

CDER Priority Drug and Biologic Approvals in Calendar Year 2008  
Updated through November 30, 2008

**Priority New Drug Application (NDA) Approvals:**

NDA Number	Proprietary Name	Established Name	Applicant	Chemical Type	Review Classification	Approval Date	Indication
N022187	Intelence	etravirine	Tibotec	1	P	18-Jan-08	Provides in combination with other antiretroviral agents for the the treatment of HIV-1 infection in treatment-experienced adult patients, who have evidence of viral replication and HIV-1 strains resistant to a non-nucleoside reverse transcriptase inhibitor (NNRTI) and other antiretroviral agents.
N022249	Treanda	bendamustine hydrochloride	Cephalon	1	P,O	20-Mar-08	Provides for the treatment of patients with chronic lymphocytic leukemia (CLL).
N021822	Aptivus	tipranavir	Boehringer Ingelheim	3	P	23-Jun-08	Provides for combination antiretroviral treatment of HIV-1 infected pediatric (age 2 to 18 years) patients who are treatment-experienced and infected with HIV-1 strains resistant to more than one protease inhibitor.
N022212	Durezol	difluprednate	Sirion	1	P	23-Jun-08	Provides for the treatment of inflammation and pain associated with ocular surgery.
N022292	Aptivus	tipranavir	Boehringer Ingelheim	3	P	23-Jun-08	Provides for combination antiretroviral treatment of HIV-1 infected pediatric (age 2 to 18 years) patients who are treatment-experienced and infected with HIV-1 strains resistant to more than one protease inhibitor.

N021894	Xenazine	tetrabenazine	Prestwick	1	P	15-Aug-08	Provides treatment for the chorea of Huntington's Disease.
N022290	Adre View	iokebenuane	GE Healthcare	1	P	19-Sep-08	Provides for the detection of primary or metastatic pheochromocytomas.
N022291	Promacta	eltrombopag olamine	GlaxoSmithKline	1	P	20-Nov-08	Provides for the treatment of short term idiopathic thrombocytopenic purpura (ITP)

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

NDA Number	Proprietary Name	Proper Name	Applicant	Chemical Type	Review Classification	Approval Date	Indication
NO21837	Stavudine;Lamivudine; Nevirapine	stavudine;lamivudine; nevirapine	Strides	4	P	20-Mar-08	Provides for the treatment of HIV-1 infection.
NO22177	Stavudine;Lamivudine; Nevirapine	stavudine;lamivudine; nevirapine	Strides	4	P	20-Mar-08	Provides for the treatment of HIV-1 infection
NO22167	Lamivudine;Stavudine	lamivudine;stavudine	Cipla Limited	3	P	19-Jun-08	Provides for the treatment of HIV-1 infection
NO22141	Tenofavir Disoproxyl Furmate/ Lamivudine	tenofavir disoproxyl furmate/ lamivudine	Matrix Labs	4	P	12-Sep-08	Provides for the treatment of HIV
NO22293	Abacavir Sulfate	abacavir sulfate	Aurobindo	3	P	12-Sep-08	Provides for the treatment of HIV-1 infection.

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 tenofavir disoproxyl 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.

**Priority Biologic License Application (BLA) Approvals:**

BLA Number	Proprietary Name	Proper Name	Applicant	Review Classification	Approval Date	Indication
125249	Arcalyst	rilonacept	Regeneron	P,O	27-Feb-08	Provides treatment for cryopyrin-associated periodic syndromes (CAPS).

NDA Chemical Type:

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

Review Classification:

- P - Priority Review - Significant improvement compared to marketed products, in the treatment, diagnosis, or prevention of a
- O - Orphan Designation - Pursuant to Section 526 of the Orphan Drug Act (Public Law 97-414 as amended).