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DIVISION OF BUSINESS ANALYSIS AND REPORTING
OFFICE OF BUSINESS INFORMATICS

New Drug Application (NDA) & Biologic License Application (BLA) Efficacy Supplement Calendar Year Approvals
As of December 31, 2011

Last Refresh Date: 1/9/2011

Selection Criteria:

User Response: Start Date: 1/1/2011 End Date: 12/31/2011

Sort Order: Approval Date

APPLICATION NUMBER	SUPPLEMENT NUMBER	SUPPLEMENT TYPE / SUBMISSION CLASS CODE	ESTABLISHED NAME	APPLICANT	PRIORITY REVIEW	RECEIPT DATE	APPROVAL DATE	TOTAL APPROVAL TIME (MONTHS)	INDICATION/DESCRIPTION
NDA 022068	6	ACCELERATED APPROVAL CONFIRMATORY STUDY	NILOTINIB	NOVARTIS PHARMACEUTICALS CORP	S	3/15/2010	1/14/2011	10.0	PROVIDES FOR REVISIONS TO THE PACKAGE INSERT AND THE MEDICATION GUIDE BASED ON 24-MONTH FOLLOW-UP DATA ON ALL PATIENTS WITH IMATINIBRESISTANT OR -INTOLERANT CHRONIC MYELOID LEUKEMIA IN CHRONIC AND ACCELERATED PHASES AS WELL AS PROPOSED MODIFICATIONS TO THE APPROVED REMS
NDA 020762	44	NEW INDICATION	MOMETASONE FUROATE NASAL SUSPENSION	SCHERING PLOUGH HEALTHCARE PRODUCTS INC	S	3/19/2010	1/19/2011	10.1	PROVIDES FOR THE ADDITION OF FINDINGS FROM A SINGLE PEDIATRIC CLINICAL TRIAL (P04292) OF NASONEX NASAL SPRAY IN THE TREATMENT OF NASAL POLYPS IN PATIENTS 6 TO <18 YEARS OF AGE TO THE PACKAGE INSERT
NDA 020786	27	RX TO OTC SWITCH	FEXOFENADINE HYDROCHLORIDE/PSEUDOEPHEDRINE HYDROCHLORIDE	SANOFI AVENTIS US LLC	S	3/25/2010	1/24/2011	10.0	PROVIDES FOR THE THE USE AS TEMPORARY RELIEF OF SYMPTOMS DUE TO HAY FEVER OR OTHER UPPER RESPIRATORY ALLERGIES IN ADULTS AND CHILDREN 12 YEARS OF AGE AND OLDER.
NDA 020872	23	RX TO OTC SWITCH	FEXOFENADINE HYDROCHLORIDE	SANOFI AVENTIS US LLC	S	3/25/2010	1/24/2011	10.0	PROVIDES FOR THE NONPRESCRIPTION USE OF CHILDREN'S ALLEGRA® ALLERGY IN ADULTS AND CHILDREN 6 YEARS OF AGE AND OLDER AND OF ALLEGRA® ALLERGY IN ADULTS AND CHILDREN 12 YEARS OF AGE AND OLDER FOR THE FOLLOWING INDICATION: TEMPORARILY RELIEVES THESE SYMPTOMS
NDA 021704	8	RX TO OTC SWITCH	FEXOFENADINE HYDROCHLORIDE 180MG/PSEUDOEPHEDRINE HYDROCHLORIDE	SANOFI AVENTIS US LLC	S	3/25/2010	1/24/2011	10.0	PROVIDES FOR THE NONPRESCRIPTION USE OF ALLEGRA-D® 24 HOUR ALLERGY & CONGESTION FOR THE TEMPORARY RELIEF OF SYMPTOMS DUE TO HAY FEVER OR OTHER UPPER RESPIRATORY ALLERGIES
NDA 021909	3	RX TO OTC SWITCH	FEXOFENADINE HYDROCHLORIDE	SANOFI AVENTIS US LLC	S	3/25/2010	1/24/2011	10.0	PROVIDES FOR THE NONPRESCRIPTION USE OF CHILDREN'S ALLEGRA® ALLERGY FOR THE TEMPORARY RELIEF OF SYMPTOMS DUE TO HAY FEVER OR OTHER UPPER RESPIRATORY ALLERGIES IN ADULTS AND CHILDREN 6 YEARS OF AGE AND OLDER
NDA 021567	25	NEW PATIENT POPULATION	ATAZANAVIR SULFATE	BRISTOL MYERS SQUIBB CO	P	8/6/2010	2/4/2011	6.0	PROVIDES DOSING RECOMMENDATIONS FOR TREATMENT OF HIV-1 INFECTION DURING PREGNANCY BASED ON DATA FROM STUDY AI424-182, A STUDY OF ATAZANAVIR/RITONAVIR IN COMBINATION WITH IDOVUDINE/LAMIVUDINE IN HIVINFECTED PREGNANT WOMEN

