



New Drug Application (NDA) & Biologic License Application (BLA) Efficacy Supplement Calendar Year Approvals As of December 31, 2010

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Selection Criteria:

User Response: Start Date: 1/1/2010 End Date: 12/31/2010

Sort Order: Approval Date

Established Name	Applicant	Application Number	Supplement Type / Submission Class Code	Supplement Number	Priority Review	FDA Received Date	Approval Date	Total Approval Time (Months)	Indication/Description
MORPHINE SULFATE ORAL SOLUTION	ROXANE LABORATORIES INC	NDA 022195	INDICATION	2	P	8/26/2009	1/25/2010	5.0	PROVIDES FOR THE RELIEF OF MODERATE TO SEVERE ACUTE AND CHRONIC PAIN
LAPATINIB TABLETS	SMITHKLINE BEECHAM CORP DBA GLAXOSMITHKLINE	NDA 022059	INDICATION	7	S	3/31/2009	1/29/2010	10.0	PROVIDES FOR THE TREATMENT OF POST MENOPAUSAL WOMEN WITH HORMONE RECEPTOR POSITIVE METASTATIC BREAST CANCER THAT OVER EXPRESS THE HER2 RECEPTOR FOR WHOM HORMONAL THERAPY IS PROVIDES.
OLMESARTAN MEDOXOMIL	DAIICHI SANKYO INC	NDA 021286	PAT POPUL	18	P	8/5/2009	2/4/2010	6.0	PROVIDES FOR THE TREATMENT OF HYPERTENSION IN PEDIATRIC PATIENTS 6 TO 16 YEARS OF AGE.
ROSUVASTATIN CALCIUM TABLETS	IPR PHARMACEUTICALS INC	NDA 021366	INDICATION	16	S	4/8/2009	2/8/2010	10.1	PROVIDES FOR THE PRIMARY PREVENTION OF CV DISEASE BASED ON THE JUPITER STUDY
NEBIVOLOL TABLETS 1.25/2.5/5/10/20MG	FOREST LABORATORIES INC	NDA 021742	INDICATION	7	S	5/1/2009	2/19/2010	9.7	PROVIDES FOR THE TREATMENT OF HYPERTENSION
OSELTAMIVIR PHOSPHATE 75 MG CAPSULES	HOFFMANN LA ROCHE INC	NDA 021087	DOSING	49	P	8/10/2009	2/22/2010	6.4	PROVIDES FOR THE TREATMENT AND PROPHYLAXIS OF INFLUENZA
OSELTAMINVIR PHOSPHATE	HOFFMANN LA ROCHE INC	NDA 021246	DOSING	35	P	8/10/2009	2/22/2010	6.4	PROVIDES FOR THE TREATMENT AND PROPHYLAXIS OF INFLUENZA

