



CDER Drug and Biologic Calendar Year Priority Approvals As of December 31, 2009

Last Refresh Date: 7/13/2011

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
NDA 022278	MEMBRANEBLUE	MEMBRANEBLUE 0.15% TRYPAN BLUE OPHTHALMI	DORC INTERNATIONAL BV	P	2/20/2009
NDA 022334	AFFINITOR	EVEROLIMUS	NOVARTIS PHARMACEUTICALS CORP	P	3/30/2009
NDA 022268	COARTEM	ARTEMETHER 20MG LUMEFANTRINE 120MG	NOVARTIS PHARMACEUTICALS CORP	P, O	4/7/2009
NDA 020725	CREON/MINIMICROSPHERE)PANCRELIPASE D-R C	PANCRELIPASE DELAYED RELEASE CAPS	SOLVAY PHARMACEUTICALS	P	4/30/2009
NDA 022348	CALDOLOR INJECTION	IBUPROFEN INJECTION	CUMBERLAND PHARMACEUTICALS INC	P	6/11/2009
NDA 022315	OZURDEX	DEXAMETHASONE BIODEGRADABLE INTRAVITREAL	ALLERGAN INC	P	6/17/2009
NDA 022425	MULTAQ	DRONEDARONE HCL	SANOVI AVENTIS US LLC	P	7/1/2009
NDA 022307	EFFIENT	PRASUGREL	ELI LILLY AND CO	P	7/10/2009
NDA 022352	COLCRYS TABLETS 0.6 MG	COLCHICINE TABLETS USP 0.6 MG	AR HOLDING CO INC	P, O	7/29/2009
NDA 022321	EMBEDA	MORPHINE SULFATE ER W SEQUESTERED NALTRE	ALPHARMA PHARMACEUTICALS LLC KING PHARMACEUTICALS	P	8/13/2009
NDA 022006	SABRIL (VIGABATRIN)	VIGABATRIN	LUNDBECK INC	P	8/21/2009
NDA 022210	ZENPEP	PANCREATIC ENZYME PRODUCT DELAYED RELEAE	EURAND INC	P	8/27/2009
NDA 022257	VALCYTE	VALGANICLOVIR HYDROCHLORIDE	ROCHE PALO ALTO LLC	P	8/28/2009
NDA 022142	EVAVIRENZ/LAMIVUDINE/TENOFOVIR DISOPROXIL FUMARATE FDC TABS (600MG/300MG/300MG)	EVAVIRENZ/LAMIVUDINE/TENOF OVIR DISOPROXIL FUMARATE FDC TABS (600MG/300MG/300MG)	MATRIX LABORATORIES LTD	P	9/3/2009
NDA 022468	FOLOTYN	PRALATREXATE INJECTION 20MG/1ML40MG/2ML	ALLOS THERAPEUTICS INC	P,O	9/24/2009
NDA 022430	LYSTEDA	TRANEXAMIC ACID TABLETS, 650 MG	XANODYNE PHARMACEUTICS INC	P	11/13/2009

Biologic License Application (BLA) Approvals:

BLA NUMBER	PROPRIETARY NAME	PROPER NAME	APPLICANT	REVIEW CLASSIFICATION	APPROVAL DATE
L 125319/0.0	ILARIS	CANAKINUMAB	NOVARTIS PHARMACEUTICALS CORPORATION	P,O	6/17/2009
L 125326/0.0	ARZERRA	OFATUMUMAB	GLAXO GROUP LIMITED D/B/A GLAXOSMITHKLINE	P,O	10/26/2009
L 125277/0.0	KALBITOR	ECALLANTIDE	DYAX CORP.	P,O	12/1/2009

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).