

# Major New Drugs of 2008

## Part 1

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### **Learning Objectives:**

#### **Pharmacists:**

After completing this lesson, for each new drug described the pharmacist should be able to:

1. List the brand and generic name, and manufacturer/distributor
2. Explain the agent's major therapeutic use(s)
3. Outline the drug's mechanism of action
4. Describe the pharmacokinetic profile and common drug-interactions
5. Discuss adverse effects and contraindications
6. Describe the dosage schedule, route of administration, strengths, and any storage issues
7. Outline monitoring parameters

#### **Pharmacy Technicians:**

After completing this lesson, for each new drug described the pharmacy technician should be able to:

1. List the brand and generic name, and manufacturer/distributor
2. Explain the agent's major therapeutic use(s)
3. Describe the dosage schedule, route of administration, strengths, and any storage issues
4. Outline monitoring parameters

In 2008, the Food and Drug Administration's (FDA) approval of new drugs was greater than the rate of approval the prior year and included more specialty/biologic medicines. The FDA approved 34 new molecular entities (NMEs) and biologic license applications (BLAs) for new entities, vaccines, imaging agents, and wound care. This CE program will provide pharmacists and pharmacy technicians with knowledge on the majority of new molecular entities approved by the FDA in 2008. Some diagnostic, anesthesia, and wound care agents will not be discussed but will be included in the summary listing.

### **Banzel (Rufinamide, Eisai)**

Banzel is a triazole derivative that modulates sodium channel activity for adjunctive treatment of seizures associated with Lennox-Gastaut syndrome in children 4 years of age and older and adults. Lennox-Gastaut syndrome is a difficult-to-treat form of childhood-onset epilepsy that most often appears between the second and sixth year of life, and is characterized by frequent seizures and different seizure types; it is often accompanied by mental retardation and behavior problems.

Banzel is well absorbed after oral administration. The absorption rate is relatively slow, decreasing with dose increases. Elimination of Banzel is in the urine, with the primary metabolite resulting from enzymatic hydrolysis of the carboxamide moiety to form the carboxylic acid. This metabolic route is not cytochrome P450 dependent. The drug's half-life is approximately 6 to 10 hours.

Banzel shows little or no inhibition of most cytochrome P450 enzymes at clinically relevant concentrations, but shows weak inhibition of CYP 2E1. Drugs that are substrates of CYP 2E1 (e.g. chlorzoxazone) may have increased plasma levels, but this has not been studied. Based on *in vivo* drug interaction studies with triazolam and oral contraceptives, Banzel is a weak inducer of the CYP 3A4 enzyme and can decrease exposure of drugs that are substrates of CYP 3A4.

Adverse events associated with Banzel include CNS-related problems such as somnolence or fatigue, coordination abnormalities, dizziness, gait disturbances, and ataxia. In addition, headache and nausea were experienced by participants during clinical trials. Multi-organ hypersensitivity syndrome has been reported mostly in the pediatric population, usually within the first four weeks of starting therapy. All patients who develop a rash while taking Banzel must be closely supervised.

The drug is contraindicated in patients with Familial Short QT syndrome. Caution should be used when administering Banzel with other drugs that shorten the QT interval.

In children, treatment is initiated at a daily dose of approximately 10 mg/kg/day administered in two equally divided doses. The dose should be increased by approximately 10 mg/kg increments every other day to a target dose of 45 mg/kg/day or 3200 mg/day, whichever is less, administered in two equally divided doses. In adults, treatment should be initiated at a daily dose of 400 to 800 mg/day administered in two equally divided doses. The dose should be increased by 400 to 800 mg/day every 2 days until a maximum daily dose of 3200 mg/day, administered in two equally divided doses is reached. The drug should be given with food.

Banzel is supplied as 200 mg (bottles of 30) and 400 mg tablets (bottles of 120) scored on both sides. The tablets can be

cut in half for dosing flexibility and may be given whole, as half tablets or crushed. It is stored at 25°C (77°F) with excursions permitted to 15° – 30°C (59°F – 86°F).

