CDER New Molecular Entity (NME)/ New BLA Calendar Year Approvals

As of December 31, 2009

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Selection Criteria:
User Response: Start Date: 1/1/2009 12:00:00 AM End Date: 12/31/2009

Sort Order: Approval Date

APPLICATION NUMBER	PROPRIETARY NAME	ESTABLISHED NAME	APPLICANT	REVIEW CLASSIFICATION	APPROVAL DATE	INDICATION
NDA 022256	SAVELLA TABLETS	MILNACIPRAN HCL TABLETS	CYPRESS BIOSCIENCE INC	S	1/14/2009	TREATMENT OF FIBROMYALGIA SYNDROME
NDA 021856	ULORIC (FEBUXOSTAT) TABLETS	FEBUXOSTAT	TAKEDA PHARMACEUTICALS NORTH AMERICA INC	S	2/13/2009	MANAGEMENT OF HYPERURICEMIA IN PATIENTS WITH GOUT
NDA 022334	AFFINITOR	EVEROLIMUS	NOVARTIS PHARMACEUTICALS CORP	P	3/30/2009	TREATMENT OF ADVANCED RENAL CELL CARCINOMA
NDA 022268	COARTEM	ARTEMETHER 20MG LUMEFANTRINE 120MG	NOVARTIS PHARMACEUTICALS CORP	P,O	4/7/2009	TREATMENT OF INFECTIONS DUE TO PLASMODIUM FALCIPARUM OR MIXED INFECTIONS INCLUDING P.FALCIPARUM
NDA 022129	ULESFIA	BENZYL ALCOHOL	SCIELE PHARMA INC	S	4/9/2009	INDICATED FOR PTS INFECTED WITH PEDICULUS HUMANUS CAPITAS (HEAD LICE) OF THE SCALP HAIR
NDA 022192	FANAPT	ILOPERIDONE	VANDA PHARMACEUTICALS INC	S	5/6/2009	SCHIZOPHRENIA
NDA 022275	SAMSCA	TOLVAPTAN (15MG / 30MG / 60MG) TABLETS	OTSUKA AMERICA PHARMACEUTICAL INC	S	5/19/2009	TREATMENT OF CLINICALLY SIGNIFICANT HYPERVOLEMIC AND EUVOLEMIC HYPONATREMIA
NDA 022308	BESIFLOXACIN HCL	BESIFLOXACIN	BAUSCH AND LOMB INC	S	5/28/2009	BACTERIAL CONJUNCTIVITIS
NDA 022425	MULTAQ	DRONEDARONE HCL	SANOFI AVENTIS US LLC	P	7/1/2009	REDUCTION IN HOSPITALIZATION OR DEATH IN PATIENTS WITH A HISTORY OF OR CURRENT ATRIAL FIBRILLATION OR ATRIAL FLUTTER
NDA 022307	EFFIENT	PRASUGREL	ELI LILLY AND CO	P	7/10/2009	ACUTE CORONARY SYNDROME
NDA 022350	ONGLYZA	SAXAGLIPTIN	BRISTOL MYERS SQUIBB CO	S	7/31/2009	TYPE 2 DIABETES MELLITUS
NDA 022363	LIVALO TABLETS	PITAVASTATIN	KOWA RESEARCH INSTITUTE INC	S	8/3/2009	FOR CHOLESTEROL TREATMENT
NDA 022117	SAPHRIS	ASENAPINE	ORGANON USA INC	S	8/13/2009	TREATMENT OF SCHIZOPHRENIA TREATMENT OF ACUTE MANIC OR MIXED EPISODES ASSOCIATED WITH BIPOLAR
NDA 020427	SABRIL (VIGABATRIN) TABLET 500MG	VIGABATRIN	LUNDBECK INC	S,O	8/21/2009	INDICATED AS ADD ON THERAPY FOR THE TREATMENT OF COMPLEX PARTIAL SEIZURES WITHOR WITHOUT SECONDARY GENERALIZATION IN ADULTS
NDA 022288	BEPOTASTINE BESILATE OPHTHALMIC SOLUTION	BEPOTASTINE BESILATE OPTHALMIC SOLUTION	ISTA PHARMACEUTICALS	S	9/8/2009	TREATMENT OF OCULAR ITCHING ASSOCIATED WITH ALLERGIC CONJUNCTIVITIS
NDA 022110	TELAVANCIN	TELAVANCIN	THERAVANCE INC	S	9/11/2009	COMPLICATED SKIN AND SKIN-STRUCTURE INFECTIONS

NDA 022468	FOLOTYN	PRALATREXATE INJECTION 20MG/1ML40MG/2ML	ALLOS THERAPEUTICS INC	P,O	9/24/2009	RELAPSED OR REFRACTORY PERIPERAL T-CELL LYMPHOMA
NDA 022465	VOTRIENT TABLETS	PAZOPANIB TABLET	GLAXOSMITHKLINE	S	10/19/2009	TREATMENT OF PATIENTS WITH ADVANCED RENAL CELL CARCINOMA
NDA 022393	ROMIDEPSIN FOR INFUSION	ROMIDEPSIN FOR INFUSION	GLOUCESTER PHARMACEUTICALS INC	S,O	11/5/2009	TREATMENT OF CUTANEOUS T-CELL LYMPHOMA (CTCL) IN PATIENTS WHO HAVE RECEIVED AT LEAST ONE PRIOR SYSTEMIC THERAPY.

New Biologic License Application (BLA) Approvals:

BLA NUMBER	PROPRIETARY NAME	PROPER NAME	APPLICANT	REVIEW CLASSIFICATION	APPROVAL DATE	INDICATION
L 125289/0.0	GOLIMUMAB	SIMPONI	CENTOCOR ORTHO BIOTECH, INC.	S	4/24/2009	NEW BLA FOR RHEUMATOID ARTHRITIS, PSORIATIC ARTHRITIS AND ANKYLOSING SPONDYLITIS.
L 125274/0.0	ABOBOTULINUMTOXINA	DYSPORT	IPSEN BIOPHARM LIMITED	S,O	4/29/2009	TREATMENT OF CERVICAL DYSTONIA (SPASMODIC TORTICOLLIS)
L 125319/0.0	CANAKINUMAB	ILARIS	NOVARTIS PHARMACEUTICALS CORPORATION	P,O	6/17/2009	TREATMENT OF CRYOPYRIN ASSOCIATED PERIODIC SYNDROME (CAPS) IN PEDIATRICS AND ADULTS
L 125261/0.0	USTEKINUMAB	STELARA	CENTOCOR ORTHO BIOTECH, INC.	S	9/25/2009	TREATMENT OF PSORIASIS
L 125326/0.0	OFATUMUMAB	ARZERRA	GLAXO GROUP LIMITED D/B/A GLAXOSMITHKLINE	P,O	10/26/2009	TREATMENT OF PATIENTS WITH CHRONIC LYMPHOCYTIC LEUKEMIA (CLL) REFRACTORY TO FLUDARABINE AND ALEMTUZUMAB
L 125277/0.0	ECALLANTIDE	KALBITOR	DYAX CORP.	P,O	12/1/2009	TREATMENT OF HEREDITARY ANGIOEDEMA

Review Classification:

P - Priority Review - Significant improvement compared to marketed products, in the treatment, diagnosis, or prevention of a disease.

S - Standard Review - Products that do not qualify for priority review.

O - Orphan Designation - Pursuant to Section 526 of the Orphan Drug Act (Public Law 97-414 as amended).