



CDER Drug and Biologic 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
NDA 022256	SAVELLA TABLETS	MILNACIPRAN HCL TABLETS	CYPRESS BIOSCIENCE INC	S	1/14/2009
NDA 022087	VECTICAL OINTMENT	CALCITRIOL OINTMENT 3 MICROGRAMS/GRAM	GALDERMA LABORATORIES LP	S	1/23/2009
NDA 022204	OXYBUTYNIN CHLORIDE TOPICAL GEL	OXYBUTYNIN CHLORIDE TOPICAL GEL	WATSON LABORATORIES INC	S	1/27/2009
NDA 022287	DEXLANSOPRAZOLE	BANILUX	TAKEDA PHARMACEUTICALS NORTH AMERICA INC	S	1/30/2009
NDA 021856	ULORIC (FEBUXOSTAT) TABLETS	FEBUXOSTAT	TAKEDA PHARMACEUTICALS NORTH AMERICA INC	S	2/13/2009
NDA 022370	TRAMADOL HYDROCHLORIDE	CIP-TRAMADOL ER CAPSULES	CIPHER PHARMACEUTICALS LTD	S	2/13/2009
NDA 050818	TOBRADEX ST	TOBRADEX ST	ALCON INC	S	2/13/2009
NDA 022278	MEMBRANEBLUE	MEMBRANEBLUE 0.15% TRYPAN BLUE OPHTHALMI	DORC INTERNATIONAL BV	P	2/20/2009
NDA 022277	TEMODAR	TEMOZOLOMIDE	SCHERING CORP	S	2/27/2009
NDA 022346	STAVUDINE/LAMIVUDINE/NEVIRAPINE FDC TABS (40MG/150MG/200MG & 30MG/150MG/200MG)	STAVUDINE/LAMIVUDINE/NEVIRAPINE FDC TABS (40MG/150MG/200MG & 30MG/150MG/200MG)	PHARMACARE LTD	S	2/27/2009
NDA 021997	ZOLPIDEM TARTRATE	ZOLPIDEM TARTRATE	MEDA PHARMACEUTICALS	S	3/13/2009
NDA 022347	LAMIVUDINE/STAVUDINE FDC TABS (150MG/40MG & 150MG/30MG)	LAMIVUDINE/STAVUDINE FDC TABS (150MG/40MG & 150MG/30MG)	PHARMACARE LTD	S	3/18/2009
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 022129	ULESFIA	BENZYL ALCOHOL	SCIELE PHARMA INC	S	4/9/2009
NDA 022154	TYZEKA (TELBIVUDINE) ORAL	TELBIVUDINE	NOVARTIS PHARMACEUTICALS CORP	S	4/28/2009
NDA 020725	CREON/MINIMICROSPHERE)PANCRELIPASE D-R C	PANCRELIPASE DELAYED RELEASE CAPS	SOLVAY PHARMACEUTICALS	P	4/30/2009
NDA 022314	EXFORGE HCT	AMLODIPINE/VALSARTAN/HYDROCHLOROTHIAZIDE	NOVARTIS PHARMACEUTICALS CORP	S	4/30/2009
NDA 021918	CIPROFLOXACIN OTIC SOLUTION 0.2%	CIPROFLOXACIN OTIC SOLUTION 0.2%	WRASER PHARMACEUTICALS LLC	S	5/1/2009
NDA 020866	CYCLOSET(BROMOCRIPTINE MESYLATE)TABS	BROMOCRIPTINE MESYLATE	VEROSCIENCE LLC	S	5/5/2009
NDA 022192	FANAPT	ILOPERIDONE	VANDA PHARMACEUTICALS INC	S	5/6/2009
NDA 022356	LAMIVUDINE/ZIDOVUDINE TABS (150MG/300MG) CO-PACKAGED WITH NEVIRAPINE TABS (200MG)	LAMIVUDINE/ZIDOVUDINE TABS (150MG/300MG) CO-PACKAGED WITH NEVIRAPINE TABS (200MG)	HETERO DRUGS LTD UNIT III	S	5/7/2009

NDA 022251	LAMICTAL ODT	LAMICTAL ODT	SMITHKLINE BEECHAM CORP DBA GLAXOSMITHKLINE	S	5/8/2009
