

New Drug and Biological Approvals of 2008

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The following is a summary of the significant new drug and biological agent approvals by the Food and Drug administration in 2008. For further information on these agents, please call the Drug Information Center at 460-6531.

Generic	Brand	Manufacturer	Form	Class/ Indication(s)	Usual Dose	Approval Category
Alvimopan	Entereg®	GlaxoSmithKline/ Adolor	Capsule	Peripherally acting μ - opioid antagonist for prevention of post-op ileus after bowel resection	12 mg 0.5-5 h before surgery followed by 12 mg twice daily for max of 15 doses	Standard
Antihemophilic factor	Xyntha™	Wyeth	Intravenous infusion	Recombinant glycoprotein to control hemophiliacs	Not to exceed 10 Bethesda Units/ml to increase the circulating antihemophilic factor to 20-40% of normal every 12-24 h	Biological
Bendamustine	Treanda®	Cephalon	Intravenous infusion	Alkylating agent for chronic lymphoid leukemia & Indolent B- cell non-Hodgkin's lymphoma	100-120 mg/m ² IV over 1 h on days 1 & 2; Repeat every 3-4 wks for max of 6-8 cycles	Standard
C1 Inhibitor (human)	Cinryze™	Lev Pharm.	Intravenous infusion	C1 esterase inhibitor that regulates the complement / fibrinolytic pathways for prevention of hereditary angioedema attacks	1000 units over 10 min every 3-4 days	Biological
Certolizumab	Cimzia™	UCB	Subcutaneous injection	Tumor necrosis factor inhibitor for resistant Crohn's disease	Initial: 400 mg on wks 1,2,4; Maintenance: 400 mg 1x/month	Biological
Clevidipine	Cleviprex™	Medicines Co.	Intravenous injection	Calcium channel blocker for hypertension	Initial: 1-2 mg/h (Max 16 mg/h); maintenance 4-6 mg/h (max 32 mg/h)	Standard
Degarelix	--	Ferring	Subcutaneous injection	GnRH receptor antagonist for advanced prostate cancer	Initial: 120 mg x 2 injections; maint: 80 mg given 1x/month	Standard
Desvenlafaxine	Pristiq®	Wyeth	Tablet	Serotonin and norepinephrine reuptake inhibitor for depression	50 mg daily	Standard
Difluprednate	Durezol™	Sirion	Ophthalmic emulsion	Ophthalmic glucocorticoid for inflammation/pain post surgery	1 drop 4x/day x 2 wks; Decrease to 2x/day x 1 wk	Priority

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Diphtheria and tetanus toxoids, acellular pertussis, inactivated poliovirus	Kinrex™	GlaxoSmithKline	Intramuscular injection	Combination vaccine for use in 4-6 year old children	0.5 ml between 4-6 years of age	Biological
Diphtheria and tetanus toxoids, acellular pertussis, inactivated poliovirus, haemophilus b	Pentacel®	Sanofi Pasteur	Intramuscular injection	Combination vaccine for use in children (6 weeks – 4 years of age)	0.5 ml at 2, 4, 6, and 18 months of age	Biological
Eltrombopag	Promacta®	GlaxoSmithKline	Tablet	Thrombopoietin receptor agonist for idiopathic thrombocytopenic purpura	50 mg daily	Priority
Etravirine	Intelence™	Tibotec	Tablet	Non-nucleoside reverse transcriptase inhibitor for advanced HIV-1	200 mg twice daily	Priority
Factor VIIa	NovoSeven®RT	Novo Nordisk	Intravenous injection	Vitamin K dependent glycoprotein which promotes hemostasis	15-30 mcg/kg over 2-5 min every 4-6 hr	Biological
Fesoterodine	Toviaz™	Pfizer	Tablet	Antimuscarinic for treatment of overactive bladder	4-8 mg daily	Standard
Fospropofol	Lusedra™	Eisai	Intravenous injection	Sedative hypnotic to induce anesthesia; prodrug of propofol	6.5 mg/kg IV bolus	Standard
Gadofosveset	Vasovist®	Epix Pharm.	Intravenous injection	Contrast imaging agent for use with magnetic resonance angiography	0.01-0.05 mmol/kg	Standard
Gadoxetate	Eovist®	Bayer Healthcare	Intravenous injection	Gadolinium based contrast agent for MRI of the liver	0.025 mmol/kg	Standard
Iobenguane I 123	AdreView™	GE Healthcare	Intravenous injection	Diagnostic radiopharmaceutical for detection of neural crest derived tumors	10 mCi IV over 1-2 min	Priority
Lacosamide	Vimpat®	UCB	Tablet	Adjunctive anticonvulsant for partial seizures	50 mg twice daily; increase weekly up to 200-400 mg daily	Standard
Methylnaltrexone	Relistor™	Wyeth	Subcutaneous injection	Peripherally acting μ antagonist to alleviate opioid induced constipation	0.15 mg/kg every other day	Standard
Plerixafor	Mozobil™	Genzyme	Subcutaneous injection	Hematopoietic stem cell mobilizer used prior to harvesting of stem cells	0.24 mg/kg 11 h prior to apheresis for up to 4 days	Priority
Regadenoson	Lexiscan™	Astellas	Intravenous injection	Adenosine A2a receptor agonist for stress test	0.4 mg over 10 seconds	Standard
Rilonacept	Arcalyst™	Regeneron	Subcutaneous injection	Decoy interleukin-1 receptor to decrease inflammation in cryopyrin associated periodic syndrome	Loading: 160 mg at 2 sites; Maint: 160 mg once weekly	Biological

