Rec'd in DMB 10/11/00

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: April 5, 2000

FROM: Peter Rickman
Acting Director, Division of Labeling and Program Support

SUBJECT: Statistical Report - Month of March 2000

TO: See Below

This memorandum represents the Office of Generic Drugs' statistical report for March 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. 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 March's 21 new generic approvals, and 9 tentative approvals follow the graphic presentations. First time generic approvals or tentative approvals are indicated by an asterisk (*). These approvals include generic equivalents for Levo-Dromoran Tablets 2 mg, indicated for the management of moderate to severe pain marketed by ICN Pharmaceuticals; Adalat CC Extended-release Tablets 30 mg, indicated for the treatment of hypertension marketed by Bayer; Nix Crème Rinse 1%, used in the treatment of infestation with scabies marketed by Warner Lambert; Tapazole Tablets 5 mg and 10 mg, indicated for the treatment of hyperthyroidism marketed by Lilly; Talacen Tablets 25 mg (base)/650 mg, indicated for the relief of mild to moderate pain marketed by Sanofi Synthelabo; and Actigall Capsules 300 mg, indicated for the prevention of gallstone formation marketed by Novartis.

905-0308

M686

cc:

Office of Pharmaceutical Science
HFD-003/H.Winkel
HFD-003/E.Sheinin
Office of Generic Drugs
HFD-600/G. Buehler
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

	Apr-99	May-99	Jun-99	Jul-99	Aug-99	Sep-99	Oct-99	Nov-99	Dec-99	Jan-00	Feb-00	Mar-00	TOTAL	AVG LAST 12 MOS	AVG LAST 3 MOS	AVG PRIOR YEAR
-- RECEIPTS --																
TOTAL ORIGINALS	19	20	25	33	20	25	17	17	16	19	24	20	285	24	21	29
AMENDMENTS	125	122	101	138	173	144	112	139	131	112	132	170	1599	133	138	115
- MAJOR	55	52	44	61	86	74	48	57	62	40	61	69	709	59	57	59
- MINOR	25	34	26	42	44	43	33	48	34	44	47	60	480	40	50	26
- FACSIMILE **	45	36	31	35	43	27	31	34	35	28	24	41	410	34	31	31
-- ACTIONS --																
APPROVALS	21	13	19	17	13	13	12	19	15	18	21	21	207	17	20	18
TENTATIVE APPROVALS+	2	4	6	4	7	4	8	3	2	3	5	9	57	5	6	4
NOT APPROVABLE	34	37	54	62	36	42	49	38	46	28	60	72	558	47	53	36
FACSIMILE REQUEST**	19	17	20	29	12	10	19	16	19	13	18	34	226	19	22	18
REFUSE TO RECEIVE	5	5	2	7	12	2	4	6	0	4	7	0	64	5	7	6
WITHDRAWALS	50	28	21	50	36	59	25	7	5	43	9	14	347	29	22	27
- OF APPROVED	44	19	21	46	25	47	15	1	5	17	4	1	272	23	17	21
- OF UNAPPROVED	6	12	0	4	11	12	10	4	2	6	5	3	75	6	5	7
--REVIEW STATUS --																
AWAITING OGD ACTION (TOTAL)***	437	436	409	399	409	427	399	415	438	414	398	376		413	396	420
AWAITING OGD ACTION (> 180 DAYS)***	99	98	100	84	76	90	67	71	74	82	73	68		82	74	90
AWAITING OGD ACTION (<=180 DAYS)***	338	338	309	315	333	337	332	344	364	332	325	308		331	322	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 March 31, 2000, 1 original application and 12 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, 1 of the 207 approvals for the year ending March 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

Quantitative Report

Table II

POST APPROVAL SUBMISSIONS TO APPLICATIONS (CHEMISTRY)

