

DRUGS USED IN THE TREATMENT OF HIV INFECTION (FDA-Approved)

The U.S. Food and Drug Administration oversees the drug approval process which is described in detail in the "Guide to Drug Development and Approval." The FDA chart below of approved AIDS drugs is current as of Summer, 2009. We recommend you check online periodically for updates at <http://www.fda.gov/oashi/aids/virals.html>.

While most antiretrovirals remain under patent protection in the U.S., the FDA has given "tentative" approval to several dozen generic AIDS drugs—most of them fixed-dose combination drugs. This enables PEPFAR, the President's Emergency Program for AIDS Relief, to purchase these drugs and distribute them outside of the U.S. When this plan was announced in 2004 by the Bush Administration the *New York Times* reported that "the quicker (approval) process is intended to encourage manufacturers to produce the fixed-dose combinations to ease delivery of drugs in remote areas in severely affected countries and to make their use safer."

The World Health Organization also operates a prequalification process for medications, including generic antiretrovirals. This is done in partnership with the FDA and other national regulatory agencies. The "Prequalification Programme" develops and maintains a list of drug products for HIV/AIDS, malaria, tuberculosis and for reproductive health which is primarily used by United Nations agencies—including UNAIDS and UNICEF—to guide their procurement decisions. The list is also used by many national governments and by the Global Fund to Fight AIDS, Tuberculosis and Malaria. The drug list can be found at <http://mednet3.who.int/prequal/>.

Brand Name	Generic Names	Manufacturer Name	Approval Date	Time to Approval
Multi-class Combination Products				
Atripla	efavirenz, emtricitabine and tenofovir disoproxil fumarate	Bristol-Myers Squibb and Gilead Sciences	12-Jul-06	2.5 months
Nucleoside Reverse Transcriptase Inhibitors (NRTIs)				
Combivir	lamivudine and zidovudine	GlaxoSmithKline	27-Sep-97	3.9 months
Emtriva	emtricitabine, FTC	Gilead Sciences	02-Jul-03	10 months
Epivir	lamivudine, 3TC	GlaxoSmithKline	17-Nov-95	4.4 months
Epzicom	abacavir and lamivudine	GlaxoSmithKline	02-Aug-04	10 months
Hivid	zalcitabine, dideoxycytidine, ddC	Hoffmann-La Roche	19-Jun-92	7.6 months
Retrovir	zidovudine, azidothymidine, AZT, ZDV	GlaxoSmithKline	19-Mar-87	3.5 months
Trizivir	abacavir, zidovudine, and lamivudine	GlaxoSmithKline	14-Nov-00	10.9 months
Truvada	tenofovir disoproxil fumarate and emtricitabine	Gilead Sciences, Inc.	02-Aug-04	5 months
Videx EC	enteric coated didanosine, ddl EC	Bristol Myers-Squibb	31-Oct-00	9 months
Videx	didanosine, dideoxyinosine, ddl	Bristol Myers-Squibb	09-Oct-91	6 months

Brand Name	Generic Names	Manufacturer Name	Approval Date	Time to Approval
Nucleoside Reverse Transcriptase Inhibitors (NRTIs) (continued)				
Viread	tenofovir disoproxil fumarate, TDF	Gilead	26-Oct-01	5.9 months
Zerit	stavudine, d4T	Bristol Myers-Squibb	24-Jun-94	5.9 months
Ziagen	abacavir sulfate, ABC	GlaxoSmithKline	17-Dec-98	5.8 months
Nonnucleoside Reverse Transcriptase Inhibitors (NNRTIs)				
Intelence	etravirine	Tibotec Therapeutics	18-Jan-08	6 months
Rescriptor	delavirdine, DLV	Pfizer	04-Apr-97	8.7 months
Sustiva	efavirenz, EFV	Bristol Myers-Squibb	17-Sep-98	3.2 months
Viramune	nevirapine, NVP	Boehringer Ingelheim	21-Jun-96	3.9 months
Protease Inhibitors (PIs)				
Agenerase	amprenavir, APV	GlaxoSmithKline	15-Apr-99	6 months
Aptivus	tipranavir, TPV	Boehringer Ingelheim	22-Jun-05	6 months
Crixivan	indinavir, IDV,	Merck & Co., Inc.	13-Mar-96	1.4 months
Fortovase	saquinavir (no longer marketed)	Hoffmann-La Roche	07-Nov-97	5.9 months
Invirase	saquinavir mesylate, SQV	Hoffmann-La Roche	06-Dec-95	3.2 months
Kaletra	lopinavir and ritonavir, LPV/RTV	Abbott Laboratories	15-Sep-00	3.5 months
Lexiva	fosamprenavir calcium, FOS-APV	GlaxoSmithKline	20-Oct-03	10 months
Norvir	ritonavir, RTV	Abbott Laboratories	01-Mar-96	2.3 months
Prezista	darunavir	Tibotec, Inc.	23-Jun-06	6 months
Reyataz	atazanavir sulfate, ATV	Bristol-Myers Squibb	20-Jun-03	6 months
Viracept	nelfinavir mesylate, NFV	Agouron Pharmaceuticals	14-Mar-97	2.6 months
Fusion Inhibitors				
Fuzeon	enfuvirtide, T-20	Hoffmann-La Roche & Trimeris	13-Mar-03	6 months
Entry Inhibitors - CCR5 co-receptor antagonist				
Selzentry	maraviroc	Pfizer	06-Aug-07	8 months
HIV integrase strand transfer inhibitors				
Isentress	raltegravir	Merck & Co., Inc.	12-Oct-07	6 months

ADDITIONAL RESOURCES

U.S. Food and Drug Administration. *Generic Drugs Used in the Treatment of HIV Infection*, <http://www.fda.gov/oashi/aids/viralsgeneric.html>

U.S. Food and Drug Administration. *Drugs Used to Treat Complications of HIV/AIDS*, http://www.fda.gov/oashi/aids/stat_app.html

U.S. Food and Drug Administration. *Drugs Used in the Treatment of Pediatric HIV Infection*, <http://www.fda.gov/oashi/aids/pedlbl.html>

World Health Organization. *WHO – Health Systems and Services: Prequalification Programme*, <http://mednet3.who.int/prequal/default.htm>

The Global Fund to Fight AIDS, Tuberculosis, and Malaria. *Lists of ARVs, TB and Malaria Products*, <http://www.theglobalfund.org/en/about/procurement/list/>

Pieperl, L. and S. Coffey. *Antiretroviral Drug Profiles*, <http://hivinsite.ucsf.edu/InSite?page=ar-drugs>

U.S. Department of Health and Human Services (DHHS). *AIDSinfo Drug Database*, <http://aidsinfo.nih.gov/drugs/>