NDA 022024	ACTOPLUS METXR	PIOGLITAZONE HCL/METFORMIN HCL EXT-REL T	TAKEDA GLOBAL RESEARCH DEVELOPMENT CENTER INC	S	5/12/2009
NDA 022327	LANSOPRAZOLE	LANSOPRAZOLE	NOVARTIS CONSUMER HEALTH INC	S	5/18/2009
NDA 022360	NICOTINE POLACRILEX MINI MINT LOZENGE	NICOTINE POLACRILEX MINI MINT LOZENGE	GLAXOSMITHKLINE CONSUMER HEALTHCARE	S	5/18/2009
NDA 022275	SAMSCA	TOLVAPTAN (15MG / 30MG / 60MG) TABLETS	OTSUKA AMERICA PHARMACEUTICAL INC	S	5/19/2009
NDA 022308	BESIFLOXACIN HCL	BESIFLOXACIN	BAUSCH AND LOMB INC	S	5/28/2009
NDA 022115	LAMICTAL XR TABLETS	LAMOTRIGINE EXTENDED-RELEASE TABLETS	SMITHKLINE BEECHAM CORP	S	5/29/2009
NDA 022348	CALDOLOR INJECTION	IBUPROFEN INJECTION	CUMBERLAND PHARMACEUTICALS INC	P	6/11/2009
NDA 022202	ZIPSOR	DICLOFENAC POTASSIUM SOFT GEL CAPSULES	XANODYNE PHARMACEUTICS INC	S	6/16/2009
NDA 022165	PRO 513	DICLOFENAC POTASSIUM	KOWA PHARMACEUTICALS AMERICA INC	S	6/17/2009
NDA 022315	OZURDEX	DEXAMETHASONE BIODEGRADABLE INTRAVITREAL	ALLERGAN INC	P	6/17/2009
NDA 022180	FERUMOXYTOL INJECTION	FERUMOXYTOL	AMAG PHARMACEUTICALS INC	S	6/30/2009
NDA 022425	MULTAQ	DRONEDARONE HCL	SANOFI AVENTIS US LLC	P	7/1/2009
NDA 022306	SO-AQUEOUS	SOTALOL HYDROCHLORIDE	ACADEMIC PHARMACEUTICALS INC	S, O	7/2/2009
NDA 021998	PLAN B ONE-STEP	LEVONORGESTREL 1.5MG TABLETS	DURAMED PHARMACEUTICALS INC	S	7/10/2009
NDA 022307	EFFIENT	PRASUGREL	ELI LILLY AND CO	P	7/10/2009
NDA 022239	SUMATRIPTAN	SUMATRIPTAN	ZOGENIX INC	S	7/15/2009
NDA 022266	FENTANYL CITRATE / BEMA FENTANYL	FENTANYL CITRATE	MEDA PHARMACEUTICALS INC	S	7/16/2009
NDA 022342	STAVUDINE/LAMIVUDINE/NEVIRAPINE FDC TABS (40MG/150MG/200MG & 30MG/150MG/200MG)	STAVUDINE/LAMIVUDINE/NEVIRAPINE FDC TABS (40MG/150MG/200MG & 30MG/150MG/200MG)	EMCURE PHARMACEUTICALS LTD	S	7/16/2009
NDA 022402	CODEINE SULFATE TABLETS 15,30,60 MG	CODEINE SULFATE TABLETS 15, 30,60 MG	ROXANE LABORATORIES INC	S	7/16/2009
NDA 022427	KETOROLAC TROMETHAMINE OPTHALMIC SOL	KETOROLAC TROMETHAMINE OPTHALMIC SOL	ALLERGAN INC	S	7/22/2009
NDA 022294	ZIDOVUDINE SCORED TABS (60MG)	ZIDOVUDINE SCORED TABS (60MG)	AUROBINDO PHARMA LTD	S	7/23/2009
NDA 022296	LAMIVUDINE/ZIDOVUDINE FDC SCORED TABS (30MG/60MG)	LAMIVUDINE/ZIDOVUDINE FDC SCORED TABS (30MG/60MG)	AUROBINDO PHARMA LTD	S	7/23/2009
NDA 022429	CETIRIZINE HCL CAPSULES	CETIRIZINE HCL CAPSULES	BANNER PHARMACAPS INC	S	7/23/2009
NDA 022352	COLCRYS TABLETS 0.6 MG	COLCHICINE TABLETS USP 0.6 MG	AR HOLDING CO INC	P, O	7/29/2009
