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

00 AUG -3 P1:40

DATE: February 4, 2000

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

SUBJECT: Statistical Report - Month of January 2000

TO: See Below

This memorandum represents the Office of Generic Drugs' statistical report for January 2000.

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, entitled "Old Counting System", pertains only to original (unapproved) applications. This table has historically been helpful in comparing quantitative data between OGD's current and former counting systems. However, in future reports this table will be deleted, as OGD is no longer reporting data using the former system. 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.

Separate lists of January's 18 new generic approvals, and 3 tentative approvals follow the graphic presentations. First time generic approvals or tentative approvals are indicated by an asterisk (*). These approvals include generic equivalents for Ocupress Ophthalmic Solution, an agent to lower intra-ocular pressure in patients with glaucoma marketed by Ciba Vision Corp.; Neoral Capsules, an immunosuppressant marketed by Novartis; and Microzide Capsules, a diuretic used in the treatment of multiple conditions including heart failure marketed by Watson Laboratories. [Note: In Janaury, the office also issued two second tentative approval letters to a generic drug applicant 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 a supplement providing for an additional strength of a previously approved drug product.

905-0308

M719

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/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

Quantitative Report

Table I

ORIGINAL APPLICATIONS

	Feb-99	Mar-99	Apr-99	May-99	Jun-99	Jul-99	Aug-99	Sep-99	Oct-99	Nov-99	Dec-99	Jan-00	TOTAL	AVG LAST 12 MOS	AVG LAST 3 MOS	AVG PRIOR YEAR
-- RECEIPTS --																
TOTAL ORIGINALS	25	22	19	20	25	33	20	25	17	17	46	19	288	24	27	29
AMENDMENTS	123	163	125	122	101	138	173	144	112	139	131	112	1583	132	127	112
- MAJOR	76	74	55	52	44	61	86	74	48	57	62	40	729	61	53	58
- MINOR	18	45	25	34	26	42	44	43	33	48	34	44	436	36	42	26
- FACSIMILE **	29	44	45	36	31	35	43	27	31	34	35	28	418	35	32	28
-- ACTIONS --																
APPROVALS	14	15	21	18	19	17	13	13	12	19	15	18	194	16	17	19
TENTATIVE APPROVALS+	5	5	2	4	6	4	7	4	8	3	2	3	53	4	3	4
NOT APPROVABLE	27	55	34	37	54	62	36	42	49	38	46	28	508	42	37	35
FACSIMILE REQUEST**	20	20	19	17	20	29	12	10	19	16	19	13	214	18	16	18
REFUSE TO FILE	11	3	5	5	2	7	12	2	4	6	0	4	61	5	3	5
WITHDRAWALS	2	10	50	28	21	50	36	59	25	7	5	43	336	28	18	31
- OF APPROVED	0	2	44	16	21	46	25	47	15	3	3	37	259	22	14	25
- OF UNAPPROVED	2	8	6	12	0	4	11	12	10	4	2	6	77	6	4	6
-- REVIEW STATUS --																
AWAITING OGD ACTION (TOTAL)***	442	439	437	436	409	399	409	427	399	415	438	414		422	422	416
AWAITING OGD ACTION (> 180 DAYS)***	105	98	99	98	100	84	76	90	67	71	74	82		87	76	86
AWAITING OGD ACTION (<=180 DAYS)***	337	341	338	338	309	315	333	337	332	344	364	332		335	347	330

* 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 January 31, 2000, 1 original application and 13 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 194 approvals for the year ending January 31, 2000, 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)

