



**CDER Drug and Biologic 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
NDA 022488	LYRICA	PREGABALIN	PFIZER INC	S	1/4/2010
NDA 022460 <sup>1</sup>	DUTASTERIDE/ TAMSULOSIN HYDROCHLORIDE	DUTASTERIDE AND TAMSULOSIN HYDROCHLORIDE	SMITHKLINE BEECHAM CORP DBA GLAXOSMITHKLINE	S	1/20/2010
NDA 022250	AMPYRA	DALFAMPRIDINE	ACORDA THERAPEUTICS INC	P.O	1/22/2010
NDA 022341	VICTOZA	LIRAGLUTIDE	NOVO NORDISK INC	S	1/25/2010
NDA 022509	LAMICTAL XR	LAMOTRIGINE	SMITHKLINE BEECHAM CORP DBA GLAXOSMITHKLINE	S	1/29/2010
NDA 022411	OLEPTRO	TRAZODONE HYDROCHLORIDE	LABOPHARM INC	S	2/2/2010
NDA 022417	NORVIR	RITONAVIR	ABBOTT LABORATORIES	S	2/10/2010
NDA 022420 <sup>2</sup>	EFAVIRENZ	EFAVIRENZ	STRIDES ARCOLAB LTD	S	2/12/2010
NDA 022421	MIRAPEX	PRAMIPEXOLE DIHYDROCHLORIDE	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	S	2/19/2010
NDA 050814	CAYSTON	AZTREONAM	GILEAD SCIENCES INC	S.O	2/22/2010
NDA 022534 <sup>1</sup>	DOCEFREZ	DOCETAXEL	SUN PHARMA GLOBAL FZE	S	2/23/2010
NDA 022299 <sup>2</sup>	NEVIRAPINE	NEVIRAPINE	AUROBINDO PHARMA LTD	S	2/24/2010
NDA 022466	ARTICAINE/EPINEPHRINE	ARTICAINE/EPINEPHRINE	PIERREL S.P.A.	S	2/26/2010
NDA 022575	VPRIV	VELAGLUCERASE ALFA	SHIRE HUMAN GENETIC THERAPIES INC	P.O	2/26/2010
NDA 021217	EXALGO	HYDROMORPHONE HCL	MALLINCKRODT INC	S	3/1/2010
NDA 022437	TRELSTAR	TRIPTORELIN PAMOATE	WATSON LABORATORIES INC	S	3/10/2010
NDA 022502	DIFFERIN LOTION	ADAPALENE	GALDERMA RESEARCH AND DEVELOPMENT INC	S	3/17/2010
NDA 022536	INDOMETHACIN	INDOMETHACIN	APP PHARMACEUTICALS LLC	S	3/17/2010
NDA 022036	SILENOR	DOXEPIN HCL	SOMAXON PHARMACEUTICALS INC	S	3/17/2010
NDA 022562	CARBAGLU	CARGLUMIC ACID	ORPHAN EUROPE	P.O	3/18/2010
NDA 022514	MIRAPEX ER	PRAMIPEXOLE DIHYDROCHLORIDE	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	S	3/19/2010
NDA 022483	ZYCLARA	IMIQUIMOD	GRACEWAY PHARMACEUTICALS LLC	S	3/25/2010
NDA 021201	ASCLERA	POLIDOCANOL	CHEMISCHE FABRIK KREUSSLER & CO. GMBH	S	3/30/2010
NDA 022272	OXYCONTIN	OXYCONTIN	PURDUE PHARMA INC	P	4/5/2010