DECITABINE	EISAI INC	NDA 021790	DOSING	6	S	5/8/2009	3/11/2010	10.1	PROVIDES FOR THE ADDITION OF CHILDREN OVER 2 YEARS OF AGE TO THE POPULATION IN WHICH MULTIHANCE IS APPROVED FOR USE.
GADOBENATE DIMEGLUMINE INJ	BRACCO DIAGNOSTICS INC	NDA 021357	PAT POPUL	6	S	4/20/2009	3/17/2010	10.9	PROVIDES FOR THE ADDITION OF CHILDREN OVER 2 YEARS OF AGE TO THE POPULATION IN WHICH MULTIHANCE IS APPROVED FOR USE.
RIFAXIMIN	SALIX PHARMACEUTICALS INC	NDA 022554	TYPE 6	1	P	6/24/2009	3/24/2010	9.0	PROVIDES FOR THE REDUCTION IN RISK OF OVERT HEPATIC ENCEPHALOPATHY (HE) RECURRENCE IN PATIENTS => 18 YEARS OF AGE
ERLOTINIB HCL	OSI PHARMACEUTICALS INC	NDA 021743	INDICATION	16	S	3/18/2009	4/16/2010	13.0	PROVIDES FOR THE MAINTENANCE TREATMENT OF PATIENTS WITH LOCALLY ADVANCED OR METASTATIC NON-SMALL CELL LUNG CANCER WHOSE DISEASE HAS NOT PROGRESSED AFTER FOUR CYCLES OF PLATINUM-BASED FIRST-LINE CHEMOTHERAPY
SOMATROPIN(RNDA ORIGIN)FOR INJ,1.5,5.8MG	SANDOZ INC	NDA 021426	INDICATION	7	S	11/25/2008	4/23/2010	16.9	PROVIDES FOR THE TREATMENT OF PRADER-WILLI SYNDROME (PWS)
SOMATROPIN(RNDA ORIGIN)FOR INJ,1.5,5.8MG	SANDOZ INC	NDA 021426	INDICATION	8	S	11/25/2008	4/23/2010	16.9	PROVIDES FOR THE TREATMENT OF SMALL FOR GESTATIONAL AGE (SGA)
LOPINAVIR; RITONAVIR	ABBOTT LABORATORIES	NDA 021251	PAT POPUL	31	S	6/29/2009	4/27/2010	9.9	PROVIDES FOR A NEW ONCE DAILY DOSING REGIMEN IN ADULT PATIENTS WITH LESS THAN THREE LOPINAVIR RESISTANCE-ASSOCIATED SUBSTITUTIONS.
LOPINAVIR; RITONAVIR	ABBOTT LABORATORIES	NDA 021906	PAT POPUL	24	S	6/29/2009	4/27/2010	9.9	PROVIDES FOR A NEW ONCE DAILY DOSING REGIMEN IN ADULT PATIENTS WITH LESS THAN THREE LOPINAVIR RESISTANCE-ASSOCIATED SUBSTITUTIONS.

	ABBOTT PRODUCTS INC	NDA 020725	PAT POPUL	3	S	7/1/2009	4/30/2010	10.0	PROVIDES FOR THE TREATMENT OF EXOCRINE PANCREATIC INSUFFICIENCY DUE TO CYSTIC FIBROSIS, CHRONIC PANCREATITIS, PANCREATECTOMY, OR OTHER CONDITIONS.
LETROZOLE	NOVARTIS PHARMACEUTICALS CORP	NDA 020726	ACCEL APP	20	S	7/1/2009	4/30/2010	10.0	PROVIDES FOR REPORTING ON THE REMAINING MANDATORY SUBPART H CLINICAL TRIAL TO CONVERT THE APPROVAL FROM ACCELERATED APPROVAL TO FULL APPROVAL
BIPHASIC INSULIN ASPART 30	NOVO NORDISK INC	NDA 021172	DOSING	45	S	6/30/2009	5/7/2010	10.2	PROVIDES FOR SUPPORTING CLINICAL DATA TO ADD INFORMATION TO THE LABELING FOR THE FOLLOWING: TREATMENT OF TYPE 2 PATIENTS WITH NOVOLOG MIX 70/30 PLUS ORAL ANTIDIABETICS (OADS) (S-045) AND POST-PRANDIAL DOSING IN PATIENTS WITH TYPE 2 DIABETES MELLITUS (S-04
DOCETAXEL	SANOFI AVENTIS US LLC	NDA 020449	PEDIATRIC	59	P	11/13/2009	5/13/2010	6.0	PROVIDES FOR THE TREATMENT OF CANCER
MOMETASONE FUROATE NASAL SUSPENSION	SCHERING PLOUGH HEALTHCARE PRODUCTS INC	NDA 020762	PAT POPUL	38	S	7/31/2009	5/26/2010	9.8	PROVIDES FOR THE TREATMENT OF NASAL CONGESTION ASSOCIATED WITH SAR IN ADULTS AND CHILDREN GREATER THAN 2 YEARS OF AGE
MARAVIROC UK-427,857	VIIV HEALTHCARE CO	NDA 022128	PAT POPUL	4	S	7/31/2009	5/27/2010	9.9	PROVIDES FOR EXPANSION OF THE PATIENT POPULATION TO INCLUDE PATIENTS WITH RENAL IMPAIRMENT.
NILOTINIB	NOVARTIS PHARMACEUTICALS CORP	NDA 022068	INDICATION	5	P	12/21/2009	6/17/2010	5.9	PROVIDES FOR THE TREATMENT OF NEWLY DIAGNOSED ADULT PATIENTS WITH PHILADELPHIA CHROMOSOME POSITIVE CHRONIC MYELOID LEUKEMIA IN CHRONIC PHASE