	Feb-99	Mar-99	Apr-99	May-99	Jun-99	Jul-99	Aug-99	Sep-99	Oct-99	Nov-99	Dec-99	Jan-00	TOTAL	AVG LAST 12 MOS	AVG LAST 3 MOS	AVG PRIOR YEAR
--RECEIPTS--																
ORIGINAL SUPPLEMENTS	150	148	157	193	260	215	291	100	139	161	116	173	2103	175	150	258
AMENDMENTS TO SUPPLEMENTS **	158	404	185	249	239	145	335	170	118	198	200	242	2643	220	213	220
--SUPPLEMENTAL ACTIONS-																
APPROVALS ***	310	283	134	235	177	143	98	67	37	40	31	42	1597	133	38	183
APPROVABLE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NOT APPROVABLE +	77	328	94	76	180	83	103	43	53	29	34	22	1122	94	28	69
WITHDRAWALS	11	23	16	5	25	21	28	7	8	10	4	13	171	14	9	22
--REVIEW STATUS--																
SUPPLEMENTS AWAITING OGD ACTION (TOTAL) *	1737	1362	1355	1298	1260	1234	1398	1404	1413	1331	1257	1119		1347	1236	1568
SUPPLEMENTS AWAITING OGD ACTION (>180 DAYS)	237	128	137	139	156	85	83	93	95	156	178	156		137	163	159
SUPPLEMENTS AWAITING OGD ACTION (<=180 DAYS)	1500	1234	1218	1159	1104	1149	1315	1311	1318	1175	1079	963		1210	1072	1409

* In September, 1991, the Office of Generic Drugs started implementation of its Application Integrity Policy by suspending review of applications tainted by fraud. Review status figures reported since this date exclude suspended applications. As of January 31, 2000, 1 original application and 13 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

Quantitative Report

Table III

POST APPROVAL SUBMISSIONS TO APPLICATIONS (LABELING)

	Feb-99	Mar-99	Apr-99	May-99	Jun-99	Jul-99	Aug-99	Sep-99	Oct-99	Nov-99	Dec-99	Jan-00	TOTAL	AVG LAST 12 MOS	AVG LAST 3 MOS	AVG PRIOR YEAR
--RECEIPTS--																
ORIGINAL SUPPLEMENTS	33	61	41	40	38	42	31	45	77	45	25	22	500	42	31	56
AMENDMENTS TO SUPPLEMENTS	49	55	38	60	44	50	60	84	101	39	61	31	672	56	44	60
--SUPPLEMENTAL ACTIONS--																
APPROVALS	31	40	46	54	47	49	54	63	49	75	42	40	590	49	52	58
APPROVABLE	17	3	4	2	5	4	12	6	6	13	3	4	79	7	7	8
NOT APPROVABLE	5	23	32	14	14	24	17	13	15	23	8	9	197	16	13	14
WITHDRAWALS	4	25	1	3	7	0	4	6	1	5	0	0	56	5	2	2
--REVIEW STATUS--																
SUPPLEMENTS AWAITING OGD ACTION (TOTAL)	339	349	323	308	299	282	256	242	284	218	229	205		278	217	346
SUPPLEMENTS AWAITING OGD ACTION (>180 DAYS)	116	109	114	106	117	117	95	90	81	81	86	83		100	83	136
SUPPLEMENTS AWAITING OGD ACTION (<=180 DAYS)	223	240	209	202	182	165	161	152	203	137	143	122		178	134	211

* 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 January 31, 2000, 1 original application and 13 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

Table IV

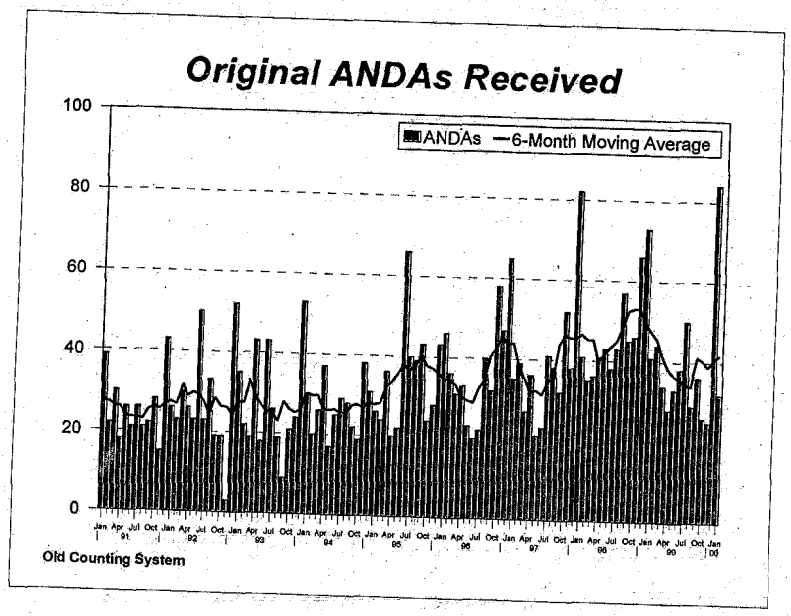
ORIGINAL APPLICATIONS - OLD COUNTING SYSTEM