NDA 022523	PANCREAZE	PANCRELIPIASE MICROTABLETS	ORTHO MCNEIL JANSSEN PHARMACEUTICALS INC	S	4/12/2010
NDA 022404	ORAVIG (MICONAZOLE) BUCCAL TABLETS	MICONAZOLE 50 MG TABLET	BIOALLIANCE PHARMA	S	4/16/2010
NDA 022255	VIMPAT	LACOSAMIDE	SCHWARZ BIOSCIENCES INC	S	4/20/2010
NDA 021560	ZORTRESS	EVEROLIMUS	NOVARTIS PHARMACEUTICALS CORP	S	4/20/2010
NDA 022484	HYPHANOX 200MG FILM-COATED TABLETS	ITRACONAZOLE 200MG FILM-COATED TABLETS	STIEFFEL LABORATORIES INC	S	4/29/2010
NDA 022511	PN 400 NAPROXEN/ESOMEPRAZOLE MAGNESIUM	PN 400 NAPROXEN/ESOMEPRAZOLE MAGNESIUM	ASTRAZENECA LP	S	4/30/2010
NDA 050821	CEFFEPIME	CEFFEPIME	B BRAUN MEDICAL INC	S	5/6/2010
NDA 022252	NATAZIA	ESTRADIAL VALERATE/DIENOGEST TABS	BAYER HEALTHCARE PHARMACEUTICALS INC	S	5/6/2010
NDA 022370	TRAMADOL HYDROCHLORIDE	TRAMADOL HYDROCHLORIDE	CIPHER PHARMACEUTICALS INC	S	5/7/2010
NDA 022382	SPRIX NASAL SPRAY	KETOROLAC TROMETHAMINE NASAL SPRAY	ROXRO PHARMA INC	S	5/14/2010
NDA 022479 <sup>2</sup>	LAMIVUDINE/STAVUDINE FDC TABS	LAMIVUDINE/STAVUDINE FDC TABS	HETERO DRUGS LTD	S	5/17/2010
NDA 022548	GATIFLOXACIN OPHTHALMIC SOLUTION	GATIFLOXACIN OPHTHALMIC SOLUTION	ALLERGAN	S	5/18/2010
NDA 022565	ADVIL CONGESTION RELIEF	IBUPROFEN 200MG/PHENYLEPHRINE HCL 10MG	WYETH CONSUMER HEALTHCARE	S	5/27/2010
NDA 022555	HEXVIX	HEXYL ANIMOLEVULATE	PHOTOCURE ASA	P	5/28/2010
NDA 022460	DUTASTERIDE/ TAMSULOSIN HYDROCHLORIDE	DUTASTERIDE AND TAMSULOSIN HYDROCHLORIDE	GLAXOSMITHKLINE	S	6/14/2010
NDA 201023	JEVTANA	CABAZITAXEL	SANOVI AVENTIS US INC	P	6/17/2010
NDA 200179	VARDENAFIL HCL	VARDENAFIL HCL	BAYER HEALTHCARE PHARMACEUTICALS INC	S	6/17/2010
NDA 022525	NAMENDA XR(MEMANTINE HCL)ER CAPSULES	MEMANTINE HCL	FOREST LABORATORIES INC	S	6/21/2010
NDA 200890	PILOCARPINE HYDROCHLORIDE OPHTHALMIC SOLUTION	PILOCARPINE HYDROCHLORIDE OPHTHALMIC SOLUTION	ALCON INC	P	6/22/2010
NDA 022518	MOMETASONE FUROATE/FORMOTEROL FUMARATE	DULERA	SCHERING CORP	S	6/22/2010