IOPROMIDE	BAYER HEALTHCARE PHARMACEUTICALS INC	NDA 021425	INDICATION	17	S	12/31/2008	6/23/2010	17.7	PROVIDES REVISIONS TO THE CLINICAL PHARMACOLOGY AND THE PRECAUTIONS SECTIONS OF THE PACKAGE INSERT TO ADD INFORMATION REGARDING DRUG INTERACTIONS BETWEEN VORICONAZOLE AND FENTANYL, VORICONAZOLE AND OXYCODONE, AND VORICONAZOLE AND NON-STEROIDAL ANTI-INFLAM
FOLLITROPIN BETA INJECTION	ORGANON USA INC	NDA 021211	INDICATION	7	S	9/18/2009	6/28/2010	9.3	PROVIDES FOR THE INDUCTION OF SPERMATOGENESIS IN MEN WITH PRIMARY AND SECONDARY HYPOGONADOTROPIC HYPOGONADISM (HH) IN WHOM THE CAUSE OF INFERTILITY IS NOT DUE TO PRIMARY TESTICULAR FAILURE
FOLLITROPIN BETA	ORGANON USA INC	NDA 021273	INDICATION	6	S	8/28/2009	6/28/2010	10.0	PROVIDES FOR THE INDUCTION OF SPERMATOGENESIS IN MEN WITH PRIMARY AND SECONDARY HYPOGONADOTROPIC HYPOGONADISM (HH) IN WHOM THE CAUSE OF INFERTILITY IS NOT DUE TO PRIMARY TESTICULAR FAILURE
	NOVEN PHARMACEUTICALS INC	NDA 021514	INDICATION	10	S	9/4/2009	6/29/2010	9.8	PROVIDES FOR THE TREATMENT OF ADHD IN ADOLESCENTS AGES 13 TO 17 YEARS OLD
TEMSIROLIMUS	WYETH PHARMACEUTICALS INC	NDA 022088	DOSING	8	S	9/10/2009	7/9/2010	9.9	PROVIDES FOR THE TREATMENT OF ADVANCED RENAL CELL CARCINOMA
PEG-3350 NACL NAHCO3 KCL BISACODYL	BRAINTREE LABORATORIES INC	NDA 021551	DOSING	13	S	9/17/2009	7/16/2010	9.9	PROVIDES FOR THE CLEANSING OF THE COLON AS A PREPARATION FOR COLONOSCOPY IN ADULTS

