M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH
OFFICE OF GENERIC DRUGS

7852 '01 AUG -3 P1:40

DATE: December 12, 1999

FROM: Robert L. West
Director, Division of Labeling and Program Support

SUBJECT: Statistical Report - Month of November 1999

TO: See Below

This memorandum provides a copy of the Office of Generic Drugs' statistical report for November 1999.

Tables I through III detail quantitative information about OGD's receipts, actions, and pending review status for both original and supplemental (CMC and labeling) applications for the past month and for the 11 preceding months. Table IV pertains only to original (unapproved) applications and is entitled "Old Counting System". This table is helpful in comparing quantitative data between OGD's current and former counting systems. Following the tables, graphic presentations of selective quantitative data are provided. These graphs allow comparisons to similar data dating back to 1991. Where appropriate, the graphs have been modified to reflect the change of AADAs to ANDAs as a result of the elimination of Section 507 of the FD&C Act under FDAMA.

Lists of November's 19 new generic drug approvals, and 3 first-time tentative approvals follow the graphic presentations. [Note: In November, the office also issued a total of 3 tentative approval letters to applicants of generic drug products whose date of final approval had been postponed through patent or exclusivity extensions granted to the innovator drug product]. A third list of supplemental approvals reveals that one applicant also received approval of an additional strength for a previously approved drug product.

First time generic approvals or tentative approvals are indicated by an asterisk (*).

The following observations are notable from the November data:

The labeling review branch approved a total of 75 supplemental applications providing for revised labeling for the generic drug product. This represents the greatest number of monthly approvals since August 1998. In addition, the total number of supplemental applications pending review

905-0308

M 717

by the labeling branch continued its steady decline to 218, the lowest number in many years!

cc:

Office of Pharmaceutical Science
HFD-003/H.Winkel
HFD-003/E.Sheinin
Office of Generic Drugs
HFD-600/D.Sporn
HFD-601/G.Buehler
HFD-600/M.Lamb/to forward to Documents Management Branch, Docket # 90S0308
HFD-600/M.Fanning
HFD-600/A.High
HFD-600/R.Hassall
HFD-600/R.Warzala
HFD-604/D.Hare
HFD-610/R.West
HFD-610/DLPS File
HFD-611/P.Rickman
HFD-613/J.Grace
HFD-613/C.Hoppes
HFD-615/H.Greenberg
HFD-617/P.Beers-Block
HFD-620/R.Patel
HFD-621/A.Rudman
HFD-623/D.Gill
HFD-625/M.Smela
HFD-629/P.Schwartz
HFD-630/A.Mueller
HFD-640/F.Holcombe
HFD-640/F.Fang
HFD-641/V.Sayeed
HFD-643/R.Adams
HFD-645/B.Arnwine
HFD-647/U.Venkataram
HFD-649/G.Smith
HFD-650/D.Conner
HFD-651/R.Patnaik
HFD-652/Y.C.Huang
HFD-655/S.Nerurkar
HFD-658/B.Davit

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Center for Drug Evaluation and Research - Office of Generic Drugs

Table I

Quantitative Report

ORIGINAL APPLICATIONS

	Dec-98	Jan-99	Feb-99	Mar-99	Apr-99	May-99	Jun-99	Jul-99	Aug-99	Sep-99	Oct-99	Nov-99	TOTAL	AVG LAST 12 MOS	AVG LAST 3 MOS	AVG PRIOR YEAR
-- RECEIPTS --																
TOTAL ORIGINALS	47	27	25	22	19	20	25	33	20	25	17	17	297	25	20	29
AMENDMENTS	130	107	123	163	125	122	101	138	173	144	112	139	1577	131	132	107
- MAJOR	62	40	76	74	55	52	44	61	86	74	48	57	729	61	60	55
- MINOR	32	27	18	45	25	34	26	42	44	43	33	48	417	35	41	27
- FACSIMILE **	36	40	29	44	45	36	31	35	43	27	31	34	431	36	31	25
-- ACTIONS --																
APPROVALS	28	10	14	15	21	18	19	17	13	13	12	19	199	17	15	18
TENTATIVE APPROVALS+	6	6	5	5	2	4	6	4	7	4	8	3	60	5	5	3
NOT APPROVABLE	29	16	27	55	34	37	54	62	36	42	49	38	479	40	43	38
FACSIMILE REQUEST**	20	9	20	20	19	17	20	29	12	10	19	16	211	18	15	19
REFUSE TO FILE	10	6	11	3	5	5	2	7	12	2	4	6	73	6	4	5
WITHDRAWALS	37	16	2	10	50	28	21	50	36	59	25	7	341	28	30	27
- OF APPROVED	16	14	0	2	44	16	21	46	25	47	15	3	249	21	22	22
- OF UNAPPROVED	21	2	2	8	6	12	0	4	11	12	10	4	92	8	9	5
-- REVIEW STATUS --																
AWAITING OGD ACTION (TOTAL)***	422	438	442	439	437	436	409	399	409	427	399	415		423	414	
AWAITING OGD ACTION (> 180 DAYS)***	88	79	105	98	99	98	100	84	76	90	67	71		88	76	85
AWAITING OGD ACTION (<=180 DAYS)***	334	359	337	341	338	338	309	315	333	337	332	344		335	338	325

* Please see last page of this report 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 November 30, 1999, 1 original application and 18 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 8 of the 199 approvals for the year ending November 30, 1999 were previously reported as tentatively approved applications. The 2 tentative approvals reported in April 1999 are actually approvable actions. One of the tentative approvals reported in May 1999 is actually an approvable action.

