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

DATE: January 5, 2000

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

SUBJECT: Statistical Report - Month of December 1999

TO: See Below

This memorandum represents the Office of Generic Drugs' statistical report for December 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 December's 15 new generic approvals, and 2 tentative approvals follow the graphic presentations. First time generic approvals or tentative approvals are indicated by an asterisk (*). Approvals include generic equivalents for Ovral Tablets, an oral contraceptive marketed by Wyeth Ayerst Laboratories; Procardia-XL Tablets, a cardiac drug marketed by Pfizer; and Lanoxin Tablets, a drug used in the treatment of heart failure marketed by Glaxo Wellcome. [Note: In December, the office also issued a second tentative approval letter 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 three applicants also received approval of supplements providing for additional strengths of previously approved drug products.

The following observations are notable from the December data:

On average, the office received 25 original applications each month during 1999. However, this number increased to a monthly high of 46 receipts in December. This increase is

similar to that observed during past years.

There were 0 refuse-to-file (RTF) actions taken during the month. This is significant because an average of 5 applications per month received this action during 1999. Hopefully, this is an indication that the quality and completeness of new submissions is continuing to improve.

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

Table I

Quantitative Report

ORIGINAL APPLICATIONS

	Jan-99	Feb-99	Mar-99	Apr-99	May-99	Jun-99	Jul-99	Aug-99	Sep-99	Oct-99	Nov-99	Dec-99	TOTAL	AVG LAST 12 MOS	AVG LAST 3 MOS	AVG PRIOR YEAR
-- RECEIPTS --																
TOTAL ORIGINALS	27	25	22	19	20	25	33	20	25	17	17	46	296	25	27	29
AMENDMENTS	107	123	163	125	122	101	138	173	144	112	139	131	1578	132	127	109
- MAJOR	40	76	74	55	52	44	61	86	74	48	57	62	729	61	56	57
- MINOR	27	18	45	25	34	26	42	44	43	33	48	34	419	35	38	26
- FACSIMILE **	40	29	44	45	36	31	35	43	27	31	34	35	430	36	33	26
-- ACTIONS --																
APPROVALS	10	14	15	21	18	19	17	13	13	12	19	15	186	16	15	19
TENTATIVE APPROVALS+	6	5	5	2	4	6	4	7	4	8	3	2	56	5	4	3
NOT APPROVABLE	16	27	55	34	37	54	62	36	42	49	38	46	496	41	44	37
FACSIMILE REQUEST**	9	20	20	19	17	20	29	12	10	19	16	19	210	18	18	19
REFUSE TO FILE	6	11	3	5	5	2	7	12	2	4	6	0	63	5	3	5
WITHDRAWALS	16	2	10	50	28	21	50	36	59	25	7	5	309	26	12	30
- OF APPROVED	14	0	2	44	16	21	46	25	47	15	3	3	236	20	7	23
- OF UNAPPROVED	2	2	8	6	12	0	4	11	12	10	4	2	73	6	5	7
-- REVIEW STATUS --																
AWAITING OGD ACTION (TOTAL)***	438	442	439	437	436	409	399	409	427	399	415	438		424	417	412
AWAITING OGD ACTION (> 180 DAYS)***	79	105	98	99	98	100	84	76	90	67	71	74		87	71	85
AWAITING OGD ACTION (<=180 DAYS)***	359	337	341	338	338	309	315	333	337	332	344	364		337	347	326

* 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 December 31, 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 3 of the 186 approvals for the year ending December 31, 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 III