	Apr-99	May-99	Jun-99	Jul-99	Aug-99	Sep-99	Oct-99	Nov-99	Dec-99	Jan-00	Feb-00	Mar-00	TOTAL	AVG LAST 12 MOS	AVG LAST 3 MOS	AVG PRIOR YEAR
--RECEIPTS--																
ORIGINAL SUPPLEMENTS	157	192	260	215	291	100	139	161	116	173	297	166	2268	189	212	253
AMENDMENTS TO SUPPLEMENTS	185	249	239	145	335	170	118	198	200	242	579	293	2953	246	371	236
--SUPPLEMENTAL ACTIONS--																
APPROVALS	134	235	177	143	98	67	37	40	31	42	30	44	1078	90	39	190
APPROVABLE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NOT APPROVABLE	94	76	180	83	103	43	53	29	34	22	38	42	797	66	34	89
WITHDRAWALS	16	15	25	21	28	7	8	10	4	13	1	4	142	12	6	19
--REVIEW STATUS--																
SUPPLEMENTS AWAITING OGD ACTION (TOTAL) *	1355	1298	1260	1234	1398	1404	1413	1331	1257	1119	1353	1223		1304	1232	1644
SUPPLEMENTS AWAITING OGD ACTION (>180 DAYS)	137	139	156	85	83	93	95	156	178	156	188	132		133	159	164
SUPPLEMENTS AWAITING OGD ACTION (<=180 DAYS)	1218	1159	1104	1149	1315	1311	1318	1175	1079	963	1165	1091		1171	1073	1481

* In September, 1991, the Office of Generic Drugs started implementation of its Application Integrity Policy by suspending review of applications suspected of by fraud. Review status figures reported since this date exclude suspended applications. As of March 31, 2000, 1 original application and 12 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 III

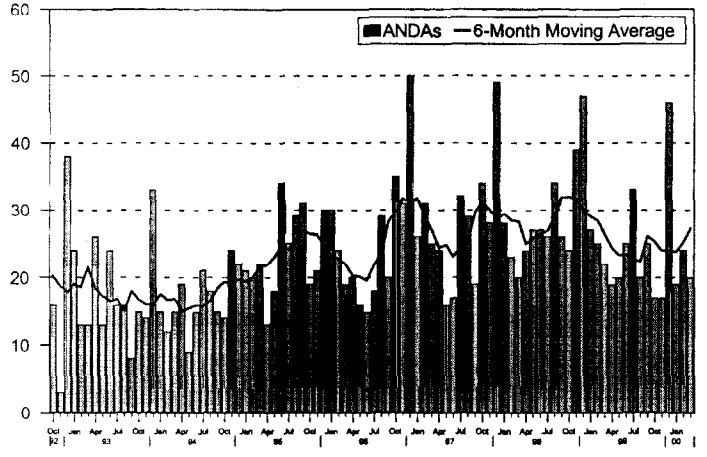
Quantitative Report

POST APPROVAL SUBMISSIONS TO APPLICATIONS (LABELING)

	Apr-99	May-99	Jun-99	Jul-99	Aug-99	Sep-99	Oct-99	Nov-99	Dec-99	Jan-00	Feb-00	Mar-00	TOTAL	AVG LAST 12 MOS	AVG LAST 3 MOS	AVG PRIOR YEAR
--RECEIPTS--																
ORIGINAL SUPPLEMENTS	41	40	38	42	31	45	77	45	25	22	47	43	496	41	37	56
AMENDMENTS TO SUPPLEMENTS	38	60	44	50	60	84	101	39	61	31	53	64	685	57	49	60
--SUPPLEMENTAL ACTIONS--																
APPROVALS	46	54	47	49	54	63	49	75	42	40	38	43	600	50	40	52
APPROVABLE	4	2	5	4	12	6	6	13	3	4	12	2	73	6	6	9
NOT APPROVABLE	32	14	14	24	17	13	15	23	8	9	7	11	187	16	9	14
WITHDRAWALS	1	3	7	0	4	6	1	5	0	0	0	1	28	2	0	5
--REVIEW STATUS--																
SUPPLEMENTS AWAITING OGD ACTION (TOTAL)	323	308	299	282	256	242	284	218	229	205	213	215		256	211	339
SUPPLEMENTS AWAITING OGD ACTION (>180 DAYS)	114	106	117	117	95	90	81	81	86	83	83	77		94	81	126
SUPPLEMENTS AWAITING OGD ACTION (<=180 DAYS)	209	202	182	165	161	152	203	137	143	122	130	138		162	130	213