Center for Drug Evaluation and Research - Office of Generic Drugs

Table II

Quantitative Report

POST APPROVAL SUBMISSIONS TO APPLICATIONS (CHEMISTRY)

	Dec-98	Jan-99	Feb-99	Mar-99	Apr-99	May-99	Jun-99	Jul-99	Aug-99	Sep-99	Oct-99	Nov-99	TOTAL	AVG LAST 12 MOS	AVG LAST 3 MOS	AVG PRIOR YEAR
--RECEIPTS--																
ORIGINAL SUPPLEMENTS	389	188	150	148	157	193	260	215	291	100	139	161	2391	199	133	237
AMENDMENTS TO SUPPLEMENTS **	156	125	158	404	185	249	239	145	335	170	118	198	2482	207	162	220
--SUPPLEMENTAL ACTIONS-																
APPROVALS ***	446	39	310	283	134	235	177	143	98	67	37	40	2009	167	48	175
APPROVABLE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NOT APPROVABLE +	77	21	77	328	94	76	180	83	103	43	53	29	1164	97	42	73
WITHDRAWALS	84	1	11	23	16	5	25	21	28	7	8	10	239	20	8	17
--REVIEW STATUS--																
SUPPLEMENTS AWAITING OGD ACTION (TOTAL) *	1749	1866	1737	1362	1355	1298	1260	1234	1398	1404	1413	1331		1451	1383	1488
SUPPLEMENTS AWAITING OGD ACTION (>180 DAYS)	234	243	237	128	137	139	156	85	83	93	95	156		149	115	99
SUPPLEMENTS AWAITING OGD ACTION (<=180 DAYS)	1515	1623	1500	1234	1218	1159	1104	1149	1315	1311	1318	1175		1302	1268	1349

* 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 November 30, 1999, 1 original application and 18 supplements were suspended. Upon completion of validity assessments, suspended applications may be returned to active pending status.

** March 1999 figure includes 203 amendments to supplements submitted by one applicant.

*** March 1999 figure includes approval of global supplements submitted by single applicant.

\+ March 1999 figure includes a total of 290 not approvable actions taken on global supplements submitted by 2 individual applicants.

Center for Drug Evaluation and Research - Office of Generic Drugs

Table III

Quantitative Report

POST APPROVAL SUBMISSIONS TO APPLICATIONS (LABELING)

	Dec-98	Jan-99	Feb-99	Mar-99	Apr-99	May-99	Jun-99	Jul-99	Aug-99	Sep-99	Oct-99	Nov-99	TOTAL	AVG LAST 12 MOS	AVG LAST 3 MOS	AVG PRIOR YEAR
--RECEIPTS--																
ORIGINAL SUPPLEMENTS	59	41	33	61	41	40	38	42	31	45	77	45	553	46	56	58
AMENDMENTS TO SUPPLEMENTS	78	55	49	55	38	60	44	50	60	84	101	39	713	59	75	55
--SUPPLEMENTAL ACTIONS-																
APPROVALS	39	39	31	40	46	54	47	49	54	63	49	75	586	49	62	56
APPROVABLE	13	4	17	3	4	2	5	4	12	6	6	13	89	7	8	7
NOT APPROVABLE	17	5	5	23	32	14	14	24	17	13	15	23	202	17	17	13
WITHDRAWALS	0	0	4	25	1	3	7	0	4	6	1	5	56	5	4	3
--REVIEW STATUS--																
SUPPLEMENTS AWAITING OGD ACTION (TOTAL)	318	338	339	349	323	308	299	282	256	242	284	218		296	248	360
SUPPLEMENTS AWAITING OGD ACTION (>180 DAYS)	125	137	116	109	114	106	117	117	95	90	81	81		107	84	142
SUPPLEMENTS AWAITING OGD ACTION (<=180 DAYS)	193	201	223	240	209	202	182	165	161	152	203	137		189	164	218

* 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 November 30, 1999, 1 original application and 18 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

