

**New Drug Application (NDA) & Biologic License Application (BLA) Efficacy Supplements
Approved (CY 2008)**

NDA Efficacy Supplements Approved (N, SE1-SE7)

ESTABLISHED NAME	APPLICANT	APPLICATION NUMBER	SUPPLEMENT TYPE	SUPPLEMENT NUMBER	PRIORITY REVIEW	RECEIPT DATE	APPROVAL DATE	TOTAL APPROVAL TIME (IN MONTHS)	INDICATIONS
TADALAFIL	ELI LILLY	021368	SE2	011		07-Dec-06	07-Jan-08	13	PROVIDES FOR THE TREATMENT OF ERECTILE DYSFUNCTION.
COLESEVELAM HYDROCHLORIDE	DAIICHI SANKYO	021176	SE1	017		22-Dec-06	18-Jan-08	12.9	PROVIDES AS AN ADJUNCT TO DIET AND EXERCISE TO IMPROVE GYLCEMIC CONTROL IN ADULTS WITH TYPE 2 DIABETES MELLITUS.
MICAFUNGIN SODIUM	ASTELLAS	021506	SE1	008		22-Dec-06	22-Jan-08	13	PROVIDES FOR THE TREATMENT OF PATIENTS WITH CANDIDEMIA, ACUTE DISSEMINATED CANDIDIASIS, CANDIDA PERITONITIS AND ABSCESESSES.
EPLERENONE	PFIZER	021437	SE5	005		01-Aug-07	31-Jan-08	6	PROVIDES FOR THE TREATMENT OF HYPERTENSION IN PEDIATRIC PATIENTS.
LAMIVUDINE	GLAXOSMITHKLINE	020564	SE5	028	Y	03-Aug-07	01-Feb-08	6	PROVIDES FOR THE TREATMENT IN PEDIATRIC PATIENTS FOR WHOM A SOLID ORAL DOSAGE FORM IS APPROPRIATE.
MOMETASONE FUROATE	SCHERING	021067	SE5	003		02-Apr-07	01-Feb-08	10	PROVIDES FOR THE MAINTENANCE TREATMENT OF ASTHMA IN CHILDREN 4-11 YEARS OF AGE.
ARIPIPRAZOLE	OTSUKA	021436	SE5	021	Y	29-Aug-07	27-Feb-08	6	PROVIDES FOR THE USE FOR THE TREATMENT OF ACUTE MANIC OR MIXED EPISODES ASSOCIATED WITH BIPOLAR I DISORDER IN PEDIATRIC PATIENTS AGED 10 TO 17 YEARS.
ARIPIPRAZOLE	OTSUKA	021713	SE5	016	Y	07-Sep-07	27-Feb-08	5.7	PROVIDES FOR THE USE FOR THE TREATMENT OF ACUTE MANIC OR MIXED EPISODES ASSOCIATED WITH BIPOLAR I DISORDER IN PEDIATRIC PATIENTS AGED 10 TO 17 YEARS.
ARIPIPRAZOLE	OTSUKA	021729	SE5	008	Y	07-Sep-07	27-Feb-08	5.7	PROVIDES FOR THE USE FOR THE TREATMENT OF ACUTE MANIC OR MIXED EPISODES ASSOCIATED WITH BIPOLAR I DISORDER IN PEDIATRIC PATIENTS AGED 10 TO 17 YEARS.
ARIPIPRAZOLE	OTSUKA	021866	SE5	008	Y	07-Sep-07	27-Feb-08	5.7	PROVIDES FOR THE USE FOR THE TREATMENT OF ACUTE MANIC OR MIXED EPISODES ASSOCIATED WITH BIPOLAR I DISORDER IN PEDIATRIC PATIENTS AGED 10 TO 17 YEARS.
PALONOSETRON HYDROCHLORIDE	HELSINN	021372	SE1	008		04-May-07	29-Feb-08	9.9	PROVIDES FOR THE PREVENTION OF POSTOPERATIVE NAUSEA AND VOMITING FOR UP TO 24 HOURS FOLLOWING SURGERY.
OCTREOTIDE ACETATE	NOVARTIS	021008	SE1	021		28-Feb-07	03-Mar-08	12.1	PROVIDES FOR THE ADDITION OF NEW INFORMATION TO THE PACKAGE INSERT REGARDING THE TUMOR SHRINKAGE POTENTIAL ON GH-SECRETING PITUITARY ADENOMAS.
INSULIN ASPART RECOMBINANT	NOVO NORDISK	020986	SE5	047		14-May-07	14-Mar-08	10	PROVIDES FOR PEDIATRIC PUMP USE.

