

CDER Drug and Biologic Approvals for Calendar Year 2008

Updated through December 31, 2008

New Drug Application (NDA) Approvals:

Application Type	Application Number	Proprietary Name	Established Name	Applicant	Chemical Type	Review Classification	505B2 FLAG	Approval Date
N	021658	ALVESCO	CICLESONIDE	NYCOMED	3	S		10-Jan-08
N	022067	FLO-PRED	PREDNISOLONE ACETATE	TARO	3	S		17-Jan-08
N	022187	INTELENCE	ETRAVIRINE	TIBOTEC	1	P		18-Jan-08
N	022107	TEKTRUNA HCT	ALISKIREN/HYDROCHLOROTHIAZIDE	NOVARTIS	4	S		18-Jan-08
N	021538	ACCRETROPIN	SOMATROPIN	CHESAPEAKE	5	S		23-Jan-08
N	050813	MOXATAG	AMOXICILLIN	MIDDLEBROOK	3	S	Y	23-Jan-08
N	022023	EMEND	FOSAPREPITANT DIMEGLUMINE	MERCK & CO	2	S		25-Jan-08
N	022157	XYZAL	LEVOCETIRZINE DIHYDROCHLORIDE	UCB, INC.	3	S	Y	28-Jan-08
N	022078	SIMCOR	NIACIN/SIMVASTATIN	ABBOTT	4	S	Y	15-Feb-08
N	022029	SALONPAS	METHYL SALICYLATE & MENTHOL	HISAMITSU	3,4	S	Y	20-Feb-08
N	022028	COSYNTROPIN	COSYNTROPIN	SANDOZ	5	S	Y	21-Feb-08
N	022101	NEXIUM	ESOMEPRAZOLE MAGNESIUM	ASTRAZENECA	3	S		27-Feb-08
N	022033	LUVOX CR	FLUVOXAMINE MALEATE	SOLVAY	3	S		28-Feb-08
N	021992	PRISTIQ	DESVENLAFAXINE SUCCINATE	WYETH	1	S		29-Feb-08
N	020140	ISOVORIN	LEUCOVORIN CALCIUM	SPECTRUM	5	S,O		07-Mar-08
N	022195	MORPHINE SULPHATE	MORPHINE SULPHATE	ROXANE	7	S	Y	17-Mar-08
N	022207	MORPHINE SULFATE	MORPHINE SULFATE	ROXANE	7	S	Y	17-Mar-08
N	022056	PRIOSEC	OMEPRAZOLE	ASTRAZENECA	3	S		20-Mar-08
N	022249	TREANDA	BENDAMUSTINE HYDROCHLORIDE	CEPHALON	1	P,O	Y	20-Mar-08

N	022009	ANTHELIOS 40	AVOBENZENE; ECAMSULE; OCTOCRYLENE; TITANIUM DIOXIDE	L'OREAL	5	S	Y	31-Mar-08
N	022161	LEXISCAN	REGADENOSON	CV THERAPEUTICS	1	S		10-Apr-08
N	021926	TREXIMET	SUMATRITAM; NAPROXEN SODIUM	POZEN	4	S	Y	15-Apr-08
N	021861	PATANASE	OLOPATADINE HYDROCHLORIDE	ALCON	3	S		15-Apr-08
N	022108	APLENZIN	BUPROPION HYDROBROMIDE	BIOVAIL LABS	2	S	Y	23-Apr-08
N	021964	RELISTOR	METHYLNALTREXONE BROMIDE	PROGENICS	1	S		24-Apr-08
N	021795	MINIRIN	DESMOPRESSIN ACETATE	FERRING	5	S	Y	08-May-08
N	022185	TACLONEX SCALP	CALCIPOTRIENE; BETAMETHASONE DIPROPIONATE	LEO PHARM PRODUCTS	3	S		09-May-08
N	022159	ORAVERSE	PHENTOLAMINE MESYLATE	NOVALAR	3	S	Y	09-May-08
N	021775	ENTEREG	ALVIMOPAN	ADOLOR	1	S		20-May-08
N	022104	VENLAFAXINE HYDROCHLORIDE	VENLAFAXINE HYDROCHLORIDE	OSMOTICA	3	S	Y	20-May-08
N	021830	ASACOL	MESALAMINE	PROCTOR AND GAMBLE	3	S		29-May-08
N	022008	REQUIP XL	ROPINIROLE	SMITHKLINE BEECHAM	3	S		13-Jun-08
N	021952	CLARITIN LIQUI-GELS	LORATADINE	SCHERING-PLOUGH	3	S		16-Jun-08
N	022220	TRIVARIA	TRIAMCINOLONE ACETONIDE	ALLERGAN	3	S	Y	16-Jun-08
N	021822	APTIVUS	TIPRANAVIR	BOEHRINGER INGELHEIM	3	P		23-Jun-08
N	022212	DUREZOL	DIFLUPREDNATE	SIRION	1	P		23-Jun-08
N	022292	APTIVUS	TIPRANAVIR	BOEHRINGER INGELHEIM	3	P		23-Jun-08
N	022386	PRANDIMET	REPAGLINIDE/METFORMIN HYDROCHLORIDE	NOVO NORDISK	4	S	Y	23-Jun-08
N	022260	EPOPROSTENOL SODIUM	EPOPROSTENOL SODIUM	GENERAMEDIX	5	S	Y	27-Jun-08
N	022090	EOVIST INJECTION	GADOXETATE DISODIUM	BAYER	1	S		03-Jul-08
N	022193	NAVSTEL	OPHTHALMIC SOLUTION; HYPROMELLOSE; DEXTROSE; GLUTATHIONE	ALCON	3	S		24-Jul-08
N	022276	NICARDIPINE HYDROCHLORIDE INJECTION	NICARDINE	TEVA PARENTERAL	5	S	Y	24-Jul-08
N	022152	STAVZOR	VALPROIC ACID	BANNER MEDICINES COMPANY	3	S	Y	29-Jul-08
N	022156	CLEVIPREX	CLEVIDIPINE BUTYRATE	BANNER MEDICINES COMPANY	1	S		01-Aug-08
N	050817	CEFEPIME INJECTION	CEFEPIME INJECTION	BAXTER	3	S	Y	05-Aug-08