Table IV

Quantitative Report

ORIGINAL APPLICATIONS - OLD COUNTING SYSTEM

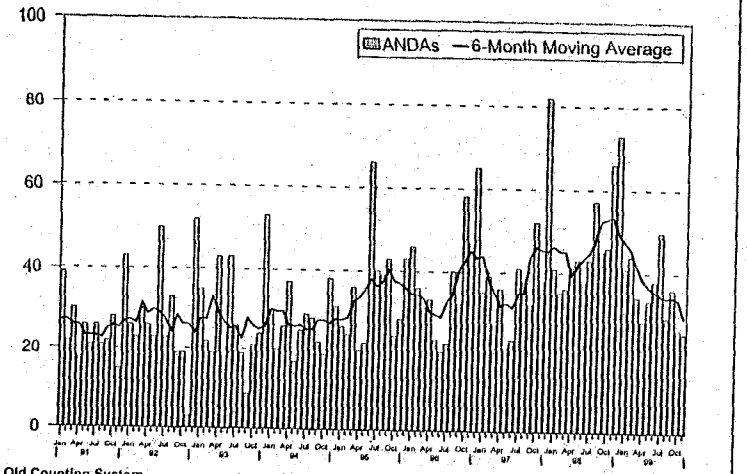
	Dec-98	Jan-99	Feb-99	Mar-99	Apr-99	May-99	Jun-99	Jul-99	Aug-99	Sep-99	Oct-99	Nov-99	TOTAL	AVG LAST 12 MOS	AVG LAST 3 MOS	AVG PRIOR YEAR
-- RECEIPTS --																
TOTAL ORIGINALS	73	41	44	34	28	33	38	50	29	36	26	25	457	38	29	48
AMENDMENTS	130	107	123	163	125	122	101	138	173	144	112	139	1577	131	132	107
- MAJOR	62	40	76	74	55	52	44	61	86	74	48	57	729	61	60	55
- MINOR	32	27	18	45	25	34	26	42	44	43	33	48	417	35	41	27
- FACSIMILE	36	40	29	44	45	36	31	35	43	27	31	34	431	36	31	25
-- ACTIONS --																
APPROVALS	47	13	16	18	33	23	21	31	20	17	16	27	282	24	20	29
TENTATIVE APPROVALS+	8	8	11	13	2	9	15	10	14	8	19	4	121	10	10	5
NOT APPROVABLE	49	29	47	91	57	54	93	100	51	62	87	56	776	65	68	58
FACSIMILE REQUEST*	20	9	20	20	19	17	20	29	12	10	19	16	211	18	15	19
REFUSE TO FILE	13	6	12	4	6	6	5	8	15	4	4	8	91	8	5	8
WITHDRAWALS	41	18	5	11	52	30	21	50	39	65	26	10	368	31	34	29
- OF APPROVED	17	14	0	2	45	16	21	46	25	49	15	4	254	21	23	23
- OF UNAPPROVED	24	4	5	9	7	14	0	4	14	16	11	6	114	10	11	6
-- REVIEW STATUS --																
AWAITING OGD ACTION (TOTAL)**	677	709	719	714	705	727	680	663	698	726	679	710		701	705	
AWAITING OGD ACTION (> 180 DAYS)	138	118	153	154	157	168	177	146	135	160	121	147		148	143	123
AWAITING OGD ACTION (<=180 DAYS)	539	591	566	560	548	559	503	517	563	566	558	563		553	562	503

* 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 November 30, 1999, 1 original application and 18 supplements were suspended. Upon completion of validity assessments, suspended applications may be returned to active pending status.

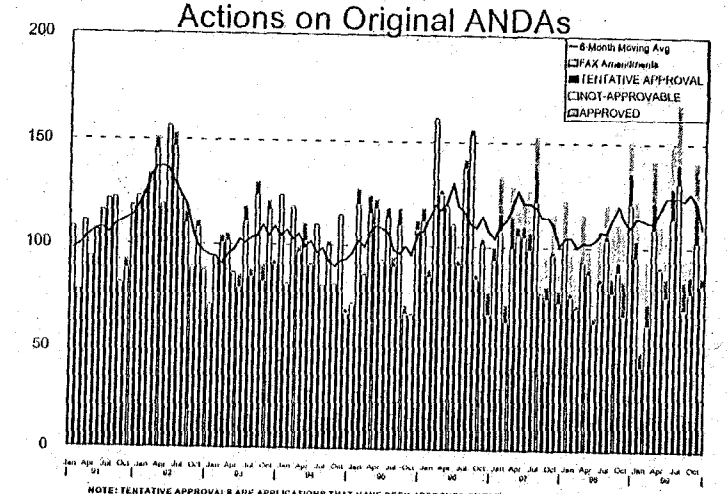
\+ Note: Tentative approvals are counted as approvals subsequently when approved. For example 8 of the 282 approvals for the year ending November 30, 1999 were previously reported as tentatively approved applications. The 2 tentative approvals reported in April 1999 are actually approvable actions. One of the tentative approvals reported in May 1999 is actually an approvable action.