VALGANCICLOVIR HYDROCHLORIDE	ROCHE PALO ALTO LLC	NDA 021304	DOSING	8	S	10/7/2009	8/5/2010	9.9	PROVIDES TO EXTEND THE CURRENT DOSING REGIMEN TO 900 MG (TWO 450 MG TABLETS) ONCE A DAY WITHIN 10 DAYS OF TRANSPLANTATION UNTIL 200 DAYS POST- TRANSPLANTATION FOR THE PREVENTION OF CYTOMEGALOVIRUS (CMV) DISEASE IN ADULT KIDNEY TRANSPLANT PATIENTS AT HIGH R
SOMATROPIN(RNDA ORIGIN)FOR INJ,1.5,5.8MG	SANDOZ INC	NDA 021426	INDICATION	15	S	10/26/2009	8/26/2010	10.0	PROVIDES FOR LONG-TERM TREATMENT OF PETRATRIC PATIENTS WHO HAVE GROWTH FAILURE DUE TO AN INADEQUATE SECRETION OF ENDOGENOUS GROWTH HORMONE.
TRAVOPROST OPHTHALMIC SOLUTION	ALCON INC	NDA 021257	INDICATION	18	S	6/2/2006	8/31/2010	51.0	PROVIDES FOR THE REDUCTION OF ELEVATED INTRAOCULAR PRESSURE IN PATIENTS WITH OPEN ANGLE GLAUCOMA OR OCULAR HYPERTENSION
TRAVOPROST OPHTHALMIC SOLUTION 0.004%	ALCON INC	NDA 021994	INDICATION	1	S	11/22/2006	8/31/2010	45.3	PROVIDES FOR THE REDUCTION OF ELEVATED INTRAOCULAR PRESSURE IN PATIENTS WITH OPEN ANGLE GLAUCOMA OR OCULAR HYPERTENSION
ASENAPINE	ORGANON USA INC	NDA 022117	INDICATION	3	S	11/9/2009	9/3/2010	9.8	PROVIDES FOR THE MAINTENANCE TREATMENT OF SCHIZOPHRENIA IN ADULTS
ASENAPINE	ORGANON USA INC	NDA 022117	INDICATION	4	S	11/9/2009	9/3/2010	9.8	PROVIDES FOR THE INDICATION OF ADJUNCTIVE THERAPY WITH LITHIUM/VALPROATE FOR ACUTE TREATMENT OF MANIC OR MIXED EPISODES ASSOCIATED/W BIPOLAR I DISORDER (S-004)

FULVESTRANT	ASTRAZENECA PHARMACEUTICALS LP	NDA 021344	DOSING	12	S	11/13/2009	9/9/2010	9.9	PROVIDES FOR THE TREATMENT OF HORMONE RECEPTOR POSITIVE METASTATIC BREAST CANCER IN POSTMENOPAUSAL WOMEN WITH DISEASE PROGRESSION FOLLOWING ANTIESTROGEN THERAPY
0.3% TRICLOSAN, 0.243% SODIUM FLUORIDE U	COLGATE PALMOLIVE	NDA 020231	MANU W CLIN	58	S	7/31/2007	9/15/2010	37.5	PROVIDES FOR A CHANGE IN THE CURRENTLY MARKETED VARIANT
DEXAMETHASONE BIODEGRADABLE INTRAVITREAL	ALLERGAN INC	NDA 022315	INDICATION	3	S	10/23/2009	9/24/2010	11.0	PROVIDES FOR THE TREATMENT OF NON-INFECTIOUS UVEITIS AFFECTING THE POSTERIOR SEGMENT OF THE EYE.
CLONIDINE HYDROCHLORIDE	SHIONOGI PHARMA INC	NDA 022331	INDICATION	1	S	9/30/2009	9/28/2010	11.9	PROVIDES FOR THE TREATMENT OF ADHD AS MONOTHERAPY
CLONIDINE HYDROCHLORIDE	SHIONOGI PHARMA INC	NDA 022331	INDICATION	2	S	9/30/2009	9/28/2010	11.9	PROVIDES FOR THE ADJUNCTIVE THERAPY TO STIMULANT MEDICATIONS
TENOFOVIR DISOPROXIL FUMARATE	GILEAD SCIENCES INC	NDA 021356	PAT POPUL	34	S	10/1/2009	10/1/2010	12.0	PROVIDES FOR THE TREATMENT OF HIV AND HBV INFECTION
NALTREXONE LONG ACTING INJECTION	ALKERMES INC	NDA 021897	INDICATION	15	P	4/12/2010	10/12/2010	6.0	PROVIDES FOR THE PREVENTION OF RELAPSE TO OPIOID DEPENDENCE, FOLLOWING OPIOID DETOXIFICATION
CORTICOTROPIN	QUESTCOR PHARMACEUTICALS INC	NDA 022432	TYPE 6	1	S	6/23/2006	10/15/2010	51.8	PROVIDES MONOTHERAPY FOR THE TREATMENT OF INFANTILE SPASMS IN INFANTS AND CHILDREN UNDER 2 YEARS OF AGE
BROMFENAC SODIUM HYDRATE OPHTHALMIC SOL	ISTA PHARMACEUTICALS INC	NDA 021664	DOSING	13	S	12/16/2009	10/16/2010	10.0	PROVIDES FOR THE TREATMENT OF POSTOPERATIVE INFLAMMATION IN PATIENTS WHO HAVE UNDERGONE CATARACT EXTRACTION
DASATINIB 20/50/70MG TABLETS	BRISTOL MYERS SQUIBB CO	NDA 021986	EFFICACY	7	S	1/29/2010	10/28/2010	8.9	PROVIDES FOR THE TREATMENT OF FOR NEWLY DIAGNOSED ADULTS WITH PHILADELPHIA CHROMOSOME-POSITIVE (PH+) CML IN CHRONIC PHASE