NDA 022377	SUMATRIPTAN SUCCINATE AUTO-INJECTOR	SUMATRIPTAN SUCCINATE AUTO-INJECTOR	KING PHARMACEUTICALS INC	S	6/29/2010
NDA 021306	BUTRANS TRANSDERMAL SYSTEM	BUPRENORPHINE	PURDUE PHARMA LP	S	6/30/2010
NDA 022524	ZUPLENZ	ONDANSETRON	PAR PHARMACEUTICAL	S	7/2/2010
NDA 200793 <sup>2</sup>	LAMIVUDINE/NEVIRAPINE/ZIDOVUDINE TABLETS FOR ORAL SUSPENSION (30MG/50MG/60MG)	LAMIVUDINE/NEVIRAPINE/ZIDOVUDINE TABLETS FOR ORAL SUSPENSION (30MG/50MG/60MG)	MATRIX LABORATORIES LTD	P	7/8/2010
NDA 050803	VELTIN	CLINDAMYCIN/ TRETINOIN	STIEFFEL A GSK CO	S	7/16/2010
NDA 022568	DONEPEZIL HYDROCHLORIDE	DONEPEZIL HYDROCHLORIDE	EISAI MEDICAL RESEARCH INC	S	7/23/2010
NDA 200175	CS-8635 COMBINATION OF OLMESARTAN MEDOXOMIL/AMLODIPINE/HYDROCHLOROTHAZIDE	CS-8635 COMBINATION OF OLMESARTAN MEDOXOMIL/AMLODIPINE/HYDROCHLOROTHAZIDE	DAIICHI SANKYO INC	S	7/23/2010
NDA 022359 <sup>1</sup>	ARGATROBAN INJECTION	ARGATROBAN INJECTION	BAXTER HEALTHCARE CORP	S	7/28/2010
NDA 022571	GLYCOPYRRROLATE ORAL SOLUTION	GLERSA	SHIONOGI PHARMA INC	S.O	7/28/2010
NDA 022134	LASTACFT (ALCAFTADINE OPHTHALMIC SOLUTION) 0.25%	VILASTA OPHTHALMIC SOLUTION	VISTAKON PHARMACEUTICALS LLC	S	7/28/2010
NDA 022541 <sup>2</sup>	LAMIVUDINE/STAVUDINE FDC TABS (150MG/30MG)	LAMIVUDINE/STAVUDINE FDC TABS (150MG/30MG)	MACLEODS PHARMACEUTICALS LTD	S	8/5/2010
NDA 022372	SUPREP BOWEL PREP KIT	SUPREP BOWEL PREP KIT	BRAINTREE LABORATORIES INC	S	8/5/2010
NDA 022474	ELLA	ULIPRISTAL ACETATE	LABORATOIRE HRA PHARMA	S	8/13/2010
NDA 022545	ALISKIREN/AMLODIPINE(SPA 100A)FIXED COMBO	ALISKIREN/AMLODIPINE(SPA 100A)FIXED COMBO	NOVARTIS PHARMACEUTICALS CORP	S	8/26/2010
NDA 022537 <sup>2</sup>	LAMIVUDINE/NEVIRAPINE/STAVUDINE FDC TABS (150MG/200MG/30MG)	LAMIVUDINE/NEVIRAPINE/STAVUDINE FDC TABS (150MG/200MG/30MG)	MACLEODS PHARMACEUTICALS LTD	S	8/30/2010
NDA 022410	SUBOXONE SUBLINGUAL FILM	BUPRENORPHINE/ NALOXONE	RECKITT BENCKISER PHARMACEUTICALS INC	S	8/30/2010
NDA 022184	LUMIGAN 0.01%	BIMATOPROST OPHTHALMIC SOLUTION	ALLERGAN INC	S	8/31/2010