Original ANDAs Received



Old Counting System

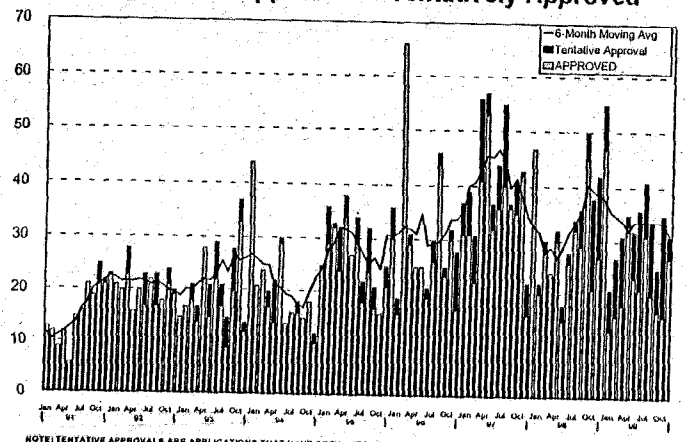
Actions on Original ANDAs



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

Old Counting System

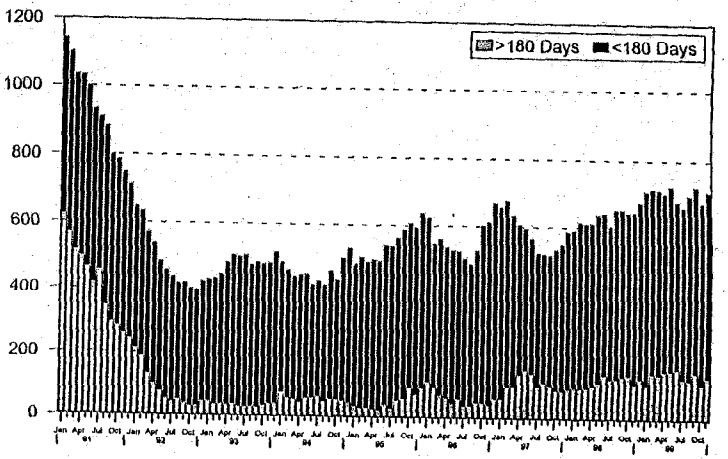
Original ANDAs Approved or Tentatively Approved



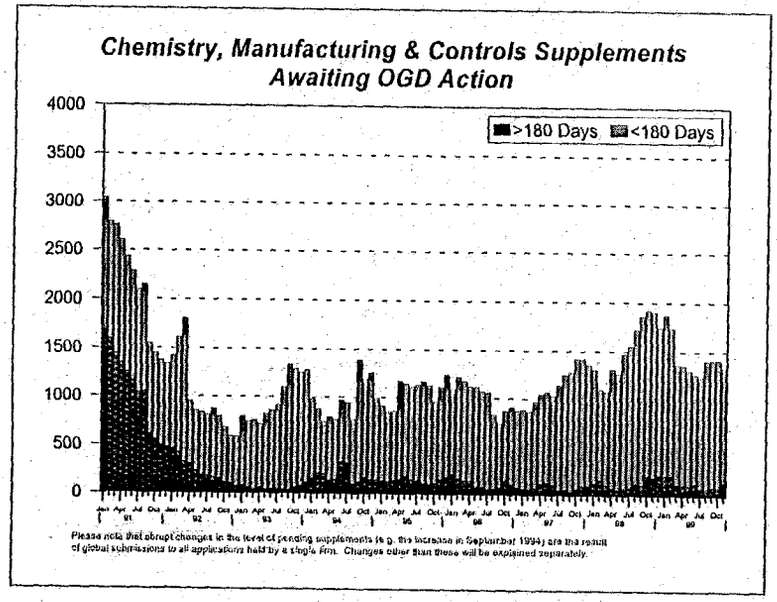
NOTE: TENTATIVE APPROVALS ARE APPLICATIONS THAT HAVE BEEN APPROVED BY THE OFFICE PENDING PATENT EXPIRATION. TENTATIVE APPROVALS ARE COUNTED AS APPROVALS SUBSEQUENTLY WHEN APPROVED. FOR EXAMPLE 44 OF 66 APPROVALS FOR FEBRUARY 1998 WERE PREVIOUSLY TENTATIVELY APPROVED. THE LARGE NUMBER OF APPROVALS RESULTED FROM A DRUG COMING OFF PATENT IN FEBRUARY.

