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: March 9, 2006

FROM: LCDR Martin Shimer
Branch Chief
Division of Labeling and Program Support

THROUGH: Peter Rickman
Director
Division of Labeling and Program Support

SUBJECT: Statistical Report – Month of February 2006

TO: See Below

This memorandum represents the Office of Generic Drugs' statistical report for February 2006.

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 2001.

Approvals for the month of January include 28 new generic full approvals and 14 tentative approvals. Of the 42 approvals, 8 applications were approved as first generics. The office also had 6 new strength supplements approved. Separate lists of the approvals for the month of December follow the graphic presentations.

Center for Drug Evaluation and Research - Office of Generic Drugs

Table I

Quantitative Report

ORIGINAL APPLICATIONS

	Mar-05	Apr-05	May-05	Jun-05	Jul-05	Aug-05	Sep-05	Oct-05	Nov-05	Dec-05	Jan-06	Feb-06	TOTAL	AVG LAST 12 MOS	AVG LAST 3 MOS	AVG PRIOR YEAR
-- RECEIPTS --																
TOTAL ORIGINALS	85	41	39	55	73	47	49	68	70	129	56	42	754	63	76	56
AMENDMENTS	299	308	292	296	312	295	289	296	275	317	305	312	3596	300	311	262
- MAJOR	149	148	163	145	143	147	148	156	138	152	170	177	1836	153	166	125
- MINOR	150	160	129	151	169	148	141	140	137	165	135	135	1760	147	145	137
-- ACTIONS --																
APPROVALS	24	41	30	27	29	34	32	25	33	40	25	28	368	31	31	30
TENTATIVE APPROVALS+	11	2	6	12	14	11	12	6	6	15	11	14	120	10	13	7
APPROVABLE+	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NOT APPROVABLE	102	63	106	110	65	109	103	63	81	84	71	77	1034	86	77	79
REFUSE TO RECEIVE	12	16	7	9	8	10	12	4	6	5	11	3	103	9	6	7
WITHDRAWALS	7	7	3	35	2	17	46	14	12	30	2	8	183	15	13	8
- OF APPROVED	3	1	0	25	2	4	44	12	8	26	1	2	128	11	10	4
- OF UNAPPROVED	4	6	3	10	0	13	2	2	4	4	1	6	55	5	4	4
-- REVIEW STATUS --																
AWAITING OGD ACTION (TOTAL)***	810	817	802	794	842	815	780	891	900	975	1004	1008		870	996	653
AWAITING OGD ACTION (> 180 DAYS)***	104	117	144	158	140	140	139	174	189	183	224	224		161	210	74
AWAITING OGD ACTION (< 180 DAYS)***	706	700	658	636	702	675	641	717	711	792	780	784		709	785	580

*** 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 February 28, 2006, 0 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)

	Mar-05	Apr-05	May-05	Jun-05	Jul-05	Aug-05	Sep-05	Oct-05	Nov-05	Dec-05	Jan-06	Feb-06	TOTAL	AVG LAST 12 MOS	AVG LAST 3 MOS	AVG PRIOR YEAR
--RECEIPTS--																
ORIGINAL SUPPLEMENTS	468	226	257	213	201	273	214	178	342	392	241	583	3588	299	405	315
AMENDMENTS TO SUPPLEMENTS	528	292	272	232	254	304	242	175	207	435	323	702	3966	331	487	383
--SUPPLEMENTAL ACTIONS-																
APPROVALS	363	184	263	157	170	338	206	377	220	177	163	309	2927	244	216	276
APPROVABLE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NOT APPROVABLE	64	26	49	29	39	29	35	51	43	55	42	29	491	41	42	81
WITHDRAWALS	17	0	12	7	3	73	5	17	9	11	30	18	202	17	20	11
--REVIEW STATUS--																
SUPPLEMENTS AWAITING OGD ACTION (TOTAL)	1567	1644	1490	1809	1809	1657	1672	1427	1545	1778	1818	2085		1692	1894	1625
SUPPLEMENTS AWAITING OGD ACTION (>180 DAYS)	173	197	222	219	348	302	310	308	310	338	379	415		293	377	130
SUPPLEMENTS AWAITING OGD ACTION (<=180 DAYS)	1394	1447	1268	1590	1456	1355	1362	1119	1235	1440	1439	1670		1398	1516	1495