DASATINIB 20/50/70MG TABLETS	BRISTOL MYERS SQUIBB CO	NDA 021986	INDICATION	8	P	4/28/2010	10/28/2010	6.0	PROVIDES FOR THE TREATMENT OF FOR NEWLY DIAGNOSED ADULTS WITH PHILADELPHIA CHROMOSOME-POSITIVE (PH+) CML IN CHRONIC PHASE
EVEROLIMUS/SUNITINIB	NOVARTIS PHARMACEUTICALS CORP	NDA 022334	INDICATION	6	P	4/30/2010	10/29/2010	6.0	PROVIDES FOR THE TREATMENT OF PATIENTS WITH SUBEPENDYMAL GIANT CELL ASTROCYTOMA ASSOCIATED WITH TUBEROUS SCLEROSIS
DULOXETINE HCL POWDER	ELI LILLY AND CO	NDA 022516	TYPE 6	1	S	5/15/2009	11/4/2010	17.7	MANAGEMENT OF CHRONIC PAIN
LISDEXAMFETAMINE DIMESYLATE	SHIRE DEVELOPMENT INC	NDA 021977	PAT POPUL	16	S	1/14/2010	11/10/2010	9.9	PROVIDES FOR THE TREATMENT OF ATTENTION DEFICIT HYPERACTIVITY DISORDER
FOSAPREPITANT DIMEGLUMINE	MERCK AND CO INC	NDA 022023	DOSING	4	S	10/13/2009	11/12/2010	13.0	PROVIDES FOR THE PREVENTION OF ACUTE AND DELAYED NAUSEA AND VOMITING ASSOCIATED WITH HIGHLY EMETOGENIC CANCER CHEMOTHERAPY
DAPTOMYCIN 250MG/VIAL AND 500MG/VIAL	CUBIST PHARMACEUTICALS INC	NDA 021572	DOSING	23	S	8/1/2008	11/30/2010	28.0	PROVIDES FOR AN ALTERNATIVE METHOD OF ADMINISTRATION AT A CONCENTRATION OF 50 MG/ML AS AN IV BOLUS INJECTION OVER APPROXIMATELY 2 MINUTES.
DARUNAVIR	TIBOTEC INC	NDA 021976	DOSING	17	S	2/19/2010	12/13/2010	9.8	PROVIDES FOR THE TREATMENT OF HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFECTION
ALFUZOSIN HCL 10MG E-R TABLETS	SANOFI AVENTIS US LLC	NDA 021287	PEDIATRIC	16	P	6/16/2010	12/15/2010	6.0	PROVIDES FOR THE TREATMENT OF THE SIGNS AND SYMPTOMS OF BENIGN PROSTATIC HYPERPLASIA

NDA Efficacy Supplements Approved (SE8)

Established Name	Applicant	Application Number	Supplement Type / Submission Class Code	Supplement Number	Priority Review	FDA Received Date	Approval Date	Total Approval Time (Months)
ATRIPLA	GILEAD SCIENCES INC	NDA 021937	LABEL W CLIN	12	S	3/9/2009	1/7/2010	10.0
DARUNAVIR	TIBOTEC INC	NDA 021976	LABEL W CLIN	12	S	3/27/2009	1/27/2010	10.1

