

## CDER Fast Track Products Approved Since 1998 through June 1, 2010

NDA #	Proprietary Name (Established or Proper Name)	Applicant	Approval Date	Use
N22268	Coartem (artemether/ lumefantrine)	Novartis	4/7/2009	Treatment of Malaria
N22059	Tykerb (lapatinib ditosylate)	GlaxoSmithKline	3/13/2007	Treatment-refractory (including Herceptin) advanced or metastatic ErbB2-overexpressing breast cancer
N22041	Cyanokit (hydroxocobalamin)	EMD	12/15/2006	For the treatment of known or suspected cyanide poisoning
N21991	Zolinza (vorinostat)	Merck	10/6/2006	Treatment of cutaneous T-cell lymphoma
N21937	Atripla (emtricitabine; tenofovir disoproxil fumarate; efavirenz)	Gilead Sciences	7/12/2006	Treatment of HIV
N21986	Sprycel (dasatinib)	Bristol Myers-Squibb	6/28/2006	Treatment of chronic myelogenous leukemia
N21976	Prezista (darunavir)	Tibotec	6/23/2006	Treatment of HIV
N21790	Dacogen (decitabine)	Supergen	5/2/2006	Treatment of myelodysplastic syndromes
N21903	NeoProfen (ibuprofen lysine)	Farmacon-IL	4/13/2006	Treatment of patent ductus arteriosus (PDA)
N21880	Revlimid (lenalidomide)	Celgene	12/27/2005	Treatment of transfusion-dependent Myelodysplastic Syndromes (MDS)
N21923	Nexavar (sorafenib tosylate)	Bayer	12/20/2005	Treatment of renal cell carcinoma
N21882	Exjade (deferasirox)	Novartis	11/2/2005	Iron chelating compound for first-line treatment of chronic iron overload; thalassemia in adults and children with transfusion-dependent anemias
N21877	Arranon (nelarabine)	GlaxoSmithKline	10/28/2005	Treatment of refractory or relapsed T-cell acute lymphoblastic leukemia (ALL) or non-Hodgkin's lymphoma in pediatric patients under the age of 21
N21737	Retisert (fluocinolone acetonide)	Bausch & Lomb	4/8/2005	Treatment of chronic non-infectious uveitis affecting the posterior segment of the eye
N21660	Abraxane (paclitaxel protein-bound particles for injectable suspension)	American BioScience	1/7/2005	Treatment of breast cancer after failure of combination chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy.
N21673	Clolar (clofarabine)	Genzyme	12/28/2004	Treatment of pediatric patients 1 to 21 years old with relapsed or refractory acute lymphoblastic leukemia after at least two prior regimens
N21756	Macugen (pegaptanib sodium)	Eyetech Pharms	12/17/2004	Treatment of exudative (wet) age-related macular degeneration