NDA 022351	COLCHICINE TABLETS USP 0.6MG		AR HOLDING CO INC	S	7/30/2009
NDA 022387	TYVASO	TREPROSTINIL FOR INHALATION	UNITED THERAPEUTICS CORP	S, O	7/30/2009
NDA 022264	INVEGA SUSTENNA	PALIPERIDONE PALMITATE 1 MONTH INJECTION	JOHNSON AND JOHNSON PHARMACEUTICAL RESEARCH AND DEVELOPMENT LLC	S	7/31/2009
NDA 022350	ONGLYZA	SAXAGLIPTIN	BRISTOL MYERS SQUIBB CO	S	7/31/2009
NDA 022436	ME-609 CREAM	ACYCLOVIR AND HYDROCORTISONE TOPICAL	MEDIVIR AB	S	7/31/2009
NDA 022363	LIVALO TABLETS	PITAVASTATIN	KOWA RESEARCH INSTITUTE INC	S	8/3/2009
NDA 022160	OXALIPLATIN	OXALIPLATIN INJECTION	TEVA PARENTERAL MEDICINES INC	S	8/7/2009

NDA 022318	REVELA	SEVELAMER CARBONATE	GENZYME CORP	S	8/12/2009
NDA 022321	EMBEDA	MORPHINE SULFATE ER W SEQUESTERED NALTRE	ALPHARMA PHARMACEUTICALS LLC KING PHARMACEUTICALS	P	8/13/2009
NDA 022117	SAPHRIS	ASENAPINE	ORGANON USA INC	S	8/13/2009
NDA 022418	FENOFIBRIC ACID TABS 35MG/105MG ORAL	FENOFIBRIC ACID TABS 35MG/105MG ORAL	AR HOLDING CO INC	S	8/14/2009
NDA 020427	SABRIL (VIGABATRIN) TABLET 500MG	VIGABATRIN	LUNDBECK INC	S,O	8/21/2009
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	VALGANCICLOVIR HYDROCHLORIDE	ROCHE PALO ALTO LLC	P	8/28/2009
NDA 022037	INTUNIV: GUANFACINE SR; TABLET FORM	GUANFACINE HYDROCHLORIDE	SHIRE DEVELOPMENT INC	S	9/2/2009
NDA 022142	EVAVIRENZ/LAMIVUDINE/TENOFOVIR DISOPROXIL FUMARATE FDC TABS (600MG/300MG/300MG)	EVAVIRENZ/LAMIVUDINE/TENOFOVIR DISOPROXIL FUMARATE FDC TABS (600MG/300MG/300MG)	MATRIX LABORATORIES LTD	P	9/3/2009
NDA 022246	METZOZOLV ODT	METOCLOPRAMIDE TABLET USP	SALIX PHARMACEUTICALS INC	S	9/4/2009
NDA 022288	BEPOTASTINE BESILATE OPHTHALMIC SOLUTION	BEPOTASTINE BESILATE OPHTHALMIC SOLUTION	ISTA PHARMACEUTICALS	S	9/8/2009
NDA 022110	TELAVANCIN	TELAVANCIN	THERAVANCE INC	S	9/11/2009
NDA 022211	ZIRGAN (GANCICLOVIR OPHTHALMIC GEL)0.15%	GANCICLOVIR	SIRION THERAPEUTICS INC	S, O	9/15/2009
NDA 022217	ALISKIREN & VALSARTAN	ALISKIREN & VALSARTAN	NOVARTIS PHARMACEUTICALS CORP	S	9/16/2009
NDA 022468	FOLOTYN	PRALATREXATE INJECTION 20MG/1ML40MG/2ML	ALLOS THERAPEUTICS INC	P,O	9/24/2009
NDA 022331	JENLOGA	CLONIDINE HYDROCHLORIDE	ADDREX PHARMACEUTICALS INC	S	9/29/2009
NDA 022362	WELCHOL POWDER FOR ORAL SUSPENSION	WELCHOL POWDER FOR ORAL SUSPENSION	DAIICHI SANKYO INC	S	10/2/2009
NDA 022401	TELMISARTAN/AMLODIPINE FIXED DOSE COM TB	TELMISARTAN/AMLODIPINE FIXED DOSE COM TB	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	S	10/16/2009
