



U.S. Food and Drug Administration
Center for Drug Evaluation and Research

NDA's Approved under Subpart H

Under Subpart H, approval may be based on a surrogate endpoint or on an effect on a clinical endpoint other than survival or irreversible morbidity ("Surrogate") [21 CFR 314.510], or a product may be approved with restrictions to assure safe use ("Restricted") [21 CFR 314.520]. (See Table below)

[21 CFR 314.510] Surrogate - Approval based on a surrogate endpoint or on an effect on a clinical endpoint other than survival or irreversible morbidity.

FDA may grant marketing approval for a new drug product on the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely, based on epidemiologic, therapeutic, pathophysiologic, or other evidence, to predict clinical benefit or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity. Approval under this section will be subject to the requirement that the applicant study the drug further, to verify and describe its clinical benefit, where there is uncertainty as to the relation of the surrogate endpoint to clinical benefit, or of the observed clinical benefit to ultimate outcome. Postmarketing studies would usually be studies already underway. When required to be conducted, such studies must also be adequate and well-controlled. The applicant shall carry out any such studies with due diligence.

[21 CFR 314.520] Restricted - Approval with restrictions to assure safe use.

(a) If FDA concludes that a drug product shown to be effective can be safely used only if distribution or use is restricted, FDA will require such postmarketing restrictions as are needed to assure safe use of the drug product, such as:

- (1) Distribution restricted to certain facilities or physicians with special training or experience; or
- (2) Distribution conditioned on the performance of specified medical procedures.
- (3) The limitations imposed will be commensurate with the specific safety concerns presented by the drug product.

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NDA #	Trade Name	Generic Name	Clock Date	Approval Date	AP Time	Approval Basis	Indication
20199	Hivid	Zalcitabine	31-Oct-91	19-Jun-92	7.6	S	Combination therapy with zidovudine in advanced HIV infection

50698	Biaxin	Clarithromycin (Suspension)	02-Nov-92	23-Dec-93	13.7	S	Treatment of disseminated mycobacterial infections due to Mycobacterium avium and Mycobacterium intracellulare
20412	Zerit	Stavudine	28-Dec-93	24-Jun-94	5.9	S	Treatment of adults with advanced HIV infection - alternative therapy
20212	Zinecard	Dexrazoxane	05-Aug-94	26-May-95	9.7 ^a	S	To reduce the incidence and severity of cardiomyopathy associated with doxorubicin administration in certain breast cancer patients
20498	Casodex	Bicalutamide	14-Sep-94	04-Oct-95	12.7	S	Use in combination therapy with a Luteinizing-Hormone Releasing Hormone (LHRH) analogue for the treatment of advanced prostate cancer
20564	Epivir	Lamivudine	07-Jul-95	17-Nov-95	4.4	S	Treatment of HIV infection in selected patients
20596	Epivir	Lamivudine	07-Jul-95	17-Nov-95	4.4	S	Treatment of HIV infection in selected patients
50718	Doxil	Doxorubicin Hydrochloride (Liposomal formulation)	02-Sep-94	17-Nov-95	14.3	S	Treatment of AIDS-related Kaposi's sarcoma in patients with disease that has progressed on prior combination chemotherapy or in patients who are intolerant to such therapy

20628	Invirase	Saquinavir Mesylate	31-Aug-95	06-Dec-95	3.2	S	Treatment of advanced HIV infection in selected patients in combination with nucleoside analogues
20659	Norvir	Ritonavir	21-Dec-95	01-Mar-96	2.3	S	In combination with nucleoside analogues or as monotherapy for the treatment of HIV infection
20680	Norvir	Ritonavir	21-Dec-95	01-Mar-96	2.3	S	In combination with nucleoside analogues or as monotherapy for the treatment of HIV infection
20685	Crixivan	Indinavir Sulfate	31-Jan-96	13-Mar-96	1.4	S	Treatment of HIV infection in adults
20449	Taxotere	Docetaxel	27-Jul-94	14-May-96	21.6	S	Treatment of patients with locally advanced or metastatic breast cancer who have progressed or relapsed during anthracycline based therapy
20571	Camptosar	Irinotecan Hydrochloride	28-Dec-95	14-Jun-96	5.6	S	Treatment of refractory colorectal cancer
20636	Viramune	Nevirapine	23-Feb-96	21-Jun-96	3.9	S	Combination with nucleoside analogues for the treatment of HIV-1 infected adults who have experienced clinical and/or immunologic deterioration
20604	Serostim	Somatropin	11-Sep-95	23-Aug-96	11.4	S	Treatment of AIDS wasting associated with catabolism loss or cachexia