DARUNAVIR	TIBOTEC INC	NDA 021976	LABEL W CLIN	13	S	3/27/2009	1/27/2010	10.1
SITAGLIPTIN PHOSPHATE	MERCK CO INC	NDA 021995	LABEL W CLIN	10	S	12/18/2008	2/26/2010	14.3
SITAGLIPTIN PHOSPHATE	MERCK CO INC	NDA 021995	LABEL W CLIN	11	S	12/19/2008	2/26/2010	14.3
SITAGLIPTIN PHOSPHATE	MERCK CO INC	NDA 021995	LABEL W CLIN	12	S	2/23/2009	2/26/2010	12.1
SITAGLIPTIN PHOSPHATE/METFORMIN HCL TABS	MERCK AND CO INC	NDA 022044	LABEL W CLIN	10	S	12/19/2008	2/26/2010	14.3
SITAGLIPTIN PHOSPHATE/METFORMIN HCL TABS	MERCK AND CO INC	NDA 022044	LABEL W CLIN	12	S	3/31/2009	2/26/2010	10.9
LETROZOLE	PHARMACEUTICALS CORP	NDA 020726	LABEL W CLIN	15	S	4/12/2007	3/2/2010	34.7
LETROZOLE	NOVARTIS PHARMACEUTICALS CORP	NDA 020726	LABEL W CLIN	16	S	4/12/2007	3/2/2010	34.7
AMINOLEVULINIC ACID HCL	DUSA PHARMACEUTICALS INC	NDA 020965	LABEL W CLIN	7	S	1/22/2008	3/12/2010	25.6
APREPITANT	MERCK AND CO INC	NDA 021549	LABEL W CLIN	17	S	5/19/2009	3/19/2010	10.0
TENOFOVIR DISOPROXIL FUMARATE	GILEAD SCIENCES INC	NDA 021356	LABEL W CLIN	33	P	9/25/2009	3/24/2010	5.9
OLOPATADINE HCL 0.6%	ALCON INC	NDA 021861	LABEL W CLIN	8	S	6/1/2009	3/31/2010	10.0
LISDEXAMFETAMINE DIMESYLATE	SHIRE DEVELOPMENT INC	NDA 021977	LABEL W CLIN	10	S	6/30/2009	4/5/2010	9.2
TEMSIROLIMUS	WYETH PHARMACEUTICALS INC	NDA 022088	LABEL W CLIN	6	S	6/26/2009	4/26/2010	10.0
BIPHASIC INSULIN ASPART 30	NOVO NORDISK INC	NDA 021172	LABEL W CLIN	49	S	6/30/2009	5/7/2010	10.2
RALTEGRAVIR POTASSIUM	MERCK SHARP AND DOHME CORP	NDA 022145	LABEL W CLIN	11	S	9/1/2009	6/29/2010	9.9
RALTEGRAVIR POTASSIUM	MERCK SHARP AND DOHME CORP	NDA 022145	LABEL W CLIN	12	S	9/1/2009	6/29/2010	9.9
SUNITINIB	CP PHARMACEUTICALS INTERNATIONAL CV	NDA 021938	LABEL W CLIN	10	S	7/10/2009	7/1/2010	11.7
RUBIDIUM-82 CHLORIDE	BRACCO DIAGNOSTICS INC	NDA 019414	LABEL W CLIN	12	S	9/29/2009	7/29/2010	10.0
ETHINYL ESTRADIOL/LEVONORGESTREL TABLETS	DURAMED RESEARCH INC	NDA 021840	LABEL W CLIN	8	S	7/1/2009	7/29/2010	12.9
PANCRELIPASE DELAYED RELEASE CAPS	ABBOTT PRODUCTS INC	NDA 020725	LABEL W CLIN	6	S	9/29/2009	7/29/2010	10.0
SITAGLIPTIN PHOSPHATE PHOSPHATE/METFORMIN HCL TABS	MERCK CO INC	NDA 021995	LABEL W CLIN	15	S	12/23/2009	9/24/2010	9.0
	MERCK AND CO INC	NDA 022044	LABEL W CLIN	14	S	12/23/2009	9/24/2010	9.0
LENALIDOMIDE	CELGENE CORP	NDA 021880	LABEL W CLIN	18	S	2/9/2009	10/12/2010	20.1