Antiepileptic drugs (AEDs) increase the risk of suicidal thoughts or behavior in patients taking these drugs. Patients should be monitored for the emergence or worsening of depression, suicidal thoughts or behavior, or any unusual changes in mood or behavior.

### **Cleviprex (Clevidipine butyrate IV, The Medicines Company)**

Cleviprex is an IV calcium channel blocker used to treat hypertension when the use of oral therapy is not feasible or not desirable.

The drug's onset of action occurs 2 to 4 minutes after infusion and lasts 5 to 15 minutes. Cleviprex is highly protein bound. It is metabolized to inactive carboxylic acid metabolite and formaldehyde through rapid hydrolysis by blood esterases. It is primarily excreted in the urine.

Cleviprex may increase the effect of magnesium salts, neuromuscular blocking agents, tituximab, and tacrolimus. It may decrease the effect of quinidine.

Adverse events most commonly associated with Cleviprex include atrial fibrillation, fever, insomnia, and nausea. Cleviprex should not be used in individuals with known hypersensitivity, impaired lipid metabolism, and severe aortic stenosis.

Cleviprex is given by IV infusion at a rate of 1 to 2 mg per hour, with the initial dose doubled every 90-seconds until the target blood pressure is reached. It is available in 50 ml and 100 ml vials with 0.5mg/ml of Cleviprex. The drug must be refrigerated with unopened vials stable for two months at room temperature and four hours once opened.

Patients who are given prolonged infusions of the drug and not transitioned to another therapy should be monitored for at least eight hours after the infusion is stopped.

### **Degarelix (Degarelix, Ferring)**

Degarelix is a new injectable gonadotropin-releasing hormone (GnRH) receptor antagonist, indicated for patients with hormonally-sensitive advanced prostate cancer. Prostate cancer grows in the presence of testosterone, therefore suppression of testosterone is a treatment goal for advanced prostate cancer. Degarelix has been shown to lower testosterone levels in clinical trials.

The drug's trade name will be created once the product is commercialized, according to Ferring.

The most common adverse reactions included injection site reactions (pain, erythema, swelling or induration), hot flushes, increased weight, fatigue, and increases in serum levels of transaminases and gamma-glutamyltransferase (GGT). The majority were mild to moderate. Degarelix is contraindicated in patients with known hypersensitivity to degarelix or to any of the product components. Degarelix is not indicated in women or pediatric patients.

Long-term androgen deprivation therapy prolongs the QT interval. As such, clinicians should consider whether the benefits of androgen deprivation therapy outweigh the potential risks in patients with congenital long QT syndrome, electrolyte abnormalities, or congestive heart failure and in

patients taking Class IA (e.g. quinidine, procainamide) or Class III (e.g. amiodarone, sotalol) antiarrhythmic medications.

In clinical trials, Degarelix was given by subcutaneous injection at a dosage 240 mg for one month with monthly maintenance doses of 80 mg.

### **Durezol (Difluprednate, Sirion)**

Durezol is a topical, corticosteroid ophthalmic emulsion used to treat pain and inflammation following ocular surgery. The drug inhibits the inflammatory response and induces lipocortin production which modulates prostaglandin and leukotriene activity.

Durezol has limited systemic absorption. Durezol was well tolerated with few treatment related adverse events in clinical studies. The most common side effect seen is a rise in intraocular pressure in 3% of the treatment subjects. Other ocular adverse reactions occurring in 5% to 15% of subjects in clinical studies with Durezol included corneal edema, ciliary and conjunctival hyperemia, eye pain, photophobia, posterior capsule opacification, anterior chamber cells, anterior chamber flare, conjunctival edema, and blepharitis.

Durezol, as with other ophthalmic corticosteroids, is contraindicated in most active viral diseases of the cornea and conjunctiva including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella, and also in mycobacterial infection of the eye and fungal diseases of ocular structures.