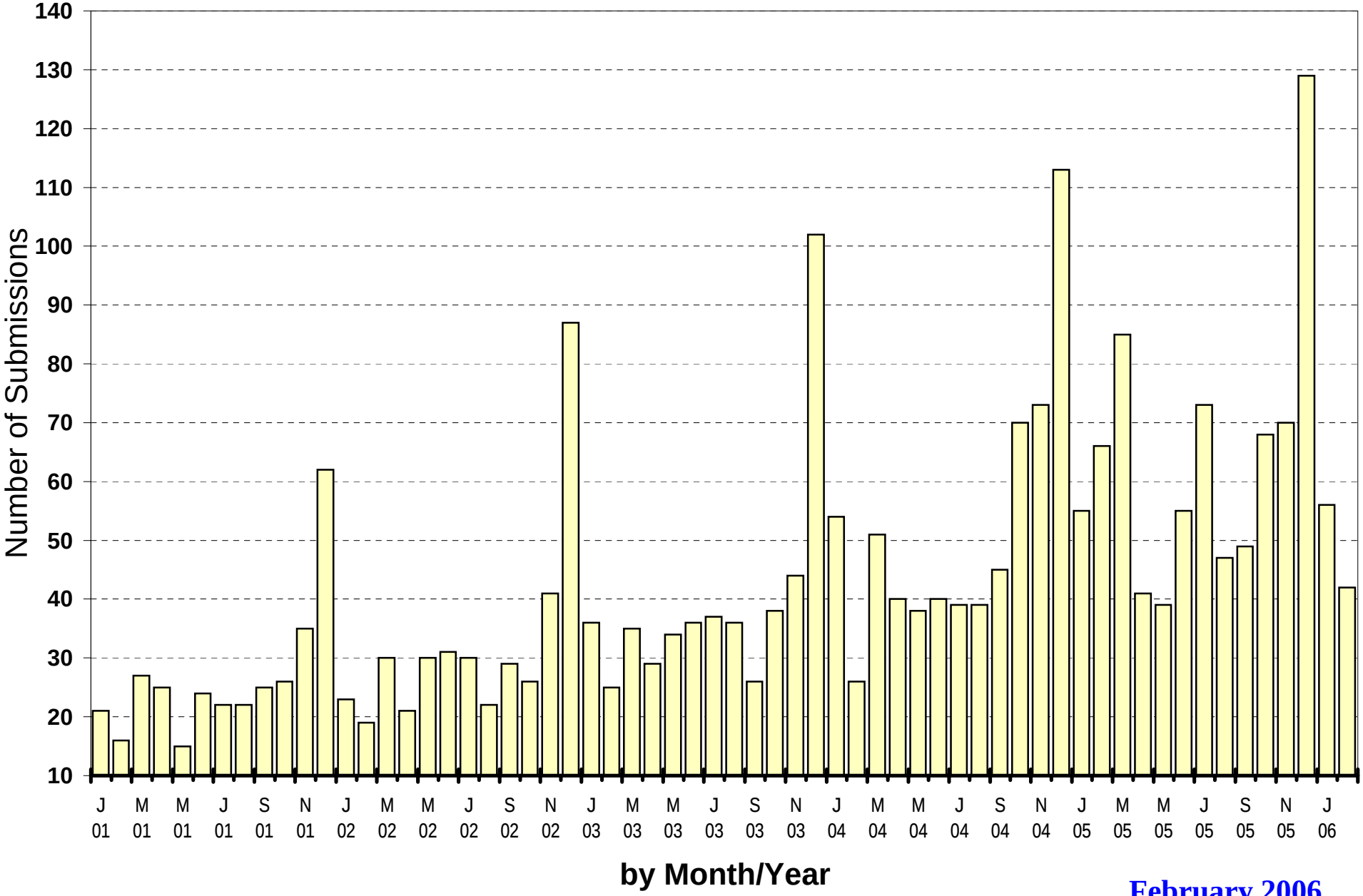
Center for Drug Evaluation and Research - Office of Generic Drugs **Table III**

