

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

Table I

ORIGINAL APPLICATIONS

	Jul-02	Aug-02	Sep-02	Oct-02	Nov-02	Dec-02	Jan-03	Feb-03	Mar-03	Apr-03	May-03	Jun-03	TOTAL	AVG LAST 12 MOS	AVG LAST 3 MOS	AVG PRIOR YEAR
-- RECEIPTS --																
TOTAL ORIGINALS	30	22	29	26	41	87	36	25	35	29	34	36	430	36	33	29
AMENDMENTS	191	168	156	186	180	174	205	171	195	192	186	196	2200	183	191	159
- MAJOR	111	76	83	81	98	88	101	74	98	94	106	96	1106	92	99	67
- MINOR	78	91	70	104	81	86	104	97	97	98	80	100	1086	91	93	77
- FACSIMILE **	2	1	3	1	1	0	0	0	0	0	0	0	8	1	0	16
-- ACTIONS --																
APPROVALS	45	19	15	25	32	19	21	18	24	23	19	26	286	24	23	23
TENTATIVE APPROVALS+	8	3	4	6	2	3	10	8	5	8	8	14	79	7	10	6
APPROVABLE+	2	0	1	0	0	1	0	0	0	0	0	0	4	0	0	2
NOT APPROVABLE	67	76	43	68	43	59	74	60	62	71	65	83	771	64	73	53
REFUSE TO RECEIVE	5	3	7	6	4	0	6	3	9	3	7	8	61	5	6	4
WITHDRAWALS	2	7	6	2	2	1	21	22	30	35	12	24	164	14	24	18
- OF APPROVED	1	3	1	2	0	1	1	7	15	28	11	3	73	6	14	11
- OF UNAPPROVED	1	4	5	0	2	0	20	15	15	7	1	21	91	8	10	7
-- REVIEW STATUS --																
AWAITING OGD ACTION (TOTAL)***	402	385	395	390	409	479	491	516	511	495	497	470		453	487	402
AWAITING OGD ACTION (> 180 DAYS)***	32	26	23	21	26	37	32	29	27	29	36	28		29	31	41
AWAITING OGD ACTION (< 180 DAYS)***	370	359	372	369	383	442	459	487	484	466	461	442		425	456	361

*** 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 June 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.

Quantitative Report

POST APPROVAL SUBMISSIONS TO APPLICATIONS (CHEMISTRY)

	Jul-02	Aug-02	Sep-02	Oct-02	Nov-02	Dec-02	Jan-03	Feb-03	Mar-03	Apr-03	May-03	Jun-03	TOTAL	AVG LAST 12 MOS	AVG LAST 3 MOS	AVG PRIOR YEAR
--RECEIPTS--																
ORIGINAL SUPPLEMENTS	208	253	204	281	226	193	152	143	182	324	302	147	2615	218	258	200
AMENDMENTS TO SUPPLEMENTS	244	369	272	295	278	252	224	188	239	368	378	238	3345	279	328	239
--SUPPLEMENTAL ACTIONS--																
APPROVALS	255	183	135	181	194	295	216	250	233	211	130	131	2414	201	157	170
APPROVABLE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NOT APPROVABLE	86	85	90	106	83	100	131	100	106	65	52	92	1096	91	70	91
WITHDRAWALS	19	17	4	7	19	16	34	16	23	13	12	12	192	16	12	15
--REVIEW STATUS--																
SUPPLEMENTS AWAITING OGD ACTION (TOTAL) *	1265	1280	1387	1423	1470	1326	1112	1088	1007	1150	1329	1300		1261	1260	1081
SUPPLEMENTS AWAITING OGD ACTION (>180 DAYS)	68	97	58	49	45	43	38	52	31	44	72	54		54	57	77
SUPPLEMENTS AWAITING OGD ACTION (<=180 DAYS)	1197	1183	1329	1374	1425	1283	1074	1036	976	1106	1257	1246		1207	1203	1004

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Quantitative Report

POST APPROVAL SUBMISSIONS TO APPLICATIONS (LABELING)

	Jul-02	Aug-02	Sep-02	Oct-02	Nov-02	Dec-02	Jan-03	Feb-03	Mar-03	Apr-03	May-03	Jun-03	TOTAL	AVG LAST 12 MOS	AVG LAST 3 MOS	AVG PRIOR YEAR
--RECEIPTS--																
ORIGINAL SUPPLEMENTS	48	60	54	62	59	35	49	32	28	63	59	57	606	51	60	59
AMENDMENTS TO SUPPLEMENTS	68	81	92	78	81	47	56	51	51	72	69	70	816	68	70	67
--SUPPLEMENTAL ACTIONS--																
APPROVALS	41	66	87	65	72	63	34	21	31	41	49	42	612	51	44	42
APPROVABLE	11	23	1	6	5	10	1	13	3	1	6	1	81	7	3	5
NOT APPROVABLE	9	12	12	10	12	17	7	13	13	7	4	7	123	10	6	12
WITHDRAWALS	1	2	2	1	3	1	6	2	2	3	6	1	30	3	3	4
--REVIEW STATUS--																
SUPPLEMENTS AWAITING OGD ACTION (TOTAL)	439	415	386	365	348	304	319	314	310	328	336	354		352	339	345
SUPPLEMENTS AWAITING OGD ACTION (>180 DAYS)	175	158	130	131	116	107	107	107	100	101	116	119		122	112	119
SUPPLEMENTS AWAITING OGD ACTION (<=180 DAYS)	264	257	256	234	232	197	212	207	210	227	220	235		229	227	226

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