Durezol's dosage regimen is one drop into the conjunctival sac of the affected eye(s) four times daily beginning 24 hours after surgery and continuing throughout the first two weeks of the postoperative period, followed by two times daily for a week and then a tapered based on the response. Durezol is provided in 5.0 mL bottles in a 0.5% concentration of difluprednate, stored at controlled room temperature.

Patients should be advised not to allow the dropper tip to touch any surface to avoid contamination. If pain develops or if redness, itching, or inflammation becomes aggravated, advise the patient to consult their physician. Patients should be advised not to wear contact lenses when using Durezol.

### **Entereg (Alvimopan, Adolor/GSK)**

Entereg is a peripherally acting mu-opioid receptor antagonist used to manage post-operative ileus by accelerating recovery time after partial small or large bowel resection surgery. Opioid analgesics are often used post surgery but are known to inhibit GI motility. Entereg antagonizes the opioid effects on GI motility.

The drug is metabolized to amide hydrolysis compound by the gut and is 1% to 19% bioavailable with a half-life of 10 to 18 hours. It is excreted in the urine. There are no known drug interactions.

Adverse events reported with Entereg include hypokalemia, dyspepsia, anemia, back pain, and urinary retention. The drug is contraindicated in patients who have taken opioids for more than seven days before surgery.

Entereg's dosage regimen is 12 mg given 30 minutes to five hours before surgery, followed by 12 mg twice daily for a maximum of seven days. Patients should not receive more than 15 doses of the drug.

Entereg is supplied as a 12-mg oral capsule for hospital use only and is stored at controlled room temperature of 77° F.

### **Intence (Etravirine, Tibotec)**

Intence is a non-nucleoside reverse transcriptase inhibitor (NNRTI) used in combination with other antiretroviral drugs for treating HIV-1 in treatment-experienced adults who have evidence of viral replication and HIV-1 strains resistant to other NNRTIs and antiretrovirals.

Intence is metabolized in the liver, primarily by CYP3A4, 2C9, and 2C19 pathways, and as a result has the potential to interact with numerous other medications. It should not be given with atazanavir, carbamazepine, fosamprenavir, phenobarbital, phenytoin, ranolazine, reverse transcriptase inhibitors, rifamycin, ritonavir, and tipranavir. Its half-life is approximately 41 hours, it is highly protein bound, and its absorption is increased if taken with food.

The most common adverse reactions associated with Intence are rash and nausea. There are no contraindications listed on the manufacturer's labeling.

Intence is provided as a 100 mg tablet in 120-tablet bottles and should be stored at controlled room temperature. The recommended dosage regimen is 200 mg twice daily after meals.

Patient should be monitored for rash and advised of potential drug interactions.

### **Mozobil (Plerixafor, Genzyme)**

Mozobil is a CXCR4 chemokine antagonist used in combination with granulocyte-colony stimulating factor (G-CSF) to mobilize hematopoietic stem cells from bone marrow in patients undergoing bone marrow transplants to treat non-Hodgkin's lymphoma and multiple myeloma.

Based on *in vitro* data, plerixafor is not a substrate, inhibitor or inducer of human cytochrome P450 isozymes. Plerixafor is not likely to be implicated in *in vivo* drug-drug interactions involving cytochrome P450s. Peak plasma concentrations of the drug occur 30 to 60 minutes after the subcutaneous dose. Following a 0.24 mg/kg dose in healthy volunteers with normal renal function, approximately 70% of the dose was excreted in the urine as the parent drug during the first 24 hours following administration. The drug's half-life ranges between 3 and 5 hours.

The most common adverse reactions associated with Mozobil are diarrhea, nausea, fatigue, injection site reactions, headache, arthralgia, dizziness, and vomiting.

Mozobil treatment is initiated after the patient has received G-CSF once daily for 4 days. It may be repeated to 4 consecutive days. The dose is based on 0.24 mg/kg actual body weight and is administered by subcutaneous injection approximately 11 hours prior to initiation of apheresis. The dose is reduced by one-third if the patient's creatinine clearance is  $\leq$  50 mL/min.