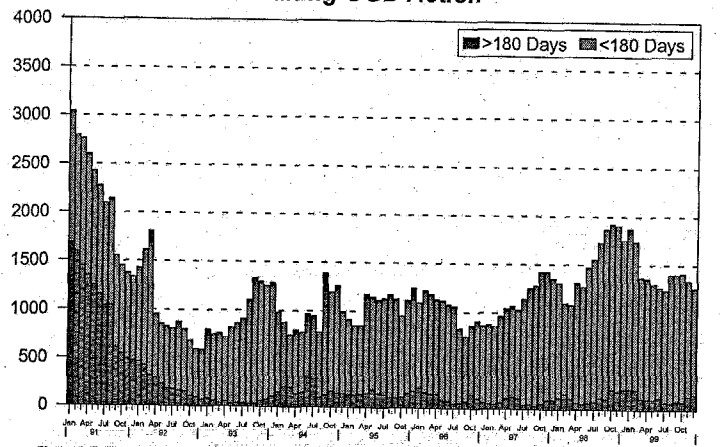
Quantitative Report

POST APPROVAL SUBMISSIONS TO APPLICATIONS (LABELING)

	Jan-99	Feb-99	Mar-99	Apr-99	May-99	Jun-99	Jul-99	Aug-99	Sep-99	Oct-99	Nov-99	Dec-99	TOTAL	AVG LAST 12 MOS	AVG LAST 3 MOS	AVG PRIOR YEAR
--RECEIPTS--																
ORIGINAL SUPPLEMENTS	41	33	61	41	40	38	42	31	45	77	45	25	519	43	49	56
AMENDMENTS TO SUPPLEMENTS	55	49	55	38	60	44	50	60	84	101	39	61	696	58	67	59
--SUPPLEMENTAL ACTIONS-																
APPROVALS	39	31	40	46	54	47	49	54	63	49	75	42	589	49	55	56
APPROVABLE	4	17	3	4	2	5	4	12	6	6	13	3	79	7	7	8
NOT APPROVABLE	5	5	23	32	14	14	24	17	13	15	23	8	193	16	15	14
WITHDRAWALS	0	4	25	1	3	7	0	4	6	1	5	0	56	5	2	3
--REVIEW STATUS--																
SUPPLEMENTS AWAITING OGD ACTION (TOTAL)	338	339	349	323	308	299	282	256	242	284	218	229		289	244	353
SUPPLEMENTS AWAITING OGD ACTION (>180 DAYS)	137	116	109	114	106	117	117	95	90	81	81	86		104	83	1
SUPPLEMENTS AWAITING OGD ACTION (<=180 DAYS)	201	223	240	209	202	182	165	161	152	203	137	143		185	161	214

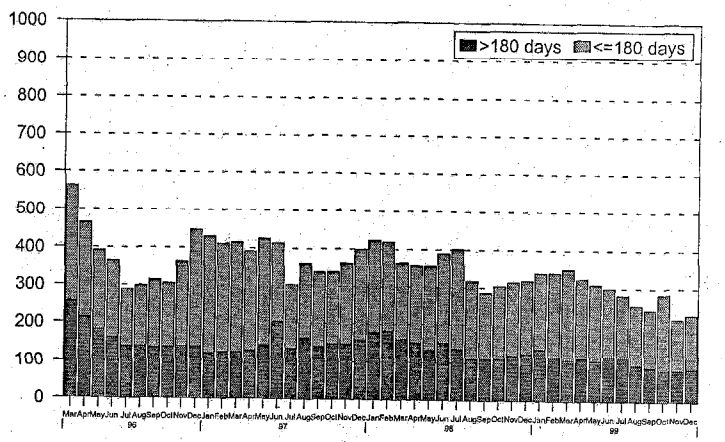
* In September, 1991, the Office of Generic Drugs started implementation of its Application Integrity Policy by suspending review of applications suspected of being tainted by fraud. Review status figures reported since this date exclude suspended applications. As of December 31, 1999, 1 original application and 18 supplements were suspended. Upon completion of validity assessments, suspended applications may be returned to active pending status.