NDA 022578	CETIRIZINE HCL ORALLY 10MG TABS	CETIRIZINE HCL ORALLY 10MG TABS	MCNEIL CONSUMER HEALTHCARE DIV MCNEIL PPC INC	S	9/3/2010
NDA 200244 <sup>2</sup>	LAMIVUDINE/NEVIRAPINE/STAVUDINE FDC TABS (150MG/200MG/30MG)	LAMIVUDINE/NEVIRAPINE/STAVUDINE FDC TABS (150MG/200MG/30MG)	HETERO DRUGS LTD UNIT III	S	9/10/2010
NDA 022527	FINGOLIMOD HCL ORAL CAPSULES	FINGOLIMOD HCL ORAL CAPSULES	NOVARTIS PHARMACEUTICALS CORP	P	9/21/2010
NDA 022532	BEYAZ	DROSPIRENONE/ETHINYL ESTRADIOL/LEVOMEFOLATE CALCIUM AND LEVOMEFOLATE CALCIUM	BAYER HEALTHCARE PHARMACEUTICALS INC	S	9/24/2010
NDA 022368	ARIDOL POWDER FOR INHALATION	MANNITOL(CAPS CONTAINING POWDER FOR INHA	PHARMAXIS INC	S	10/5/2010
NDA 022563	CALCIPOTRIEN FOAM 0.005%	CALCIPOTRIEN FOAM 0.005%	STIEFFEL LABORATORIES INC	S	10/6/2010
NDA 022560	ATELVIA		WARNER CHILCOTT CO LLC	S	10/8/2010
NDA 022512	PRADAXA	DABIGATRAN ETEXILATE MESYLATE	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	P	10/19/2010
NDA 200534	OXYCODONE HCL CAPSULES	OXYCODONE HCL CAPSULES	LEHIGH VALLEY TECHNOLOGIES INC	S	10/20/2010
NDA 200535	OXYCODONE ORAL SOLUTION 20MG/ML (100MG/5ML)	OXYCODONE ORAL SOLUTION 20MG/ML (100MG/5ML)	LEHIGH VALLEY TECHNOLOGIES INC	S	10/20/2010
NDA 022501	LOESTRIN 1/10 FE	LOESTRIN 1/10 FE	WARNER CHILCOTT CO INC	S	10/21/2010
NDA 200603	LURASIDONE HCL	LURASIDONE HCL	SUNOVION PHARMACEUTICALS INC	S	10/28/2010
NDA 200327	CEFTAROLINE FOSAMIL FOR INJECTION	CEFTAROLINE FOSAMIL FOR INJECTION	CEREXA INC	S	10/29/2010
NDA 021879	NEURODEX	DEXTRMETHORPHAN PLUS QUINIDINE	AVANIR PHARMACEUTICALS INC	P	10/29/2010
NDA 022450	OFIRMEV	ACETAMINOPHEN	CANDENCE PHARMACEUTICALS INC	P	11/2/2010
NDA 200678	SAXAGLIPTIN + METFORMIN XR	SAXAGLIPTIN + METFORMIN XR	BRISTOL MYERS SQUIBB	S	11/5/2010
NDA 022505	EGRIFTA	TESAMORELIN	THERATECHNOLOGIES INC	S	11/10/2010
NDA 201532	ERIBULIN MESYLATE	ERIBULIN MESYLATE	EISAI INC	P	11/15/2010
NDA 022462	BACLOFEN INTRATHECAL	BACLOFEN INTRATHECAL	CNS THERAPEUTICS INC	S	11/19/2010
NDA 022428	MOXIFLOXACIN ALTERNATIVE FORMULATION OP	MOXIFLOXACIN ALTERNATIVE FORMULATION OP	ALCON PHARMACEUTICALS LTD	S	11/19/2010
NDA 022504	TESTOSTERONE	TESTOSTERONE MD LOTION	ACRUX PHARMA PTY LTD	S	11/23/2010
NDA 200733 <sup>2</sup>	ABACAVIR SULFATE	ABACAVIR SULFATE	MATRIX LABORATORIES LTD	S	11/29/2010
NDA 022574	SAFYRAL	DROSPIRENONE/ETHINYL ESTRADIOL/LEVOMEFOLATE	BAYER HEALTHCARE PHARMACEUTICALS INC	S	12/16/2010
NDA 200045	ALISKIREN/AMLODIPINE	ALISKIREN/AMLODIPINE	NOVARTIS PHARMACEUTICALS CORP	S	12/21/2010
NDA 022573	NORETHINDRONE AND ETHINYL ESTRADIOL TABLETS, CHEWABLE AND FERROUS FUMARATE TABLETS, CHEWABLE	NORETHINDRONE AND ETHINYL ESTRADIOL TABLETS, CHEWABLE AND FERROUS FUMARATE TABLETS, CHEWABLE	WARNER CHILCOTT INC	S	12/22/2010
NDA 021463	FORTESTA	TESTOSTERONE GEL	ENDO PHARMACEUTICALS INC	S	12/29/2010

#### Biologic License Application (BLA) Approvals:

BLA NUMBER	PROPRIETARY NAME	PROPER NAME	APPLICANT	REVIEW CLASSIFICATION	APPROVAL DATE
L 125276/0.0	ACTEMRA	TOCILIZUMAB	GENENTECH, INC.	S	1/8/2010
L 125338/0.0	XIAFLEX	CLOSTRIDIAL COLLAGENASE	AUXILIUM PHARMACEUTICALS, INC.	P.O	2/2/2010
L 125291/0.0	LUMIZYME	ALGLUCOSIDASE ALFA2	GENZYME CORPORATION	P.O	5/24/2010
L 125320/0.0	PROLIA	DENOSUMAB TO	AMGEN, INC.	S	6/1/2010
L 125360/0.0	XEOMIN	INCOBOTULINUMTOXINA	MERZ PHARMACEUTICALS GMBH	S	7/30/2010
L 125293/0.0	KRYSTEXA	PEGLOTICASE	SAVIENT PHARMACEUTICALS, INC.	P.O	9/14/2010

<sup>1</sup> Application has been tentatively approved.

<sup>2</sup> Application has been tentatively approved under PEPFAR.

#### 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).