The drug is available in single-use vials containing 1.2 mL of a 20 mg/mL solution and should be stored at controlled room temperature of 77° F.

Patients should be advised to watch for the signs and symptoms of potential systemic reactions such as urticaria, periorbital swelling, dyspnea, or hypoxia during and following injection. Patients should be advised to contact their physician immediately if symptoms of vasovagal reactions such as

orthostatic hypotension or syncope occur during or shortly after injection. Patients should be informed of the drug's side effect and how to manage specific gastrointestinal disorders. Finally, female patients with reproductive potential should be counseled to use effective contraceptive methods during Mozobil use.

### **Pristiq (Desvenlafaxine, Wyeth)**

Pristiq is an active metabolite of Wyeth's selective serotonin and norepinephrine reuptake inhibitor (SNRI) Effexor XR and is indicated for the treatment of major depressive disorder in adults. It is not approved for use in children.

Steady-state plasma concentrations are achieved in 4 to 5 days. The drug's half-life is 11 hours. Approximately 45% of Pristiq is excreted unchanged in urine at 72 hours after oral administration. The drug is primarily metabolized by conjugation and, to a minor extent, through oxidative metabolism via the CYP3A4 pathway. The CYP2D6 metabolic pathway is not involved. The concurrent use of a potent CYP3A4 inhibitor (ketoconazole, clarithromycin) may increase Pristiq's effect. Monoamine oxidase inhibitors (MAOI's) should be avoided as should other CNS-active drugs and alcohol.

The most common adverse reactions associated with Pristiq are nausea, dizziness, insomnia, hyperhidrosis, constipation, somnolence, decreased appetite, anxiety, and specific male sexual function disorders. Patients should avoid taking Pristiq if they have hypersensitivity to any active/inactive ingredients. MAOIs should be stopped for at least 14 days before starting Pristiq, and 7 days should be allowed after stopping Pristiq before starting an MAOI.

The recommended dose of Pristiq is 50 mg once daily with or without food. Gradual dose reduction is recommended whenever possible if treatment is to be stopped. Pristiq tablets are available as 50 mg and 100 mg tablets in bottles of 14, 30, and 90 tablets. The tablets must not be crushed, chewed, broken or dissolved.

Patients, their families, and their caregivers should be advised about the benefits and risks associated with treatment with Pristiq and counseled about the drug's appropriate use.

Advise patients, their families, and their caregivers to read the Medication Guide and assist them in understanding its contents. Importantly, patients, their families, and caregivers should be counseled to look for the emergence of suicidality, especially early during treatment and when the dose is adjusted up or down.

### **Promacta (Eltrombopag, GSK)**

Promacta received priority FDA review. The drug is an oral thrombopoietin receptor antagonist used to treat thrombocytopenia in patients with chronic immune thrombocytopenic purpura (ITP) who have insufficient response to corticosteroids, immunoglobulins, or splenectomy. ITP is a disorder marked by increased platelet destruction and/or inadequate platelet production in the blood, which causes an increased risk of bruising and bleeding. There are estimated to be approximately 60,000 individuals diagnosed with chronic ITP in the U.S. People with chronic ITP often bleed from small blood vessels causing bruises, nosebleeds, or

even fatal gastrointestinal or intra cerebral bleeds, although these are rare.

Promacta is the first agent of its kind and may help ITP patients without lowering their immune system.

*In vitro* studies demonstrate that CYP1A2 and CYP2C8 are involved in the oxidative metabolism of Promacta. But the significance of the drug's coadministration with moderate or strong inhibitors of CYP 1A2 (e.g., ciprofloxacin, fluvoxamine) and CYP 2C8 (e.g., gemfibrozil, trimethoprim) and inducers of CYP 1A2 (e.g., tobacco, omeprazole) and CYP 2C8 (e.g., rifampin) has not been established in clinical studies. Patients should be monitored for signs and symptoms of excessive exposure when the drug is given concomitantly with these moderate or strong inhibitors of CYP1A2 or CYP2C8.