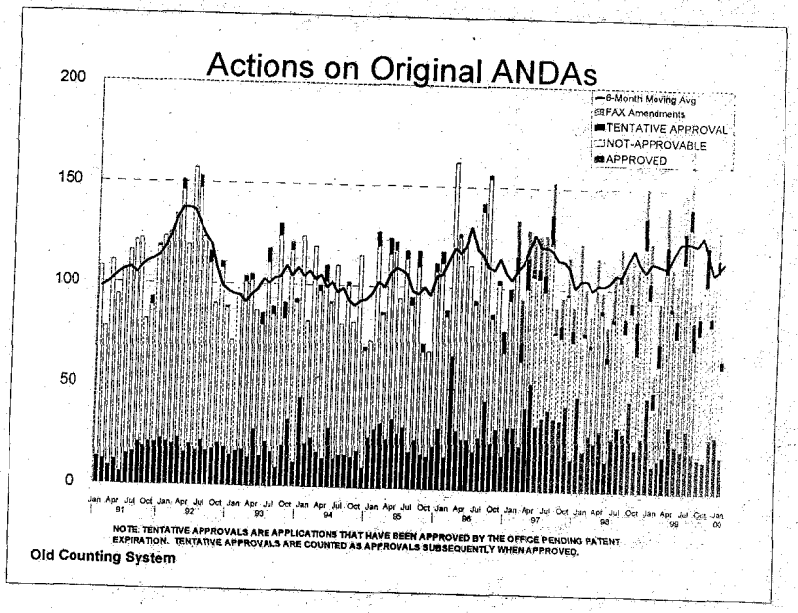
	Feb-99	Mar-99	Apr-99	May-99	Jun-99	Jul-99	Aug-99	Sep-99	Oct-99	Nov-99	Dec-99	Jan-00	TOTAL	AVG LAST 12 MOS	AVG LAST 3 MOS	AVG PRIOR YEAR
-- RECEIPTS --																
TOTAL ORIGINALS	44	34	28	33	38	50	29	36	26	25	84	32	459	38	47	47
AMENDMENTS	123	163	125	122	101	138	173	144	112	139	131	112	1583	132	127	112
- MAJOR	76	74	55	52	44	61	86	74	48	57	62	40	729	61	53	58
- MINOR	18	45	25	34	26	42	44	43	33	48	34	44	436	36	42	26
- FACSIMILE	29	44	45	36	31	35	43	27	31	34	35	28	418	35	32	28
-- ACTIONS --																
APPROVALS	16	18	33	23	21	31	20	17	16	27	28	18	268	22	24	28
TENTATIVE APPROVALS+	11	13	2	9	15	10	14	8	19	4	6	4	115	10	5	6
NOT APPROVABLE	47	91	57	54	93	100	51	62	87	56	82	44	824	69	6	55
FACSIMILE REQUEST*	20	20	19	17	20	29	12	10	19	16	19	13	214	18	16	18
REFUSE TO FILE	12	4	6	6	5	8	15	4	4	8	0	9	81	7	6	9
WITHDRAWALS	5	11	52	30	21	50	39	65	26	10	5	47	361	30	21	33
- OF APPROVED	0	2	45	16	21	46	25	49	15	4	3	40	266	22	16	25
- OF UNAPPROVED	5	9	7	14	0	4	14	16	11	6	2	7	95	8	5	8
-- REVIEW STATUS --																
AWAITING OGD ACTION (TOTAL)**	719	714	705	727	680	663	698	726	679	710	736	705		705	717	644
AWAITING OGD ACTION (> 180 DAYS)	153	154	157	168	177	146	135	160	121	147	132	146		150	142	128
AWAITING OGD ACTION (<=180 DAYS)	566	560	548	559	503	517	563	566	558	563	604	559		556	575	516