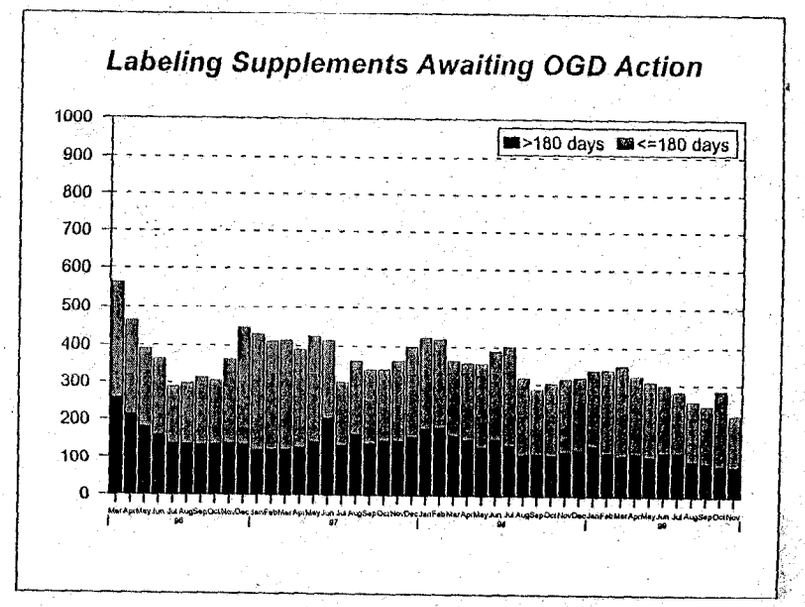
Old Counting System

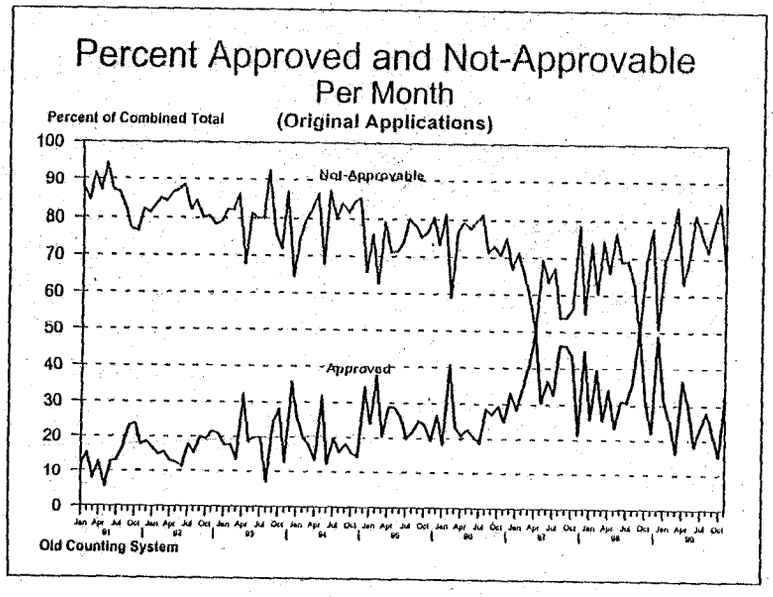
Original ANDAs Pending Per Month

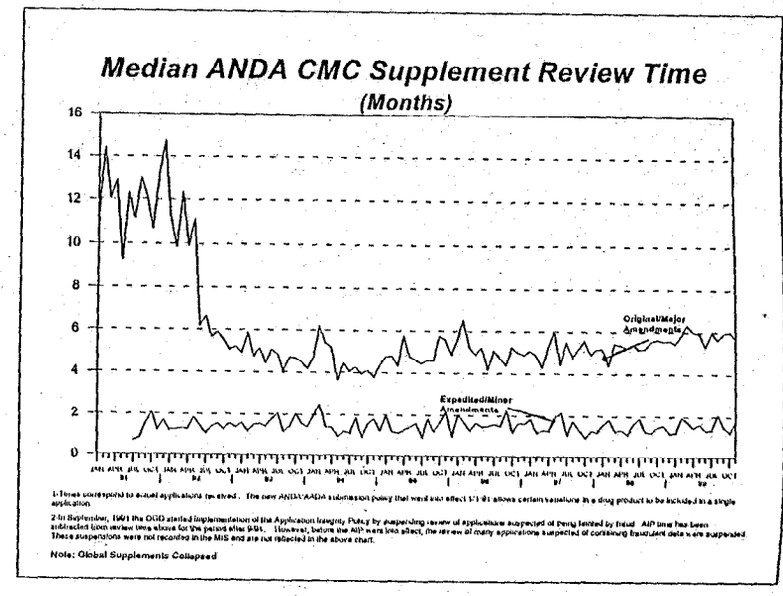


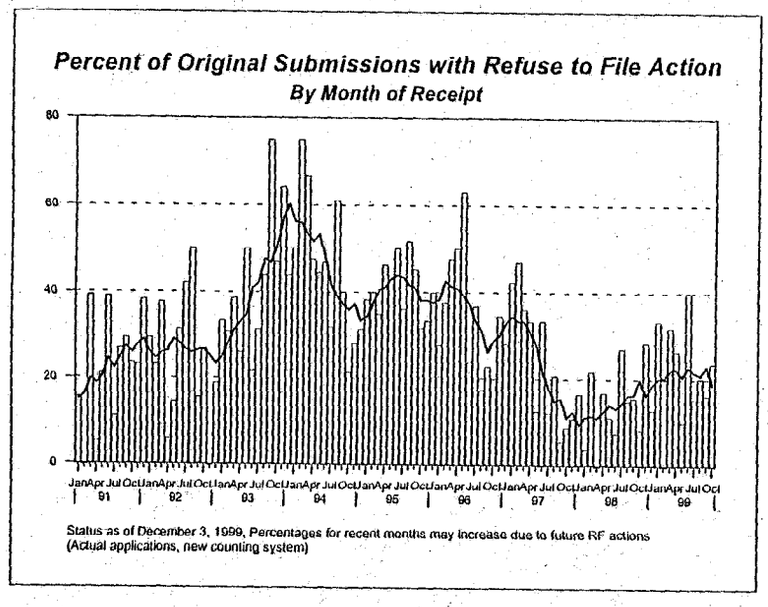
Old Counting System

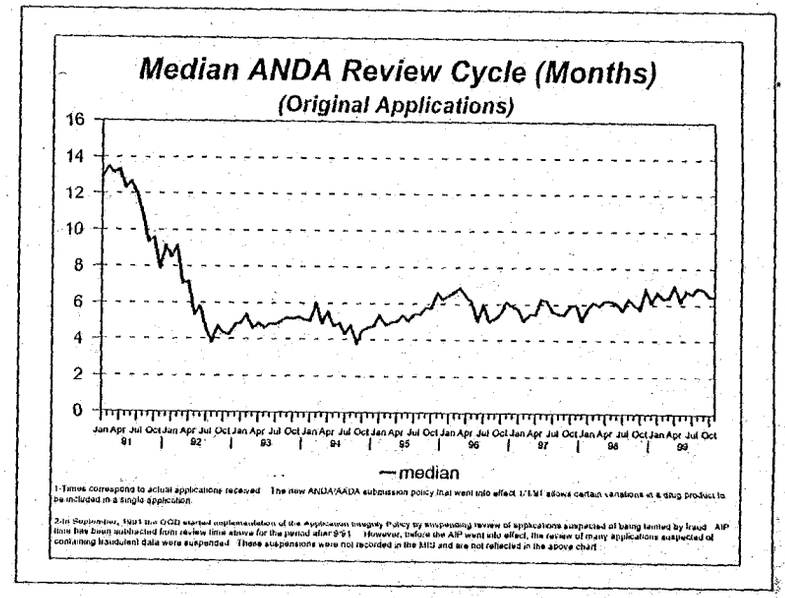

Chemistry, Manufacturing & Controls Supplements
Awaiting OGD Action
>180 Days
<180 Days
4000
3500
3000
2500
2000
1500
1000
500
0
Please note that abrupt changes in the level of pending supplements (e.g. the increase in September 