N	022186	AK-FLUOR	FLUORESCHEIN INJECTION	AKORN	3	S	Y	08-Aug-08
N	022234*	DOCETAXEL INJECTION	DOCETAXEL INJECTION	HOSPIRA INC	5	S		11-Aug-08
N	021894	XENAZINE	TETRABENAZINE	PRESTWICK	1	P,O		15-Aug-08
N	022233	ALOXI	PALONOSETRAN HYDROCHLORIDE	HELSINN	3	S		22-Aug-08
N	021810	NOVOLOG MIX 50/50	BIPHASIC INSULIN ASPART 50/50	NOVO NORDISK	3	S		26-Aug-08
N	022198	SANCUSO	GRAINSETRON TRANSDERMAL SYSTEM/GRANISETR	STRAKAN	2	S	Y	12-Sep-08
N	022285	KEPPRA EXTENDED RELEASE TABLETS	LEVETIRACETAM	UCB INC	3	S		12-Sep-08
N	022290	ADRE VIEW	IOBENUANE I 123 INJECTION	GE HEALTHCARE	1	P,O	Y	19-Sep-08
N	022221	AKTEN	LIDOCAINE HYDROCHLORIDE	AKORN	3	S	Y	07-Oct-08
N	022206	RAPAFLO	SILODOSIN	WATSON LABS	1	S		08-Oct-08
N	022203	ASTEPRO NASAL SPRAY	AZELASTINE HYDROCHLORIDE	MEDPOINTE	5	S		15-Oct-08
N	022226*	PANTOPRAZOLE SODIUM	PANTOPRAZOLE SODIUM	TEVA PARENTERAL	5	S		20-Oct-08
N	050819	ACANYA	CLINDAMYCIN PHOSPHATE ALUCEN	DOW PHARMACEUTICAL	5	S	Y	23-Oct-08
N	022262	LO SEASONIQUE	LEVONORGESTREL / ETHINYL ESTRADIOL	DURAMED	3	S		24-Oct-08
N	022253	VIMPAT TABLETS	LACOSAMIDE	SCHWARZ BIOSCIENCES	1	S		28-Oct-08
N	022254	VIMPAT INJECTION	LACOSAMIDE	SCHWARZ BIOSCIENCES	3	S		28-Oct-08
N	022030	TOVIAZ	FESOTERODINE FUMARATE	PFIZER	1	S		31-Oct-08
N	022301	APRISO	MESALAMINE	SALIX	3	S	Y	31-Oct-08
N	021911	BANZEL ORAL TABS	RUFINAMIDE TABLETS	EISAI	1	S,O		14-Nov-08
N	022291	PROMACTA	ELTROMBOPAG OLAMINE	GLAXOSMITHKLINE	1	P,O		20-Nov-08
N	022304	TAPENTADOL	TAPENTADOL	ORTHO MCNEIL JANSSEN	1	S		20-Nov-08
N	021788	CENESTIN	CENESTIN VAGINAL CREAM	DURAMED	3	S		28-Nov-08
N	022320	EPIDUO	ADAPALENE AND BENZOYL PEROXIDE	GALDERMA	4	S	Y	08-Dec-08
N	022244	LUSEDRA	FOSPROPOFOL DISODIUM	EISAI MEDICAL	1	S		12-Dec-08
N	022224	TRILIPIX	FENOFIBRIC ACID	ABBOTT	2	S	Y	15-Dec-08