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NDA 021436	29	NEW INDICATION	ARIPIPRAZOLE TABLETS	OTSUKA PHARMACEUTICAL CO LTD	S	4/16/2010	2/16/2011	10.1	PROVIDE FOR THE USE OF ABILIFY (ARIPIPRAZOLE) TABLET FOR THE MAINTENANCE TREATMENT OF BIPOLAR I DISORDER AS AN ADJUNCT TO LITHIUM OR VALPROATE
NDA 021713	21	NEW INDICATION	ARIPIPRAZOLE ORAL SOLUTION	OTSUKA PHARMACEUTICAL DEVELOPMENT AND COMMERCIALIZATION INC	S	4/23/2010	2/16/2011	9.8	PROVIDE FOR THE USE OF ABILIFY (ARIPIPRAZOLE) ORAL SOLUTION FOR THE MAINTENANCE TREATMENT OF BIPOLAR I DISORDER AS AN ADJUNCT TO LITHIUM OR VALPROATE
NDA 021729	14	NEW INDICATION	ARIPIPRAZOLE ORALLY DISINTEGRATING TABLETS	OTSUKA PHARMACEUTICAL CO LTD	S	4/23/2010	2/16/2011	9.8	PROVIDE FOR THE USE OF ABILIFY (ARIPIPRAZOLE) ORALLY DISINTEGRATING TABLET FOR THE MAINTENANCE TREATMENT OF BIPOLAR I DISORDER AS AN ADJUNCT TO LITHIUM OR VALPROATE
NDA 021866	16	NEW INDICATION	ARIPIPRAZOLE SINGLE DOSE VIAL	OTSUKA PHARMACEUTICAL CO LTD	S	4/23/2010	2/16/2011	9.8	PROVIDE FOR THE USE OF ABILIFY (ARIPIPRAZOLE) INJECTABLE FORMULATION FOR THE MAINTENANCE TREATMENT OF BIPOLAR I DISORDER AS AN ADJUNCT TO LITHIUM OR VALPROATE
NDA 021688	15	NEW INDICATION	CINACALCET HYDROCHLORIDE	AMGEN INC	S	4/27/2010	2/25/2011	10.0	PROVIDES FOR: 1. A NEW INDICATION, “TREATMENT OF SEVERE HYPERCALCEMIA IN PATIENTS WITH PRIMARY HYPERPARATHYROIDISM WHO ARE UNABLE TO UNDERGO PARATHYROIDECTOMY.” 2. THE INCLUSION OF DATA FROM AN ADDITIONAL 19 SUBJECTS WITH HYPERCALCEMIA FROM PARATHYROID CA
NDA 022037	2	PEDIATRIC	GUANFACINE HYDROCHLORIDE	SHIRE DEVELOPMENT INC	S	4/28/2010	2/25/2011	10.0	PROVIDES FOR THE USE OF INTUNIV AS ADJUNCTIVE TREATMENT WITH LONG-ACTING ORAL PSYCHOSTIMULANTS FOR THE TREATMENT OF ATTENTION DEFICIT HYPERACTIVITY DISORDER (ADHD)
NDA 022291	1	ACCELERATED APPROVAL CONFIRMATORY STUDY	ELTROMBOPAG	GLAXOSMITHKLINE	S	3/19/2009	2/25/2011	23.3	PROVIDES FOR CONVERSION OF ACCELERATED APPROVAL TO FULL APPROVAL STATUS, REVISED LABELING, AND PROPOSED MODIFICATIONS TO THE APPROVED REMS
NDA 022074	3	NEW DOSING REGIMEN	LANREOTIDE INJECTION	BEAUFOUR IPSEN PHARMA	S	5/3/2010	3/4/2011	10.0	PROVIDES FOR THE ADDITION OF A NEW DOSING REGIMEN OF EVERY 6 TO 8 WEEKS FOR THE 120 MG STRENGTH FOR PATIENTS WHO ARE CONTROLLED ON SOMATULINE DEPOT 60 MG OR 90 MG IN THE DOSAGE AND ADMINISTRATION SECTION OF THE PACKAGE INSERT
NDA 021342	20	COMPARATIVE EFFICACY CLAIM	LEVOTHYROXINE SODIUM FOR INJECTION,200MCG(AND 500MCG) VIAL(S)	ALARA PHARMACEUTICAL CORP	S	5/10/2010	3/9/2011	10.0	DEMONSTRATES BIOEQUIVALENCE BETWEEN LEVO-T AND UNITHROID IN ORDER TO OBTAIN AN AB RATING

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NDA 021676	8	NEW INDICATION	DROSPIRENONE 3MG/ETHINYL ESTRADIOL 0.020	BAYER HEALTHCARE PHARMACEUTICALS INC	S	2/12/2010	3/11/2011	12.9	PROVIDES FOR THE INCLUSION OF NEW INFORMATION REGARDING THE INCREASED RISK OF VENOUS THROMBOEMBOLIC EVENTS (VTE) IN WOMEN USING COMBINED ORAL CONTRACEPTIVES (COCS) IN WARNINGS AND PRECAUTIONS, SUBSECTION THROMBOEMBOLIC DISORDERS AND OTHER VASCULAR PROBLEM
NDA 021462	33	PEDIATRIC	PEMETREXED DISODIUM	ELI LILLY AND CO	P	9/17/2010	3/17/2011	6.0	PROVIDES FOR CHANGES TO THE 8.4 PEDIATRIC USE SECTION, MINOR FORMATTING CHANGES TO THE PACKAGE INSERT, AND PATIENT PACKAGE INSERT INCORPORATING THE FINDINGS OF PEDIATRIC STUDIES: H3E-USJMFC(JMFC) AND H3E-MCJMHW (JMHW)
NDA 022483	1	NEW INDICATION	IMIQUIMOD 3.75% CREAM	GRACEWAY PHARMACEUTICALS LLC	S	6/9/2010	3/24/2011	9.5	PROVIDES FOR THE USE OF ZYCLARA (IMIQUIMOD) CREAM FOR THE TREATMENT OF EXTERNAL GENITAL AND PERIANAL WARTS/CONDYLOMA ACUMINATA IN PATIENTS 12 YEARS OR OLDER
NDA 018780	120	NEW ROUTE OF ADMINISTRATION	INSULIN RECOMBINANT HUMAN	ELI LILLY AND CO	S	4/30/2008	3/25/2011	34.8	PROVIDES FOR THE ADDITION OF THE INTRAVENOUS ROUTE OF ADMINISTRATION
NDA 021999	24	PEDIATRIC	PALIPERIDONE	ORTHO MCNEIL JANSSEN PHARMACEUTICALS INC	P	10/8/2010	4/6/2011	5.9	PROVIDES FOR THE USE OF INVEGA (PALIPERIDONE) FOR THE TREATMENT OF SCHIZOPHRENIA IN ADOLESCENTS 12-18
NDA 022115	6	NEW PATIENT POPULATION	LAMOTRIGINE EXTENDED-RELEASE TABLETS	SMITHKLINE BEECHAM CORP	S	3/31/2010	4/25/2011	12.8	PROVIDES FOR THE USE AS MONOTHERAPY IN PATIENTS 13 YEARS OF AGE AND OLDER WITH PARTIAL SEIZURES WHO ARE RECEIVING THERAPY WITH A SINGLE ANTIEPILEPTIC DRUG (AED).
NDA 020140	2	NEW INDICATION	LEVOLEUCOVORIN FOR INJECTION	SPECTRUM PHARMACEUTICALS INC	S	12/8/2008	4/29/2011	28.7	PROVIDES FOR THE USE OF FUSILEV FOR USE IN COMBINATION CHEMOTHERAPY WITH 5-FLUOROURACIL IN THE PALLIATIVE TREATMENT OF PATIENTS WITH ADVANCED METASTATIC COLORECTAL CANCER.
NDA 021689	17	NEW PATIENT POPULATION	ESOMEPRAZOLE SODIUM	ASTRAZENECA LP	S	3/31/2010	4/29/2011	13.0	[PROVIDES FOR THE USE OF NEXIUM I.V. FOR THE TREATMENT OF GASTROESOPHAGEAL REFLUX DISEASE (GERD) WITH EROSIVE ESOPHAGITIS IN PATIENTS AGED 1 MONTH TO 17 YEARS, INCLUSIVE , AS AN ALTERNATIVE TO ORAL THERAPY WHEN ORAL NEXIUM IS NOT POSSIBLE OR APPROPRIATE.
NDA 022334	9	NEW INDICATION	EVEROLIMUS/SUNITINIB	NOVARTIS PHARMACEUTICALS CORP	P	11/5/2010	5/5/2011	6.0	PROVIDES FOR THE USE OF AFINITOR FOR THE TREATMENT OF PROGRESSIVE NEUROENDOCRINE TUMORS OF PANCREATIC ORIGIN (PNET) IN PATIENTS WITH UNRESECTABLE, LOCALLY ADVANCED OR METASTATIC DISEASE

