

# New Medications You May Be Seeing in Your Pharmacy

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1.0 Credit Hour (0.10 CEU)

## Objectives:

After completing this knowledge-based activity, the participant will be able to:

- Provide side effects and unique counseling points for new chemical entities;
- Define proper storage and dispensing conditions for new medications;
- List new medications on the market since January 2010.

A total of 84 new approvals for medications have been made by the FDA from January 1, 2010 to April 1, 2011. That number is inclusive of new chemical entities, biologics, new combinations and new dosage forms. This article will focus on 14 new chemical entities that have been approved.

## CNS

**Ampyra™** (dalfampridine) is an oral potassium channel blocker indicated to improve walking in patients with multiple sclerosis (MS) by increasing walking speeds. The mechanism of this broad spectrum extended-release tablet is not fully understood. The maximum recommended dose is 10mg twice daily as additional benefit was not seen with doses higher than 20mg per day. Due to an increased incidence in seizures during clinical studies, dalfampridine is contraindicated in patients with history of seizures. Renal impairment may increase the likelihood of seizure occurrence and warrants a contraindication in patients with a creatinine clearance less than 50 mL/min. Other than the serious side effect of seizures, less worrisome side effects have been observed. The most common side effects include urinary tract infection, insomnia, dizziness, headache, nausea, asthenia, back pain, balance disorder, multiple sclerosis relapse, paresthesia, nasopharyngitis, constipation, dyspepsia and pharyngolaryngeal pain. Dalfampridine may also cause drowsiness or dizziness; therefore, it is important to tell patients to see how the medication affects them before driving. Although this medication may be taken without regard to food, tell the patient to take it with food if it upsets their stomach.

Also for patients with multiple sclerosis, **Gilenya™** (fingolimod) is a sphingosine 1-phosphate receptor modulator indicated for the treatment of patients with relapsing forms of MS to reduce the frequency of clinical exacerbations and delay physical disability. Although its mechanism is not fully understood, its therapeutic effects are believed due to the reduction of lymphocyte migration into the central nervous system. Gilenya™ is an oral capsule dosed as 0.5 mg once daily and may be given with or without food. There are no contraindications to the use of Gilenya™; however, there are three evaluations that should be done before initiating treatment. First, due to an observed decrease in heart rate, a baseline ECG must be obtained. After the first dose is administered, patients should be observed for 6 hours for signs and symptoms of bradycardia. Tell the patient if they stop taking the medication for two or more weeks, they need to be monitored by a physician when restarting this medication. Secondly, it has been reported that Gilenya™ may increase the risk of infections; therefore, a recent CBC should be obtained, and the patient should be monitored for signs and symptoms of infection during treatment and for two months following discontinuation. Counsel the patient on signs and symptoms of infection and inform the patient that some vaccines may not be as effective if received within 2 months of

discontinuation of Gilenya™. Recommend that patients who have not had the chickenpox or who have not been vaccinated consider VZV (varicella zoster virus) vaccination before starting Gilenya™. Lastly, an ophthalmologic evaluation should be performed at baseline and three to four months after initiation of treatment due to the risk of macular edema. You can counsel the patient on visual symptoms such as blurred vision or decreased visual acuity. However, some patients in studies were asymptomatic with macular edema being discovered at a routine ophthalmologic examination. Along with bradyarrhythmias, atrioventricular blocks, infection and macular edema, other serious adverse reactions include respiratory effects (decrease in lung function) and hepatic effects (elevated liver enzymes). Patients should be told to contact their physician if they experience difficulty breathing or unexplained nausea, vomiting, abdominal pain, fatigue, anorexia, jaundice or dark urine. The most common side effects are headache, influenza, diarrhea, back pain, liver enzyme elevations and cough.