1994) are the result of global submissions to all applications held by a single firm. Changes other than these will be explained separately.

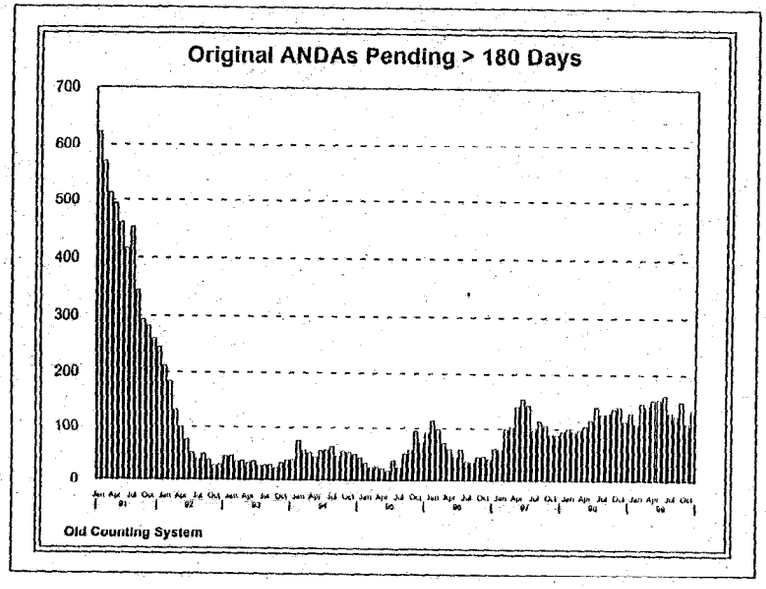

Labeling Supplements Awaiting OGD Action
>180 days
<=180 days
1000
900
800
700
600
500
400
300
200
100
0

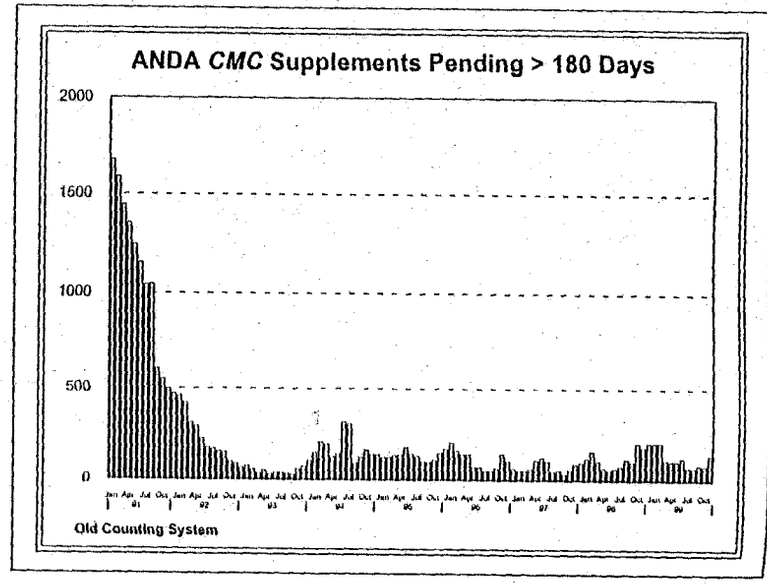

Percent Approved and Not-Approvable
Per Month
(Original Applications)
Percent of Combined Total
Not-Approvable
Approved
100
90
80
70
60
50
40
30
20
10
0
Old Counting System