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Romiplostim	Nplate™	Amgen	Subcutaneous injection	Thrombopoietin receptor agonist in treatment of idiopathic thrombocytopenic purpura	Initial: 1 mcg/kg once weekly; Adjust to platelet count of 50 x 10 ⁹ /L; max weekly dose: 10 mcg/kg	
Rotavirus vaccine, live	Rotarix®	GlaxoSmithKline	Oral	Vaccine to prevent rotavirus gastroenteritis in children	1 ml orally at 2-4 months of age; next dose by 8 months of age	Biological
Rufinamide	Banzel™	Eisai	Tablet	Antiepileptic for Lennox-Gastaut syndrome	Initial: 200-400 mg given twice daily; increase up to 1600 mg given twice daily	Standard
Sildenafil	Rapaflo™	Watson	Capsule	Alpha-1 adrenergic blocker for benign prostatic hypertrophy	8 mg daily	Standard
Tapentadol	--	J&J	Tablet	Opioid for moderate to severe pain	50-100 mg every 4-6 h	Standard
Tetrabenazine	Xenazine®	Ovation	Tablet	Monoamine depletor for treatment of involuntary movements in Huntington's disease	Initial: 12.5 mg daily; max 100 mg daily	Priority
Thrombin , topical	Recothrom®	ZymoGenetics	Topical	Recombinant formulation to control minor bleeding	Direct application of 1000 international unit/ml solution to affected site	Biological

Recommendations for Disposal of Unused Medications

A public-private partnership between the U.S. Fish and Wildlife Service, the American Pharmacists Association, and the Pharmaceutical Research and Manufacturers of America SMARxT Disposal, has been launched to raise public awareness regarding safe and environmentally responsible disposal of unused medications. The following recommendations are from the SMARxT Disposal website (<http://www.smarxtdisposal.net>).

Follow your medication prescriber's instructions and use all medications as instructed. If you do not use all of your prescribed or over-the-counter medication, you can take a few small steps to make a huge impact in safeguarding lives and protecting the environment by disposing of unused medicines properly:

- DO NOT FLUSH unused medications and DO NOT POUR them down a sink or drain*
- Be Proactive and Dispose of Unused Medication In Household Trash. When discarding unused medications, ensure you protect children and pets from potentially negative effects:
 - a. Pour medication into a sealable plastic bag. If medication is a solid (pill, liquid capsule, etc.), crush it or add water to dissolve it.
 - b. Add kitty litter, sawdust, coffee grounds (or any material that mixes with the medication and makes it less appealing for pets and children to eat) to the plastic bag.
 - c. Seal the plastic bag and put it in the trash.
 - d. Remove and destroy ALL identifying personal information (prescription label) from all medication containers before recycling them or throwing them away.

*The FDA advises that the following drugs be flushed down the toilet instead of thrown in the trash:

Actiq® (oral transmucosal fentanyl citrate)	Tequin® tablets (gatifloxacin)
Daytrana® transdermal patch (methylphenidate)	Zerit® oral solution (stavudine)
Duragesic® transdermal system (fentanyl)	Meperidine HCl tablets
OxyContin® tablets (oxycodone)	Percocet® tablets (oxycodone and acetaminophen)
Avinza® capsules (morphine sulfate)	Xyrem® oral solution (sodium oxybate)
Baraclude® tablets (entecavir)	Fentora® buccal tablet (fentanyl)
Reyataz® capsules (atazanavir sulfate)	