The most common adverse reactions experienced by patients taking Promacta were: nausea, vomiting, menorrhagia, myalgia, paresthesia, cataract, dyspepsia, ecchymosis, thrombocytopenia, increased ALT/AST and conjunctival hemorrhage. The drug can cause liver toxicity so liver chemistries must be measured before the initiation of treatment and regularly during treatment.

The starting dose of Promacta is 50 mg once daily. For patients of East Asian ancestry or patients with moderate or severe hepatic insufficiency, the starting dose is 25 mg once daily. The drug should be given on an empty stomach (1 hour before or 2 hours after a meal) and a 4-hour interval should be allowed between taking Promacta and other medications, foods, or supplements containing polyvalent cations (e.g., iron, calcium, aluminum, magnesium, selenium and zinc). If the platelet count does not increase after 4 weeks at the maximum 75 mg dose, the drug should be discontinued.

Promacta is supplied as 25 mg and 50 mg tablets in bottle of 30. It is stored at controlled room temperature. Because of the risk for hepatotoxicity and other risks, the drug is available only through a restricted distribution program via 1-877-9-PROMACTA.

### **Rapaflo (Silodosin, Watson)**

Rapaflo is an alpha-1 adrenergic receptor antagonist for the treatment of benign prostatic hyperplasia (BPH.) BPH is a disease wherein the prostate gland enlarges in men as they age. By age 50, roughly 50% of all men suffer from BPH. By age 80, that number jumps to 75%. Rapaflo works by blocking the alpha-1 adrenoreceptors in the prostate, bladder, and urethra. By blocking these receptors, this treatment allows the smooth muscle in these tissues to relax, resulting in a reduction in BPH symptoms.

During clinical trials, the most common adverse effect seen with Rapaflo is reduced or no semen during orgasm, which is reversible with discontinuation of the product. Other side effects include dizziness, light-headedness, diarrhea, orthostatic hypotension, headache, nasopharyngitis, and nasal congestion. Patients planning cataract surgery should notify their ophthalmologist that they are taking Rapaflo because of the possibility of a condition called Intraoperative Floppy Iris Syndrome (IFIS), a complication associated with cataract surgery in patients on alpha-1 adrenoreceptor blocker medications. The drug is contraindicated in patients on alpha-blockers or those who have severe kidney or liver impairment.

Rapaflo will be available as an 8 mg oral capsule given once daily. For patients with moderate kidney impairment, a 4 mg daily dose is recommended. The product has not been marketed as of January 2009.

**Tapentadol (Tapentadol, Johnson & Johnson)**

Tapentadol is a centrally acting oral analgesic for the relief of moderate to severe acute pain in adults 18 years of age or older. The drug has two mechanisms of action, combining mu-opioid receptor agonism and norepinephrine reuptake inhibition.

Mu-opioid agonists are drugs that bind to and activate mu-opioid receptors in the central nervous system. These drugs modify sensory and affective aspects of pain, inhibit the transmission of pain at the spinal cord and affect activity at parts of the brain that control how pain is perceived.

Norepinephrine reuptake inhibitors are a type of central nervous system medication that increases the level of norepinephrine in the brain by inhibiting its re-absorption into nerve cells; these compounds have analgesic properties.

The most common adverse events in clinical trials were nausea, dizziness, vomiting, somnolence and headache. The development of a potentially life-threatening serotonin syndrome may occur with use of SNRI products, including tapentadol, particularly with concomitant use of serotonergic drugs such as SSRIs, SNRIs, TCAs, MAOIs and triptans, and with drugs which impair metabolism of serotonin (including MAOIs).