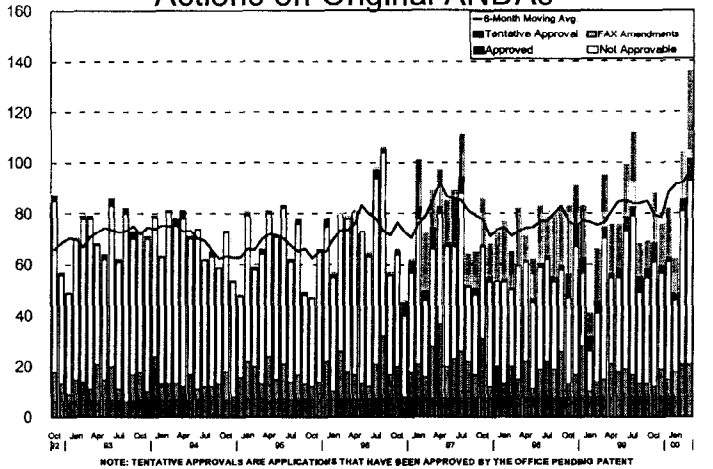
* In September, 1991, the Office of Generic Drugs started implementation of its Application Integrity Policy by suspending review of applications suspected of being tainted by fraud. Review status figures reported since this date exclude suspended applications. As of March 31, 2000, 1 original application and 12 supplements were suspended. Upon completion of validity assessments, suspended applications may be returned to active pending status.

Original ANDAs Received



Actual Counting System

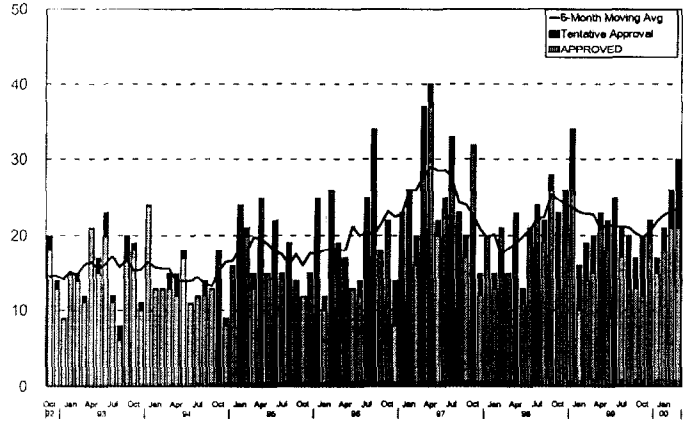
Actions on Original ANDAs



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

Actual Counting System

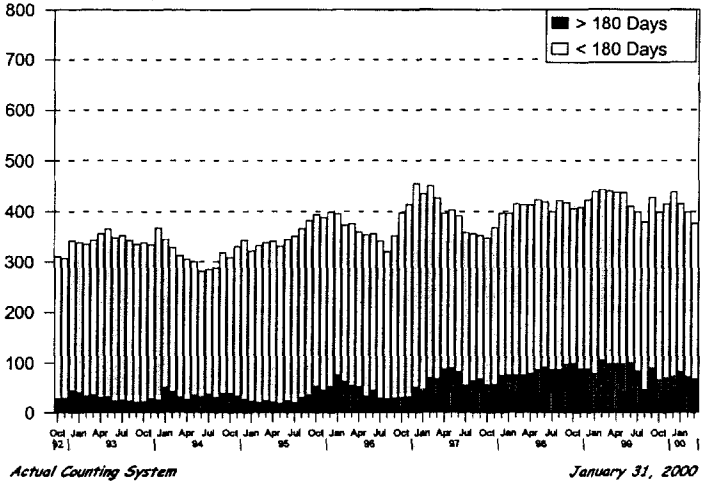
Original ANDAs Approved or Tentatively Approved



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 1996 WERE PREVIOUSLY TENTATIVELY APPROVED. THE LARGE NUMBER OF APPROVALS RESULTED FROM A DRUG COMING OFF PATENT IN FEBRUARY.

