



## CDER New Molecular Entity (NME) & New BLA Calendar Year Approvals

As of December 31, 2010

Last Refresh Date: 7/13/2011

**Selection Criteria:**

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

**Sort Order: Approval Date**

APPLICATION NUMBER	PROPRIETARY NAME	ESTABLISHED NAME	APPLICANT	REVIEW CLASSIFICATION	APPROVAL DATE	INDICATION
NDA 022250	AMPYRA	DALFAMPRIDINE	ACORDA THERAPEUTICS INC	P,O	1/22/2010	INDICATED TO IMPROVE WALKING ABILITY IN PATIENTS WITH MULTIPLE SCLEROSIS (MS). THIS WAS DEMONSTRATED BY AN INCREASE IN WALKING SPEED.
NDA 022341	VICTOZA	LIRAGLUTIDE	NOVO NORDISK INC	S	1/25/2010	INDICATED AS AN ADJUNCT TO DIET AND EXERCISE TO IMPROVE GLYCEMIC CONTROL IN ADULTS WITH TYPE 2 DIABETES MELLITUS
NDA 022575	VPRIV	VELAGLUCERASE ALFA	SHIRE HUMAN GENETIC THERAPIES INC	P,O	2/26/2010	INDICATED FOR LONG-TERM ENZYME REPLACEMENT THERAPY (ERT) FOR PEDIATRIC AND ADULT PATIENTS WITH TYPE 1 GAUCHER DISEASE.
NDA 022562	CARBAGLU	CARGLUMIC ACID	ORPHAN EUROPE	P,O	3/18/2010	INDICATED FOR USE IN PEDIATRIC AND ADULT PATIENTS AS AN ADJUNCTIVE THERAPY FOR THE TREATMENT OF ACUTE HYPERAMMONEMIA DUE TO NAGS DEFICIENCY, AND AS MAINTENANCE THERAPY FOR CHRONIC HYPERAMMONEMIA DUE TO NAGS DEFICIENCY
NDA 021201	ASCLERA	POLIDOCANOL	CHEMISCHE FABRIK KREUSSLER AND CO GMBH	S	3/30/2010	INDICATED TO TREAT UNCOMPLICATED SPIDER VEINS (VARICOSE VEINS <= 1MM IN DIAMETER) AND UNCOMPLICATED RETICULAR VEINS (VARICOX VEINS 1 TO 3 MM IN DIAMETER) IN THE LOWER EXTREMITY.
NDA 022252	NATAZIA	ESTRADIAL VALERATE/DIENOGEST TABS	BAYER HEALTHCARE PHARMACEUTICALS INC	S	5/6/2010	INDICATED FOR PREVENTION OF PREGNANCY
NDA 201023	JEVTANA	CABAZITAXEL	SANOVI AVENTIS US INC	P	6/17/2010	INDICATED FOR THE TREATMENT OF PATIENTS WITH HORMONE REFRACTORY METASTATIC PROSTATE CANCER PREVIOUSLY TREATED WITH A DOCETAXEL-CONTAINING TREATMENT REGIMEN.
NDA 022134	LASTACAFT	VILASTA OPHTHALMIC SOLUTION	VISTAKON PHARMACEUTICALS LLC	S	7/28/2010	INDICATED FOR THE PREVENTION OF ITCHING ASSOCIATED WITH ALLERGIC CONJUNCTIVITIS.
NDA 022474	ELLA	ULIPRISTAL ACETATE	LABORATOIRE HRA PHARMA	S	8/13/2010	INDICATED FOR THE PREVENTION OF PREGNANCY FOLLOWING UNPROTECTED INTERCOURSE OR A KNOWN OR SUSPECTED CONTRACEPTIVE FAILURE. ELLA IS NOT INTENDED FOR ROUTINE USE AS A CONTRACEPTIVE.
NDA 022527	FINGOLIMOD HCL ORAL CAPSULES	FINGOLIMOD HCL ORAL CAPSULES	NOVARTIS PHARMACEUTICALS CORP	P	9/21/2010	INDICATED FOR THE TREATMENT OF PATIENTS WITH RELAPSING FORMS OF MULTIPLE SCLEROSIS TO REDUCE THE FREQUENCY OF RELAPSES AND TO DELAY THE ACCUMULATION OF PHYSICAL DISABILITY.
NDA 022512	PRADAXA	DABIGATRAN ETEXILATE MESYLATE	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	P	10/19/2010	INDICATED TO REDUCE THE RISK OF STROKE AND SYSTEMIC EMBOLISM IN PATIENTS WITH NON-VALVULAR ATRIAL FIBRILLATION
NDA 200603	LURASIDONE HCL	LURASIDONE HCL	SUNOVION PHARMACEUTICALS INC	S	10/28/2010	INDICATED FOR THE TREATMENT OF SCHIZOPHRENIA IN ADULTS
NDA 200327	CEFTAROLINE FOSAMIL FOR INJECTION	CEFTAROLINE FOSAMIL FOR INJECTION	CEREXA INC	S	10/29/2010	INDICATED FOR THE TREATMENT OF ACUTE BACTERIAL SKIN AND SKIN STURCTURE INFECTIONS AND COMMUNITY ACQUIRED PNEUMONIA
NDA 022505	EGRIFTA	TESAMORELIN	THERATECHNOLOGIES INC	S	11/10/2010	INDICATED FOR THE REDUCTION OF EXCESS ABDOMINAL FAT IN HIV-INFECTED PATIENTS WITH LIPODYSTROPHY
NDA 201532	ERIBULIN MESYLATE	ERIBULIN MESYLATE	EISAI INC	P	11/15/2010	INDICATED FOR FOR THE TREATMENT OF PATIENTS WITH METASTATIC BREAST CANCER WHO HAVE PREVIOUSLY RECEIVED AT LEAST TWO CHEMOTHERAPEUTIC REGIMENS FOR THE TREATMENT OF METASTATIC DISEASE.