19815	ProAmatine	Midodrine Hydrochloride	25-Sep-95	06-Sep-96	11.4 _b	S	Treatment of symptomatic orthostatic hypotension
20778	Viracept	Nelfinavir Mesylate	26-Dec-96	14-Mar-97	2.6	S	Treatment of HIV infection when therapy is warranted
20779	Viracept	Nelfinavir Mesylate	26-Dec-96	14-Mar-97	2.6	S	Treatment of HIV infection when therapy is warranted
20705	Rescriptor	Delavirdine Mesylate	15-Jul-96	04-Apr-97	8.7	S	Treatment of HIV infection in combination with appropriate antiretroviral agents when therapy is warranted
20896	Xeloda	Capecitabine	31-Oct-97	30-Apr-98	6	S	Treatment of patients with metastatic breast cancer resistant to both paclitaxel and an anthracycline-containing chemotherapy regimen or resistant to paclitaxel and for whom further anthracycline therapy may be contraindicated
19832	Sulfamylon	Mafenide Acetate	31-Mar-97	05-Jun-98	14.2 ^c	S	Indicated for use as an adjunctive topical antimicrobial agent to control bacterial infection when used under moist dressings over meshed autografts on excised burn wounds
21024	Priftin	Rifapentine	22-Dec-97	22-Jun-98	6	S	Priftin is indicated for the treatment of pulmonary tuberculosis (TB)

20785	Thalomid	Thalidomide	20-Dec-96	16-Jul-98	18.8	R	Thalomid is indicated for the acute treatment of the cutaneous manifestations of moderate to severe erythema nodosum leprosum (ENL) and as maintenance therapy for prevention and suppression of the cutaneous manifestations of ENL recurrences
20933	Viramune	Nevirapine	20-Apr-98	11-Sep-98	4.7	S	Provides for an oral suspension, which is indicated for use in combination therapy with other antiretroviral agents for the treatment of HIV-1 infection
20972	Sustiva	Efavirenz	11-Jun-98	17-Sep-98	3.2	S	Provides for the use of efavirenz in combination with other antiretroviral agents for the treatment of HIV-1 infection
20747	Actiq	Fentanyl Citrate	13-Nov-96	04-Nov-98	23.7	R	For the management of breakthrough cancer pain in patients with malignancies who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain

20977	Ziagen	Abacavir Sulfate	24-Jun-98	17-Dec-98	5.8	S	Provides for the use of Ziagen (abacavir sulfate), in combination with other antiretroviral agents, for the treatment of HIV-1 infection
20978	Ziagen	Abacavir Sulfate	24-Jun-98	17-Dec-98	5.8	S	Provides for the use of Ziagen (abacavir sulfate), in combination with other antiretroviral agents, for the treatment of HIV-1 infection
21041	DepoCyt	Cytarabine Liposomal Injection	05-Oct-98	01-Apr-99	5.9	S	Depocyt is indicated for the intrathecal treatment of lymphomatous meningitis
21029	Temodar	Temozolomide (Capsules)	13-Aug-98	11-Aug-99	11.9	S	Treatment of adult patients with refractory anaplastic astrocytoma, i.e., patients at first relapse who have experienced disease progression on a drug regimen containing a nitrosourea and procarbazine
21007	Agenerase	Amprenavir	16-Oct-98	15-Apr-99	6	S	Provides for the use of Agenerase (amprenavir), in combination with other antiretroviral agents, for the treatment of HIV-1 infection
21039	Agenerase	Amprenavir	08-Dec-98	15-Apr-99	4.2	S	Provides for the use of Agenerase (amprenavir), in combination with other antiretroviral agents, for the treatment of HIV-1 infection