Tapentadol is contraindicated in any situation where mu-opioid agonists are contraindicated (i.e., significant respiratory depression, acute or severe bronchial asthma or hypercapnia); in patients with paralytic ileus; or in patients currently using or within 14 days of using monoamine oxidase inhibitors (MAOI). Like other drugs with mu-opioid agonist activity, tapentadol should not be used in patients susceptible to increased intracranial pressure, impaired consciousness, or coma.

Clinical study data from 2,100 patients showed tapentadol provided significant relief of moderate to severe acute pain compared to placebo. The drug is current being reviewed by the U.S. Drug Enforcement Agency for scheduling, and it cannot be sold until it receives a scheduling classification.

Tapentadol tablets have been approved in 50 mg, 75 mg and 100 mg doses. A trade name for tapentadol has not yet been determined.

**Relistor (Methylnaltrexone bromide, Progenics/Wyeth)**

Relistor is a selective peripherally acting mu-opioid receptor antagonist for the treatment of opioid-induced constipation in patients with advanced illness who are receiving palliative care.

Relistor undergoes limited metabolism with about half a dose eliminated in the urine. Peak plasma concentrations are achieved within 30 minutes after administration. In an *in vitro* study, methylnaltrexone bromide was a weak inhibitor of cytochrome P450 (CYP) isozyme CYP2D6 activity, but in an *in vivo* study it did not significantly affect the metabolism of the CYP2D6 substrate, dextromethorphan.

The most common adverse events with Relistor include abdominal pain, flatulence, nausea, dizziness, and diarrhea. The drug is contraindicated in patients with known or suspected mechanical gastrointestinal obstruction.

Relistor is administered subcutaneously and is available in 12 mg/0.6 ml strength in a 6 ml single use vial. It is given every other day as needed. The dose for patients weighing 38 to 61 kg is 8 mg and for patients weighing 62 to 114 kg, 12 mg. Relistor should be stored at 68-77°F with excursions permitted to 59-86°F. It should be protected from light.

## New Molecular Entities 2008

Brand Name	Generic Name	Sponsor	Indication	Route of Administration	Date Approved
AdreView	Lobenguane I 123	GE Healthcare	Diagnostic radionuclide for detection of primary/metastatic pheochromocytoma or neuroblastoma	IV	9/19/2008
Banzel	Rufinamide	Eisai	Lennox-Gastaut syndrome seizures	Oral	11/14/2008
Cleviprex	Clevidipine butyrate IV	The Medicines Company	IV Ca Channel blocker	IV	8/1/2008
Degarelix	Degarelix	Ferring	Advanced prostate cancer	Subcutaneous injection	12/24/2008
Durezol	Difluprednate ophthalmic emulsion	Sirion	Topical corticosteroid for inflammation/pain associated with ocular surgery	Eye drop	6/23/2008
Entereg	Alvimopan	Adolor/GSK	Accelerate bowel function in patients who have undergone partial large/small bowel resection	Oral	5/20/2008
Eovist	Gadoxetate, IV	Bayer	Diagnostic MRI of liver	IV	7/3/2008
Intelence	Etravirine	Tibotec	HIV	Oral	1/18/2008
Lexiscan	Regadenosan IV	CV Therapeutics/Astellas	Pharmacologic stress agent used in myocardial perfusion imaging	IV	4/10/2008
Lusedra	Fospropofol IV	Eisai	Sedative-hypnotic agent for monitored anesthesia	IV	12/12/2008
Mozobil	Plerixafor	Genzyme	Bone marrow transplant agent used with granulocyte-colony stimulating factor (G-CSF)	Subcutaneous injection	12/15/2008
Pristiq	Desvenlafaxine	Wyeth	Major depressive disorder	Oral	2/29/2008
Promacta	Eltrombopag	GSK	Thrombocytopenia	Oral	11/20/2008
Rapaflo	Silodosin	Watson	Benign prostatic hyperplasia	Oral	10/8/2008
Tapentadol	Tapentadol	Johnson & Johnson	Moderate to severe acute pain	Oral	11/20/2008
Relistor	Methylnaltrexone bromide	Progenics/Wyeth	Opioid-induced constipation	Injection	4/24/2008
Toviaz	Fesoterodine	Pfizer	Overactive Bladder	Oral	10/31/2008
Treanda	Bendamustine IV	Cephalon	Chronic lymphocytic leukemia	IV	03/20/2008
Vasovist	Gadofosveset	Epix	Evaluation of aortoiliac occlusive disease in peripheral vascular disease	IV	12/22/2008
Vimpat	Lacosamide	Schwarz	Partial onset seizures in epilepsy	IV	10/28/2008
Xenazine	Tetrabenazine	Prestwick	Chorea of Huntington's disease	Oral	08/15/2008