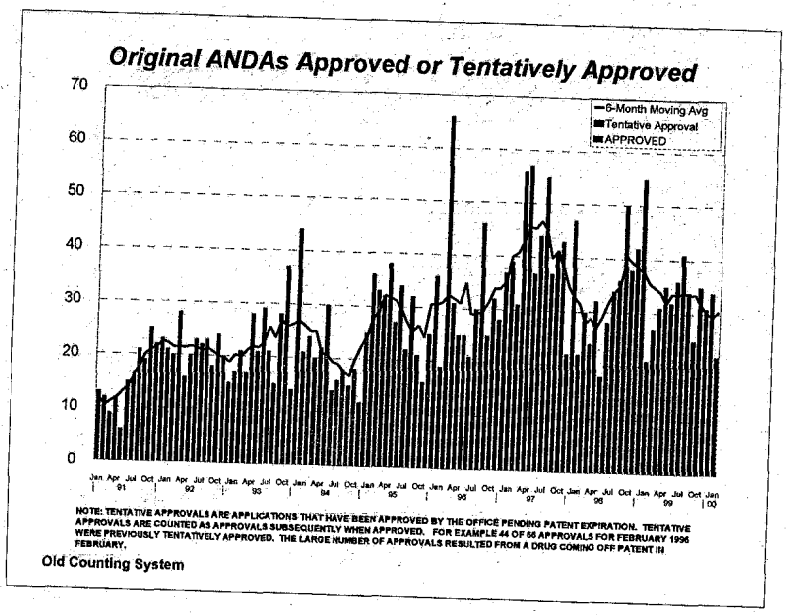
* Facsimile policy went into effect in January of 1997

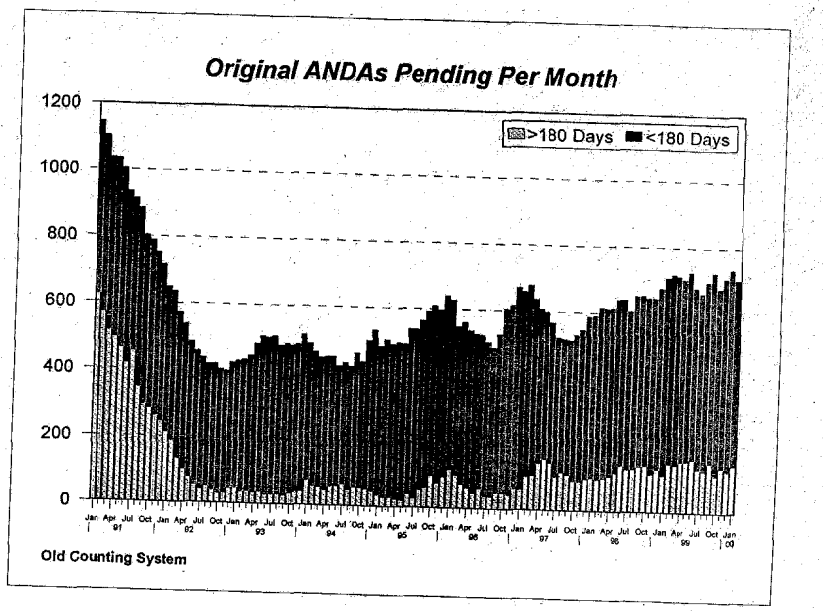
** In September, 1991, the Office of Generic Drugs started implementation of its Application Integrity Policy by suspending review of applications suspected of being tainted by fraud. Review status figures reported since this date exclude suspended applications. As of January 31, 2000, 1 original application and 13 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 268 approvals for the year ending January 31, 2000, 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.