**Latuda™** (lurasidone) is a new atypical antipsychotic approved for the treatment of patients with schizophrenia. It comes in two strengths, a 40mg and 80mg oral tablet. Counsel the patient to take the tablet with food consisting of at least 350 calories. Coadministration with strong CYP3A4 inhibitors such as ketoconazole and inducers such as rifampin is contraindicated. A black box warning has been added to the labeling that states elderly patients with dementia-related psychosis treated with antipsychotic medications are at an increased risk for mortality. Other warnings and precautions include cerebrovascular events such as stroke, neuroleptic malignant syndrome (NMS), tardive dyskinesia, metabolic changes including hyperglycemia, dyslipidemia and weight gain, hyperprolactinemia, leucopenia, neutropenia and agranulocytosis, orthostatic hypotension and syncope, seizures, cognitive impairment and suicide. Patients should be made aware of these risks and should be counseled on signs and symptoms of NMS. The most common,

less serious side effects are somnolence, akathisia, nausea, parkinsonism and agitation.

**Viibryd™** (vilazodone) is a new antidepressant that works by a dual mechanism of action. It works by both selective inhibition of serotonin reuptake and as a partial agonist at 5-HT<sub>1A</sub> receptors; however, its effect is not completely known. Indicated for the treatment of major depressive disorder (MDD), this antidepressant comes in a 10mg, 20mg and 40mg tablet. Typical dosing is 40mg once daily, but titration is required starting with 10mg for 7 days, followed by 20mg for 7 days and then the targeted dose of 40mg daily. Patients should be counseled to take the medication with food to reach adequate concentrations of the drug. Viibryd should not be discontinued abruptly; the dose must be reduced gradually. Concomitant use of MAOIs or use of Viibryd within 14 days of stopping an MAOI is contraindicated and increases the risk for serotonin syndrome or neuroleptic malignant syndrome. The signs and symptoms of these two syndromes should be described to the patient. A black box warning has been added to increase awareness of the risk of suicidality with antidepressants. Other serious adverse reactions include seizures, abnormal bleeding, activation of mania or hypomania and hyponatremia. Counsel patients on the increased risk of bleeding with concomitant use of aspirin, NSAIDs, warfarin and other anticoagulants. The most common side effects are diarrhea, nausea, vomiting and insomnia.

### **Endocrine**

Similar to Byetta™, the glucagon-like peptide-1 receptor agonist brought to the market in 2005, **Victoza™** (liraglutide) is an incretin mimetic used as adjunct treatment for improved glucose control in type II diabetes mellitus patients. It works by increasing glucose-dependent insulin secretion, decreasing postprandial glucagon secretion, slowing gastric emptying which increases satiety and in turn decreases food intake. A key difference between the two subcutaneous GLP-1 analogs is their dosing regimen. While Byetta™ is administered by subcutaneous injection twice a day within 60 minutes

of the 2 main meals of the day, Victoza™ is administered subcutaneously once a day without regards to meals or time of day. Dose-dependent and treatment-duration-dependent thyroid C-cell tumors have been observed in studies with both rats and mice. Due to the uncertainty of this risk in humans, a contraindication was added to the labeling for patients with a personal or family history of medullary thyroid carcinoma or in patients with multiple endocrine neoplasia syndrome type 2. Also for this reason, Victoza™ is not recommended first line and should be used only when the benefit outweighs its risks. Patients should be counseled on the symptoms of thyroid cancer such as a mass in the neck, difficulty swallowing, difficulty breathing or persistent hoarseness. An increase in pancreatitis similar to Byetta™ has also been demonstrated in clinical trials. Although pancreatitis is not included as an absolute contraindication, because sufficient studies in patients with pancreatitis have not been conducted, Victoza™ should be used with caution in patients with pancreatitis. Tell patients to report persistent, severe abdominal pain. The most common side effects are headache, nausea and diarrhea. Patients who are taking other agents known to cause hypoglycemia should be counseled on the increased risk of hypoglycemia while using Victoza. It is also important to remind patients of the importance of a proper diet, regular physical activity and monitoring of blood glucose and A<sub>1c</sub> levels.