50747	Synercid	Quinupristin/Dalfopristin I.V.	05-Sep-97	21-Sep-99	7.8 ^d	S	Treatment of vancomycin resistant <i>Enterococcus faecium</i>
21174	Mylotarg	Gemtuzumab Ozogamicin	29-Oct-99	17-May-00	6.6	S	Treatment of patients with CD33 positive acute myeloid leukemia in first relapse who are 60 years of age or older and who are not considered candidates for cytotoxic chemotherapy
21226	Kaletra	Lopinavir/Ritonavir	01-Jun-00	15-Sep-00	3.5	S	Kaletra in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients age six months and older
21251	Kaletra	Lopinavir/Ritonavir	01-Jun-00	15-Sep-00	3.5	S	Kaletra in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients age six months and older
20687	Mifeprex	Mifepristone	18-Mar-96	28-Sep-00	18.0 ^e	R	For medical termination of intrauterine pregnancy through 49 days' pregnancy
21205	Trizivir	Abacavir Sulfate, Lamivudine, and Zidovudine	17-Dec-99	14-Nov-00	10.9	S	Provides for the use of Trizivir either alone or in combination with other antiretroviral agents for the treatment of HIV-1 infection

21335	Gleevec	Imatinib Mesylate	27-Feb-01	10-May-01	2.4	S	Provides for the use of Gleevec (imatinib mesylate) 50 and 100 mg capsules for the treatment of patients with chronic myeloid leukemia (CML) in blast crisis, accelerated phase, or in chronic phase after failure of interferon-alpha therapy
21356	Viread	Tenofovir Disoproxil Fumarate	01-May-01	26-Oct-01	5.9	S	In combination with other antiretroviral agents for the treatment of HIV-1 infection in adults
21290	Tracleer	Bosentan	17-Nov-00	20-Nov-01	12.1	R	Treatment of pulmonary arterial hypertension
21272	Remodulin	Treprostnil Sodium	16-Oct-00	21-May-02	19.1	S	Provides for the use of Remodulin (treprostnil sodium) Injection 1.0, 2.5, 5.0, and 10.0 mg/ml for the treatment of pulmonary arterial hypertension (PAH)

^a -- Approval time based on the receipt of significant new clinical data on 8/4/94 supporting a new indication. The original receipt date of this application was 2/10/92.

^b -- Significant new clinical data needed for approval was received on 9/25/95; before this only partial clinical data had been received. This date was used to calculate total approval time. The original receipt date was (28-Apr-88).

^c -- Significant new clinical data supporting a new indication were received on 31-Mar-97. This date was used to calculate the total approval time. The original receipt date was 19-Feb-88.

^d -- The total approval time was adjusted for N050747 because of a negative plant inspection. The time period until an acceptable inspection was received (05-Mar-98 to 26-Jul-99) was excluded from this time.

^e -- The total approval time for N020687, Mifeprex was adjusted. The time period from 9-18-96 to 8-19-99 was excluded because the sponsor had to find a new manufacturer, the final study report for the US Clinical trial was completed and submitted late in the review, and stability issues had to be addressed before the sponsor could resubmit the application for review. The time period from 2-18-00 to 3-31-00 was excluded while the sponsor prepared for a facilities reinspection.

S - Surrogate - Approval based on a surrogate endpoint or on an effect on a clinical endpoint other than survival or irreversible morbidity as recorded in 21 CFR 314.510 (Subpart H).

R - Restricted - Approval with restrictions to ensure safe use as recorded in 21 CFR 314.520 (Subpart H).

Type 6 NDAs follow the same performance rules as efficacy supplements and are included with supplement approvals.

This list is updated quarterly. Updated through 06/30/02.

Top of Page

FDA/Center for Drug Evaluation and Research
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