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NDA 020839	51	PEDIATRIC	CLOPIDOGREL BISULFATE	SANOFI AVENTIS US LLC	P	7/15/2010	5/6/2011	9.7	RESPONDS TO THE OCTOBER 15, 2001 PEDIATRIC WRITTEN REQUEST, AS AMENDED AUGUST 24, 2007. THE PIVOTAL TRIAL SUBMITTED TO SUPPORT YOUR SNDA WAS CLARINET, A TRIAL OF ADMINISTERING CLOPIDOGREL TO PATIENTS WITH CYANOTIC CONGENITAL HEART DISEASE PALLIATED WITH A
NDA 021529	7	MANUFACTURING CHANGE WITH CLINICAL DATA	ETONOGESTREL IMPLANT	ORGANON USA INC	S	7/30/2009	5/13/2011	21.4	PROVIDES FOR A NEW RADIOPAQUE VERSION OF THE ETONOGESTREL IMPLANT FOR THE INDICATION OF “USE BY WOMEN TO PREVENT PREGNANCY” AND A NEW DEVICE FOR INSERTION OF THE IMPLANT
NDA 021344	13	PEDIATRIC	FULVESTRANT	ASTRAZENECA PHARMACEUTICALS LP	P	11/17/2010	5/17/2011	6.0	PROVIDES FOR THE ADDITION OF SAFETY, EFFICACY AND PHARMACOKINETIC INFORMATION FOR FASLODEX IN THE PEDIATRIC POPULATION, SPECIFICALLY FOR GIRLS WITH PROGRESSIVE PRECOCIOUS PUBERTY ASSOCIATED WITH MCCUNE-ALBRIGHT SYNDROME, TO THE PEDIATRIC USE SECTION OF TH
NDA 020563	105	NEW PATIENT POPULATION	INSULIN LISPRO [RDNA ORIGIN]	ELI LILLY AND CO	S	5/6/2010	5/18/2011	12.4	PROVIDES FOR PEDIATRIC USE OF HUMALOG IN A CONTINUOUS INSULIN INFUSION PUMP
NDA 021938	13	NEW INDICATION	SUNITINIB MALATE	CP PHARMACEUTICALS INTERNATIONAL CV	P	12/14/2009	5/20/2011	17.2	INDICATED FOR THE TREATMENT OF PROGRESSIVE, WELL-DIFFERENTIATED PANCREATIC NEUROENDOCRINE TUMORS IN PATIENTS WITH UNRESECTABLE LOCALLY ADVANCED OR METASTATIC DISEASE.
NDA 021319	23	NEW INDICATION	DUTASTERIDE	GLAXOSMITHKLINE	S	3/12/2010	6/9/2011	14.9	PROVIDES FOR REVISIONS TO THE LABELING REGARDING THE RISK OF HIGH-GRADE PROSTATE CANCER AND THE EFFECT OF AVODART ON SERUM PROSTATE SPECIFIC ANTIGEN (PSA) LEVELS. IT ALSO REVISES THE PRESCRIBING INFORMATION TO INCLUDE 4-YEAR RESULTS FROM THE COMBAT STUDY
NDA 022393	4	NEW INDICATION	ROMIDEPSIN FOR INJECTION	CELGENE CORP	P	12/17/2010	6/16/2011	6.0	PROVIDES FOR THE USE OF ISTODAX (ROMIDEPSIN) FOR THE TREATMENT OF PERIPHERAL T-CELL LYMPHOMA (PTCL) IN PATIENTS WHO HAVE RECEIVED AT LEAST ONE PRIOR THERAPY
NDA 020517	30	NEW DOSING REGIMEN	LEUPROLIDE ACETATE	ABBOTT ENDOCRINE INC	S	12/11/2009	6/17/2011	18.2	PROVIDES FOR DATA TO SUPPORT A NEW FORMULATION OF LUPRON DEPOT, FOR THE PALLIATIVE TREATMENT OF ADVANCED PROSTATIC CANCER
NDA 022287	8	NEW INDICATION	DEXLANSOPRAZOLE	TAKEDA PHARMACEUTICALS NORTH AMERICA INC	S	8/17/2010	6/17/2011	10.0	PROVIDES FOR THE EXPANSION OF THE MAINTENANCE OF HEALED EROSIVE ESOPHAGITIS INDICATION TO INCLUDE THE RELIEF OF HEARTBURN
NDA 020505	42	PEDIATRIC	TOPIRAMATE	JANSSEN PHARMACEUTICALS INC	S	2/1/2010	7/15/2011	17.4	PROVIDE FOR THE EXPANSION OF THE INITIAL MONOTHERAPY INDICATION IN PATIENTS DOWN TO 2 YEARS OF AGE WITH PARTIAL ONSET OR PRIMARY GENERALIZED TONIC-CLONIC SEIZURES.