**Carbaglu™** (carglumic acid) is a carbamoyl phosphate synthetase 1 activator indicated as adjunctive therapy for the treatment of acute hyperammonemia and maintenance therapy for the treatment of chronic hyperammonemia both associated with a deficiency of the hepatic enzyme-N-acetylglutamate synthase. The dosing recommendation is weight based with an initial dosage range for acute hyperammonemia of 100mg/kg/day to 250 mg/kg/day. Maintenance doses are titrated to target a normal plasma ammonia level. The daily dose should be divided into two or four doses and should be administered immediately before meals or feedings. Carbaglu™ comes as a scored

200mg tablet. Counsel the patient to disperse the tablet in a minimum of 2.5 milliliters of water and take immediately. The tablet will not completely dissolve so remaining particles are normal. To ensure the patient is receiving the full dose, they should be counseled to rinse the mixing container with additional volumes of water and to swallow the contents immediately. It may be administered by an oral syringe or through a nasogastric tube. Initially, patients will be placed on a protein restricted diet. Ammonia levels should be monitored throughout therapy. When ammonia levels have normalized, protein is usually reintroduced in the diet. The most common adverse reactions are vomiting, abdominal pain, pyrexia, tonsillitis, anemia, ear infection, diarrhea, nasopharyngitis and headache. Counseling points include to store the unopened container in a refrigerator. Once the container is opened, it should not be stored in the refrigerator. Tell the patient to write the date of opening on the container. The tablets will expire 1 month after the container is opened and should be discarded after that date.

**Egrifta™** (tesamorelin) is indicated for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy. It is supplied in two boxes. The first box is the medication box which includes 60 Egrifta™ 1mg powder vials and should be stored in the refrigerator. The second box is the injection box containing 30 10mL bottles of sterile water for injection, 30 sterile 3mL syringes with attached needles, 30 individual 1 ½” 18 gauge needles used for mixing and 30 individual ½” 27 gauge needles for injection. The injection box should be stored at room temperature. The medication must be reconstituted by the patient before each injection. Counsel the patient to read the “Instructions for Use” that comes with the medication. This insert explains in detail how to reconstitute the medication and how to inject it. Pharmacists should familiarize themselves with this information and counsel the patient on proper administration. The recommended dose is 2mg and requires the use of two powder vials per dose. Counsel the patient to rotate their injection site daily. Inform the patient of the risk of fluid retention,

glucose intolerance and injection site reactions. Direct the patient to get emergency help if they experience a serious allergic reaction. Common side effects include joint pain, pain in legs and arms, swelling in legs, muscle soreness, tingling, numbness, nausea, vomiting, rash and itching.

### **Hormone**

**Natazia™** (estradiol valerate/dienogest), a 28-day, four-phase estrogen/progestin combined oral contraceptive. The patient should be instructed to start Natazia™ on day one of her menstrual cycle. A back-up non-hormonal contraceptive should be used during the first 9 days. Natazia™ tablets must be taken in the order directed on the blister pack and like other oral contraceptives, should be taken at the same time each day. Counsel patients on proper administration of Natazia™ and missed dose instructions which differ from those of other birth control pills. If a patient taking Natazia™ misses a dose by more than 12 hours, a back-up method of contraception must be used for 9 days. Serious adverse reactions include thrombotic events such as venous thromboembolism, other cardiovascular events such as myocardial infarction and stroke and liver disease including hepatic adenomas, hepatocellular carcinomas and cholestasis. Other common side effects include irregular uterine bleeding, nausea, breast tenderness and headache. Patients should be told that cigarette smoking increases the risk of cardiovascular events, especially over the age of 35. It should be understood by the patient that oral contraceptives do not protect against HIV and other sexually transmitted diseases.

Available by prescription only, **Ella™** (ulipristal acetate) is the newest emergency contraceptive on the market. It is a progesterone agonist/antagonist indicated for the prevention of pregnancy following unprotected intercourse or contraceptive failure. As opposed to Plan B™ and Next Choice™ which must be taken within 72 hours after unprotected intercourse, Ella™ can be taken within 5 days after unprotected intercourse as it remains efficacious for 120 hours. One 30mg tablet should be taken by mouth. The patient should be counseled to see a

physician if lower abdominal pain occurs three to five weeks after taking Ella™ as ectopic pregnancy is a possibility. If a patient's period is delayed by more than one week after taking Ella™, the possibility of pregnancy should be considered. It is possible that Ella™ may decrease the effectiveness of regular hormonal contraception; therefore, the patient should be counseled to use a barrier method of contraception during the same menstrual cycle. The most common side effects of Ella™ are headache, nausea, abdominal pain, dysmenorrhea, tiredness and dizziness.