**New Biologic License Application (BLA) Approvals:**

BLA NUMBER	PROPRIETARY NAME	PROPER NAME	APPLICANT	REVIEW CLASSIFICATION	APPROVAL DATE	INDICATION
L 125276/0.0	ACTEMRA	TOCILIZUMAB	GENENTECH, INC.	S	1/8/2010	PROVIDES TREATMENT FOR REDUCING SIGNS AND SYMPTOMS IN ADULT PATIENTS WITH MODERATELY TO SEVERELY ACTIVE RA
L 125338/0.0	XIAFLEX	CLOSTRIDIAL COLLAGENASE	AUXILIUM PHARMACEUTICALS, INC.	P,O	2/2/2010	PROVIDES TREATMENT OF ADVANCED DUPUYTREN'S DISEASE
L 125291/0.0	LUMIZYME	ALGLUCOSIDASE ALFA2	GENZYME CORPORATION	P,O	5/24/2010	PROVIDES TREATMENT OF NON-INFANTILE-ONSET PATIENTS WITH POMPE DISEASE
L 125320/0.0	PROLIA	DENOSUMAB TO	AMGEN, INC.	S	6/1/2010	PROVIDES TREATMENT FOR PREVENTION OF OSTEOPOROSIS IN POSTMENOPAUSAL WOMEN
L 125360/0.0	XEOMIN	INCOBOTULINUMTOXINA	MERZ PHARMACEUTICALS GMBH	S	7/30/2010	PROVIDES TREATMENT OF CERVICAL DYSTONIA
L 125293/0.0	KRYSTEXXA	PEGLOTICASE	SAVIENT PHARMACEUTICALS, INC.	P,O	9/14/2010	PROVIDES FOR THE TREATMENT OF INTRAVENOUS INFUSION INTENDED FOR PATIENTS WITH TREATMENT FAILURE GOUT TO CONTROL HYPERURICEMIA AND MANAGE THE SIGNS AND SYMPTOMS OF GOUT

**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).