Quantitative Report

POST APPROVAL SUBMISSIONS TO APPLICATIONS (LABELING)

	Mar-05	Apr-05	May-05	Jun-05	Jul-05	Aug-05	Sep-05	Oct-05	Nov-05	Dec-05	Jan-06	Feb-06	TOTAL	AVG LAST 12 MOS	AVG LAST 3 MOS	AVG PRIOR YEAR
--RECEIPTS--																
ORIGINAL SUPPLEMENTS	123	97	68	39	67	120	54	62	41	47	46	82	846	71	58	55
AMENDMENTS TO SUPPLEMENTS	146	112	90	56	92	140	59	79	53	46	63	101	1037	86	70	72
--SUPPLEMENTAL ACTIONS-																
APPROVALS	44	110	85	93	92	101	60	37	33	39	33	44	771	64	39	49
APPROVABLE	8	8	7	5	6	12	4	0	0	3	8	1	62	5	4	3
NOT APPROVABLE	9	8	5	4	6	5	4	2	4	7	5	1	60	5	4	9
WITHDRAWALS	0	6	6	5	0	3	2	1	0	1	3	7	34	3	4	2
--REVIEW STATUS--																
SUPPLEMENTS AWAITING OGD ACTION (TOTAL)	524	477	451	408	338	372	370	392	396	404	420	453		417	426	387
SUPPLEMENTS AWAITING OGD ACTION (>180 DAYS)	187	135	121	110	95	92	104	121	135	135	151	185		131	157	134
SUPPLEMENTS AWAITING OGD ACTION (<=180 DAYS)	337	342	330	298	243	280	266	271	261	269	269	268		286	269	253

Original ANDAs Received



February 2006

Office of Generic Drugs ANDA Full Approvals
For Month of February 2006

1. **76-395** DILTIAZEM HYDROCHLORIDE EXTENDED-RELEASE CAPSULES USP, 120 MG, 180 MG, 240 MG, 300 MG, AND 360 MG (ONCE-A-DAY DOSAGE)
   APOTEX INC.
   AP'd on: **2/1/2006**

2. **76-820** BENAZEPRIL HYDROCHLORIDE TABLETS, 5 MG, 10 MG, 20 MG, AND 40 MG
   BIOKEY, INC.
   AP'd on: **2/3/2006**

3. **77-280** GLIMEPIRIDE TABLETS, 1 MG, 2 MG, AND 4 MG
   COBALT PHARMACEUTICALS, INC.
   AP'd on: **2/3/2006**

4. **77-291** CYCLOBENZAPRINE HYDROCHLORIDE TABLETS USP, 5 MG
   AMIDE PHARMACEUTICAL, INC.
   AP'd on: **2/3/2006**

5. **40-609** HYDROCORTISONE AND ACETIC ACID OTIC SOLUTION USP, 1%/2%
   VINTAGE PHARMACEUTICALS, LLC
   AP'd on: **2/6/2006**

6. **65-311** CEFADROXIL CAPSULES USP, 500 MG
   HIKMA PHARMACEUTICALS
   AP'd on: **2/7/2006**

7. **76-829** AMMONIUM LACTATE CREAM, 12% (AS LACTIC ACID)
   PADDOCK LABORATORIES, INC.
   AP'd on: **2/7/2006**

8. **77-102** CALCITRIOL INJECTION, 0.001 MG/ML (1 MCG/ML); 1 ML VIALS
   GENIX THERAPEUTICS, INC.
   AP'd on: **2/8/2006**

9. **77-336** METFORMIN HYDROCHLORIDE EXTENDED-RELEASE TABLETS, 500 MG AND 750 MG
   SUN PHARMACEUTICAL INDUSTRIES, LTD.
   AP'd on: **2/9/2006**