ZOLEDRONIC ACID	NOVARTIS	021223	SE5	016	Y	24-Sep-07	20-Mar-08	5.9	PROVIDES FOR THE PHARMACOKINETICS, EFFICACY AND SAFETY DATA IN PEDIATRIC PATIENTS WITH SEVERE OSTEOGENESIS IMPERFECTA IN RESPONSE TO FDA'S PEDIATRIC WRITTEN REQUEST.
DIVALPROEX SODIUM	ABBOTT	019680	SE5	024	Y	24-Sep-07	24-Mar-08	6	PROVIDES FOR USE AS MONOTHERAPY AND ADJUNCTIVE THERAPY OF COMPLEX PARTIAL SEIZURES AND SIMPLE AND COMPLEX ABSENCE SEIZURES; ADJUNCTIVE THERAPY IN PATIENTS WITH MULTIPLE SEIZURE TYPES THAT INCLUDE ABSENCE SEIZURES.
DIVALPROEX SODIUM	ABBOTT	021168	SE5	015	Y	24-Sep-07	24-Mar-08	6	PROVIDES FOR USE AS: (1) AN ACUTE TREATMENT OF MANIC OR MIXED EPISODES ASSOCIATED WITH BIPOLAR DISORDER, WITH OR WITHOUT PSYCHOTIC FEATURES. (2) MONOTHERAPY AND ADJUNCTIVE THERAPY OF COMPLEX PARTIAL SEIZURES AND SIMPLE AND COMPLEX ABSENCE SEIZURES; ADJUNCTIVE THERAPY IN PATIENTS WITH MULTIPLE SEIZURE TYPES THAT INCLUDE ABSENCE SEIZURES. (3) PROPHYLAXIS OF MIGRAINE HEADACHES.
DIVALPROEX SODIUM	ABBOTT	022267	N	000	Y	24-Sep-07	24-Mar-08	6	PROVIDES FOR TREATMENT IN MANIA ASSOCIATED WITH BIPOLAR DISORDER IN CHILDREN AND ADOLESCENTS.
ATAZANAVIR SULFATE	BRISTOL MYERS SQUIBB	021567	SE5	015	Y	26-Sep-07	25-Mar-08	6	PROVIDES FOR THE TREATMENT OF HIV-1 INFECTION IN PEDIATRIC PATIENTS (AGES 6 TO 18 YEARS OF AGE).
ALOSETRON HYDROCHLORIDE	PROMETHEUS	021107	SE2	013		01-Jun-07	01-Apr-08	10	PROVIDES FOR THE ADDITION OF ITEMS TO THE PACKAGE INSERT (1) CHANGES TO THE DOSING REGIMEN FOR PATIENTS WHO BECOME CONSTIPATED WHILE USING LOTRONEX. (2) THE ADDITION OF CLINICAL STUDY INFORMATION FOR 0.5 MG ONCE DAILY DOSING. (3) THE ADDITION OF CLINICAL PHARMACOLOGY INFORMATION FOR THE METABOLISM OF LOTRONEX. (4) THE ADDITION OF DRUG INTERACTION INFORMATION. (5) THE PACKAGE INSERT HAS BEEN REFORMATTED TO MEET THE PHYSICIAN'S LABELING RULE FORMAT.
FLUVOXAMINE MALEATE	JAZZ	22235	N	000		21-Jun-07	14-Apr-08	9.8	PROVIDES FOR MAINTENANCE TREATMENT OF OBSESSIVE COMPULSIVE DISORDER (OCD)
RISEDRONATE SODIUM	PROCTER GAMBLE	020835	SE2	030		22-Jun-07	22-Apr-08	10	PROVIDES FOR THE USE (150 MG TABLETS) AS A ONCE DAILY DOSE TO TREAT POSTMENOPAUSAL OSTEOPOROSIS (PMO).
LISDEXAMFETAMINE DIMESYLATE	SHIRE DEVELOPMENT	021977	SE5	001		29-Jun-07	23-Apr-08	9.8	PROVIDES FOR THE TREATMENT OF ATTENTION DEFICIT HYPERACTIVITY DISORDER IN THE ADULT POPULATION.
LUBIPROSTONE	SUCAMPO	021908	SE1	005		29-Jun-07	29-Apr-08	10	PROVIDES FOR THE TREATMENT OF IRRITABLE BOWEL SYNDROME WITH CONSTIPATION IN WOMEN ≥ 18 YEARS OLD.
FLUTICASONE PROPIONATE AND SALMETEROL XINAFOATE	GLAXOSMITHKLINE	021077	SE2	029		10-Oct-06	30-Apr-08	18.7	PROVIDES FOR THE MAINTENANCE TREATMENT OF AIRFLOW OBSTRUCTION AND REDUCING EXACERBATIONS IN PATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD), INCLUDING CHRONIC BRONCH.