Actual Counting System

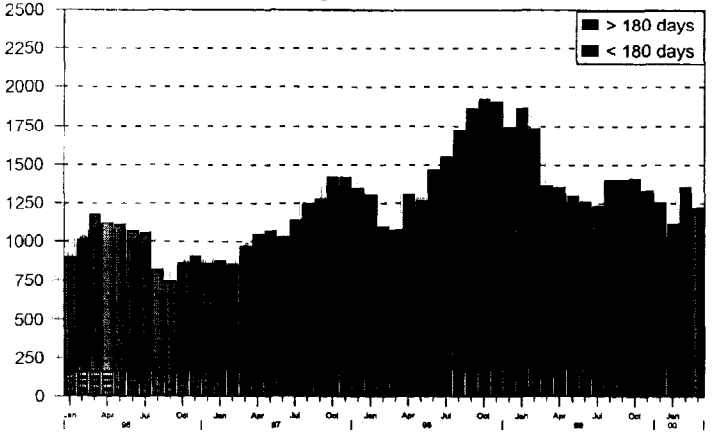
Original ANDAs Pending Per Month



Actual Counting System

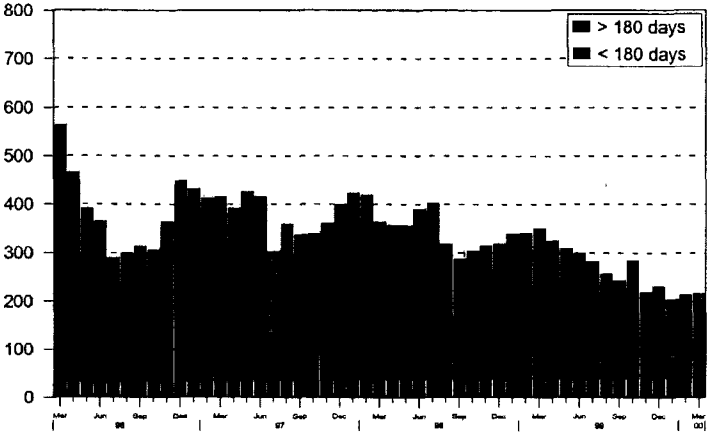
January 31, 2000

Chemistry, Manufacturing & Controls Supplements Awaiting OGD Action



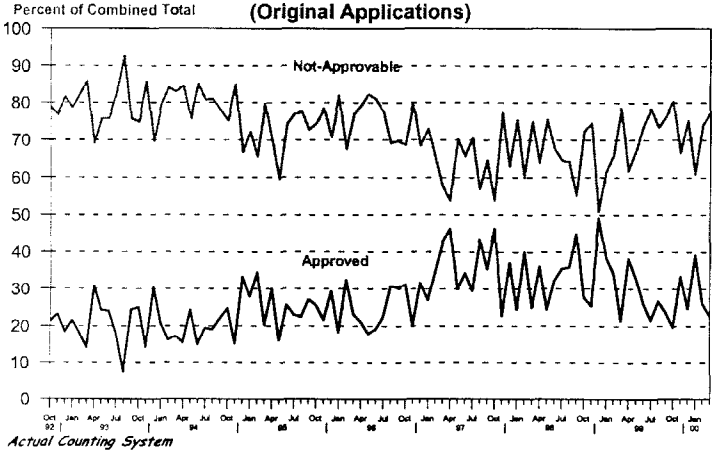
Please note that abrupt changes in the level of pending supplements (e.g. the increase in September 1994) are the result of global submissions by all applications held by a single firm. Changes other than these will be explained separately