10. **77-098** OFLOXACIN TABLETS, 200 MG, 300 MG, AND 400 MG
    DR. REDDY'S LABORATORIES LIMITED
    AP'd on: **2/10/2006**

11. **77-450** OCTREOTIDE ACETATE INJECTION,
0.2 MG(BASE)/ML AND 1 MG(BASE)/ML; 5 ML VIALS
AMERICAN PHARMACEUTICAL PARTNERS, INC.
AP'd on: **2/10/2006**

12. **77-457** OCTREOTIDE ACETATE INJECTION,
0.05 MG(BASE)/ML, 0.1 MG(BASE)/ML, AND 0.5 MG (BASE)/ML; 1 ML VIALS (PRESERVATIVE-FREE)
AMERICAN PHARMACEUTICAL PARTNERS, INC.
AP'd on: **2/10/2006**

13. **77-486** GLIMEPIRIDE TABLETS,
1 MG, 2 MG, AND 4 MG
GENPHARM INC.
AP'd on: **2/10/2006**

14. **65-312** CEFOXITIN FOR INJECTION USP,
10 G/VIAL (PHARMACY BULK PACKAGE)
ORCHID HEALTHCARE
AP'd on: **2/13/2006**

15. **40-649** PROMETHAZINE HYDROCHLORIDE AND DEXTROMETHORPHAN HYDROBROMIDE SYRUP, 6.25 MG/15 MG PER 5 ML
VINTAGE PHARMACEUTICALS, LLC
AP'd on: **2/14/2006**

16. **65-254** CLINDAMYCIN PHOSPHATE TOPICAL SOLUTION USP, (PLEDGETS)
1%
ALTANA, INC.
AP'd on: **2/14/2006**

17. **76-471** LORATADINE TABLETS USP, (OTC)
10 MG
APOTEX INC.
AP'd on: **2/14/2006**

18. **65-245** CEFTRIAXONE FOR INJECTION USP,
250 MG/VIAL, 500 MG/VIAL, 1 G/VIAL, AND 2 G/VIAL
AMERICAN PHARMACEUTICAL PARTNERS, INC.
AP'd on: **2/15/2006**

19. **65-252** CEFTRIAXONE FOR INJECTION USP,
10 GRAMS/VIAL (PHARMACY BULK PACKAGE)
AMERICAN PHARMACEUTICAL PARTNERS, INC.
AP'd on: **2/15/2006**

20. **77-266** CARBOPLATIN INJECTION,
10 MG/ML; 5 ML, 15 ML, 45 ML, AND 60 ML VIALS
AMERICAN PHARMACEUTICAL PARTNERS, INC.
AP'd on: **2/15/2006**

21. **77-404** MEGESTROL ACETATE ORAL SUSPENSION USP,
40 MG/ML
APOTEX INC.
AP'd on: **2/16/2006**

22. **77-458** RANITIDINE INJECTION USP,
25 MG/ML; 40 ML VIAL (PHARMACY BULK PACKAGE)
BEDFORD LABORATORIES
AP'd on: **2/16/2006**

23. **76-504** FLUTICASONE PROPIONATE NASAL SPRAY,
0.05 MG (50 MCG)/ SPRAY
ROXANE LABORATORIES, INC.
AP'd on: **2/22/2006**

24. **77-622** LISINOPRIL TABLETS USP,
2.5 MG, 5 MG, 10 MG, 20 MG, 30 MG, AND 40 MG
AUROBINDO PHARMA LIMITED
AP'd on: **2/22/2006**

25. **75-900** FLUVOXAMINE MALEATE TABLETS
25 MG, 50 MG, AND 100 MG
CARACO PHARMACEUTICAL LABORATORIES, LTD.
AP'd on: **2/23/2006**