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NDA 020844	36	PEDIATRIC	TOPIRAMATE	JANSSEN PHARMACEUTICALS INC	S	2/1/2010	7/15/2011	17.4	PROVIDE FOR THE EXPANSION OF THE INITIAL MONOTHERAPY INDICATION IN PATIENTS DOWN TO 2 YEARS OF AGE WITH PARTIAL ONSET OR PRIMARY GENERALIZED TONIC-CLONIC SEIZURES.
NDA 022483	3	NEW DOSING REGIMEN	IMIQUIMOD 3.75% CREAM	GRACEWAY PHARMACEUTICALS LLC	S	9/17/2010	7/15/2011	9.9	PROVIDES FOR THE TOPICAL TREATMENT OF CLINICALLY TYPICAL VISIBLE OR PALPABLE ACTINIC KERATOSES OF THE FACE OR BALDING SCALP IN IMMUNOCOMPETENT ADULTS
NDA 017858	34	NEW INDICATION	TC-99M SULFUR COLLOID KIT	PHARMALUCENCE INC	S	9/24/2010	7/22/2011	9.9	PROVIDES FOR A NEW INDICATION FOR THE LOCALIZATION OF LYMPH NODES DRAINING A PRIMARY TUMOR IN PATIENTS WITH BREAST CANCER WHEN USED WITH A HAND-HELD GAMMA COUNTER AND THE ASSOCIATED NEW ROUTE OF ADMINISTRATION, SUBCUTANEOUS INJECTION.
NDA 021426	17	NEW INDICATION	somatropin [rDNA origin] injection	SANDOZ INC	S	9/30/2010	7/22/2011	9.7	PROVIDES FOR A NEW INDICATION FOR THE TREATMENT OF PEDIATRIC PATIENTS WITH GROWTH FAILURE ASSOCIATED WITH TURNER SYNDROME (TS).
NDA 021445	30	NEW INDICATION	EZETIMIBE	MSP SINGAPORE CO LLC	S	9/30/2010	7/29/2011	9.9	PROVIDES FOR THE ADDITION OF THE LIPID PARAMETER NON-HDL-C
NDA 021511	22	NEW PATIENT POPULATION	RIBAVIRIN	HOFFMANN LA ROCHE INC	S	12/18/2009	8/9/2011	19.7	PROVIDES TO EXPAND THE PATIENT POPULATION TO INCLUDE CHRONIC HEPATITIS C PATIENTS WITH RENAL IMPAIRMENT (CREATININE CLEARANCE LESS THAN 50 ML/MIN), INCLUDING THOSE WHO ARE RECEIVING CHRONIC HEMODIALYSIS.
NDA 020263	36	NEW DOSING REGIMEN	LEUPROLIDE ACETATE	ABBOTT ENDOCRINE INC	S	7/15/2010	8/15/2011	13.0	PROPOSES A 3-MONTH DOSAGE REGIMEN FOR THE 11.25 MG AND 30 MG STRENGTHS AND A CONVERSION OF THE CURRENTLY APPROVED LUPRON DEPOT-PED PACKAGE INSERT (MONTHLY DOSAGE REGIMEN FOR THE 7.5 MG, 11.25 MG AND 15 MG STRENGTHS) INTO THE PHYSICIAN'S LABELING RULE (PLR) FORMAT.
NDA 021211	11	NEW DOSING REGIMEN	FOLLITROPIN BETA INJECTION	ORGANON USA INC	S	10/22/2010	8/22/2011	10.0	PROVIDES FOR THE ADDITION OF NEW EFFICACY DATA (SECTION 14.2) AND A REVISED DOSING REGIMEN (SECTION 2.3) IN THE PACKAGE INSERT, SUPPORTING THE INDICATION OF "PREGNANCY IN NORMAL OVULATORY WOMEN UNDERGOING CONTROLLED OVARIAN STIMULATION AS PART OF AN IN VITRO FERTILIZATION (IVF) OR INTRACYTOPLASMIC SPERM INJECTION (ICSI) CYCLE."
NDA 021511	23	PEDIATRIC	RIBAVIRIN	HOFFMANN LA ROCHE INC	P	2/22/2011	8/22/2011	6.0	EXPAND THE PATIENT POPULATION TO INCLUDE 5 TO 17 YEAR OLDS
NDA 021368	20	NEW INDICATION	TADALAFIL	ELI LILLY AND CO	S	12/6/2010	10/6/2011	10.0	PROVIDES FOR THE TREATMENT OF THE SIGNS AND SYMPTOMS OF BENIGN PROSTATIC HYPERPLASIA (BPH)
NDA 021368	21	NEW INDICATION	TADALAFIL	ELI LILLY AND CO	S	12/6/2010	10/6/2011	10.0	PROVIDES FOR THE TREATMENT OF ERECTILE DYSFUNCTION (ED) AND THE SIGNS AND SYMPTOMS OF BPH.