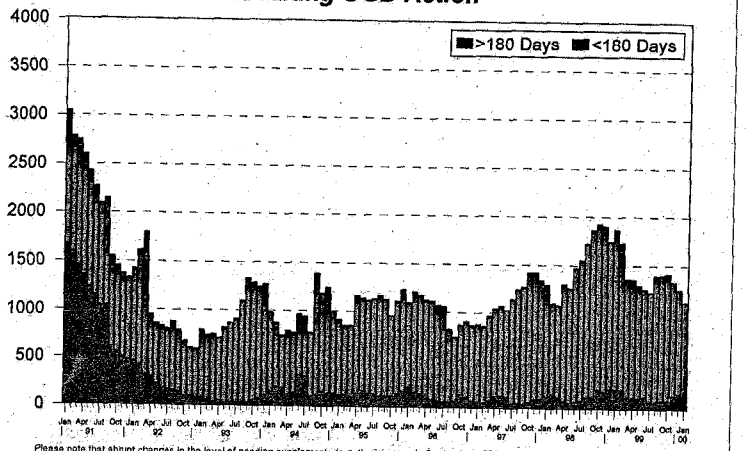

Original ANDAs Received
ANDAs
6-Month Moving Average
100
80
60
40
20
0
Old Counting System


Actions on Original ANDAs
6-Month Moving Avg
FAX Amendments
TENTATIVE APPROVAL
NOT-APPROVABLE
APPROVED
200
150
100
50
0
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
6-Month Moving Avg
Tentative Approval
APPROVED
70
60
50
40
30
20
10
0
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 56 APPROVALS FOR FEBRUARY 1996 WERE PREVIOUSLY TENTATIVELY APPROVED. THE LARGE NUMBER OF APPROVALS RESULTED FROM A DRUG COMING OFF PATENT IN FEBRUARY.
Old Counting System

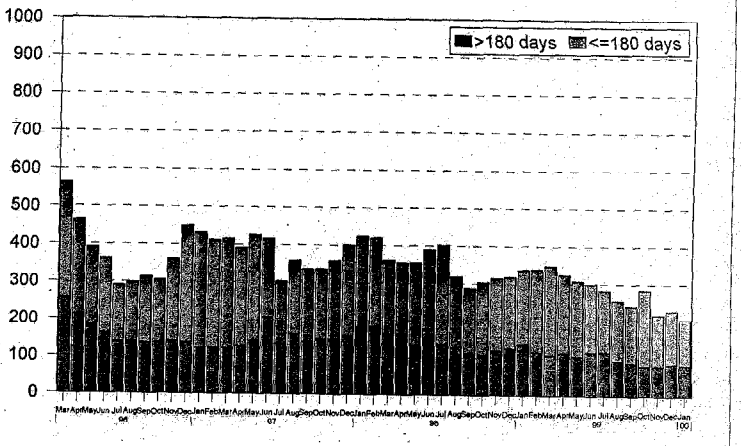

Original ANDAs Pending Per Month
>180 Days
<180 Days
1200
1000
800
600
400
200
0
Old Counting System

Chemistry, Manufacturing & Controls Supplements Awaiting OGD Action

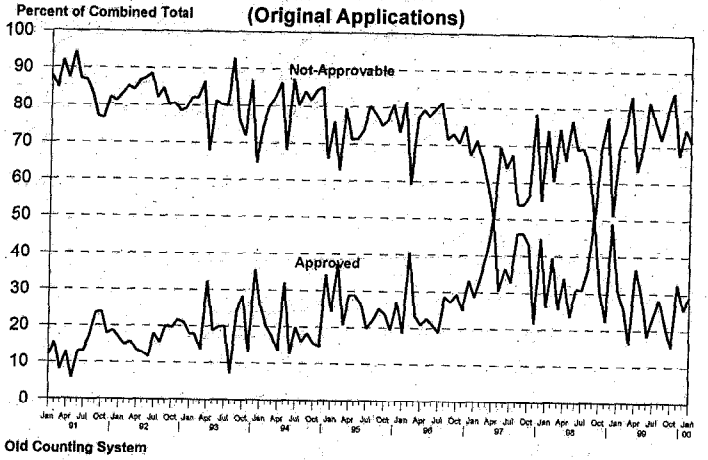


Please note that abrupt changes in the level of pending supplements (e.g. the increase in September 1994) are the result of global submissions to all applications held by a single firm. Changes other than these will be explained separately.