26. **77-659** AMANTADINE HYDROCHLORIDE CAPSULES USP,
100 MG
AMIDE PHARMACEUTICAL, INC.
AP'd on: **2/23/2006**

27. **76-760** RANITIDINE TABLETS USP, (OTC)
75 MG
WOCKHARDT LIMITED
AP'd on: **2/24/2006**

28. **65-287** DOXYCYCLINE HYCLATE TABLETS USP,
20 MG (BASE)
PAR PHARMACEUTICAL
AP'd on: **2/28/2006**

Office of Generic Drugs ANDA Tentative Approvals
For Month of February 2006

1. **77-210** PIOGLITAZONE HYDROCHLORIDE TABLETS, 15 MG (BASE), 30 MG (BASE), AND 45 MG (BASE)
   TEVA PHARMACEUTICALS USA
   TA'd on: **2/7/2006**

2. **77-425** ADENOSINE INJECTION USP, 3 MG/ML; 20 ML AND 30 ML VIALS
   SICOR PHARMACEUTICALS, INC.
   TA'd on: **2/10/2006**

3. **75-576** OMEPRAZOLE DELAYED-RELEASE CAPSULES USP, 10 MG AND 20 MG
   DR. REDDY'S LABORATORIES LIMITED
   TA'd on: **2/13/2006**

4. **76-893** DONEPEZIL HYDROCHLORIDE TABLETS, 5 MG AND 10 MG
   PAR PHARMACEUTICAL, INC.
   TA'd on: **2/13/2006**

5. **77-481** FOSPHENYTOIN SODIUM INJECTION USP, 75 MG/ML (50 MG PE/ML); 100 MG PE/2 ML AND 500 MG PE/10 ML VIALS [PE=PHENYTOIN SODIUM EQUIVALENTS]
   BEDFORD LABORATORIES
   TA'd on: **2/14/2006**

6. **76-822** RABEPRAZOLE SODIUM DELAYED-RELEASE TABLETS, 20 MG
   TEVA PHARMACEUTICALS USA
   TA'd on: **2/15/2006**

7. **77-316** CARVEDILOL TABLETS, 3.125 MG, 6.25 MG, 12.5 MG, AND 25 MG
   MYLAN PHARMACEUTICALS, INC.
   TA'd on: **2/22/2006**

8. **76-759** ONDANSETRON INJECTION USP, 2 MG/ML; 2 ML VIALS
   TEVA PHARMACEUTICALS USA
   TA'd on: **2/24/2006**

9. **76-797** RISPERIDONE ORAL SOLUTION, 1 MG/ML
   PAR PHARMACEUTICAL, INC.
   TA'd on: **2/24/2006**

10. **76-876** ONDANSETRON INJECTION USP, 2 MG/ML; 20 ML VIALS
    TEVA PHARMACEUTICALS USA
    TA'd on: **2/24/2006**

11. **77-106** SERTRALINE HYDROCHLORIDE TABLETS, 25 MG (BASE), 50 MG (BASE), AND 100 MG (BASE)
    ZYDUS PHARMACEUTICALS USA, INC.
    TA'd on: **2/24/2006**

12. **77-303** ONDANSETRON HYDROCHLORIDE TABLETS, 4 MG (BASE), 8 MG (BASE), 16 MG (BASE), AND 24 MG (BASE)
KALI LABORATORIES, INC.
TA'd on: **2/27/2006**

13. **76-252** ONDANSETRON HYDROCHLORIDE TABLETS, 4 MG (BASE), 8 MG (BASE), AND 24 MG (BASE)
TEVA PHARMACEUTICALS USA
TA'd on: **2/28/2006**