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NDA 021567	26	NEW DOSING REGIMEN	ATAZANAVIR SULFATE	BRISTOL MYERS SQUIBB CO	S	12/17/2010	10/17/2011	10.0	PROVIDES TO REVISE THE DOSAGE AND ADMINISTRAION, “RECOMMENDED PEDIATRIC DOSAGE” SUBSECTION TO REVISE THE CAPSULE DOSING RECOMMENDATION FOR BOTH TREATMENT-NAÏVE AND TREATMENT-EXPERIENCED PEDIATRIC PATIENTS BASED ON MODELING AND SIMULATION DATA AND CLINICAL DATA OBTAINED IN PATIENTS RECEIVING THE PROPOSED DOSES OR HIGHER; REVISE ADVERSE REACTIONS, “CLINICAL TRIAL EXPERIENCE IN PEDIATRIC PATIENTS” SECTION WITH SAFETY DATA UP TO 96 WEEKS; REVISE CLINICAL PHARMACOLOGY, 12.3 PHARMACOKINETICS, ”PEDIATRICS” SUBSECTION TO INCLUDE PREDICTED PK PARAMETERS IN PEDIATRIC PATIENTS BASED ON THE REVISED DOSES; REVISE CLINICAL STUDIES, 14.3 “PEDIATRIC PATIENTS” SUBSECTION WITH EFFICACY DATA UP TO 96 WEEKS
NDA 022065	6	PEDIATRIC		BRISTOL MYERS SQUIBB CO	P	1/18/2011	10/18/2011	9.0	PROVIDES FOR FULFILLMENT OF THE PEDIATRIC WRITTEN REQUEST REQUIREMENT AND SUBSEQUENTLY REVISED LABELING TO THE PEDIATRIC USE SECTION OF THE PACKAGE INSERT
NDA 020489	25	NEW DOSING REGIMEN	TESTOSTERONE	WATSON LABORATORIES INC	S	12/22/2010	10/20/2011	9.9	PROVIDES FOR THE USE OF NEW DOSAGE STRENGTHS 2 MG AND 4 MG
NDA 050606	28	COMPARATIVE EFFICACY CLAIM	VANCOMYCIN HYDROCHLORIDE FOR INJECTION	VIROPHARMA INC	S	4/23/2010	12/14/2011	19.7	PROVIDES FOR UPDATES TO THE PRESCRIBING INFORMATION J81WITH CLINICALLY RELEVANT NEW SAFETY AND EFFICACY INFORMATION. IN ADDITION, THIS SUPPLEMENT PROVIDES FOR THE CONVERSION OF THE CURRENT LABEL INTO PHYSICIAN’S LABELING RULE (PLR) FORMAT.
NDA 021957	4	NEW PATIENT POPULATION	ESOMEPRAZOLE MAGNESIUM 20/40MG	ASTRAZENECA LP	P	12/18/2008	12/15/2011	35.9	PROVIDES FOR THE SHORT-TERM TREATMENT (UP TO 6 WEEKS) OF EROSIVE ESOPHAGITIS DUE TO ACID-MEDIATED GERD IN INFANTS 1 MONTH TO LESS THAN 1 YEAR
NDA 020864	18	NEW PATIENT POPULATION	RIZATRIPTAN BENZOATE	MERCK AND CO INC	P	3/25/2011	12/16/2011	8.7	INDICATED TO TO EXTEND THE ACUTE TREATMENT OF MIGRAINE INDICATION TO PEDIATRIC PATIENTS FROM 6 THROUGH 17 YEARS OF AGE
NDA 020865	20	PEDIATRIC	RIZATRIPTAN BENZOATE	MERCK AND CO INC	P	3/25/2011	12/16/2011	8.7	INDICATED TO TO EXTEND THE ACUTE TREATMENT OF MIGRAINE INDICATION TO PEDIATRIC PATIENTS FROM 6 THROUGH 17 YEARS OF AGE
NDA 021035	73	NEW PATIENT POPULATION	LEVETIRACETAM	UCB INC	P	3/19/2008	12/16/2011	44.9	INDICATED FOR USE AS ADJUNCTIVE THERAPY IN THE TREATMENT OF PARTIAL ONSET SEIZURES IN CHILDREN 1 MONTH TO LESS THAN 4 YEARS.
NDA 021505	19	NEW PATIENT POPULATION	LEVETIRACETAM 100MG/ML	UCB INC	P	3/19/2008	12/16/2011	44.9	INDICATED FOR USE AS ADJUNCTIVE THERAPY IN THE TREATMENT OF PARTIAL ONSET SEIZURES IN CHILDREN 1 MONTH TO LESS THAN 4 YEARS.

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NDA 022145	22	PEDIATRIC	RALTEGRAVIR POTASSIUM	MERCK SHARP AND DOHME CORP	P	7/1/2011	12/21/2011	5.7	PROVIDES FOR THE TREATMENT OF HIV-1 INFECTION IN PEDIATRIC PATIENTS 6 TO 18 YEARS OF AGE (IN COMBINATION WITH OTHER ANTIRETROVIRAL AGENTS)

NDA Efficacy Supplements Approved (SE8)