Chemistry, Manufacturing & Controls Supplements Awaiting OGD Action

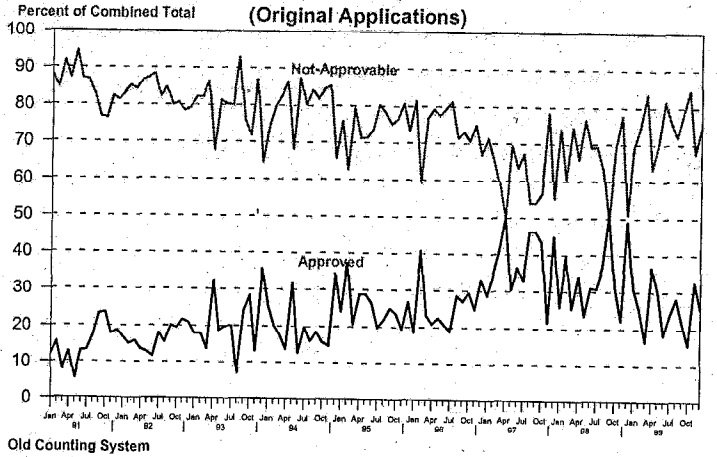


Please note that abrupt changes in the level of pending supplements (e.g. the increase in September 1994) are the result of global submissions to all applications held by a single firm. Changes other than these will be explained separately.

Labeling Supplements Awaiting OGD Action

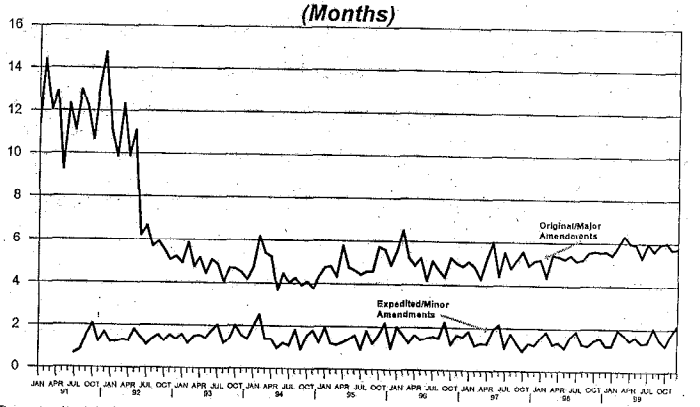


Percent Approved and Not-Approvable Per Month (Original Applications)



Old Counting System

Median ANDA CMC Supplement Review Time (Months)

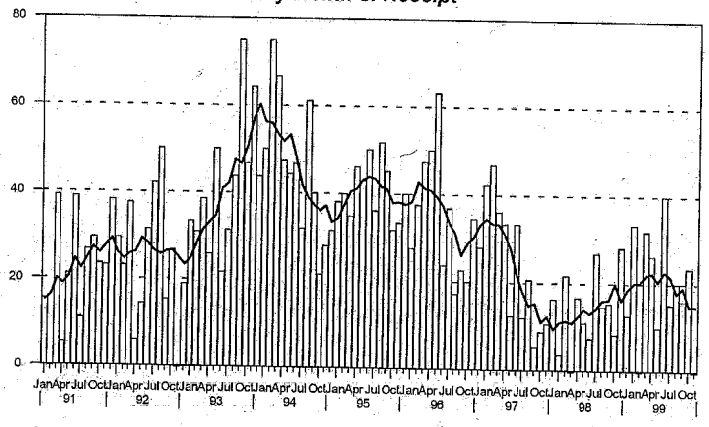


1-Times correspond to actual applications received. The new ANDA/AADA submission policy that went into effect 1/1/91 allows certain variations in a drug product to be included in a single application.

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.

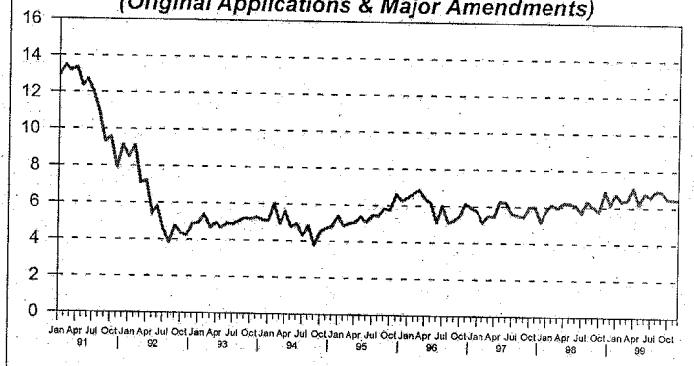
Note: Global Supplements Collapsed

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



Status as of January 5, 2000, Percentages for recent months may increase due to future RF actions
(Actual applications, new counting system)