Labeling Supplements Awaiting OGD Action

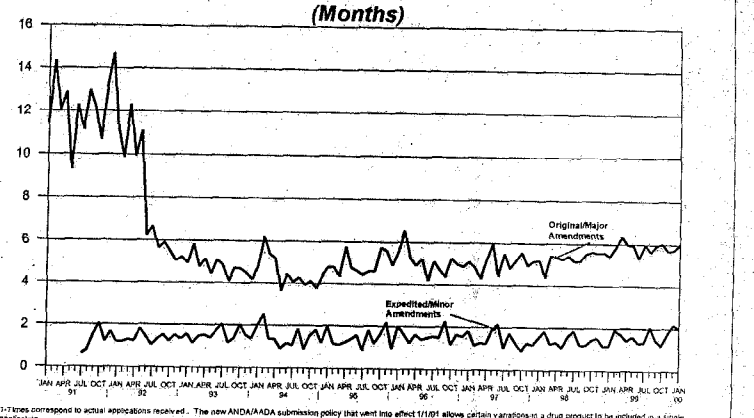


Percent Approved and Not-Approvable Per Month (Original Applications)



Old Counting System

Median ANDA CMC Supplement Review Time (Months)

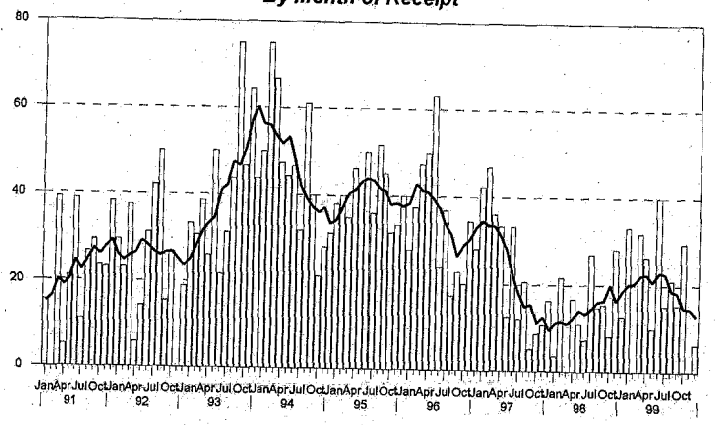


1-Times correspond to actual applications received. The new ANDA/AADA submission policy that went into effect 1/1/01 allows certain variations in a drug product to be included in a single application.

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.

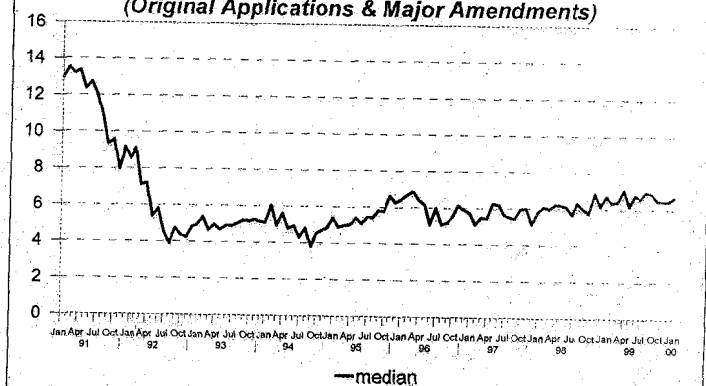
Note: Global Supplements Collapsed

Percent of Original Submissions with Refuse to File Action
By Month of Receipt



Status as of February 4, 2000, Percentages for recent months may increase due to future RF actions
(Actual applications, new counting system)