TECHNETIUM TC-99M SESTAMIBI	LANTHEUS MEDICAL IMAGING	019785	SE5	018		29-Oct-07	30-Apr-08	6	PROVIDES FOR PEDIATRIC STUDY REPORTS SUBMITTED IN RESPONSE TO THE AGENCY'S WRITTEN REQUEST TO QUALIFY THIS PRODUCT FOR PEDIATRIC EXCLUSIVITY.
LEVOFLOXACIN	ORTHO-MCNEIL-JANSSEN	020634	SE5	047		05-Jul-07	05-May-08	10	PROVIDES FOR INHALATIONAL ANTHRAX (POST-EXPOSURE) TO REDUCE THE INCIDENCE OR PROGRESSION OF DISEASE FOLLOWING EXPOSURE TO AEROSOLIZED BACILLUS ANTHRACIS IN PEDIATRIC PATIENTS (>6 MONTH OF AGE AND OLDER)(TABLETS).
LEVOFLOXACIN	ORTHO-MCNEIL-JANSSEN	020635	SE5	051		05-Jul-07	05-May-08	10	PROVIDES FOR INHALATIONAL ANTHRAX (POST-EXPOSURE) TO REDUCE THE INCIDENCE OR PROGRESSION OF DISEASE FOLLOWING EXPOSURE TO AEROSOLIZED BACILLUS ANTHRACIS IN PEDIATRIC PATIENTS (>6 MONTH OF AGE AND OLDER)(INJECTION).
LEVOFLOXACIN	ORTHO-MCNEIL-JANSSEN	021721	SE5	015		05-Jul-07	05-May-08	10	PROVIDES FOR INHALATIONAL ANTHRAX (POST-EXPOSURE) TO REDUCE THE INCIDENCE OR PROGRESSION OF DISEASE FOLLOWING EXPOSURE TO AEROSOLIZED BACILLUS ANTHRACIS IN PEDIATRIC PATIENTS (>6 MONTH OF AGE AND OLDER)(ORAL SOLUTION).
ARIPIPRAZOLE	OTSUKA	021436	SE1	020		11-Jul-07	06-May-08	9.9	PROVIDES FOR THE USE AS ADJUNCTIVE THERAPY ADDED TO LITHIUM OR VALPROATE IN THE SHORT-TERM TREATMENT OF BIPOLAR DISORDER, MANIC OR MIXED, AGAIN AT A STARTING DOSE OF 15 MG/DAY.
ARIPIPRAZOLE	OTSUKA	021436	SE2	019		11-Jul-07	06-May-08	9.9	PROVIDES FOR THE USE AS MONOTHERAPY IN THE ACUTE TREATMENT OF BIPOLAR DISORDER, MANIC OR MIXED, AGAIN AT A STARTING DOSE OF 15MG/DAY.
ARIPIPRAZOLE	OTSUKA	021713	SE1	015		29-Aug-07	06-May-08	8.3	PROVIDES FOR THE USE AS AN ADJUNCTIVE THERAPY ADDED TO LITHIUM OR VALPROATE IN THE SHORT-TERM TREATMENT OF BIPOLAR DISORDER, MANIC OR MIXED, AGAIN AT A STARTING DOSE OF 15MG/DAY.
ARIPIPRAZOLE	OTSUKA	021713	SE2	014		29-Aug-07	06-May-08	8.3	PROVIDES FOR THE USE AS MONOTHERAPY IN THE ACUTE TREATMENT OF BIPOLAR DISORDER, MANIC OR MIXED, AGAIN AT A STARTING DOSE OF 15MG/DAY.
ARIPIPRAZOLE	OTSUKA	021729	SE1	007		29-Aug-07	06-May-08	8.3	PROVIDES FOR THE USE AS AN ADJUNCTIVE THERAPY ADDED TO LITHIUM OR VALPROATE IN THE SHORT-TERM TREATMENT OF BIPOLAR DISORDER, MANIC OR MIXED, AGAIN AT A STARTING DOSE OF 15MG/DAY.
ARIPIPRAZOLE	OTSUKA	021729	SE2	006		29-Aug-07	06-May-08	8.3	PROVIDES FOR THE USE AS MONOTHERAPY IN THE ACUTE TREATMENT OF BIPOLAR DISORDER, MANIC OR MIXED, AGAIN AT A STARTING DOSE OF 15MG/DAY.
ARIPIPRAZOLE	OTSUKA	021866	SE1	007		29-Aug-07	06-May-08	8.3	PROVIDES FOR THE USE AS AN ADJUNCTIVE THERAPY ADDED TO LITHIUM OR VALPROATE IN THE SHORT-TERM TREATMENT OF BIPOLAR DISORDER, MANIC OR MIXED, AGAIN AT A STARTING DOSE OF 15MG/DAY.

