The new ANDA/AADA submission policy that went into effect 1/1/91 allows certain variations in a drug product to be included in a single application.

2-In September, 1991 the OGD started implementation of the Application Integrity Policy by suspending review of applications suspected of being tainted by fraud. AIP time has been subtracted from review time above for the period after 9/91. However, before the AIP went into effect, the review of many applications suspected of containing fraudulent data were suspended. These suspensions were not recorded in the MIS and are not reflected in the above chart.

Median ANDA Supplemental Review Time (Months)



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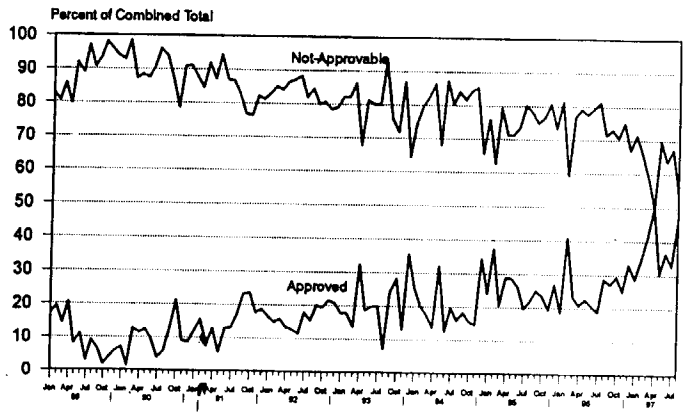
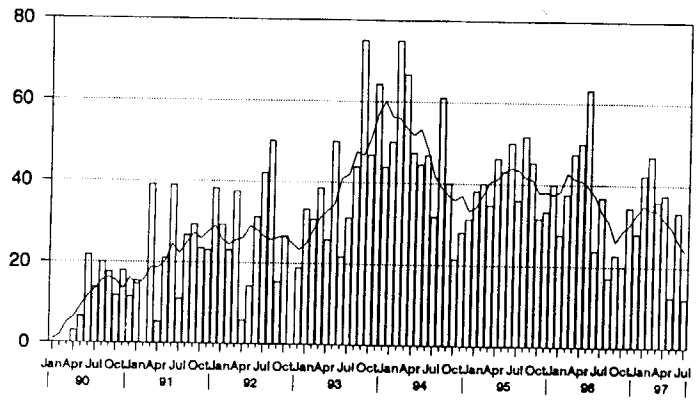
Note: Global Supplements Collapsed

Percent Approved and Not-Approvable Per Month



Percent of Submissions With Refuse to File Action By Month of Receipt



Status as of September 6, 1997. Percentages for recent months may increase due to future RF actions
(Actual applications, new counting system)

1.	74-541	CIMETIDINE HYDROCHLORIDE ORAL SOLUTION 300 MG (BASE)/5ML	ROXANE LABORATORIES, INC.	08/05/97
2.	40-210	HYDROCODONE BITARTRATE AND ACETAMINOPHEN TABLETS, USP 10MG/500 MG	PEACHTREE PHARMACEUTICALS	08/13/97
3.	74-818	ESTAZOLAM TABLETS 1 MG, 2 MG	ROYCE LABORATORIES, INC.	08/19/97
4.	73-045	ALBUTEROL INHALATION AEROSOL 90 MCG/INHALATION	ALPHARMA, USPD	08/19/97
5.	74-023	RANTIDINE TABLETS, USP 150 MG (AS HCL), 300 MG (AS HCL)	GENPHARM INC.	08/22/97
6.	74-906	ACYCLOVIR CAPSULES 200 MG	PUREPAC PHARMACEUTICAL CO.	08/26/97
7.	74-894	DILTIAZEM HYDROCHLORIDE INJECTION 5 MG/ML	GENSIA LABORATORIES, LTD.	08/26/97
8.	74-905	FLUOCINONIDE OINTMENT, USP 0.05%	ALTANA, INC.	08/26/97
9.	74-969	ACYCLOVIR SODIUM FOR INJECTION 500 MG (BASE), 1 G (BASE)	GENSIA LABORATORIES, LTD.	08/26/97
10.	74-958	CLOMIPRAMINE HYDROCHLORIDE CAPSULES 25 MG, 50 MG, 75 MG	LEMMON COMPANY	08/26/97
11.	40-109	ACETAMINOPHEN, CAFFEINE, AND DIHYDROCODEINE BITARTRATE CAPSU 356/30/16 MG	MIKART, INC.	08/26/97
12.	40-151	PROMETHAZINE HYDROCHLORIDE AND CODEINE PHOSPHATE SYRUP 6.25 MG/10 MG PER 5 ML	HI TECH PHARMACAL COMPANY, INC.	08/26/97
13.	40-187	THIORIDAZINE HYDROCHLORIDE ORAL SOLUTION, USP (CONCENTRATE) 30 MG/ML	PHARMACEUTICAL ASSOCIATES, INC.	08/28/97
14.	74-730	LOPERAMIDE HYDROCHLORIDE ORAL SOLUTION 1 MG/5 ML	MORTON GROVE PHARMACEUTICALS, INC.	08/28/97
15.	74-544	LEUCOVORIN CALCIUM TABLETS, USP 5 MG (BASE), 25 MG (BASE)	PAR PHARMACEUTICAL, INC.	08/28/97
16.	40-220	METHYLPHENIDATE HYDROCHLORIDE TABLETS, USP 5 MG, 10 MG, 20 MG	DANBURY PHARMACAL, INC.	08/29/97
17.	74-662	RANITIDINE TABLETS, USP 150 MG (BASE), 300 MG (BASE)	BOEHRINGER LABORATORIES, INC.	08/29/97

18.	74-467	RANITIDINE TABLETS, USP 150 MG (BASE), 300 MG (BASE)	GENEVA PHARMACEUTICALS, INC.	08/29/97
19.	74-979	CLONAZEPAM TABLETS, USP 0.5 MG, 1 MG, 2 MG	EON LABS MANUFACTURING, INC.	08/29/97
20.	74-840	ETODOLAC CAPSULES 200 MG, 300 MG	GENEVA PHARMACEUTICALS, INC.	08/29/97

1.	64-105	CEFACLOR, USP NON-STERILE BULK	RANBAXY LABORATORIES, LIMITED	08/05/97
2.	64-156	CEFACLOR CAPSULES, USP 250 MG (BASE), 500 MG (BASE)	RANBAXY LABORATORIES LIMITED	08/28/97

1. 74-704 PROPOFOL INJECTABLE EMULSION ABBOTT LABORATORIES 08/06/97
1%