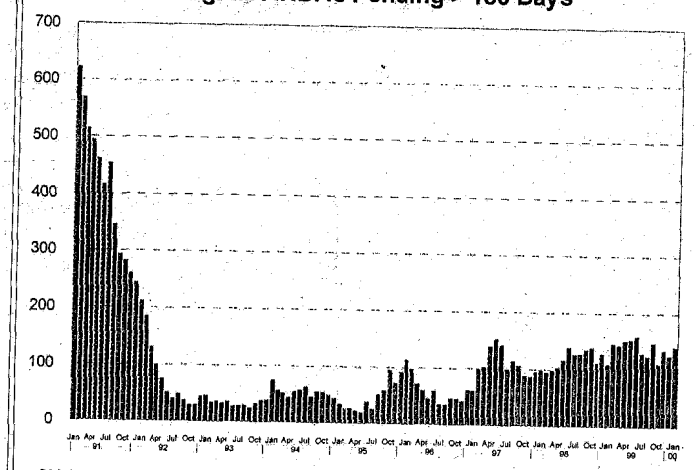
Median ANDA Review Cycle (Months)
(Original Applications & Major Amendments)



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.

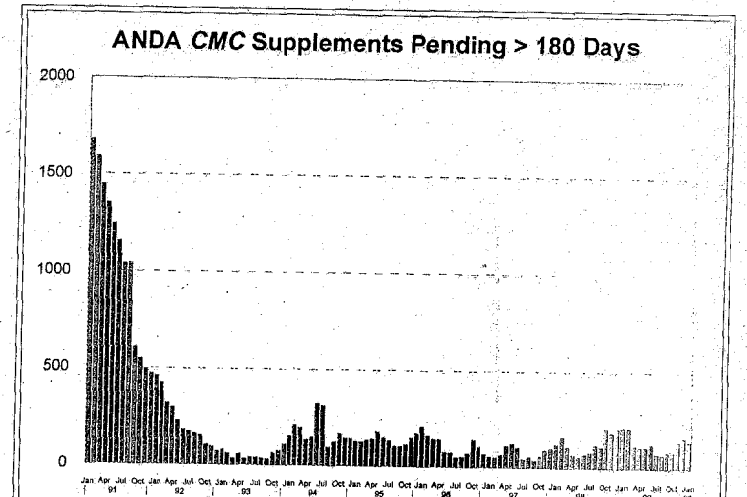
2-In September, 1991 the OGD started implementation of the Application Integrity Policy by suspending review of applications suspected of being tainted by fraud. AIP time has been subtracted from review time above for the period after 9/91. However, before the AIP went into effect, the review of many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

Original ANDAs Pending > 180 Days

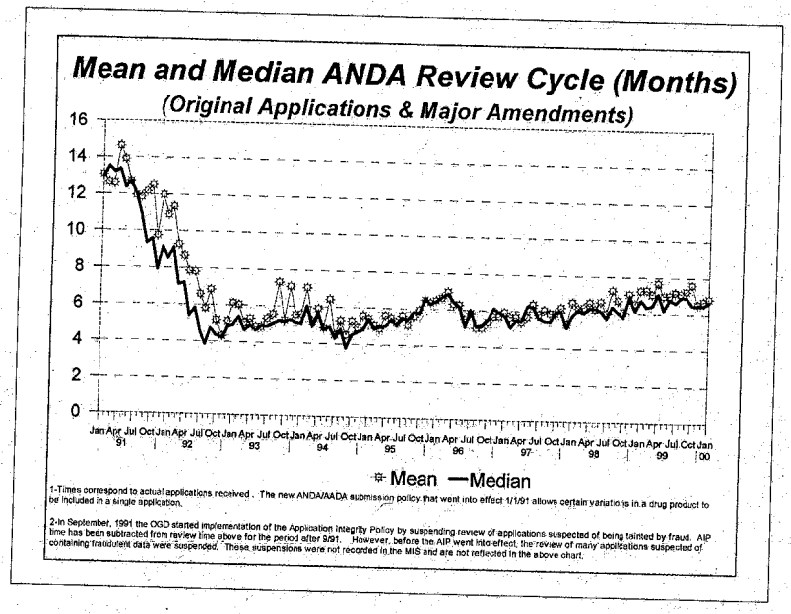


Old Counting System

ANDA *CMC* Supplements Pending > 180 Days



Old Counting System


Mean and Median ANDA Review Cycle (Months)
(Original Applications & Major Amendments)
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 Jan
91
92
93
94
95
96
97
98
99
00
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 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.