### **Cardiovascular**

A Warfarin™ competitor has reached the market. **Pradaxa™** (dabigatran) is a direct thrombin inhibitor indicated to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation. It works to prevent the formation of a thrombus by inhibiting the conversion from fibrinogen to fibrin. The oral capsule comes in two strengths, 150mg given twice daily for patients with a creatinine clearance greater than 30 mL/min and a 75mg capsule given twice daily for patients with a creatinine clearance between 15 and 30 mL/min. There are currently no recommendations for patients with a creatinine clearance less than 15 mL/min or for those on dialysis. Because of its risk of serious and sometimes fatal bleeding, Pradaxa™ is contraindicated in patients with active pathological bleeding. When switching from Warfarin™ to Pradaxa™, Warfarin™ should first be discontinued and Pradaxa™ should be started when the INR is below two. Switching from Pradaxa™ to Warfarin™ is based on creatinine clearance and the patient should be counseled accordingly. It is important to remind patients not to discontinue the medication without consulting their prescribing physician first. Counsel patients not to break or chew the capsules or empty the contents of the capsule as doing so may increase the exposure to the active ingredient. If a dose is missed, it should be skipped if it cannot be taken at least 6 hours before the next scheduled dose. The dose should never be doubled. Pradaxa must be

stored in the original container and discarded 30 days after opening.

Just approved in February 2011 is an angiotensin II receptor blocker, **Edarbi™** (azilsartan) indicated for the treatment of hypertension either alone or in combination with other antihypertensives. Edarbi™ is supplied as a 40mg and 80mg oral tablet. Typical dosing is 80mg taken by mouth once daily without regard to food; however, a starting dose of 40mg should be considered for patients who are taking high doses of diuretics such as furosemide 600mg by mouth per day or hydrochlorothiazide 50 mg per day. When dispensing to females, first make sure the patient is not pregnant or does not plan to become pregnant due to the risk of fetal and neonatal morbidity and mortality with greatest danger during the second and third trimesters. Although a dosage adjustment is not required in those with renal impairment, Edarbi™ should be used cautiously in those patients. The most common side effect reported during clinical trials was diarrhea. As with any other antihypertensive, it is important to counsel the patient on potential side effects such as dizziness and hypotension.

### **Respiratory**

Also new to the market in February is **Daliresp™** (roflumilast), an oral tablet indicated to reduce the risk of COPD exacerbations in patients with severe COPD associated with chronic bronchitis and a history of exacerbations. The first of its kind, Daliresp™ is a phosphodiesterase-4 enzyme inhibitor which is thought to exert its therapeutic action by increasing levels of cyclic AMP in lung cells. The recommended dose is 500 mcg per day taken with or without food. The most common adverse effects are diarrhea, weight decrease, nausea, headache, back pain, influenza, insomnia, dizziness and decreased appetite. Patients should be counseled to monitor their weight regularly. If significant weight is lost, a physician should be consulted and the discontinuation of Daliresp™ should be considered. The risks and benefits of using Daliresp™ in patients with a history of depression or suicidal thoughts or behavior should be carefully weighed, because there

is a risk of psychiatric events including suicidality associated with Daliresp™ therapy. Patients and caregivers should be aware of mood changes and be told to contact their physician if changes occur. It is also important for patients to know that Daliresp™ is not a bronchodilator and should not be used for acute bronchospasms.

### **Ophthalmology**

The new ophthalmic solution, **Lastacaft™** (alcaftadine) 0.25% is a H<sub>1</sub> histamine receptor antagonist indicated for the prevention of itching due to allergic conjunctivitis. Direct the patient to instill one drop in each eye once daily. The patient should be counseled on the proper administration of eye drops including how to minimize the risk of contamination by not touching the tip of the dropper to any surface. Contact lenses should be removed before instillation of Lastacaft™. The most common ocular adverse effects are eye irritation, burning, stinging, eye redness and ocular pruritis. Non-ocular side effects include nasopharyngitis, headache and influenza.