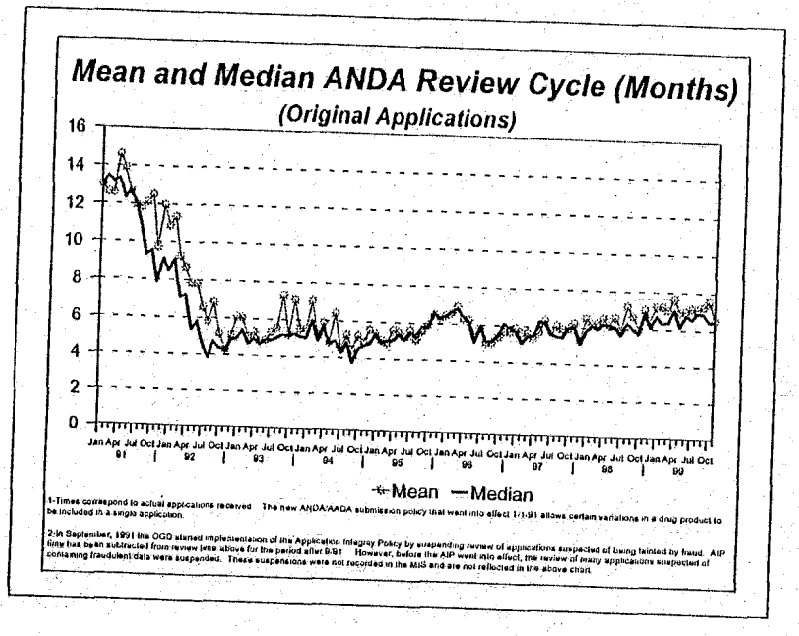

Median ANDA CMC Supplement Review Time
(Months)
16
14
12
10
8
6
4
2
0
Original/Major Amendments
Expedited/Minor Amendments
Note: Global Supplements Collapsed


Percent of Original Submissions with Refuse to File Action
By Month of Receipt
60
40
20
0
Jan Apr Jul Oct Jan Apr Jul Oct Jan Apr Jul Oct Jan Apr Jul Oct Jan Apr Jul Oct Jan Apr Jul Oct Jan Apr Jul Oct
91 92 93 94 95 96 97 98 99
Status as of December 3, 1999, Percentages for recent months may increase due to future RF actions
(Actual applications, new counting system)


Median ANDA Review Cycle (Months)
(Original Applications)
16
14
12
10
8
6
4
2
0
Jan Apr Jul Oct Jan Apr Jul Oct Jan Apr Jul Oct Jan Apr Jul Oct Jan Apr Jul Oct Jan Apr Jul Oct Jan Apr Jul Oct Jan Apr Jul Oct
91 92 93 94 95 96 97 98 99
median
1-Times correspond to actual applications received. The new ANDA/AADA submission policy that went into effect 1/1/97 allows certain variations of a drug product to be included in a single application.
2-In September, 1997 the OGD started implementation of the Application Integrity Policy by suspending review of applications suspected of being tainted by fraud. AIP data has been subtracted from review time above for the period after 9/97. 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.


Original ANDAs Pending > 180 Days
700
600
500
400
300
200
100
0
Jan Apr Jul Oct Jan Apr Jul Oct Jan Apr Jul Oct Jan Apr Jul Oct Jan Apr Jul Oct Jan Apr Jul Oct Jan Apr Jul Oct Jan Apr Jul Oct
91 92 93 94 95 96 97 98 99
Old Counting System


ANDA CMC Supplements Pending > 180 Days
2000
1600
1000
500
0
Jan Apr Jul Oct Jan Apr Jul Oct Jan Apr Jul Oct Jan Apr Jul Oct Jan Apr Jul Oct Jan Apr Jul Oct Jan Apr Jul Oct Jan Apr Jul Oct
91 92 93 94 95 96 97 98 99
Old Counting System


Mean and Median ANDA Review Cycle (Months)
(Original Applications)
16
14
12
10
8
6
4
2
0
Jan Apr Jul Oct Jan Apr Jul Oct Jan Apr Jul Oct Jan Apr Jul Oct Jan Apr Jul Oct Jan Apr Jul Oct Jan Apr Jul Oct Jan Apr Jul Oct Jan Apr Jul Oct
91
92
93
94
95
96
97
98
99
Mean
Median
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 Applicants' Integrity Policy by suspending review of applications suspected of being tainted by fraud. A/P firms 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.