Application Number	Supplement Number	Supplement Type / Submission Class Code	Established Name	Applicant	Priority Review	Receipt Date	Approval Date	Total Approval Time (Months)
NDA 020363	37	LABELING CHANGE WITH CLINICAL DATA	FAMCICLOVIR	NOVARTIS PHARMACEUTICALS CORP	S	3/31/2010	1/31/2011	10.1
NDA 020896	26	LABELING CHANGE WITH CLINICAL DATA	CAPECITABINE	HOFFMANN LA ROCHE INC	S	8/6/2008	2/5/2011	30.0
NDA 022350	1	LABELING CHANGE WITH CLINICAL DATA	SAXAGLIPTIN	BRISTOL MYERS SQUIBB CO	S	4/19/2010	2/18/2011	10.0
NDA 022350	2	LABELING CHANGE WITH CLINICAL DATA	SAXAGLIPTIN	BRISTOL MYERS SQUIBB CO	S	4/19/2010	2/18/2011	10.0
NDA 021588	30	LABELING CHANGE WITH CLINICAL DATA	IMATINIB MESYLATE	NOVARTIS PHARMACEUTICALS CORP	S	6/2/2010	4/1/2011	10.0
NDA 020541	26	LABELING CHANGE WITH CLINICAL DATA	ANASTROZOLE	ASTRAZENECA UK LTD	S	5/25/2010	4/18/2011	10.8
NDA 021481	20	LABELING CHANGE WITH CLINICAL DATA	ENFUVIRTIDE LYPHOLIZED POWDER 90 MG	HOFFMANN LA ROCHE INC	S	5/20/2010	4/28/2011	11.3
NDA 020239	23	LABELING CHANGE WITH CLINICAL DATA	GRANISETRON HYDROCHLORIDE	HOFFMANN LA ROCHE INC	S	3/31/2010	4/29/2011	13.0
NDA 020667	25	LABELING CHANGE WITH CLINICAL DATA	PRAMIPEXOLE TABLETS	BOEHRINGER INGELHEIM	S	7/13/2010	5/13/2011	10.0
NDA 020725	8	LABELING CHANGE WITH CLINICAL DATA		ABBOTT PRODUCTS INC	S	9/15/2010	7/12/2011	9.9
NDA 022000	5	LABELING CHANGE WITH CLINICAL DATA	MESALAMINE 1 G TABLETS	SHIRE DEVELOPMENT INC	S	6/14/2010	7/14/2011	13.0
NDA 022527	2	LABELING CHANGE WITH CLINICAL DATA	FINGOLIMOD HAVL ORAL CAPSULES	NOVARTIS PHARMACEUTICALS CORP	S	12/10/2010	7/20/2011	7.3
NDA 021928	19	LABELING CHANGE WITH CLINICAL DATA	VARENICLINE	PFIZER INC	S	9/23/2010	7/22/2011	9.9
NDA 021928	20	LABELING CHANGE WITH CLINICAL DATA	VARENICLINE	PFIZER INC	S	9/23/2010	7/22/2011	9.9
NDA 021928	21	LABELING CHANGE WITH CLINICAL DATA	VARENICLINE	PFIZER INC	S	9/23/2010	7/22/2011	9.9
NDA 020246	35	LABELING CHANGE WITH CLINICAL DATA	MEDROXYPROGESTERONE ACETATE	PHARMACIA AND UPJOHN CO	S	3/23/2009	7/28/2011	28.2
NDA 020664	12	LABELING CHANGE WITH CLINICAL DATA	CABERGOLINE	PHARMACIA AND UPJOHN CO	S	10/13/2010	8/11/2011	9.9
NDA 021356	37	LABELING CHANGE WITH CLINICAL DATA	TENOFOVIR DISOPROXIL FUMARATE	GILEAD SCIENCES INC	S	12/10/2010	9/19/2011	9.3
NDA 020263	37	LABELING CHANGE WITH CLINICAL DATA	LEUPROLIDE ACETATE	ABBOTT ENDOCRINE INC	S	12/9/2010	10/8/2011	10.0
NDA 021773	29	LABELING CHANGE WITH CLINICAL DATA	EXENATIDE INJECTION, 250UG/ML	AMYLIN PHARMACEUTICALS INC	S	12/22/2010	10/19/2011	9.9
NDA 021773	30	LABELING CHANGE WITH CLINICAL DATA	EXENATIDE INJECTION, 250UG/ML	AMYLIN PHARMACEUTICALS INC	S	12/22/2010	10/19/2011	9.9
NDA 021976	18	LABELING CHANGE WITH CLINICAL DATA	DARUNAVIR	TIBOTEC INC	S	12/22/2010	10/19/2011	9.9
NDA 021064	11	LABELING CHANGE WITH CLINICAL DATA	PERFLUTREN	LANTHEUS MEDICAL IMAGING INC	S	9/29/2010	10/24/2011	12.8
NDA 021602	30	LABELING CHANGE WITH CLINICAL DATA	BORTEZOMIB	MILLENNIUM PHARMACEUTICALS INC	S	7/11/2011	11/1/2011	3.7
NDA 021462	29	LABELING CHANGE WITH CLINICAL DATA	PEMETREXED DISODIUM	ELI LILLY AND CO	S	7/16/2010	11/18/2011	16.1

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NDA 022068	8	LABELING CHANGE WITH CLINICAL DATA	NILOTINIB	NOVARTIS PHARMACEUTICALS CORP	S	1/21/2011	11/18/2011	9.9
NDA 021976	20	LABELING CHANGE WITH CLINICAL DATA	DARUNAVIR	TIBOTEC INC	P	6/28/2011	12/16/2011	5.6
NDA 022350	4	LABELING CHANGE WITH CLINICAL DATA	SAXAGLIPTIN	BRISTOL MYERS SQUIBB CO	S	2/17/2011	12/16/2011	9.9
NDA 021880	23	LABELING CHANGE WITH CLINICAL DATA	LENALIDOMIDE	CELGENE CORP	S	7/1/2010	12/21/2011	17.7