ARIPRAZOLE	OTSUKA	021866	SE2	006		29-Aug-07	06-May-08	8.3	PROVIDES FOR THE USE AS MONOTHERAPY IN THE ACUTE TREATMENT OF BIPOLAR DISORDER, MANIC OR MIXED, AGAIN AT A STARTING DOSE OF 15MG/DAY.
ATOMOXETIN HYDROCHLORIDE	ELI LILLY	021411	SE1	005		16-Mar-04	07-May-08	49.7	PROVIDES FOR THE MAINTENANCE TREATMENT OF ATTENTION-DEFICIT HYPERACTIVITY DISORDER (ADHD) IN CHILDREN AND ADOLESCENTS.
QUETIAPINE FUMARATE	ASTRAZENECA	020639	SE1	037		19-Jul-07	13-May-08	9.8	PROVIDES FOR THE USE AS MAINTENANCE TREATMENT FOR BIPOLAR I DISORDER, AS ADJUNCTIVE THERAPY TO LITHIUM OR DIVALPROEX.
LEVETIRACETAM	UCB	021872	SE1	005		16-Jul-07	16-May-08	10	PROVIDES FOR THE USE AS ADJUNCTIVE THERAPY IN THE TREATMENT OF PRIMARY GENERALIZED TONIC-CLONIC SEIZURES IN ADULTS AND CHILDREN 16 YEARS OF AGE AND OLDER WITH IDIOPATHIC GENERALIZED EPILEPSY.
ZOLEDRONIC ACID	NOVARTIS	021817	SE1	001		03-Aug-07	03-Jun-08	10	PROVIDES FOR THE INCLUSION OF INFORMATION UNDER CLINICAL STUDIES ON THE EFFICACY AND SAFETY TO RECLAST IN PATIENTS WITH A RECENT LOW-TRAUMA HIP FRACTURE.
EZETIMIBE	SCHERING	021445	SE5	020	Y	17-Dec-07	05-Jun-08	5.6	PROVIDES FOR THE RESULTS OF A PEDIATRIC STUDY IN ADOLESCENT BOYS AND POSTMENARCHAL GIRLS, AGES 10 TO 17 YEARS OF AGE, WITH HETEROZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA.
DOXORUBICIN HYDROCHLORIDE LIPOSOME	ALZA	050718	SE7	033		10-Aug-07	10-Jun-08	10	PROVIDES FOR THE TREATMENT OF AIDS-RELATED KAPOSI'S SARCOMA AFTER FAILURE OF PRIOR SYSTEMIC CHEMOTHERAPY OR INTOLERANCE TO SUCH THERAPY.
SOMATROPIN	PFIZER	020280	SE1	060		02-Jul-07	12-Jun-08	11.4	PROVIDES FOR THE TREATMENT OF IDIOPATHIC SHORT STATURE IN PEDIATRIC PATIENTS WHOSE EPIPHYSES ARE NOT CLOSED AND FOR WHOM DIAGNOSTIC EVALUATION EXCLUDES OTHER CAUSES ASSOCIATED WITH SHORT STATURE THAT SHOULD BE OBSERVED OR TREATED BY OTHER MEANS.
EZETIMIBE/SIMVASTATIN	MERCK & CO	021687	SE5	023	Y	19-Dec-07	13-Jun-08	5.8	PROVIDES THE RESULTS OF A PEDIATRIC STUDY OF THE USE IN ADOLESCENT BOYS AND POSTMENARCHAL GIRLS, AGES 10 TO 17 YEARS OF AGE, WITH HETEROZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA.
DULOXETINE HYDROCHLORIDE	ELI LILLY	022148	N	000		14-Aug-07	13-Jun-08	10	PROVIDES FOR THE MANAGEMENT OF FIBROMYALGIA.
DUTASTERIDE	GLAXOSMITHKLINE	021319	SE1	014		21-Aug-07	19-Jun-08	10	PROVIDES FOR THE USE IN COMBINATION WITH TAMUSULOSIN FOR THE TREATMENT OF SYMPTOMATIC BENIGN PROSTATIC HYPERPLASIA (BPH).
LOPINAVIR/RITONAVIR	ABBOTT	021251	SE5	022	Y	21-Dec-07	20-Jun-08	6	PROVIDES FOR THE TREATMENT OF HIV-1 INFECTION IN PEDIATRIC PATIENTS 14 DAYS TO 6 MONTHS OF AGE AND FROM 12 TO 18 YEARS OF AGE.
BORTEZOMIB	MILLENNIUM	021602	SE1	015	Y	20-Dec-07	20-Jun-08	6	PROVIDES FOR THE TREATMENT OF PATIENTS WITH MULTIPLE MYELOMA.