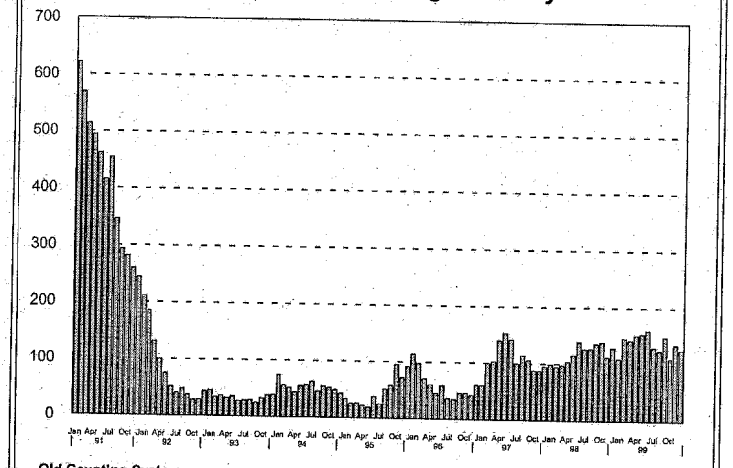
Median ANDA Review Cycle (Months)
(Original Applications & Major Amendments)



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.

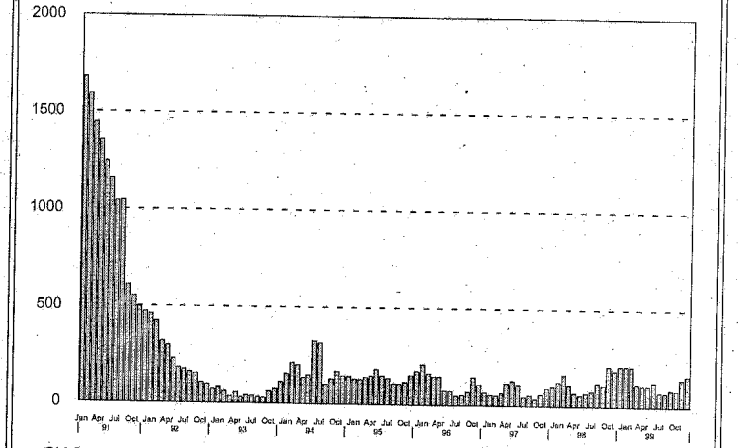
2-In September, 1991 the OGD started implementation of the Application Integrity Policy by suspending review of applications suspected of being tainted by fraud. AIP time has been subtracted from review time above for the period after 9/91. However, before the AIP went into effect, the review of many 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