TENOFOVIR DISOPROXIL FUMARATE	GILEAD SCIENCES INC	NDA 021356	LABEL W CLIN	35	S	12/14/2009	10/14/2010	10.0
ENTECAVIR TABLETS 0.5/1MG	BRISTOL MYERS SQUIBB	NDA 021797	LABEL W CLIN	10	S	12/15/2009	10/15/2010	10.0
ENTECAVIR ORAL SOLUTION 0.05MG/ML	BRISTOL MYERS SQUIBB	NDA 021798	LABEL W CLIN	11	S	12/15/2009	10/15/2010	10.0
MEDROXYPROGESTERONE ACETATE	PHARMACIA AND UPJOHN CO	NDA 020246	LABEL W CLIN	36	S	12/17/2009	10/15/2010	9.9
NITRIC OXIDE INHALED GAS 400PPM	INO THERAPEUTICS INC	NDA 020845	LABEL W CLIN	11	P	6/25/2010	12/21/2010	5.9
RIBAVIRIN	HOFFMANN LA ROCHE INC	NDA 021511	LABEL W CLIN	21	S	12/14/2009	12/21/2010	12.2
LIRAGLUTIDE	NOVO NORDISK INC	NDA 022341	LABEL W CLIN	1	S	2/23/2010	12/22/2010	9.9

BLA Efficacy Supplements Approved

PROPER NAME	APPLICANT	BLA NUMBER	SUPPLEMENT NUMBER	PRIORITY REVIEW	RECEIPT DATE	APPROVAL DATE	TOTAL APPROVAL TIME (IN MONTHS)	INDICATION
OMALIZUMAB	GENENTECH, INC.	L 103976	5166	S	12/5/2008	1/4/2010	13.0	RESPONSE TO PREA COMMITMENT & ADDITION OF PREA PEDIATRIC INFO IN THE LABEL
RITUXIMAB	GENENTECH, INC.	L 103705	5311	P	5/18/2009	2/18/2010	9.1	FOR THE TREATMENT OF PREVIOUSLY TREATED PATIENTS WITH CD20 POSITIVE B-CELL CHRONIC LYMPHOCYTIC LEUKEMIA (CLL)
RITUXIMAB	GENENTECH, INC.	L 103705	5312	P	5/18/2009	2/18/2010	9.1	FOR THE TREATMENT OF PREVIOUSLY UNTREATED PATIENTS WITH CD20-POSITIVE B-CELL CHRONIC LYMPHOCYTIC LEUKEMIA (CLL)
ONABOTULINUMTOXINA	ALLERGAN, INC.	L 103000	5189	P	8/22/2008	3/9/2010	18.5	TO TREAT UPPER LIMB SPASTICITY IN POST-STROKE ADULT PATIENTS
DARBEPOETIN ALFA	AMGEN, INC.	L 103951	5175	S				2/11/2008

RANIBIZUMAB	GENENTECH, INC.	L 125156	53	P	12/22/2009	6/22/2010	6.0	NEW INDICATION FOR THE TREATMENT OF MACULAR EDEMA FOLLOWING RETINAL VEIN OCCLUSION
INTERFERON ALFACON-1	THREE RIVERS PHARMACEUTICALS, LLC	L 103663	5069	S	7/2/2008	7/2/2010	24.0	UPDATE PACKAGE INSERT WITH RESULTS OF DIRECT TRIALS
TRASTUZUMAB	GENENTECH, INC.	L 103792	5250	P	4/20/2010	10/20/2010	6.0	INCLUDE A NEW INDICATION FOR THE TREATMENT OF PATIENTS WITH HER2 OVEREXPRESSING METASTATIC GASTRIC OR GASTROESOPHAGEAL JUNCTION ADENOCARCINOMA, WHO HAVE NOT RECEIVED PRIOR TREATMENT FOR METASTATIC DISEASE.
DENOSUMAB TO	AMGEN, INC.	L 125320	7	P	5/19/2010	11/18/2010	6.0	TREATMENT OF PATIENTS WITH ADVANCED MALIGNANCIES INVOLVING BONE, INCLUDING MULTIPLE MYELOMA