Office Of Generic Drugs ANDAs Approvals

Wednesday, December 01, 1999

1.	40-296	ESTROPIPATE TABLETS, USP 0.75 MG 1.5 MG 3 MG	DURAMED PHARMACEUTICALS, INC.	11/1/99
2.	75-316	TICLOPIDINE HYDROCHLORIDE TABLETS 250 MG	MYLAN PHARMACEUTICALS, INC.	11/2/99
3.	75-299	KETOROLAC TROMETHAMINE INJECTION, USP 15 MG/ML (SYRINGE) 30 MG/ML (1 ML & 2 ML SYRINGES)	BAXTER PHARMACEUTICAL PRODUCTS, INC.	11/3/99
4.	75-342	BUTORPHANOL TARTRATE INJECTION, USP (PRESERVATIVE-FREE) 1 MG/ML 2 MG/ML (1 ML & 2 ML VIALS)	MERIDIAN MEDICAL TECHNOLOGIES, INC.	11/4/99
5.	75-343	ALBUTEROL SULFATE INHALATION SOLUTION 0.083% (BASE); 3 ML UNIT-DOSE VIALS	STERIPAK LIMITED	11/9/99
6.	74-992	NITROGLYCERIN TRANSDERMAL SYSTEM 0.6 MG/HOUR	MYLAN TECHNOLOGIES, INC.	11/12/99
7.	75-073	NITROGLYCERIN TRANSDERMAL SYSTEM 0.2 MG/HOUR	MYLAN TECHNOLOGIES, INC.	11/12/99
8.	75-075	NITROGLYCERIN TRANSDERMAL SYSTEM 0.4 MG/HOUR	MYLAN TECHNOLOGIES, INC.	11/12/99
9.	75-076	NITROGLYCERIN TRANSDERMAL SYSTEM 0.1 MG/HOUR	MYLAN TECHNOLOGIES, INC.	11/12/99
10.	40-312	ESTRADIOL TABLETS, USP 0.5 MG 1 MG 2 MG	NOVO NORDISK PHARMACEUTICALS, INC.	11/16/99
✳ 11.	75-383	CYTARABINE INJECTION 2 G/20 ML (100 MG/ML); SINGLE-DOSE VIAL	FAULDING PHARMACEUTICAL CO.	11/22/99

12.	75-394	ALBUTEROL SULFATE INHALATION SOLUTION 0.083% (BASE); 3 ML UNIT-DOSE VIALS	MORTON GROVE PHARMACEUTICALS, INC.	11/22/99
13.	75-239	LABETALOL HYDROCHLORIDE INJECTION, USP 5 MG/ML (20 MG/4 ML CARPUJECT)	ABBOTT LABORATORIES	11/29/99
14.	75-240	LABETALOL HYDROCHLORIDE INJECTION, USP 5 MG/ML (100 MG/20 ML & 200 MG/40 ML MUL	ABBOTT LABORATORIES	11/29/99
* 15.	75-310	BUPROPION HYDROCHLORIDE TABLETS 75 MG 100 MG	TEVA PHARMACEUTICALS USA	11/29/99
16.	75-355	LABETALOL HYDROCHLORIDE INJECTION, USP 5 MG/ML (MULTIPLE-DOSE VIAL)	APOTHECON, INC.	11/29/99
17.	75-431	LABETALOL HYDROCHLORIDE INJECTION, USP 5 MG/ML (100 MG/20 ML & 200 MG/40 ML MDV	TAYLOR PHARMACEUTICALS	11/29/99
18.	75-524	LABETALOL HYDROCHLORIDE INJECTION, USP 5 MG/ML (20 MG/4 ML & 40 MG/8 ML SYRINGE	TAYLOR PHARMACEUTICALS	11/29/99
* 19.	75-095	ETHAMBUTOL HYDROCHLORIDE TABLETS, USP 100 MG 400 MG	WEST-WARD PHARMACEUTICAL CORP.	11/30/99

Office of Generic Drugs ANDAs Tentative Approvals

01-Dec-99

1.	75-263	MIDAZOLAM HYDROCHLORIDE INJECTION 5 MG (BASE)/ML; (2 ML SYRINGE)	ASTRA PHARMACEUTICALS, L.P.	11/8/99
2.	75-421	MIDAZOLAM HYDROCHLORIDE INJECTION 1 MG (BASE)/ML (VIALS) 5 MG (BASE)/ML (VIALS)	BEN VENUE LABORATORIES, INC.	11/23/99
3.	75-040	PROPOFOL INJECTABLE EMULSION 10 MG/ML (1%)	ESI LEDERLE	11/24/99

Office Of Generic Drugs Supplement Approvals

Wednesday, December 01, 1999

1.	64-103 S-003	DAUNORUBICIN HYDROCHLORIDE FOR INJECTION, USP 50 MG (BASE)/VIAL	BEDFORD LABORATORIES	11/19/99