N20635 SE1-035	Levaquin (levofloxacin)	Ortho McNeil	11/24/2004	Treatment of inhalational anthrax (post-exposure)
N20634 SE1-035	Levaquin (levofloxacin)	Ortho McNeil	11/24/2004	Treatment of inhalational anthrax (post-exposure)
N21743	Tarceva (erlotinib)	OSI Pharms	11/18/2004	Treatment of locally advanced or metastatic Non Small-Cell Lung Cancer after failure of at least one prior chemotherapy regimen
N21677	Alimta (pemetrexed)	Lilly	8/19/2004	Treatment of non-small cell lung cancer
N50794	Vidaza (azacitidine)	Pharmion	5/19/2004	Treatment of patients with certain subtypes of myelodysplastic syndrome
N21264	Apokyn (apomorphine)	Bertek	4/20/2004	Treatment of acute, intermittent hypomobility, "off" episodes ("end-of-dose wearing off" and unpredictable "on/off" episodes) associated with advanced Parkinson's disease
N21462	Alimta (pemetrexed disodium)	Lilly	2/4/2004	Treatment of malignant pleural mesothelioma
N21548	Lexiva (fosamprenavir calcium)	GlaxoSmithKline	10/20/2003	Treatment of HIV
N21348	Zavesca (miglustat)	Actelion Pharms	7/31/2003	Treatment of type I Gaucher disease
N21500	Emtriva (emtricitabine)	Gilead	7/2/2003	Treatment of HIV
N21602	Velcade (bortezomib)	Millennium Pharms	5/13/2003	Treatment of relapsed/refractory multiple myeloma
N21399	Iressa (gefitinib)	AstraZeneca	5/5/2003	Treatment of non-small cell lung cancer
N21106	Somavert (pegvisomant)	Pharmacia and Upjohn	3/25/2003	Treatment of acromegaly
N21481	Fuzeon (enfuvirtide)	Hoffmann-La Roche	3/13/2003	Treatment of HIV
N20541 SE1-010	Arimidex (anastrozole)	AstraZeneca	9/5/2002	Adjuvant treatment of early breast cancer in postmenopausal women
N21492	Eloxatin (oxaliplatin)	Sanofi- Synthelabo	8/9/2002	Treatment of colorectal cancer
N21232	Orfadin (nitisinone)	Swedish Orphan	1/18/2002	Treatment of hereditary tyrosinemia type I
N21356	Viread (tenofovir disoproxil fumarate)	Gilead	10/26/2001	Treatment of HIV
N21335	Gleevec (imatinib mesylate)	Novartis Pharms	5/10/2001	Treatment of Chronic Myeloid Leukemia

N21227	Candidas (casprofungin acetate)	Merck	1/26/2001	Treatment of aspergillus infections for patients who are refractory to or intolerant of other therapies
N21248	Trisenox (arsenic trioxide)	Cell Therapeutics	9/25/2000	Treatment of acute promyelocytic leukemia
N21226	Kaletra (lopinavir/ritonavir) Capsules	Abbott Labs	9/15/2000	Treatment of HIV
N21251	Kaletra (lopinavir/ritonavir) Oral Solution	Abbott Labs	9/15/2000	Treatment of HIV
N20449 SE1-011	Taxotere (docetaxel)	Aventis Pharms	12/23/1999	For the treatment of locally advanced or metastatic non-small cell lung cancer
N21007	Agenerase (amprenavir)	Capsules Glaxo Wellcome	4/15/1999	Treatment of HIV
N21039	Agenerase (amprenavir)	Oral Solution Glaxo Wellcome	4/15/1999	Treatment of HIV
N20978	Ziagen (abacavir sulfate)	Oral Solution Glaxo Wellcome	12/17/1998	Treatment of HIV
N20977	Ziagen (abacavir sulfate)	Tablets Glaxo Wellcome	12/17/1998	Treatment of HIV
N20972	Sustiva (efavirenz)	DuPont Pharms	9/17/1998	Treatment of HIV