14. **76-810** ONDANSETRON ORALLY DISINTEGRATING TABLETS, 4 MG AND 8 MG
TEVA PHARMACEUTICALS USA
TA'd on: **2/28/2006**

Office Of Generic Drugs Supplement Approvals

1.	71-611 S-038	CYCLOBENZAPRINE HYDROCHLORIDE TABLETS USP, 5 MG AND 7.5 MG (NEW STRENGTHS)	WATSON LABORATORIES, INC.	2/3/2006
2.	72-854 S-014	CYCLOBENZAPRINE HYDROCHLORIDE TABLETS USP, 5 MG (NEW STRENGTH)	SANDOZ INC.	2/3/2006
3.	73-144 S-009	CYCLOBENZAPRINE HYDROCHLORIDE TABLETS USP, 5 MG (NEW STRENGTH)	MYLAN PHARMACEUTICALS, INC.	2/3/2006
4.	74-777 S-001	RANITIDINE INJECTION USP, 25 MG/ML; 6 ML VIALS (NEW PACKAGE SIZE)	BEN VENUE LABORATORIES, INC.	2/15/2006
5.	76-307 S-001	MIRTAZAPINE ORALLY DISINTEGRATING TABLETS, 45 MG (NEW STRENGTH)	BARR LABORATORIES, INC.	2/28/2006
6.	77-376 S-001	MIRTAZAPINE ORALLY DISINTEGRATING TABLETS, 45 MG (NEW STRENGTH)	AUROBINDO PHARMA LIMITED	2/28/2006

77-425 ADENOSINE INJECTION USP, 3 MG/ML; 20 ML AND 30 ML VIALS
SICOR PHARMACEUTICALS, INC.
Submitted: 12/7/2004
Innovator: ASTELLAS PHARMA US, INC.
RLD: ADENOSCAN INJECTION
TENTATIVELY APPROVED: 2/10/2006

* * * * * * *

71-611 S-03 CYCLOBENZAPRINE HYDROCHLORIDE TABLETS USP, 5 MG AND 7.5 MG (NEW STRENGTHS)
WATSON LABORATORIES, INC.
Submitted: 11/12/2004
Innovator: MCNEIL CONSUMER & SPECIALTY PHARMACEUTICALS
RLD: FLEXERIL TABLETS
APPROVED: 2/3/2006

* * * * * * *

72-854 S-01 CYCLOBENZAPRINE HYDROCHLORIDE TABLETS USP, 5 MG (NEW STRENGTH)
SANDOZ INC.
Submitted: 2/4/2005
Innovator: MCNEIL CONSUMER & SPECIALTY PHARMACEUTICALS
RLD: FLEXERIL TABLETS
APPROVED: 2/3/2006

* * * * * * *

73-144 S-00 CYCLOBENZAPRINE HYDROCHLORIDE TABLETS USP, 5 MG (NEW STRENGTH)
MYLAN PHARMACEUTICALS, INC.
Submitted: 5/24/2004
Innovator: MCNEIL CONSUMER AND SPECIALTY PHARMACEUTICALS
RLD: FLEXERIL TABLETS
APPROVED: 2/3/2006

* * * * * * *

77-291 CYCLOBENZAPRINE HYDROCHLORIDE TABLETS USP, 5 MG
AMIDE PHARMACEUTICAL, INC.
Submitted: 9/27/2004
Innovator: MCNEIL CONSUMER & SPECIALTY PHARMACEUTICALS
RLD: FLEXERIL TABLETS
APPROVED: 2/3/2006

* * * * * * *

74-777 S-00 RANITIDINE INJECTION USP, 25 MG/ML; 6 ML VIALS (NEW PACKAGE SIZE)
BEN VENUE LABORATORIES, INC.
Submitted: 3/14/2005
Innovator: GLAXOSMITHKLINE
RLD: ZANTAC INJECTION
APPROVED: 2/15/2006

* * * * * * *

77-458 RANITIDINE INJECTION USP, 25 MG/ML; 40 ML VIAL (PHARMACY BULK PACKAGE)
BEDFORD LABORATORIES
Submitted: 12/22/2004
Innovator: GLAXOSMITHKLINE
RLD: ZANTAC INJECTION (PHARMACY BULK PACKAGE)
APPROVED: 2/16/2006

* * * * * * *

76-504 FLUTICASONE PROPIONATE NASAL SPRAY, 0.05 MG (50 MCG)/ SPRAY
ROXANE LABORATORIES, INC.
Submitted: 10/4/2002
Innovator: GLAXOSMITHKLINE
RLD: FLONASE NASAL SPRAY
APPROVED: 2/22/2006

* * * * * * *