Office Of Generic Drugs ANDAs Approvals

1.	75-476	CARTEOLOL HYDROCHLORIDE OPHTHALMIC SOLUTION, USP 1%	ALCON LABORATORIES, INC.	1/3/00
2.	75-232	LOPERAMIDE HYDROCHLORIDE TABLETS , USP (OTC) 2 MG	L. PERRIGO CO.	1/6/00
3.	65-017	CYCLOSPORINE CAPSULES, USP (MODIFIED) 25 MG 100 MG	EON LABS MANUFACTURING, INC.	1/13/00
4.	75-132	RANITIDINE TABLETS, USP 75 MG (OTC)	RANBAXY LABORATORIES, LTD.	1/14/00
5.	75-212	RANITIDINE TABLETS, USP 75 MG (OTC)	CHELSEA LABORATORIES, INC.	1/14/00
6.	75-254	RANITIDINE TABLETS, USP 75 MG (OTC)	RANBAXY PHARMACEUTICALS, INC.	1/14/00
7.	75-296	RANITIDINE TABLETS, USP 75 MG (OTC)	ZENITH GOLDLINE PHARMACEUTICALS, INC.	1/14/00
8.	75-497	RANITIDINE TABLETS, USP 75 MG (OTC)	GENPHARM INC.	1/14/00
9.	75-271	CROMOLYN SODIUM INHALATION SOLUTION, USP 10 MG/ML (2 ML UNIT-DOSE VIALS)	STERIPAK LIMITED	1/18/00
10.	40-322	PREDNISOLONE SYRUP, USP 15 MG/5 ML	COPLEY PHARMACEUTICAL, INC.	1/19/00
11.	75-546	CARTEOLOL HYDROCHLORIDE OPHTHALMIC SOLUTION, USP 1%	BAUSCH & LOMB PHARMACEUTICALS, INC.	1/20/00
12.	65-035	DAUNORUBICIN HYDROCHLORIDE INJECTION 20 MG (BASE)/4 ML & 50 MG (BASE)/10 ML	GENSIA SICOR PHARMACEUTICALS, INC.	1/24/00

13. 74-973	TRIMETHOPRIM HYDROCHLORIDE ORAL SOLUTION 50 MG (BASE)/5 ML	ASCENT PEDIATRICS, INC.	1/24/00
14. 40-333	FLUOROURACIL INJECTION, USP 50 MG/ML (10 ML (500 MG)SINGLE-DOSE VIAL	GENSIA SICOR PHARMACEUTICALS, INC.	1/27/00
15. 75-235	METAPROTERENOL SULFATE SYRUP, USP 10 MG/5 ML	NOVEX PHARMA	1/27/00
16. 64-160	CLINDAMYCIN PHOSPHATE GEL, USP 1% (BASE)	ALTANA INC.	1/28/00
17. 75-407	MORPHINE SULFATE EXTENDED-RELEASE TABLETS 15 MG	ESI LEDERLE	1/28/00
18. 75-640	HYDROCHLOROTHIAZIDE CAPSULES 12.5 MG	MYLAN PHARMACEUTICALS, INC.	1/28/00

Office of Generic Drugs ANDAs Tentative Approvals

01-Feb-00

1.	75-452	FLUOXETINE CAPSULES, USP 10 MG (BASE) 20 MG (BASE)	TEVA PHARMACEUTICALS USA	1/3/00
2.	75-619	MINOXIDIL TOPICAL SOLUTION, USP 5% (FOR MEN) (OTC)	COPLEY PHARMACEUTICAL, INC.	1/18/00
3.	75-571	ENALAPRILAT INJECTION 1.25 MG/1 ML & 2.5 MG/2 ML VIALS	FAULDING PHARMACEUTICAL CO.	1/28/00

Office Of Generic Drugs Supplement Approvals

Tuesday, February 01, 2000

1.	75-155 S-002	ISOSORBIDE MONONITRATE EXTENDED-RELEASE TABLETS 30 MG	KREMERS URBAN	1/13/00