BLA Efficacy Supplements Approved

BLA NUMBER	SUPPLEMENT NUMBER	SUPPLEMENT TYPE	PROPER NAME	APPLICANT	PRIORITY REVIEW	RECEIPT DATE	APPROVAL DATE	TOTAL APPROVAL TIME (MONTHS)	INDICATION
L 125276	10	EFFICACY	TOCILIZUMAB	GENENTECH, INC.	S	3/16/2010	1/4/2011	9.7	ADDITION OF INDUCING MAJOR CLINICAL RESPONSE FOR RHEUMATOID ARTHRITIS TO CLINICAL STUDIES SECTION OF PI, ALONG W/ADDL CHANGES TO ADVERSE REACTIONS & CLINICAL PHARMACOLOGY SECTIONS (UNBUNDLED FROM 125276/7)
L 125276	11	EFFICACY	TOCILIZUMAB	GENENTECH, INC.	S	3/16/2010	1/4/2011	9.7	ADDITION OF IMPROVING PHYSICAL FUNCTION FOR RHEUMATOID ARTHRITIS TO CLINICAL STUDIES SECTION OF PI, ALONG W/ADDL CHANGES TO ADVERSE REACTIONS & CLINICAL PHARMACOLOGY SECTIONS (UNBUNDLED FROM 125276/7)
L 125276	7	EFFICACY	TOCILIZUMAB	GENENTECH, INC.	S	3/16/2010	1/4/2011	9.7	ADDITION OF INHIBITING THE PROGRESSION OF STRUCTURAL DAMAGE FOR RHEUMATOID ARTHRITIS TO CLINICAL STUDIES SECTION OF PI, W/ADDL CHANGES TO ADVERSE REACTIONS & CLINICAL PHARMACOLOGY SECTIONS (INITIAL SUBM UNBUNDLED TO INCL SUPPL 10 & 11); REMS ASSESSMENT WD
L 103705	5332	EFFICACY	RITUXIMAB	GENENTECH, INC.	S	3/31/2010	1/28/2011	10.0	NEW INDICATION FOR USE AS SINGLE-AGENT MAINTENANCE THERAPY IN PATIENTS WITH PREVIOUSLY UNTREATED FOLLICULAR, CD20-POSITIVE, B-CELL NON-HODGKIN'S LYMPHOMA (NHL) WHO ACHIEVE A RESPONSE TO RITUXAN IN COMBINATION WITH CHEMOTHERAPY
L 125057	215	EFFICACY	ADALIMUMAB	ABBOTT LABORATORIES	S	4/30/2010	2/25/2011	9.9	UPDATES TO ADVERSE REACTIONS AND CLINICAL STUDIES SECTIONS OF LABELING, IN RESPONSE TO 1/18/08 APPROVAL LETTER, SPECIFICALLY FOR PMC #3 & PMC #4
L 103949	5153	EFFICACY	PEGINTERFERON ALFA-2B	SCHERING CORPORATION	P	9/27/2007	3/29/2011	42.0	NEW INDICATION OF ADJUVANT TREATMENT OF MELANOMA WITH MICROSCOPIC OR GROSS NODAL INVOLVEMENT WITHIN 84 DAYS OF DEFINITIVE SURGICAL RESECTION INCLUDING COMPLETE LYMPHADENECTOMY

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L 125276	22	EFFICACY	TOCILIZUMAB	GENENTECH, INC.	P	10/15/2010	4/15/2011	6.0	TREATMENT OF ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS IN PATIENTS 2 YEARS OF AGE AND OLDER AND A PROPOSED MODIFICATION TO THE APPROVED REMS
L 103705	5344	EFFICACY	RITUXIMAB	GENENTECH, INC.	P	10/18/2010	4/19/2011	6.0	RITUXAN IN COMBINATION WITH GLUCOCORTICOIDS FOR THE TREATMENT OF.PATIENTS WITH WEGENER'S GRANULOMATOSIS (WG) AND MICROSCOPIC POLYANGIITIS (MPA)
L 125117	86	EFFICACY	GALSULFASE	BIOMARIN PHARMACEUTICAL INC.	S	6/28/2010	4/28/2011	10.0	PHYSICIAN LABELING RULE COMPLIANCE AND SAFETY AND EFFICACY DATA FROM CLINICAL TRIALS
L 125117	88	EFFICACY	GALSULFASE	BIOMARIN PHARMACEUTICAL INC.	S	7/16/2010	4/28/2011	9.4	PHYSICIAN LABELING RULE COMPLIANCE AND SAFETY AND EFFICACY DATA FROM CLINICAL TRIALS
L 125117	90	EFFICACY	GALSULFASE	BIOMARIN PHARMACEUTICAL INC.	S	8/4/2010	4/28/2011	8.8	PHYSICIAN LABELING RULE COMPLIANCE AND SAFETY AND EFFICACY DATA FROM CLINICAL TRIALS
L 103964	5184	EFFICACY	PEGINTERFERON ALFA-2A	HOFFMANN-LA ROCHE INC.	S	12/14/2009	5/27/2011	17.4	PROPOSES MINOR REVISIONS TO THE LANGUAGE PROVIDED IN THE WARNINGS AND PRECAUTIONS AND THE CONTRAINDICATIONS SECTIONS OF THE PACKAGE INSERT TO INCLUDE INFORMATION OBTAINED FROM THE HIV/HCV CO-INFECTION STUDY REGARDING TREATMENT OF PATIENTS WITH HEPATIC DEC
L 103234	5166	EFFICACY	EPOETIN ALFA	AMGEN, INC.	S	12/26/2007	6/24/2011	42.0	PROPOSES TO AMEND BLA TO INCLUDE REPORTS, DATASETS, AND RESULTS OF ANALYSES FOR MULTIPLE STUDIES/CLINICAL TRIALS SUBMITTED TO ADDRESS ITEMS 3, 4, AND 5 OF OUR MAY 31, 2007, SUPPLEMENT REQUEST LETTER REGARDING ADVICE PROVIDED DURING THE MAY 10, 2007, ONCOL
L 103951	5173	EFFICACY	DARBEPOETIN ALFA	AMGEN, INC.	S	12/26/2007	6/24/2011	42.0	PROPOSES TO AMEND BLA TO INCLUDE REPORTS, DATASETS, AND RESULTS OF ANALYSES FOR MULTIPLE STUDIES/CLINICAL TRIALS SUBMITTED TO ADDRESS ITEMS 3, 4, AND 5 OF OUR MAY 31, 2007, SUPPLEMENT REQUEST LETTER REGARDING ADVICE PROVIDED DURING THE MAY 10, 2007, ONCOL
L 125360	7	EFFICACY	INCOBOTULINUMTOXINA	MERZ PHARMACEUTICALS GMBH	S	9/21/2010	7/20/2011	9.9	THIS "PRIOR APPROVAL" EFFICACY SUPPLEMENT TO YOUR BIOLOGICS LICENSE APPLICATION PROVIDES FOR THE USE OF XEOMIN (INCOBOTULINUMTOXINA) FOR THE TEMPORARY IMPROVEMENT IN THE APPEARANCE OF MODERATE TO SEVERE GLABELLAR LINES ASSOCIATED WITH CORRUGATOR AND/OR PR
L 125118	122	EFFICACY	ABATACEPT	BRISTOL-MYERS SQUIBB COMPANY	S	10/4/2010	7/29/2011	9.8	PROPOSES THE SUBCUTANEOUS USE OF ABATACEPT FOR RHEUMATOID ARTHRITIS.
L 103964	5186	EFFICACY	PEGINTERFERON ALFA-2A	HOFFMANN-LA ROCHE INC.	S	12/18/2009	8/9/2011	19.7	EXPAND THE PATIENT POPULATION FOR COMBO THERAPY TO INCLUDE RENALLY IMPAIRED PATIENTS WHO ARE RECEIVING CHRONIC HEMODIALYSIS