Fast Track Designated Products Approved since 1998

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

NDA #	Proprietary Name (Established or Proper Name)	Applicant	Approval Date	Use
N22299	nevirapine 50mg Tablets	Aurobindo	2/24/2010	Treatment of HIV
N22420	efavirenz 200mg Tablets	Strides Arcolab	2/12/2010	Treatment of HIV
N22464	lamivudine 150mg; nevirapine 200mg; zidovudine 300mg Fixed-Dose Tablets	Strides Arcolab	12/22/2009	Treatment of HIV
N22461	efavirenz 50mg Tablets & efavirenz 100mg Tablets & efavirenz 200mg Tablets	Matrix	11/24/2009	Treatment of HIV
N22142	efavirenz 600mg; lamivudine 300mg; tenofovir disoproxil 300mg Fixed-Dose Tablets	Matrix	9/3/2009	Treatment of HIV
N22294	zidovudine 60mg Tablets	Aurobindo	7/23/2009	Treatment of HIV
N22296	lamivudine 30mg; zidovudine 60mg Fixed-Dose Tablets	Aurobindo	7/23/2009	Treatment of HIV
N22295	abacavir sulfate 60mg; lamivudine 30mg Fixed-Dose Tablets	Aurobindo	12/19/2008	Treatment of HIV
N22297	efavirenz 100mg Tablets	Aurobindo	12/12/2008	Treatment of HIV
N22061	lamivudine 150mg; nevirapine 200mg; zidovudine 300mg Fixed-Dose Tablets	Matrix	10/21/2008	Treatment of HIV
N22141	lamivudine 300mg; tenofovir disoproxil 300mg Fixed-Dose Tablets	Matrix	9/12/2008	Treatment of HIV
N22293	abacavir sulfate 60mg Tablets	Aurobindo	9/12/2008	Treatment of HIV
N22167	lamivudine 60mg; stavudine 12mg Fixed-Dose Tablets & lamivudine 30mg; stavudine 6mg Fixed-Dose Tablets	Cipla	6/19/2008	Treatment of HIV
N21837	lamivudine 150mg; stavudine 40mg; nevirapine 200 mg Fixed-Dose Tablets	Strides Arcolab	3/20/2008	Treatment of HIV
N22177	lamivudine 150mg; stavudine 30mg; nevirapine 200mg Fixed-Dose Tablets	Strides Arcolab	3/20/2008	Treatment of HIV
N22085	lamivudine 150mg; stavudine 40mg Fixed-Dose Tablets & lamivudine 150mg; stavudine 30mg Fixed-Dose Tablets	Matrix	11/2/2007	Treatment of HIV
N21972	lamivudine 30mg; stavudine 6mg; nevirapine 50 mg Dispersible Tablets & lamivudine 30mg; stavudine 6mg; nevirapine 50 mg Dispersible Tablets	Cipla	8/13/2007	Treatment of HIV

N22096	lamivudine 150mg; zidovudine 300mg Fixed-Dose Tablets Co- Packaged with efavirenz 600mg Tablets	Strides Arcolab	6/1/2007	Treatment of HIV
N22097	lamivudine 150mg; stavudine 40mg Fixed-Dose Tablets Co- Packaged with efavirenz 600mg Tablets	Strides Arcolab	6/1/2007	Treatment of HIV
N21854	stavudine 40mg; lamivudine 150mg tablets Co-Packaged with nevirapine 200mg tablets	Strides Arcolab	3/13/2007	Treatment of HIV
N21838	stavudine 40mg; lamivudine 150mg Fixed-Dose Combination Tablets	Strides Arcolab	3/13/2007	Treatment of HIV
N21988	lamivudine 150mg; zidovudine 300mg Fixed-Dose Tablets Co- Packaged with nevirapine 200mg	Strides Arcolab	3/2/2007	Treatment of HIV
N21971	Duovir-N (lamivudine 150mg; zidovudine 300mg; nevirapine 200mg tablets)	Cipla	1/31/2007	Treatment of HIV
N21974	lamivudine 150mg; stavudine 30mg & 40mg fixed dose combination tablets	Cipla	1/19/2007	Treatment of HIV
N21969	lamivudine 150mg; stavudine 30mg & 40mg; nevirapine 200mg fixed dose combination tablets	Cipla	11/17/2006	Treatment of HIV
N22018	lamivudine 150mg; zidovudine 300mg Fixed-Dose Tablets	Pharmacare	8/23/2006	Treatment of HIV
N21944	lamivudine 150mg; zidovudine 300mg Fixed-Dose Tablets Co- Packaged with abacavir 300mg tablets	Aurobindo	7/26/2006	Treatment of HIV
N21939	lamivudine 150mg; zidovudine 300 mg; nevirapine 200mg Fixed-Dose Tablets	Aurobindo	6/30/2006	Treatment of HIV
N21943	lamivudine 150mg zidovudine 300mg Fixed-Dose Tablets copackaged with efavirenz 600mg tablets	Aurobindo	3/6/2006	Treatment of HIV
N21841	lamivudine 150mg; zidovudine 300mg tablets co-packaged with nevirapine 200mg tablets	Aspen Pharmacare	1/24/2005	Treatment of HIV

N/A = Not Applicable