TIPRANAVIR	BOEHRINGER INGELHEIM	021814	SE1	005	Y	21-Dec-07	23-Jun-08	6.1	PROVIDES FOR THE TREATMENT OF HIV-1 INFECTED PEDIATRIC (AGE 2 TO 18 YEARS) PATIENTS WHO ARE TREATMENT-EXPERIENCED AND INFECTED WITH HIV-1 STRAINS RESISTANT TO MORE THAN ONE PROTEASE INHIBITOR.
NEVIRAPINE	BOEHRINGER INGELHEIM	020636	SE5	027	Y	20-Dec-07	24-Jun-08	6.1	PROVIDES FOR THE TREATMENT OF HIV-1 INFECTION IN PEDIATRIC PATIENTS 15 DAYS AND OLDER AND FOR PATIENTS WITH HEPATIC IMPAIRMENT.
NEVIRAPINE	BOEHRINGER INGELHEIM	020933	SE5	017	Y	20-Dec-07	24-Jun-08	6.1	PROVIDES FOR THE TREATMENT OF NEONATES AND INFANTS < 2 MONTHS OF AGE, PEDIATRIC PATIENTS > 2 MONTHS OF AGE, AND FOR PATIENTS WITH HEPATIC IMPAIRMENT.
METHYLPHENIDATE HYDROCHLORIDE	ORTHO-MCNEIL-JANSSEN	021121	SE5	017		29-Aug-07	27-Jun-08	10	PROVIDES FOR THE USE OF TREATMENT OF ATTENTION DEFICIT HYPERACTIVITY DISORDER (ADHD) IN ADULTS (18 AND OLDER).
RABEPRAZOLE SODIUM	EISAI MEDICAL	020973	SE5	022		31-Dec-07	30-Jun-08	6	PROVIDES FOR SHORT-TERM TREATMENT SYMPTOMATIC GERD IN ADOLESCENT PATIENTS 12 YEARS OF AGE AND ABOVE.
AMLODIPINE BESYLATE/VALSARTAN	NOVARTIS	021990	SE1	003		24-Sep-07	23-Jul-08	10	PATIENTS LIKELY TO NEED MULTIPLE DRUGS TO ACHIEVE THEIR BLOOD PRESSURE GOALS.
CASPOFUNGIN ACETATE	MERCK	021227	SE5	021	Y	31-Jan-08	29-Jul-08	5.9	EMPIRICAL THERAPY, CANDIDEMIA (CANDIDA INFECTIONS), ESOPHAGEAL CANDIDIASIS, AND FOR INVASIVE ASPERGILLOSIS.
VALSARTAN	NOVARTIS	020818	SE1	036		14-Dec-06	31-Jul-08	19.6	PROVIDES FOR THE USE AS INITIAL
TENOFOVIR DISOPROXIL FUMARATE	GILEAD	021356	SE1	025		11-Oct-07	11-Aug-08	10	PROVIDES FOR TREATMENT OF CHRONIC HEPATITIS B.
ROCURONIUM BROMIDE	ORGANON USA	020214	SE5	030	Y	11-Jan-08	28-Aug-08	7.6	PROVIDES FOR USE IN PEDIATRIC PATIENTS.
VALACYCLOVIR HCL	GLAXOSMITHKLINE	020487	SE5	014	Y	10-Dec-07	02-Sep-08	8.8	PROVIDES FOR THE TREATMENT OF HERPES ZOSTER
ALBUTEROL SULFATE	TEVA GLOBAL	021457	SE5	013		16-Nov-07	16-Sep-08	10	PROVIDES FOR THE TREATMENT OR PREVENTION OF BRONCHOSPASM WITH REVERSIBLE OBSTRUCTIVE AIRWAY DISEASE/ FOR THE PREVENTION OF EXERCISE-INDUCED BRONCHOSPASM
ZIDOVUDINE	GLAXOSMITHKLINE	019655	SE2	046		17-Sep-08	19-Sep-08	0.1	PROVIDES FOR THE TREATMENT OF ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS) AND AIDS-RELATED COMPLEX (ARC).
ZIDOVUDINE	GLAXOSMITHKLINE	19910	SE2	033	Y	21-Mar-08	19-Sep-08	6	PROVIDES FOR THE MANAGEMENT OF CERTAIN ADULT PATIENTS WITH SYMPTOMATIC HIV INFECTION
TRIAMCINOLONE ACETONIDE	SANOVI AVENTIS	020468	SE5	024		19-Nov-07	19-Sep-08	10	PROVIDES FOR THE TREATMENT OF SEASONAL AND PERENNIAL RHINITIS SYMPTOMS
ZIDOVUDINE	GLAXOSMITHKLINE	020518	SE2	016		17-Sep-08	19-Sep-08	0.1	PROVIDES FOR THE TREATMENT OF HIV INFECTION
ERLOTINIB HCL	OSI	021743	SE2	011		21-Nov-07	19-Sep-08	10	PROVIDES FOR THE TREATMENT OF PATIENTS WITH LOCALLY ADVANCED OR METASTATIC NON-SMALL CELL LUNG CANCER AFTER FAILURE OF AT LEAST ONE PRIOR CHEMOTHERAPY REGIMEN AND STUDY OF SKIN
PEMETREXED DISODIUM	LILLY	021462	SE1	015		28-Aug-07	26-Sep-08	13	PROVIDES FOR THE TREATMENT OF MALIGNANT PLEURAL MESOTHELIOMA
IMATINIB MESYLATE TABLETS	NOVARTIS	021588	SE7	024		29-Nov-07	26-Sep-08	9.9	PROVIDES FOR THE TREATMENT OF PHILADELPHIA POSITIVE CHRONIC MYELOID LEUKEMIA
DIDANOSINE	BRISTOL MYERS SQUIBB	021183	SE5	020	Y	01-Apr-08	29-Sep-08	6	PROVIDES FOR THE TREATMENT OF ADULT PATIENTS WITH HIV