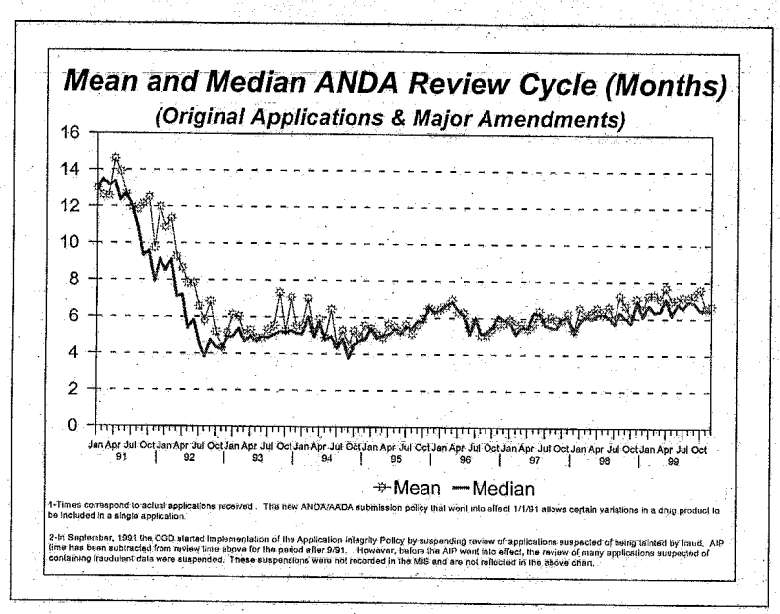


Old Counting System

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
91
92
93
94
95
96
97
98
99
Mean
Median
1-Times correspond to actual applications received. This 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 CDD 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 shown 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. 40-311	MEDROXYPROGESTERONE ACETATE TABLETS, USP 2.5 MG 5 MG 10 MG	DURAMED PHARMACEUTICALS, INC.	12/1/99
	2. 75-172	HYDROCORTISONE ENEMA, USP 100 MG/60 ML	PADDOCK LABORATORIES, INC.	12/3/99
	3. 75-568	AZATHIOPRINE TABLETS, USP 50 MG	GENPHARM INC.	12/13/99
	4. 40-262	LEUCOVORIN CALCIUM FOR INJECTION 350 MG (BASE)/VIAL	PHARMACHEMIE B.V.	12/15/99
*	5. 75-406	NORGESTREL AND ETHINYL ESTRADIOL TABLETS, USP 0.5 MG/0.05 MG (21 DAY CYCLE) 0.5 MG/0.05 MG (28-DAY CYCLE)	SCS PHARMACEUTICALS	12/15/99
*	6. 75-108	NIFEDIPINE EXTENDED-RELEASE TABLETS 30 MG	MYLAN PHARMACEUTICALS, INC.	12/17/99
	7. 74-984	DILTIAZEM HCL EXTENDED-RELEASE CAPSULES, USP (ONCE-A-DAY) 120 MG 180 MG 240 MG 300 MG	PUREPAC PHARMACEUTICAL CO.	12/20/99
*	8. 40-282	DIGOXIN TABLETS, USP 0.125 MG 0.25 MG	AMIDE PHARMACEUTICAL, INC.	12/23/99
	9. 64-180	MITOMYCIN FOR INJECTION, USP 5 MG 20 MG	ESI LEDERLE	12/23/99
	10. 65-021	AMOXICILLIN TABLETS, USP (CHEWABLE) 125 MG 250 MG	RANBAXY PHARMACEUTICALS, INC.	12/23/99
	11. 75-116	DILTIAZEM HCL EXTENDED-RELEASE CAPSULES, USP (ONCE-A-DAY) 120 MG 180 MG 240 MG 300 MG	BIOVAIL LABORATORIES, INC.	12/23/99
	12. 75-597	KETOCONAZOLE TABLETS, USP 200 MG	MYLAN PHARMACEUTICALS, INC.	12/23/99

13. 40-231	CHLORPROMAZINE ORAL CONCENTRATE, USP 30 MG/ML	PHARMACEUTICAL ASSOCIATES, INC.	12/30/99
14. 40-303	OXYCODONE AND ACETAMINOPHEN CAPSULES, USP 5 MG/500 MG	ENDO PHARMACEUTICALS, INC.	12/30/99
15. 75-047	ACEBUTOLOL HYDROCHLORIDE CAPSULES 200 MG (BASE) 400 MG (BASE)	ALPHAPHARM PTY. LTD.	12/30/99

Office of Generic Drugs ANDAs Tentative Approvals

1.	75-413	BUSPIRONE HYDROCHLORIDE TABLETS, USP 5 MG 10 MG 15 MG	GENEVA PHARMACEUTICALS, INC.	12/21/99
2.	75-467	BUSPIRONE HYDROCHLORIDE TABLETS, USP 5 MG 7.5 MG 10 MG 15 MG	PAR PHARMACEUTICAL, INC.	12/28/99

Office Of Generic Drugs Supplement Approvals (New Strengths)

1. 73-403 S-002	CHOLESTYRAMINE TABLETS 800 MG	APOTHECON, INC.	12/27/99
2. 75-286 S-001	PEMOLINE TABLETS 18.75 MG	INVAMED INC.	12/27/99
3. 75-009 S-002	ETODOLAC TABLETS 500 MG	TEVA PHARMACEUTICALS USA	12/28/99