### **Topical**

**Natroba™** (spinosad) is a topical suspension indicated for the treatment of head lice in patients four years and older. It is supplied as a 120mL bottle containing spinosad 0.9% topical suspension. Counsel the patient to shake the bottle well and to apply an amount of the suspension sufficient to cover the scalp and hair avoiding contact to the eyes. Scalp and hair should be dry before application. The product should be rinsed off with warm water after 10 minutes. A fine-tooth comb may be used to remove lice and nits from the hair and scalp. Treatment can be repeated in 7 days if live lice are still seen. The most common adverse effects seen are application site and ocular erythema. The patient or caregiver should be counseled on non-pharmacological measures such as washing all personal items exposed to hair or lice in hot water as well as other measures to prevent the spread of lice.

### **Conclusion**

Each year, there are numerous medications brought

to the market. The FDA may approve completely new chemical entities or biologics or just new combinations or dosage forms. It is important for pharmacists to stay up-to-date on new products that you soon may be dispensing in your pharmacies. Pharmacists are utilized for health information more

than any other healthcare professional. Whether you are a pharmacist working in the hospital setting, retail, long-term care or industry, you must keep up with the most current information to serve as a resource to your patients and provide the best quality of care possible.

**Table 1 – New Drug Approvals**

<b>Brand Name</b>	<b>Generic Name</b>	<b>Company</b>	<b>Approval Date</b>	<b>Indication</b>
ABBOTT Prism Chagas	Trypanosoma cruzi (E. coli, recombinant antigen)	Abbott Labs	4/30/2010	To screen individual human donors, including volunteer donors of whole blood and blood components and other living donors for the presence of antibodies to T. cruzi. The assay is also intended for use in testing serum and plasma specimens to screen organ donors when specimens are obtained while the donor's heart is still beating, in testing blood specimens to screen cadaveric donors. It is not intended for use in testing cord blood specimens.
Actemra	Tocilizumab	Genentech	1/8/2010	Provides treatment for reducing signs and symptoms in adult patients with moderately to severely active rheumatoid arthritis
Ampyra	Dalfampridine	Acorda	1/22/2010	Indicated to improve walking ability in patients with multiple sclerosis (MS).
Asclera	Polidocanol	BioForm Medical	3/30/2010	Indicated to treat uncomplicated spider veins (varicose veins $\leq$ 1mm in diameter) and uncomplicated reticular veins (varicose veins 1 to 3 mm in diameter) in the lower extremity.
Benlysta	Belimumab	Human Genome Sciences	3/10/2011	A B-lymphocyte stimulator-specific inhibitor for systemic lupus erythematosus
Carbaglu	Carglumic acid	Orphan Europe	3/18/2010	Indicated for use in pediatric and adult patients as and adjunctive therapy for the treatment of acute hyperammonemia due to NAGS deficiency, and as maintenance therapy for chronic hyperammonemia due to NAGS

				deficiency
Corifact	Factor XIII concentrate (human)	CSL Behring	2/17/2011	Indicated for routine prophylactic treatment to prevent bleeding in patients with congenital factor XIII deficiency
Daliresp	roflumilast	Forest	2/28/2011	An oral phosphodiesterase type 4 inhibitor to reduce the risk of COPD exacerbations
Datscan	Ioflupane I-123	GE Healthcare	1/14/2011	Diagnostic imaging agent to evaluate patients with suspected Parkinsonian syndromes
Edarbi	azilsartan	Takeda	2/25/2011	An angiotensin II receptor blocker (ARB) for hypertension
Egrifta	Tesamorelin	EMD Serono	11/10/2010	Indicated for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy.
Ella	Ulipristal acetate	Watson	8/13/2010	Indicated for the prevention of pregnancy following unprotected intercourse or a known or suspected contraceptive failure. Not intended for routine use as a contraceptive.
Gadavist	Gadobutrol	Bayer HealthCare	3/14/2011	Contrast agent indicated for intravenous use in diagnostic MRI in adults and children 2 years of age and older to detect and visualize areas with disrupted blood brain barrier or abnormal vascularity
Gilenya	Fingolimod HCL	Novartis	9/21/2010	Indicated for the treatment of patients with relapsing forms of multiple sclerosis to reduce the frequency of relapses and to delay the accumulation of physical disability.
Glassia	Alpha1-proteinase inhibitor (human)	Kamada	7/1/2010	Treatment of chronic augmentation and maintenance therapy in individuals with emphysema due to congenital deficiency of alpha-1-proteinase inhibitor, also known as alpha1-antitrypsin.
Halaven	Eribulin mesylate	Eisai	11/15/2010	Indicated for the treatment of patients with metastatic breast cancer who have previously received at least two chemotherapeutic regimens for the treatment of metastatic disease.
Hizentra	Immune globulin	CSL Behring	3/4/2010	Treatment of primary