ATAZANAVIR SULFATE	BRISTOL MYERS SQUIBB	021567	SE5	017			21-Dec-07	30-Sep-08	9.3	PROVIDES FOR AN ALTERNATIVE DOSING REGIMEN CO-ADMINISTERED WITH RITONAVIR FOR THE TREATMENT OF HIV-1 INFECTION IN TREATMENT NAIVE PATIENTS
AZITHROMYCIN EXTENDED RELEASE FOR ORAL S	PFIZER GLOBAL	050797	SE5	008			22-Oct-07	07-Oct-08	11.5	PROVIDES FOR THE TREATMENT OF COMMUNITY ACQUIRED PNEUMONIA, ACUTE BACTERIAL SINUSITIS
QUETIAPINE FUMARATE	ASTRAZENECA	022047	SE1	006			19-Dec-07	08-Oct-08	9.7	PROVIDES FOR THE TREATMENT OF SCHIZOPHRENIA
QUETIAPINE FUMARATE	ASTRAZENECA	022047	SE1	007			19-Dec-07	08-Oct-08	9.7	PROVIDES FOR THE TREATMENT OF SCHIZOPHRENIA
QUETIAPINE FUMARATE	ASTRAZENECA	022047	SE1	008			19-Dec-07	08-Oct-08	9.7	PROVIDES FOR THE TREATMENT OF SCHIZOPHRENIA
ZOLMITRIPTAN NASAL SPRAY 0.5/2.5/5 MG	ASTRAZENECA	021450	SE5	005			14-Dec-07	14-Oct-08	10	PROVIDES FOR THE ACUTE TREATMENT OF MIGRAINE WITH OR WITHOUT AURA IN ADULTS
DEXMEDETOMIDINE	HOSPIRA	021038	SE1	010			19-Dec-07	17-Oct-08	10	PROVIDES FOR SEDATION OF INITIALLY INTUBATED AND MECHANICALLY VENTILATED PATIENTS IN AN ICU
DARUNAVIR	TIBOTEC	021976	SE5	007			21-Dec-07	21-Oct-08	10	PROVIDES FOR THE TREATMENT OF HIV INFECTION
DARUNAVIR	TIBOTEC	021976	SE7	006			21-Dec-07	21-Oct-08	10	PROVIDES FOR THE TREATMENT OF HIV INFECTION
INSULIN GLULISINE	SANOI AVENTIS	021629	SE5	015			28-Jun-07	24-Oct-08	15.9	PROVIDES FOR THE TREATMENT OF DIABETES MELLITUS
LANSOPRAZOLE	TAKEDA	020406	SE5	067	Y		28-Apr-08	28-Oct-08	6	PROVIDES FOR THE TREATMENT OF REFLUX ESOPHAGITIS/REFLUX ESOPHAGITIS: MAINTENANCE
LANSOPRAZOLE	TAKEDA	021281	SE5	024	Y		28-Apr-08	28-Oct-08	6	PROVIDES FOR THE SHORT TERM TREATMENT FOR HEALING/SYMPTOM RELIEF OF ESOPHAGITIS EROSIVE
LANSOPRAZOLE	TAKEDA	021428	SE5	017	Y		28-Apr-08	28-Oct-08	6	PROVIDES FOR THE TREATMENT FOR GASTROESOPHAGEAL REFLUX
FESOTERODINE FUMARATE	PFIZER	022303	N	000			31-Dec-07	31-Oct-08	10.0	PROVIDES FOR THE TREATMENT OF PATIENTS WITH INDOLENT B-CELL NON-HODGKIN'S LYMPHOMA (NHL)
RANOLAZINE	CV	021526	SE1	004	Y		27-Sep-07	05-Nov-08	13.3	PROVIDES FOR THE TREATMENT OF CHRONIC ANGINA
ROSUVASTATIN CALCIUM	ASTRAZENECA	021366	SE1	013	Y		10-Jan-08	06-Nov-08	9.9	PROVIDES FOR THE TREATMENT OF PATIENTS WITH PRIMARY DYSBETALIPOPROTEINEMIA (FREDRICKSON TYPE III HYPERLIPOPROTEINEMIA) AS AN ADJUNCT TO DIET
ESTROGENS CONJUGATED	WYETH	020216	SE1	060	Y		25-Sep-07	07-Nov-08	13.4	PROVIDES FOR THE TREATMENT OF MODERATE TO SEVERE DYSPAREUNIA DUE TO MENOPAUSE AND A NEW DOSAGE REGIMEN OF TWICE WEEKLY
MARAVIROC	PFIZER	022128	SE7	001	Y		31-Jan-08	25-Nov-08	9.8	TREATMENT OF PATIENTS WITH CCR5-TROPIC HIV-1
IBANDRONATE SODIUM	ROCHE	021455	SE1	007	Y		28-Jan-08	28-Nov-08	10	PROVIDES FOR THE TREATMENT AND PREVENTION OF POSTMENOPAUSAL OSTEOPOROSIS

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SIROLIMUS	WYETH	N	021083	SE8	033		14-Dec-06	14-Jan-08	13
SIROLIMUS	WYETH	N	021110	SE8	043		14-Dec-06	14-Jan-08	13
SITAGLIPTIN METFORMIN HYDROCHLORIDE	MERCK	N	022044	SE8	003		27-Apr-07	26-Feb-08	10
SITAGLIPTIN METFORMIN HYDROCHLORIDE	MERCK	N	022044	SE8	004		11-May-07	26-Feb-08	9.6
PALONOSETRON HYDROCHLORIDE	HELSINN	N	021372	SE8	010		04-May-07	29-Feb-08	9.9
DAPSONE	QLT USA	N	021794	SE8	005		23-May-07	14-Mar-08	9.7
ALBUTEROL SULFATE	GLAXOSMITHKLINE	N	020983	SE8	016	Y	28-Sep-07	26-Mar-08	5.9