Labeling Supplements Awaiting OGD Action



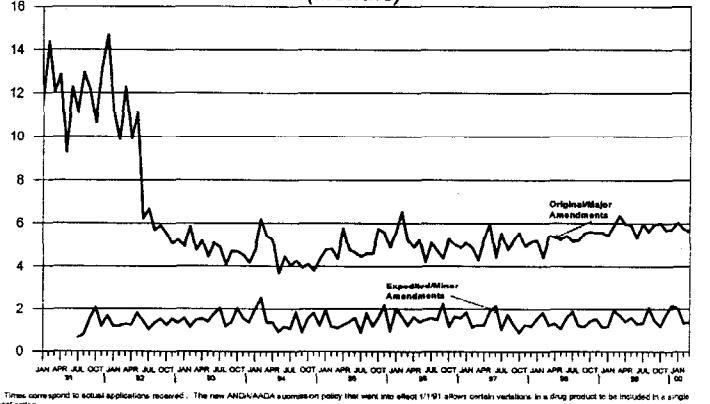
Percent Approved and Not-Approvable Per Month

(Original Applications)



Median ANDA CMC Supplement Review Time

(Months)



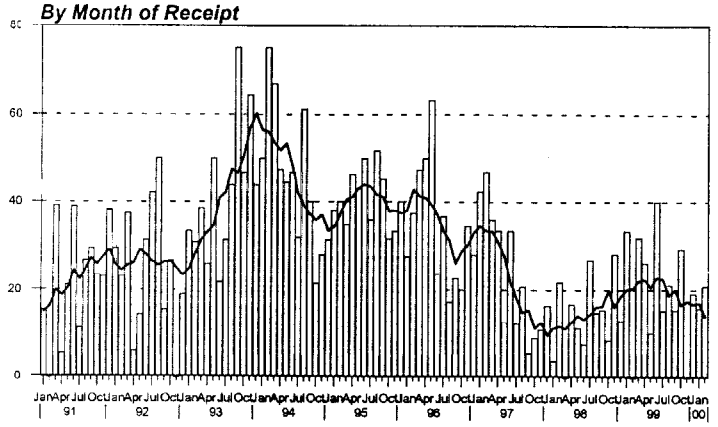
1 Times correspond to actual applications received. The new ANDA/AADA submission policy that went into effect 1/1/91 allows certain variations in a drug product to be included in a single application.

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 Receive Action

By Month of Receipt

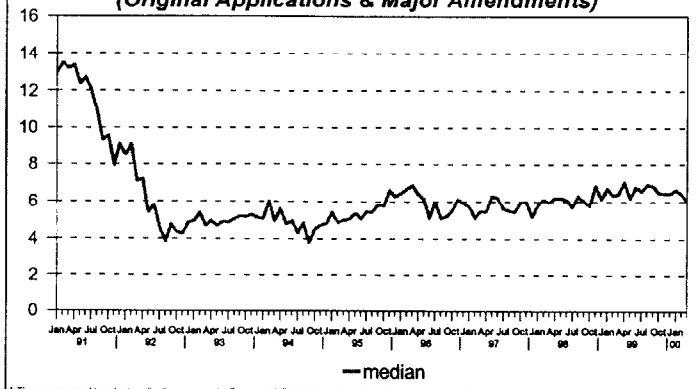


Status as of April 4, 2000, Percentages for recent months may increase due to future RR actions

(Actual applications, new counting system)

Median ANDA Review Cycle (Months)

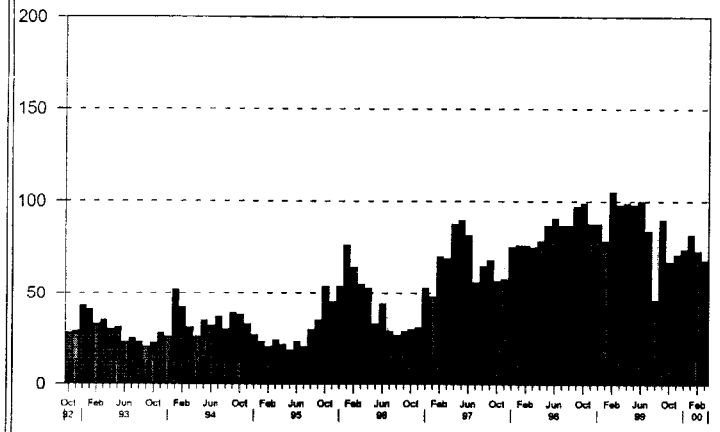
(Original Applications & Major Amendments)



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.