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L 125388	6	EFFICACY	BRENTUXIMAB VEDOTIN	SEATTLE GENETICS, INC.	P	2/28/2011	8/19/2011	5.7	TREATMENT OF PATIENTS WITH SYSTEMIC ANAPLASTIC LARGE CELL LYMPHOMA (SALCL) AFTER FAILURE OF AT LEAST ONE PRIOR MULTI-AGENT CHEMOTHERAPY REGIMEN
L 103964	5213	EFFICACY	PEGINTERFERON ALFA-2A	HOFFMANN-LA ROCHE INC.	P	2/22/2011	8/22/2011	6.0	TO EXPAND THE INDICATION FOR PEGASYS AND COPEGUS COMBINATION THERAPY TO INCLUDE THE TREATMENT OF CHRONIC HEPATITIS C IN PATIENTS 5 TO 17 YEARS OF AGE AND TO UPDATE THE MEDICATION GUIDES WITH PEDIATRIC INFORMATION.
L 103000	5232	EFFICACY	ONABOTULINUMTOXINA	ALLERGAN, INC.	S	10/27/2010	8/24/2011	9.9	PROVIDES FOR A NEW INDICATION FOR THE TREATMENT OF ADULTS WITH URINARY INCONTINENCE DUE TO DETRUSOR OVERACTIVITY ASSOCIATED WITH A NEUROLOGIC CONDITION (E.G., SPINAL CORD INJURY, MULTIPLE SCLEROSIS) WHO HAVE AN INADEQUATE RESPONSE TO OR ARE INTOLERANT OF
L 103772	5301	EFFICACY	INFLIXIMAB	JANSSEN BIOTECH, INC.	P	12/23/2010	9/23/2011	9.0	PROPOSES TO ADD PEDIATRIC ULCERATIVE COLITIS TO THE CURRENT INDICATION.
L 125166	172	EFFICACY	ECULIZUMAB	ALEXION PHARMACEUTICALS, INC.	P	3/25/2011	9/23/2011	6.0	FOR THE TREATMENT OF ATYPICAL HEMOLYTIC UREMIC SYNDROME (AHUS) AS A SECOND INDICATION FOR SOLIRIS (ECULIZUMAB)
L 103964	5204	EFFICACY	PEGINTERFERON ALFA-2A	HOFFMANN-LA ROCHE INC.	S	11/30/2010	9/29/2011	10.0	PROVIDES FOR THE USE OF A 135 MCG/0.5ML AND 180 MCG/0.5 ML PEGASYS DISPOSABLE AUTOINJECTOR (DAI), REVISIONS TO THE PACKAGE INSERT, AND A PROPOSED MODIFICATION TO THE APPROVED RISK EVALUATION AND MITIGATION STRATEGY (REMS)
L 125084	153	EFFICACY	CETUXIMAB	IMCLONE LLC A WHOLLY-OWNED SUBSIDARY OF ELI LILLY AND COMPANY	P	8/29/2008	11/7/2011	38.3	NEW INDICATION FOR THE FIRST-LINE TREATMENT OF PATIENTS WITH RECURRENT LOCOREGIONAL DISEASE OR METASTATIC SQUAMOUS CELL CARCINOMA OF THE HEAD AND NECK IN COMBINATION WITH PLATINUM-BASED THERAPY WITH 5-FU.
L 125103	120	EFFICACY	PALIFERMIN	SWEDISH ORPHAN BIOVITRUM AB (PUBL)	S	1/14/2011	11/14/2011	10.0	NEW LIMITATIONS OF USE FOR PATIENTS UNDERGOING AUTOLOGOUS TRANSPLANTATION FOLLOWING A "CHEMOTHERAPY-ONLU" PREPARATIVE REGIMEN (1.2), THE ADDTIONS OF NEW INFORMATION TO THE CLINICAL STUDIES
L 125019	194	EFFICACY	IBRITUMOMAB TIUXETAN	SPECTRUM PHARMACEUTICALS, INC.	S	1/20/2011	11/18/2011	9.9	PROPOSES TO REMOVE FROM THE LABELING, THE REFERENCES TO THE INDIUM-111 (IN-11) ZEVALIN PRE-TREATMENT IMAGING EVALUATION FOR ASSESSMENT OF BIODISTRIBUTION