NDA 022353	COLCHICINE TABLETS USP 0.6MG		MUTUAL PHARMACEUTICAL CO INC	S	10/16/2009
NDA 022465	VOTRIENT TABLETS	PAZOPANIB TABLET	GLAXOSMITHKLINE	S	10/19/2009
NDA 020947	PENNSAID(DICLOFENAC SODIUM)1.5% TOP LOTI	DICLOFENAC SODIUM	NUVO RESEARCH INC	S	11/4/2009
NDA 022393	ROMIDEPSIN FOR INFUSION	ROMIDEPSIN FOR INFUSION	GLOUCESTER PHARMACEUTICALS INC	S,O	11/5/2009
NDA 022459	LAMIVUDINE/TENOFOVIR DISOPROXIL FUMARATE FDC TABS (300MG/300MG)	LAMIVUDINE/TENOFOVIR DISOPROXIL FUMARATE FDC TABS (300MG/300MG)	HETERO DRUGS LTD	S	11/5/2009
NDA 022430	LYSTEDA	TRANEXAMIC ACID TABLETS, 650 MG	XANODYNE PHARMACEUTICS INC	P	11/13/2009
NDA 022395	QUTENZA	CAPSAICIN PATCH 8%	NEUROGESX INC	S, O	11/16/2009
NDA 022473	REVATIO	SILDENAFIL CITRATE	PFIZER INC	S	11/18/2009
NDA 022461	EFAVIRENZ NONSCORED TABS (50MG, 100MG, 200MG)	EFAVIRENZ NONSCORED TABS (50MG, 100MG, 200MG)	MATRIX LABORATORIES LTD	S	11/24/2009
NDA 022470	KETOPROFEN ORAL-ORAL DISSOLVING STRIPS	KETOPROFEN ORAL-ORAL DISSOLVING STRIPS	NOVARTIS CONSUMER HEALTH INC	S	11/25/2009
NDA 022281	ZEGERID OTC CAPSULES	OMEPRAZOLE 20MG SODIUM BICARBONATE 1100M	SCHERING PLOUGH HEALTHCARE PRODUCTS INC	S	12/1/2009

NDA 022499	CLONIDINE POLISTIREX ER ORAL SUSPENSION		TRIS PHARMA INC	S	12/3/2009
NDA 022500	CLONIDINE POLISTIREX ER ORAL TABLETS		TRIS PHARMA INC	S	12/3/2009
NDA 022456	ZEGERID	OMEPRAZOLE/SODIUM BICARBONATE/MAGNESIUM	SANTARUS INC	S	12/4/2009
NDA 022173	ZYPREXA/ADHERA	OLANZAPINE LONG ACTING INJ	ELI LILLY CO	S	12/11/2009
NDA 022234	DOCETAXEL INJECTION	DOCETAXEL INJECTION 20 MG AND 80 MG	HOSPIRA INC	S	12/11/2009
NDA 022464	LAMIVUDINE/NEVIRAPINE/ZIDOVUDIN TABS (150MG/200MG/300MG)	LAMIVUDINE/NEVIRAPINE/ZIDOVUDIN TABS (150MG/200MG/300MG)	STRIDES ARCOLAB LTD	S	12/22/2009

Biologic License Application (BLA) Approvals:

BLA NUMBER	PROPRIETARY NAME	PROPER NAME	APPLICANT	REVIEW CLASSIFICATION	APPROVAL DATE
L 125289/0.0	SIMPONI	GOLIMUMAB	CENTOCOR ORTHO BIOTECH, INC.	S	4/24/2009
L 125274/0.0	DYSPOPT	ABOBOTULINUMTOXINA	IPSEN BIOPHARM LIMITED	S,O	4/29/2009
L 125319/0.0	ILARIS	CANAKINUMAB	NOVARTIS PHARMACEUTICALS CORPORATION	P,O	6/17/2009
L 125290/0.0	EXTAVIA	INTERFERON BETA-1B	NOVARTIS PHARMACEUTICALS CORPORATION	S	8/14/2009
L 125261/0.0	STELARA	USTEKINUMAB	CENTOCOR ORTHO BIOTECH, INC.	S	9/25/2009
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).