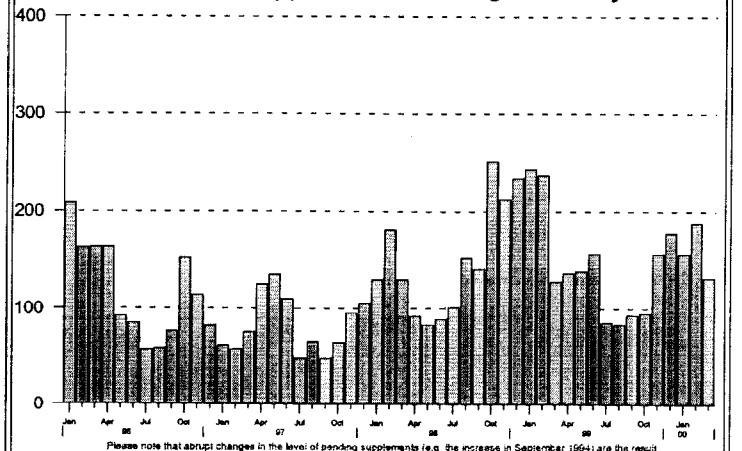
Original ANDAs Pending > 180 Days



Actual Counting System

February 29, 2000

ANDA *CMC* Supplements Pending > 180 Days

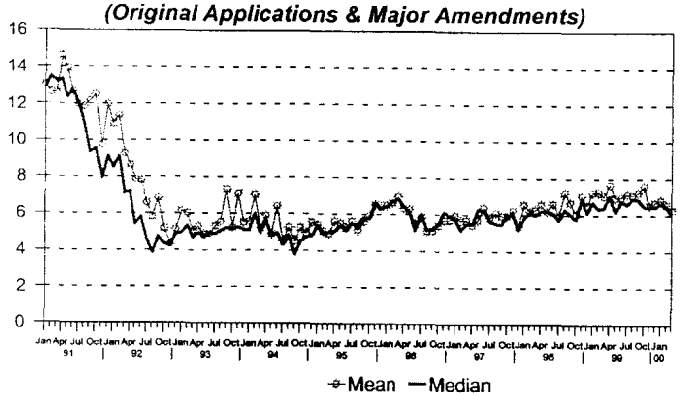


Please note that abrupt changes in the level of pending supplements (e.g. the increase in September 1994) are the result of global submissions to all applications held by a single firm. Changes other than these will be explained separately.

Actual Counting System

Mean and 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.

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Office Of Generic Drugs ANDAs Approvals

1.	65-025	CYCLOSPORINE ORAL SOLUTION USP (MODIFIED) 100 mg/mL	ABBOTT LABORATORIES	3/3/00
2.	75-434	NALTREXONE HYDROCHLORIDE TABLETS USP 50 MG	EON LABS MANUFACTURING INC.	3/8/00
3.	65-031	BLEOMYCIN FOR INJECTION USP 15 UNITS (BASE)/VIAL 30 UNITS (BASE)/VIAL	FAULDING PHARMACEUTICAL CO.	3/10/00
4.	75-128	NIFEDIPINE EXTENDED-RELEASE TABLETS 30 MG	ELAN PHARMACEUTICAL RESEARCH CORPORATION	3/10/00
5.	73-416	CHLORHEXIDINE GLUCONATE TOPICAL SCRUB 4% (WITH BRUSH/SPONGE APPLICATOR)	BECKTON, DICKENSON SURGICAL SYSTEM	3/14/00
6.	75-517	URSODIOL CAPSULES, USP 300 MG	AMIDE PHARMACEUTICAL , INC	3/14/00
7.	75-560	CIMETIDINE HYDROCHLORIDE ORAL SOLUTION 300 MG (BASE)/5 ML	NOVEX PHARMA	3/15/00
8.	40-277	PROPARACAINE HYDROCHLORIDE OPHTHALMIC SOLUTION, USP 0.5%	TAYLOR PHARMACEUTICALS	3/16/00
9.	74-793	LORAZEPAM INJECTION, USP 2 MG/ML (VIALS) 4 MG/ML (VIALS)	MOVA PHARMACEUTICAL CORPORATION	3/16/00
10.	75-395	ISOSORBIDE MONONITRATE EXTENDED-RELEASE TABLETS 30 MG 60 MG 120 MG	KV PHARMACEUTICAL COMPANY	3/16/00