Adapted from the FDA (<http://www.fda.gov/cder/rdmt/InternetNDA08.pdf>), Pharmaceuticals Approvals Monthly December 2008, and PhRMA's New Drug Approvals 2008 <http://www.phrma.org/files/2008%20Approvals%20011209.pdf>

## Biologicals and Vaccines Approved in 2008

Brand Name	Generic Name	Sponsor	Indication	Route of Administration	Date Approved
Afluria	Influenza virus vaccine	CSL Limited	Influenza immunization in adults 18 and over	IM	07/30/2008
Arcalyst	Rilonacept, inj.	Regeneron	Familial cold auto-inflammatory syndrome & Muckle-Wells Syndrome	Subcutaneous injection	2/27/2008
Artiss	Febrin sealant (human)	Baxter	Medical adhesive for adhering autologous skin grafts to surgically prepared wound beds in burn patients	Sealant	3/19/2008
Cimzia	Certolizumab pegol, inj	UCB	Crohn's disease	Injection	4/22/2008
Cinryze	C1-esterase inhibitor	Lev/Viro-Pharma	Hereditary angioedema	Injection	10/10/2008
Fluarix	Influenza virus vaccine	GSK	Influenza immunization in adults 18 and over	IM	08/05/2008
FluLaval	Influenza virus vaccine	ID Biomedical	Influenza immunization in adults 18 and over	IM	07/28/2008
FluMist	Influenza virus vaccine, live, intranasal	MedImmune Vaccines	Influenza immunization in individuals 2-49 years	Intranasal	07/25/2008
FluVirin	Influenza virus vaccine	Novartis	Influenza immunization in persons 4 years of age and older	IM	08/01/2008
FluZone	Influenza virus vaccine	Sanofi Pasteur	Influenza immunization in persons 6 months of age and older	IM	07/14/2008
Kinrix	Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed and Inactivated Poliovirus Vaccine	GSK	Active immunization against diphtheria, tetanus, and acellular pertussis and the 4 <sup>th</sup> dose in the inactivated poliovirus vaccine series in children 4-6 years	IM	06/24/2008
Nplate	Romiplostim	Amgen	Idiopathic thrombocytopenic purpura	Subcutaneous injection	08/22/2008
Pentacel	Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed and Inactivated Poliovirus Vaccine and Haemophilus B Conjugate (Tetanus Toxoid Conjugate)	Sanofi Pasteur	Active immunization against diphtheria, tetanus, pertussis, poliomyelitis and invasive disease caused by Haemophilus influenza for persons 6 weeks to 4 years.	IM	6/20/2008
Recothrom	Thrombin (recombinant)	ZymoGenetics	Hemostasis aid		1/17/2008
Rotarix	Rotavirus gastroenteritis	GSK	Prevention of rotavirus in infants/children ages 6-24 weeks	Oral	3/19/2008
Xyntha	Moroctocog alfa (Antihemophilic Factor recombinant)	Wyeth	Control of bleeding in hemophilia A	IV	02/21/2008

Adapted from the FDA (<http://www.fda.gov/cder/rdmt/InternetNDA08.pdf>), Pharmaceuticals Approvals Monthly December 2008, and PhRMA's New Drug Approvals 2008 <http://www.phrma.org/files/2008%20Approvals%20011209.pdf>