	subcutaneous (human), 20% liquid			immunodeficiency
Jevtana	Cabazitaxel	Sanofi-aventis	6/17/2010	Indicated for the treatment of patients with hormone refractory metastatic prostate cancer previously treated with a docetaxel-containing treatment regimen.
Krystexxa	Pegloticase	Savient	9/14/2010	Provides for the treatment of intravenous infusion intended for patients with treatment failure gout to control hyperuricemia and manage the signs and symptoms of gout
Lastacaft	Vilasta ophthalmic solution	Vistakon Pharma	7/28/2010	Indicated for the prevention of itching associated with allergic conjunctivitis.
Latuda	Lurasidone HCL	Sunovion Pharma	10/28/2010	Indicated for the treatment of schizophrenia in adults
Lumizyme	Alglucosidase alfa-2	Genzyme	5/24/2010	Provides treatment of non-infantile-onset patients with Pompe disease
Menveo	Meningococcal vaccine	Novartis	2/19/2010	A vaccine to prevent meningococcal disease caused by <i>Neisseria meningitidis</i> serogroups A, C, Y, and W-135 in persons 11 to 55 years of age
Natazia	Estradiol valerate/dienogest	Bayer HealthCare	5/6/2010	A four-phasic, 28-day oral contraceptive with two placebo tablets indicated for prevention of pregnancy
Natroba	Spinosad	ParaPRO/Pernix	1/18/2011	Topical pediculicide for treatment of head lice
Pradaxa	Dabigatran etexilate mesylate	Boehringer Ingelheim	10/19/2010	Indicated to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation.
Prenar 13	Pneumococcal 13-valent conjugate vaccine	Wyeth	2/24/2010	An active immunization to prevent <i>Streptococcus pneumoniae</i> -related infections in children 6 weeks through 5 years
Prolia	Denosumab	Amgen	6/1/2010	A RANK ligand inhibitor for treatment of osteoporosis in postmenopausal women
Provenge	Sipuleucel-T	Dendreon	4/29/2010	Autologous cellular immunotherapy for treatment of men with asymptomatic or minimally symptomatic metastatic hormone refractory prostate cancer
TachoSil	Fibrin Sealant Patch	Nycomed	4/5/2010	Fibrin sealant patch indicated for

				use as an adjunct to hemostasis in cardiovascular surgery when control of bleeding by standard and surgical techniques, such as suture, ligature or cautery, is ineffective or impractical.
Teflaro	Ceftaroline fosamil for injection	Forest Labs	10/29/2010	Indicated for the treatment of acute bacterial skin and skin structure infections and community acquired pneumonia.
Victoza	Liraglutide	Novo Nordisk	1/25/2010	A GLP-1 agonist indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
Viibryd	Vilazodone HCL	Trovis Pharm	1/21/2011	An SSRI/serotonin receptor partial agonist for depression
VPRIV	Velaglucerase alfa	Shire	2/26/2010	Indicated for long-term enzyme replacement therapy (ERT) for pediatric and adult patients with type I Gaucher disease.
Xeomin	Incobotulinumtoxin-A	Merz Pharms	7/30/2010	An acetylcholine release inhibitor and neuromuscular blocking agent for cervical dystonia and blepharospasm
Xgeva	denosumab	Amgen	6/1/2010	More concentrated formulation of <i>Prolia</i> to prevent fracture/pain associated with bone metastases
Xiaflex	Collagenase clostridium hystolyticum	Auxilium Pharm	2/2/2010	A proteolytic enzyme for treatment of Dupuytren's contracture (a progressive hand disease which affects connective tissue in the palm of the hand)
Yervoy	Ipilimumab	Bristol Myers Squibb	3/25/2011	A human cytotoxic T-lymphocyte antigen 4 blocking antibody indicated for the treatment of unresectable or metastatic melanoma