Office of Generic Drugs ANDAs Tentative Approvals

06-Apr-00

1.	75-579	BISOPROLOL FUMARATE AND HYDROCHLOROTHIAZIDE TABLETS 2.5 MG/6.25 MG 5 MG/6.25 MG 10 MG/6.25 MG	EON LABS MANUFACTURING, INC.	3/2/00
2.	75-409	MIDAZOLAM HYDROCHLORIDE INJECTION 1 MG (BASE)/ML (SYRINGE) 5 MG (BASE)/ML (SYRINGE)	ABBOTT LABORATORIES	3/15/00
3.	75-628	FAMOTIDINE TABLETS, USP 20 MG 40 MG	APOTHECON, INC.	3/16/00
4.	75-416	NAPROXEN SODIUM EXTENDED-RELEASE TABLETS 500 MG (BASE)	ANDRX PHARMACEUTICALS, INC	3/17/00
5.	75-650	FAMOTIDINE TABLETS, USP 20 MG 40 MG	PUREPAC PHARMACEUTICAL CO.	3/17/00
6.	75-347	OMEPRAZOLE DELAYED-RELEASE CAPSULES 10 MG 20 MG 40 MG	ANDRX PHARMACEUTICALS, INC.	3/23/00
7.	75-583	ENALAPRIL MALEATE TABLETS, USP 2.5 MG 5 MG 10 MG 20 MG	APOTHECON, INC.	3/29/00
8.	75-685	CIPROFLOXACIN TABLETS, USP 750 MG	MYLAN PHARMACEUTICALS, INC.	3/30/00
9.	75-527	BISOPROLOL FUMARATE AND HYDROCHLOROTHIAZIDE 2.5 MG/6.25 MG 5 MG/6.25 MG 10 MG/6.25 MG	INVAMED INC.	3/31/00

11. 75-523	PENTAZOCINE AND NALOXONE HYDROCHLORIDES TABLETS, USP 50 MG (BASE)/0.5 MG (BASE)	RANBAXY LABORATORIES LIMITED	3/17/00
12. 75-559	BUTORPHANOL TARTRATE INJECTION, USP 1 MG/ML (SYRINGE) 2 MG/ML (SYRINGE)	ABBOTT LABORATORIES	3/20/00
13. 64-200	CEFOTAXIME FOR INJECTION 500 MG /10 ML VIAL 1 G /10 ML VIAL 2 G/10 ML VIAL 1 G /100 ML VIAL 2 G /100 ML VIAL	AMERICAN PHARMACEUTICAL PARTNERS, INC.	3/24/00
14. 64-201	CEFOTAXIME FOR INJECTION 10 G/VIAL (PHARMACY BULK PACKAGE) 20 G/VIAL (PHARMACY BULK PACKAGE)	AMERICAN PHARMACEUTICAL PARTNERS, INC.	3/24/00
15. 74-699	PENTAZOCINE HYDROCHLORIDE AND ACETAMINOPHEN TABLETS 25 MG (BASE)/650 MG	WATSON LABORATORIES, INC.	3/24/00
16. 75-014	PERMETHRIN LOTION 1%	ALPHARMA	3/28/00
17. 75-294	RANITIDINE TABLETS, USP (OTC) 75 MG	CHEMINOR DRUGS LTD.	3/28/00
18. 40-350	METHIMAZOLE TABLETS, USP 5 MG 10 MG	GENPHARM INC.	3/29/00
19. 75-358	ALBUTEROL SULFATE INHALATION SOLUTION 0.083% (BASE)	BAUSCH & LOMB PHARMACEUTICALS, INC.	3/29/00
20. 40-320	METHIMAZOLE TABLETS, USP 5 MG 10 MG	APPLIED ANALYTICAL INDUSTRIES	3/31/00
21. 74-278	LEVORPHANOL TARTRATE TABLETS, USP 2 MG	ROXANE LABORATORIES, INC.	3/31/00