

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

Table I

ORIGINAL APPLICATIONS

	Sep-02	Oct-02	Nov-02	Dec-02	Jan-03	Feb-03	Mar-03	Apr-03	May-03	Jun-03	Jul-03	Aug-03	TOTAL	AVG LAST 12 MOS	AVG LAST 3 MOS	AVG PRIOR YEAR
-- RECEIPTS --																
TOTAL ORIGINALS	29	26	41	87	36	25	35	29	35	36	37	36	452	38	36	30
AMENDMENTS	156	186	180	174	205	171	195	192	186	196	217	233	2291	191	215	162
- MAJOR	83	81	98	88	101	74	98	94	106	96	102	120	1141	95	106	73
- MINOR	70	104	81	86	104	97	97	98	80	100	115	113	1145	95	109	78
- FACSIMILE **	3	1	1	0	0	0	0	0	0	0	0	0	5	0	0	11
-- ACTIONS --																
APPROVALS	15	25	32	19	21	18	24	23	19	26	13	20	255	21	20	25
TENTATIVE APPROVALS+	4	6	2	3	10	8	5	8	8	14	7	4	79	7	8	6
APPROVABLE+	1	0	0	1	0	0	0	0	0	0	0	0	2	0	0	3
NOT APPROVABLE	43	68	43	59	74	60	62	71	65	83	65	78	771	64	75	55
REFUSE TO RECEIVE	7	6	4	0	6	3	9	3	7	8	7	2	62	5	6	5
WITHDRAWALS	6	2	2	1	21	22	30	35	12	24	6	10	171	14	13	15
- OF APPROVED	1	2	0	1	1	7	15	28	11	3	3	9	81	7	5	10
- OF UNAPPROVED	5	0	2	0	20	15	15	7	1	21	3	1	90	8	8	6
-- REVIEW STATUS --																
AWAITING OGD ACTION (TOTAL)***	395	390	409	479	491	516	511	495	497	470	498	524		473	497	407
AWAITING OGD ACTION (> 180 DAYS)***	23	21	26	37	32	29	27	29	36	28	47	60		33	45	42
AWAITING OGD ACTION (< 180 DAYS)***	372	369	383	442	459	487	484	466	461	442	451	464		440	452	365

*** 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 30, 2003, 2 original application and 2 supplements were suspended.

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

+ Note: Approvable and Tentative approvals are counted as approvals subsequently when approved.

Center for Drug Evaluation and Research - Office of Generic Drugs

Table II

Quantitative Report

POST APPROVAL SUBMISSIONS TO APPLICATIONS (CHEMISTRY)

	Sep-02	Oct-02	Nov-02	Dec-02	Jan-03	Feb-03	Mar-03	Apr-03	May-03	Jun-03	Jul-03	Aug-03	TOTAL	AVG LAST 12 MOS	AVG LAST 3 MOS	AVG PRIOR YEAR
--RECEIPTS--																
ORIGINAL SUPPLEMENTS	204	281	226	193	152	143	182	324	302	147	260	372	2786	232	260	210
AMENDMENTS TO SUPPLEMENTS	272	295	278	252	224	188	239	368	378	238	313	395	3440	287	315	255
--SUPPLEMENTAL ACTIONS																
APPROVALS	135	181	194	295	216	250	233	211	130	131	250	342	2568	214	241	172
APPROVABLE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NOT APPROVABLE	90	106	83	100	131	100	106	65	52	92	84	100	1109	92	92	89
WITHDRAWALS	4	7	19	16	34	16	23	13	12	12	122	19	297	25	51	16
--REVIEW STATUS--																
SUPPLEMENTS AWAITING OGD ACTION (TOTAL) *	1387	1423	1470	1326	1112	1088	1007	1150	1329	1300	1308	1285		1265	1298	1107
SUPPLEMENTS AWAITING OGD ACTION (>180 DAYS)	58	49	45	43	38	52	31	44	72	54	46	66		50	55	81
SUPPLEMENTS AWAITING OGD ACTION (<=180 DAYS)	1329	1374	1425	1283	1074	1036	976	1106	1257	1246	1262	1219		1216	1242	1026

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Quantitative Report

POST APPROVAL SUBMISSIONS TO APPLICATIONS (LABELING)

	Sep-02	Oct-02	Nov-02	Dec-02	Jan-03	Feb-03	Mar-03	Apr-03	May-03	Jun-03	Jul-03	Aug-03	TOTAL	AVG LAST 12 MOS	AVG LAST 3 MOS	AVG PRIOR YEAR
--RECEIPTS--																
ORIGINAL SUPPLEMENTS	54	62	59	35	49	32	28	63	59	57	44	49	591	49	50	61
AMENDMENTS TO SUPPLEMENTS	92	78	81	47	56	51	51	72	69	70	64	65	796	66	66	72
--SUPPLEMENTAL ACTIONS--																
APPROVALS	87	65	72	63	34	21	31	41	49	42	57	48	610	51	49	44
APPROVABLE	1	6	5	10	1	13	3	1	6	1	5	2	54	5	3	6
NOT APPROVABLE	12	10	12	17	7	13	13	7	4	7	6	8	116	10	7	12
WITHDRAWALS	2	1	3	1	6	2	2	3	6	1	5	8	40	3	5	3
--REVIEW STATUS--																
SUPPLEMENTS AWAITING OGD ACTION (TOTAL)	386	365	348	304	319	314	310	328	336	354	336	343		337	344	366
SUPPLEMENTS AWAITING OGD ACTION (>180 DAYS)	130	131	116	107	107	107	100	101	116	119	116	118		114	118	127
SUPPLEMENTS AWAITING OGD ACTION (<=180 DAYS)	256	234	232	197	212	207	210	227	220	235	220	225		223	227	239

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