LOPERAMIDE HYDROCHLORIDE; SIMETHICONE	MCNEIL CONSUMER HEALTHCARE	N	020606	SE8	014		29-Dec-06	30-Apr-08	16
LOPERAMIDE HYDROCHLORIDE; SIMETHICONE	MCNEIL CONSUMER HEALTHCARE	N	021140	SE8	011		29-Dec-06	30-Apr-08	16
ARGATROBAN	ENCYSIVE	N	020883	SE8	014	Y	29-Jun-05	05-May-08	34.2
TENOFOVIR DISOPROXIL FUMARATE	GILEAD	N	021356	SE8	024		17-Jul-07	16-May-08	10
EMTRICITABINE	GILEAD	N	021500	SE8	011		17-Jul-07	16-May-08	10
EMTRICITABINE/TENOFOVIR DISOPROXIL	GILEAD	N	021752	SE8	016		17-Jul-07	16-May-08	10
EMTRICITABINE	GILEAD	N	021896	SE8	005		18-Jul-07	16-May-08	10
OXALIPLATIN	SANOI-AVENTIS	N	021492	SE8	010		21-Nov-07	21-May-08	6
EFAVIRENZ/EMTRICITABINE/TEN OFOVIR DISOPROXIL FUMARATE	GILEAD	N	021937	SE8	009		17-Jul-07	06-Jun-08	10.7
METHYL AMINOLEVULINATE HYDROCHLORIDE	CATO	N	021415	SE8	003		28-Jun-07	26-Jun-08	12
VERTEPORFIN	QLT	N	021119	SE8	013		08-Jul-04	30-Jun-08	47.8
ROSIGLITAZONE MALEATE	GLAXOSMITHKLINE	N	021071	SE8	026		28-Feb-07	10-Jul-08	16.4
ABACAVIR SULFATE	GLAXOSMITHKLINE	N	020977	SE8	017		20-Sep-07	18-Jul-08	9.9
ABACAVIR SULFATE	GLAXOSMITHKLINE	N	020978	SE8	020		20-Sep-07	18-Jul-08	9.9
ATOMOXETINE HYDROCHLORIDE	ELI LILLY	N	021411	SE8	024		27-Sep-07	23-Jul-08	9.9
ENTECAVIR	BRISTOL-MYERS SQUIBB	N	021797	SE8	005		27-Sep-07	25-Jul-08	9.9
ENTECAVIR	BRISTOL-MYERS SQUIBB	N	021798	SE8	006		27-Sep-07	25-Jul-08	9.9
FLUOCINOLONE ACETONIDE	BAUSCH AND LOMB	N	021737	SE8	010		05-Oct-07	05-Aug-08	10
AZACITIDINE	PHARMION	N	050794	SE8	011	Y	29-Feb-08	20-Aug-08	5.7
PHOTOFRIN	AXCAN SCANDI	N	020451	SE8	019		10-Aug-07	08-Sep-08	13
CLOFARABINE	GENZYME	N	021673	SE8	005		19-Dec-07	17-Oct-08	10
DEXMETHYLPHENIDATE ER CAPSULES	NOVARTIS PHARMS	N	021802	SE8	012		21-Dec-07	17-Oct-08	9.9
RAMELTEON	TAKEDA GLOBAL	N	021782	SE8	008		20-Dec-07	20-Oct-08	10
RAMELTEON	TAKEDA GLOBAL	N	021782	SE8	009		20-Dec-07	20-Oct-08	10
RAMELTEON	TAKEDA GLOBAL	N	021782	SE8	010		20-Dec-07	20-Oct-08	10

BLA Efficacy Supplements Approved

PROPER NAME	APPLICANT	BLA NUMBER	SUPPLEMENT NUMBER	PRIORITY REVIEW	RECEIPT DATE	APPROVAL DATE	TOTAL APPROVAL TIME (IN MONTHS)	INDICATION
NATALIZUMAB	BIOGEN IDEC	125104	33		15-Dec-06	14-Jan-08	13	PROVIDES FOR INDUCING AND MAINTAINING CLINICAL RESPONSE AND REMISSION IN ADULT PATIENTS WITH MODERATELY TO SEVERELY ACTIVE CROHN'S DISEASE (CD) WITH EVIDENCE OF INFLAMMATION WHO HAVE HAD AN INADEQUATE RESPONSE TO, OR ARE UNABLE TO TOLERATE, CONVENTIONAL CD THERAPIES AND INHIBITORS OF TNF-A, SUBMITTED UNDER SECTION 351 OF THE PUBLIC HEALTH SERVICE ACT.
ADALIMUMAB	ABBOTT	125057	110		23-Mar-07	18-Jan-08	9.9	INCLUDES A NEW INDICATION FOR THE TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE CHRONIC PLAQUE PSORIASIS WHO ARE CANDIDATES FOR SYSTEMIC THERAPY OR PHOTOTHERAPY, AND WHEN OTHER SYSTEMIC THERAPIES ARE MEDICALLY LESS APPROPRIATE, HAS BEEN APPROVED.
HERCEPTIN	GENENTECH	103792	5175		22-Dec-06	18-Jan-08	12.9	REVISE THE INDICATION FOR USE AS A SINGLE AGENT, FOR THE ADJUVANT TREATMENT OF HER2-OVEREXPRSING NODE-NEGATIVE (ER/PR NEGATIVE OR WITH ONE HIGH-RISK FEATURE) OR NODE-POSITIVE BREAST CANCER, FOLLOWING MULTI-MODALITY ANTHRACYCLINE BASED THERAPY HAS BEEN APPROVED.

