

Fast Track Approvals for Drugs, 1998-2007, including PEPFAR

NDA or BLA #	Proprietary Name (Established or Proper Name)	Applicant	Approval Date	Use
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
BL103772 5145	Remicade (infliximab)	Centocor	10/13/2006	Maintenance of clinical remission and mucosal healing in the treatment of patients with moderately to severely active ulcerative colitis (UC), who have had an inadequate response to conventional therapy
N21991	Zolinza (vorinostat)	Merck	10/6/2006	Treatment of cutaneous T-cell lymphoma
BL125147	Vectibix (panitumumab)	Amgen	9/27/2006	Treatment of metastatic carcinoma of the colon or rectum in patients who have failed standard, irinotecan- and/or oxaliplatin-containing, chemotherapy regimens.
BL125151	Elaprase (idursulfase)	Transkaryotic	7/24/2006	Enzyme replacement therapy for patients with Hunter syndrome (Mucopolysaccharidosis II, MPS II)
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
BL125141	Myozyme (alglucosidase alfa)	Genzyme	4/28/2006	Treatment of patients with a confirmed diagnosis of Pompe disease (GAA deficiency)
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
BL125118	Orencia (abatacept)	Bristol-Myers Squibb	11/23/2005	Treatment of moderately to severely active rheumatoid arthritis in adult patients who have had an inadequate response to one or more Disease Modifying Anti-Rheumatoid Drugs
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
BL103772 5113.0	Remicade (infliximab)	Centocor	9/15/2005	Treatment of moderately to severely active ulcerative colitis in patients who had an inadequate response to conventional therapy
BL125117	Naglazyme (galsulfase)	BioMarin	5/31/2005	Treatment of patients with Mucopolysaccharidosis type VI (MPS-VI)
N21737	Retisert (fluocinolone acetonide)	Bausch & Lomb	4/8/2005	Treatment of chronic non-infectious uveitis affecting the posterior segment of the eye
BL103964 5039.0	Pegasys (peginterferon alfa-2a)	Hoffmann-La Roche	2/25/2005	Alone or in combination with ribavirin (Copegus) for treatment of chronic hepatitis C in patients co-infected with HIV, who have clinically stable HIV disease
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	Clofar (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
BL125011 24.0	Bexxar (tositumomab and iodine I 131 tositumomab)	Corixa	12/22/2004	Expand the indication to include patients with relapsed or refractory, low-grade, follicular or transformed CD20 positive non-Hodgkin's lymphoma who have not received rituximab
N21756	Macugen (pegaptanib sodium)	Eyeteck Pharms	12/17/2004	Treatment of exudative (wet) age-related macular degeneration
BL125103	Kepivance (palifermin)	Amgen	12/15/2004	Decrease the incidence and duration of severe oral mucositis in patients with hematologic malignancies receiving myelotoxic therapy requiring hematopoietic stem cell support
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
BL125085	Avastin (bevacizumab)	Genentech	2/26/2004	For the first-line treatment of patients with metastatic carcinoma of the colon and rectum (in combination with intravenous 5-fluorouracil-based chemotherapy)
BL125084	Erbix (cetuximab)	ImClone Systems	2/12/2004	Treatment of EGFR-expressing, metastatic colorectal carcinoma in patients who are refractory to irinotecan-based chemotherapy (in combination with irinotecan); treatment of EGFR-expressing, metastatic colorectal carcinoma in patients who are intolerant to irinotecan-based chemotherapy (administered as a single agent)
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
BL125011	Bexxar (tositumomab and iodine I 131 tositumomab)	Corixa Corporation	6/27/2003	Treatment of patients with CD20 positive, follicular, non-Hodgkin's lymphoma, with and without transformation, whose disease is refractory to Rituximab and has relapsed following chemotherapy.
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
BL125058	Aidurazyme (laronidase)	Biomarin Pharm	4/30/2003	Treatment of patients with Hurler and Hurler-Scheie forms of Mucopolysacchar- idosis I (MPS I) and for patients with the Scheie form who have moderate to severe symptoms
BL103979	Fabrazyme (agalsidase beta)	Genzyme Corporation	4/24/2003	Use in patients with Fabry disease to reduce globo- triaoylyceramide (GL-3) deposition in capillary endothelium of the kidney and certain other cell types
N21106	Somavert (pegvisomant)	Pharmacia and Upjohn	3/25/2003	Treatment of acromegaly
N21481	Fuzeon (enfuvirtide)	Hoffmann-La Roche	3/13/2003	Treatment of HIV
BL103964 5000	Pegasys (peginterferon alfa-2a)	Hoffmann-La Roche	12/3/2002	PEGASYS, peginterferon alfa-2a, alone or in combination with COPEGUS, for the treatment of adults with chronic hepatitis C virus infection who have compensated liver disease and have not been previously treated with interferon alpha

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
BL125019	Zevalin (ibritumomab tiuxetan)	IDEC Pharms	2/19/2002	Treatment of patients with relapsed or refractory low-grade, follicular, or transformed B-cell non-Hodgkin's lymphoma: (not acc. app.) including patients with Rituximab (Rituxan) refractory follicular non-Hodgkin's lymphoma
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
BL103948	Campath (alemtuzumab)	ILEX Pharms	5/7/2001	Treatment of B-cell chronic lymphocytic leukemia (B-CLL) in patients who have been treated with alkylating agents and who have failed fludarabine therapy
N21227	Candidas (caspofungin acetate)	Merck	1/26/2001	Treatment of aspergillus infections for patients who are refractory to or intolerant of other therapies
BL103772 1007.0	Remicade (infliximab)	Centocor	12/29/2000	Expand the indication to include the inhibition of progression of structural damage in patients with rheumatoid arthritis who have had an inadequate response to methotrexate
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
BL103836 1001.0	Actimmune (interferon gamma-1b)	InterMune	2/10/2000	Delaying time to disease progression in patients with severe, malignant osteopetrosis
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
BL103795	Enbrel (etanercept)	Immunex	10/2/1998	Treatment of rheumatoid arthritis
BL103792	Herceptin (trastuzumab)	Genentech	9/25/1998	Treatment of metastatic breast cancer
N020972	Sustiva (efavirenz)	DuPont Pharms	9/17/1998	Treatment of HIV

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

NDA or BLA #	Proprietary Name (Established or Proper Name)	Applicant	Approval Date	Use
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 co-packaged 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

Chart includes Fast Track Approvals of Therapeutic Biologic Products which were transferred from CBER to CDER effective 10/1/2003.

* The expedited review and tentative approval of new drug applications by FDA for Fixed Dose Combinations and co-packaged antiretroviral medications is a component of the President's Emergency Plan for AIDS Relief (PEPFAR).

N/A = Not Applicable