



**CDER Drug and Biologic Calendar Year Priority 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 022250	AMPYRA	DALFAMPRIDINE	ACORDA THERAPEUTICS INC	P,O	1/22/2010
NDA 022575	VPRIV	VELAGLUCERASE ALFA	SHIRE HUMAN GENETIC THERAPIES INC	P,O	2/26/2010
NDA 022562	CARBAGLU	CARGLUMIC ACID	ORPHAN EUROPE	P,O	3/18/2010
NDA 022272	OXYCONTIN	OXYCONTIN	PURDUE PHARMA INC	P	4/5/2010
NDA 022555	HEXVIX	HEXYL ANIMOLEVULATE	PHOTOCURE ASA	P	5/28/2010
NDA 201023	JEVTANA		SANOFI AVENTIS US INC	P	6/17/2010
NDA 200890	PILOCARPINE HYDROCHLORIDE OPTHALMIC SOLUTION, 1%, 2% AND 4%		ALCON INC	P	6/22/2010
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 022527	FINGOLIMOD HCL ORAL CAPSULES	FINGOLIMOD HCL ORAL CAPSULES	NOVARTIS PHARMACEUTICALS CORP	P	9/21/2010
NDA 022512	PRADAXA	DABIGATRAN ETEXILATE MESYLATE	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	P	10/19/2010
NDA 021879	NEURODEX	DEXTROMETHORPHAN PLUS QUINIDINE	AVANIR PHARMACEUTICALS INC	P	10/29/2010
NDA 022450	OFIRMEV	ACETAMINOPHEN	CADENCE PHARMACEUTICALS INC	P	11/2/2010
NDA 201532	ERIBULIN MESYLATE	ERIBULIN MESYLATE	EISAI INC	P	11/15/2010

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

BLA NUMBER	PROPRIETARY NAME	PROPER NAME	APPLICANT	REVIEW CLASSIFICATION	APPROVAL DATE
L 125338/0.0	XIAFLEX	CLOSTRIDIAL COLLAGENASE	AUXILIUM PHARMACEUTICALS, INC.	P,O	2/2/2010
L 125291/0.0	LUMIZYME	ALGLUCOSIDASE ALFA3	GENZYME CORPORATION	P,O	5/24/2010
L 125293/0.0	KRYSTEXXA	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.

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