**Table 2 – New Dosage Forms and Combinations**

<b>Brand Name</b>	<b>Generic Name</b>	<b>Company</b>	<b>Approval Date</b>	<b>Indication</b>
Omeprazole and Clarithromycin and Amoxicillin	Omeprazole/ Clarithromycin/ Amoxicillin	Dava Pharms	2/8/2011	To reduce the development of drug-resistant bacteria and maintain the effectiveness of antibacterial drugs
Abstral	Fentanyl citrate	ProStrakan	1/7/2011	Sublingual tablets for management of breakthrough

				pain in cancer patients tolerant to opioid therapy
Advil Congestion Relief	Ibuprofen/phenylephrine hydrochloride	Wyeth	5/27/2010	A new OTC combination indicated for the temporary relief of headache, fever, sinus pressure, nasal congestion, minor aches and pain.
Alsuma	Sumatriptan succinate	King	6/29/2010	A triptan for subcutaneous use indicated for the acute treatment of migraine attacks and the acute treatment of cluster headache episodes
Amturnide	Aliskiren hemifumarate/amlodipine besylate/hydrochlorothiazide	Novartis	12/21/2010	Combination renin inhibitor, calcium channel blocker, and thiazide diuretic for hypertension
Aricept	Donepezil hydrochloride	Eisai	7/23/2010	A new dosage strength of 23mg
Aridol	mannitol	Pharmaxis	10/5/2010	Inhalation formulation for assessment of bronchial hyperresponsiveness
Atelvia	Risedronate sodium	Warner Chilcott	10/8/2010	Delayed-release bisphosphonate taken AFTER breakfast
Axiron	testosterone	Eli Lilly	11/23/2010	Topical solution formulation for underarm application
Banzel	Rufinamide	Eisai	3/3/2011	New oral suspension formulation for seizures
Beyaz	Drospirenone/ethinyl estradiol/levomefolate calcium	Bayer HealthCare	9/24/2010	New oral contraceptive (similar to YAZ) which also contains folate
Butrans	buprenorphine	Purdue Pharma	6/30/2010	Transdermal patch for moderate to severe chronic pain
Carpine	Pilocarpine hydrochloride	Alcon	6/22/2010	A muscarinic cholinergic agonist ophthalmic solution indicated to reduce elevated intraocular pressure
Cayston	aztreonam	Gilead	Gilead	Inhaled antibiotic for cystic fibrosis patients with <i>Pseudomonas aeruginosa</i>
Cuvposa	glycopyrrolate	Shionogi Pharma	7/28/2010	Oral solution for chronic drooling in children (3 to 16 years) with neurologic disorders
Cysview Kit	Hexaminolevulinate hydrochloride	Photocure ASA	5/28/2010	Optical imaging solution for intravesical use in the cystoscopic detection of non-muscle invasive papillary cancer of the bladder among patients suspected or known to have lesions on the basis of prior cystoscopy