RITUXIMAB	GENENTECH	103705	5256		28-Mar-07	25-Jan-08	9.9	EXPANDS THE INDICATION TO INCLUDE A CLAIM TO SLOW THE PROGRESSION OF STRUCTURAL DAMAGE.
ADALIMUMAB	ABBOTT	125057	114		26-Apr-07	21-Feb-08	9.9	EXPANDS THE INDICATION TO INCLUDE THE TREATMENT OF JUVENILE IDIOPATHIC ARTHRITIS AND ADD A 20MG PRE-FILLED SYRINGE.
BEVACIZUMAB	GENENTECH	125085	91	Y	24-May-06	22-Feb-08	21.4	PROVIDES FOR THE USE IN COMBINATION WITH PACLITAXEL FOR THE TREATMENT OF PATIENTS WHO HAVE NOT RECEIVED CHEMOTHERAPY FOR METASTATIC HER2 NEGATIVE BREAST CANCER.
PEGINTERFERON ALFA-2; RIBAVIRIN	SCHERING	103949	5123		10-May-06	26-Mar-08	22.6	PATIENTS INFECTED WITH CHRONIC HEPATITIS C (HCV), A SHORTER DURATION OF TREATMENT FOR HCV PATIENTS
ABATACEPT	BRISTOL-MYERS SQUIBB	125118	45		8-Jun-07	7-Apr-08	10	PROVIDES FOR A NEW INDICATION FOR THE TREATMENT OF MODERATE TO SEVERE POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (JIA).
RANIBIZUMAB	GENENTECH	125156	11		20-Apr-07	23-Apr-08	12.1	PROVIDES TO INCLUDE CUMULATIVE 2 YEAR STUDY AND EFFICACY DATA
DARBEPOETIN ALFA	AMGEN	103951	5111		19-Dec-05	5-May-08	28.5	PROVIDES TO EXPAND THE INDICATION TO INCLUDE A NEW DOSING REGIMEN OF 0.75 MCG/KG ONCE EVERY TWO WEEKS (Q2W) FOR DENOVO CORRECTION OF ANEMIA IN PATIENTS WITH CHRONIC RENAL FAILURE WHO ARE NOT RECEIVING DIALYSIS HAS BEEN APPROVED.
HERCEPTIN	GENENTECH	103792	5187		29-Jun-07	22-May-08	10.8	PROVIDES TO EXPAND THE INDICATION AS PART OF A TREATMENT REGIMEN CONTAINING DOXORUBICIN, CYCLOPHOSPHAMIDE, AND DOCETAXEL, FOR THE ADJUVANT TREATMENT OF HER2 OVER-EXPRESSING, NODE-POSITIVE OR HIGH-RISK NODE-NEGATIVE, BREAST CANCER.
HERCEPTIN	GENENTECH	103792	5189		5-Jul-07	22-May-08	10.6	PROVIDES TO EXPAND THE INDICATION AS PART OF A TREATMENT REGIMEN CONTAINING DOCETAXEL AND CARBOPLATIN, FOR THE ADJUVANT TREATMENT OF HER2 OVER-EXPRESSING, NODE-POSITIVE OR HIGH-RISK NODE-NEGATIVE, BREAST CANCER.
VECTIBIX	AMGEN	125147	26		24-Aug-07	23-Jun-08	10	PROVIDES TO REVISE THE CLINICAL STUDIES SECTION OF THE PACKAGE INSERT TO INCLUDE A SUMMARY OF THE TRIAL DESIGN AND RESULTS OF STUDY 20040249 (PACCE)
DROTRECOGIN ALFA (ACTIVATED)	ELI LILLY & COMPANY	125029	95		10-Dec-07	9-Oct-08	10	PROVIDES FOR IMMUNOGENICITY LABELING REVISIONS; FINAL STUDY REPORTS FOR POSTMARKETING COMMITMENTS #19, 20 & 21; LABELING FORMAT AND CONTENT
DENILEUKIN DIFTITOX	EISAI MEDICAL RESEARCH INC.	103767	5094	Y	15-Apr-08	15-Oct-08	18	PROVIDES FOR THE TREATMENT OF PATIENTS WITH PERSISTENT OR RECURRENT CUTANEOUS T-CELL LYMPHOMA

Supplement Type	Description								
N	TYPE 6 NDA - NEW INDICATION								
SE1	NEW OR MODIFIED INDICATION								
SE2	NEW DOSAGE REGIMEN								
SE3	NEW ROUTE OF ADMINISTRATION								
SE4	COMPARATIVE EFFICACY CLAIM								
SE5	PATIENT POPULATION ALTERED								
SE6	CHANGE THE MARKETING STATUS FROM PRESCRIPTION TO OVER-THE-COUNTER USE								
SE7	COMPLETE THE TRADITIONAL APPROVAL OF A PRODUCT ORIGINALLY APPROVED UNDER SUBPART H (ACCELERATED APPROVAL)								
SE8	INCORPORATE OTHER INFORMATION BASED ON AT LEAST ONE ADEQUATE AND WELL-CONTROLLED CLINICAL STUDY								

Updated through 11/30/08