N	022311	MOZOBIL	PLERIXAFOR	GENZYME	1	P,O		15-Dec-08
N	022273	FLUDARABINE PHOSPHATE	FLUDARABINE PHOSPHATE	ANTISOMA	5	S,O		18-Dec-08
N	022196	ZOLPIMIST	ZOLPIDEM TARTRATE	NOVADEL	3	S	Y	19-Dec-08
N	021711	VASOVIST	GADOFOSVESET TRISODIUM	EPIX	1	S		22-Dec-08
N	022201	DEGARELIX	DEGARELIX	FERRING	1	S		24-Dec-08
N	022325	NEXTERONE	AMIODARONE HYDROCHLORIDE	PRISM	3	S	Y	24-Dec-08
N	021745	RYZOLT	TRAMADOL HYDROCHLORIDE	LABOPHARM CANADA	5	S	Y	30-Dec-08

*= DOCETAXEL INJECTION AND PANTOPRAZOLE SODIUM HAVE BEEN TENTATIVELY APPROVED

New Drug Application (NDA) Tentative Approvals under the President's Emergency Plan for AIDS Relief (PEPFAR):

Application Number	Proprietary Name	Established Name	Applicant	Chemical Type	Review Classification	505B2 FLAG	Approval Date
021837	STAVUDINE; LAMIVUDINE; NEVIRAPINE	STAVUDINE; LAMIVUDINE; NEVIRAPINE	STRIDES	4	P		20-Mar-08
022177	STAVUDINE; LAMIVUDINE; NEVIRAPINE	STAVUDINE; LAMIVUDINE; NEVIRAPINE	STRIDES	4	P		20-Mar-08
022167	LAMIVUDINE; STAVUDINE	LAMIVUDINE; STAVUDINE	CIPLA LIMITED	3	P		19-Jun-08
022141	TENOFAVIR DISOPROXYL FURMATE/LAMIVUDINE	TENOFAVIR DISOPROXYL FURMATE/LAMIVUDINE	MATRIX LABS	4	P		12-Sep-08
022293	ABACAVIR SULFATE	ABACAVIR SULFATE	AUROBINDO	3	P		12-Sep-08
022061	LANIVUDINE; ZIDOVUDINE; NEVIRAP	LANIVUDINE; ZIDOVUDINE; NEVIRAP	MATRIX LABS LTD	3	S		21-Oct-08
022297	EFAVIRENZ	EFAVIRENZ	AUROBINDO	3	P		12-Dec-08
022295	ABACAVIR SULFATE ANDLAMIVUDINE	ABACAVIR SULFATE ANDLAMIVUDINE	AUROBINDO	4	P		19-Dec-08

N021837 stavudine 40mg/lamivudine 150mg/nevirapine 200mg Tablets was tentatively approved on 03/20/2008 under PEPFAR

N022177 stavudine 30mg/lamivudine 150mg/nevirapine 200mg Tablets was tentatively approved on 03/20/2008 under PEPFAR.

N022167 lamivudine 30mg/stavudine 6mg Tablets was tentatively approved on 06/19/2008 under PEPFAR.

N022141 tenofovir disoproxil furmate/lamivudine was tentatively approved on 09/12/2008 under PEPFAR.

N022293 acacavir sulfate 60mg tablets was tentatively approved on 09/12/2008 under PEPFAR.

Biologic License Application (BLA) Approvals:

BLA Number	Proprietary Name	Proper Name	Applicant	Review Classification	Approval Date
125249	ARCALYST	RILONACEPT	REGENERON	P,O	27-Feb-08
125160	CIMZIA	CERTOLIZUMAB PEGOL	UCB	S	22-Apr-08
125196	PEGPAK	PEGINTERFERON; RIBAVIRIN	SCHERING	S	13-Jun-08
125268	NPLATE	ROMIPLOSTIM	AMGEN	P,O	22-Aug-08

NDA Chemical Type:

- 1 - New molecular entity
- 2 - New ester, new salt, or other noncovalent derivative
- 3 - New dosage form
- 4 - New combination
- 5 - New formulation or new manufacturer
- 7 - Drug already marketed, but without an approved NDA
- 8 - OTC switch

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).