Differin	adapalene	Galderma	3/17/2010	First retinoid lotion formulation for acne
Dulera	Mometasone furoate/ formoterol fumarate	Schering	6/22/2010	Combination steroid/long acting beta-agonist inhaler for asthma
Exalgo	Hydromorphone	Covidien	3/1/2010	New extended-release opioid for moderate to severe chronic pain
Fortesta	testosterone	Endo	12/29/2010	Topical gel formulation for thigh application
Gralise	Gabapentin	Abbott	1/28/2011	Once-daily formulation for postherpetic neuralgia
Jalyn	Dutasteride/ tamsulosin hydrochloride	GSK	01/20/2010	New combination of a 5-alpha-reductase inhibitor and an alpha-blocker for treatment of benign prostatic hyperplasia (BPH)
Kombigylze XR	Saxagliptin/ metformin	BMS/AstraZeneca	11/5/2010	New combination product for treatment of type 2 diabetes
Lo Loestrin FE	Norethindrone acetate/ ethinyl estradiol/ ferrous fumarate	Warner Chilcott	10/21/2010	New very low dose oral contraceptive containing 10 mcg of ethinyl estradiol
Lyrica	pregabalin	Pfizer	1/4/2010	New oral solution formulation
Mirapex ER	pramipexole	Boehringer Ingelheim	2/19/2010	New extended-release formulation for Parkinson's disease
Moxeza	Moxifloxacin hydrochloride	Alcon	11/19/2010	Ophthalmic fluoroquinolone solution indicated for the treatment of bacterial conjunctivitis caused by susceptible strains
Namenda XR	memantine	Forest Labs	6/21/2010	New extended-release formulation for moderate to severe Alzheimer's disease
Norvir	Ritonavir	Abbott Labs	2/10/2010	New oral tablet indicated for use in combination with other antiretroviral agents for the treatment of HIV-1 infection.
Nuedexta	Dextromethorphan/ quinidine	Avanir Pharma	10/29/2010	New combination product for treatment of involuntary episodes of laughing and/or crying (pseudobulbar affect [PBA])
Olepto	Trazodone	Labopharm	2/2/2010	New extended-release formulation for depression
Oravig	miconazole	Strativa Pharma	4/16/2010	Buccal tablet formulation for oropharyngeal candidiasis
Silenor	doxepin	Somaxon Pharma	3/17/2010	New 3 mg and 6 mg tablets for treatment of insomnia
Sprix	Ketorolac tromethamine	Roxro Pharma	5/14/2010	Nasal spray formulation for moderate to moderately severe pain
Staxyn	vardenafil	GSK/Schering	6/17/2010	New orally disintegrating tablet

				formulation for erectile dysfunction
Suboxone	Buprenorphine/ naloxone	Reckitt Benckiser	8/30/2010	New sublingual film formulation for treatment of opioid dependence
Suprep Bowel Prep Kit	Sodium/ potassium/ magnesium sulfate	Braintree Labs	8/5/2010	Osmotic laxative bowel prep kit for colon cleansing prior to colonoscopy
Tekamlo	Aliskiren/ amlodipine	Novartis	8/26/2010	New combination renin inhibitor and calcium channel blocker for hypertension
Tramadol	Tramadol hydrochloride	Cipher	5/7/2010	Oral extended release capsule
Trelstar	Triptorelin pamoate	Watson	3/10/2010	New 22.5mg base per vial for intramuscular use indicated for the palliative treatment of advance prostate cancer
Tribenzor	Olmesartan/ amlodipine/ hydrochlorothiazide	Daiichi Sankyo	7/23/2010	Combination ARB, calcium channel blocker, and diuretic for treatment of hypertension
Vimovo	Naproxen/ esomeprazole magnesium	AstraZeneca	4/30/2010	NSAID/PPI combination for arthritis patients at risk of NSAID-associated gastric ulcers
Vimpat	Lacosamide	UCB	4/30/2010	New oral solution for partial-onset seizures
Viramune XR	Nevirapine	Boehringer Ingelheim	3/25/2011	New extended release dosage tablet indicated for combination antiretroviral treatment of HIV-1 infected adults
Zuplenz	ondansetron	Par/ Strativa Pharma	7/2/2010	An oral soluble film formulation for prevention of nausea and vomiting
Zyrtec Allergy	Cetirizine	McNeil Consumer	9/3/2010	New orally disintegrating tablet for relief of allergy symptoms

**Resources:**

*Clinical Pharmacology. Accessed at [clinicalpharmacology.com](http://clinicalpharmacology.com)*

*Drug Approval Reports. Drugs@FDA. U.S. Department of Health & Human Services. Accessed at <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Reports.ReportsMenu>. Lexicomp Online. Accessed at [online.lexi.com](http://online.lexi.com).*

*New Drugs Approved by the FDA. Pharmacist's Letter. Accessed at <http://pharmacistsletter.therapeuticresearch.com/pl/NewDrugs.aspx?cs=STUDENT&s=PL>*