

Current FDA-Related Drug Information

New Drugs Approved by the FDA

New Dosage Forms and Indications Approved by the FDA

Agents Pending FDA Approval

New Drug/Biologics License Applications Filed by Manufacturer

Supplemental Applications Filed by Manufacturer

Significant Labeling Changes or "Dear Health Care Professional" Letters Related to Safety

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This monthly feature will help readers keep current on new drugs, new indications, dosage forms, and safety-related changes in labeling or use. Efforts have been made to ensure the accuracy of this information; however, if there are any questions, please let us know at hospitalpharmacy@drugfacts.com.

**TABLE 1. NEW DRUGS APPROVED BY THE US FOOD AND DRUG ADMINISTRATION (FDA):
MARCH 15 THROUGH APRIL 17, 2009**

<i>Generic Name Brand Name (Company)</i>	<i>Comparative Agents</i>	<i>Indication</i>	<i>Mechanism of Action</i>	<i>Common Adverse Effects</i>	<i>Dosage Form and Strength</i>	<i>Package Insert</i>
Benzyl alcohol <i>Benzyl Alcohol Lotion 5%</i> (Sciele Pharma)	Pyrethrins	Treatment of head lice	Asphyxiation; inhibits lice from closing their respiratory spiracles, allow- ing the vehicle to obstruct the spiracles and causing the lice to asphyxiate	Ocular irritation, application-site irritation, application-site anesthesia, and hypoesthesia	Lotion 5%	http://www.fda.gov/cder/foi/label/2009/022129lbl.pdf

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TABLE 1. NEW DRUGS APPROVED BY THE US FOOD AND DRUG ADMINISTRATION (FDA): MARCH 15 THROUGH APRIL 17, 2009 (CONT.)

<i>Generic Name Brand Name (Company)</i>	<i>Comparative Agents</i>	<i>Indication</i>	<i>Mechanism of Action</i>	<i>Common Adverse Effects</i>	<i>Dosage Form and Strength</i>	<i>Package Insert</i>
Everolimus <i>Afinitor</i> (Novartis)	None	Treatment of advanced kidney cancer in patients whose disease has progressed after treatment with other cancer therapies	Kinase inhibitor; blocking mammalian target of rapamycin resulting in disruption of growth, division, and metabolism of cancer cells	Inflammation in the mouth, loss of strength, diarrhea, poor appetite, fluid buildup in the extremities, shortness of breath, coughing, nausea, vomiting, rash, and fever	Tablet 5 and 10 mg	http://www.pharma.us.novartis.com/product/pi/pdf/afinitor.pdf
Japanese encephalitis vaccine, inactivated, adsorbed <i>IXIARO</i> (Intercell AG/Novartis)	None	Prevention of Japanese encephalitis for adult travelers and military personnel	Vaccine	Headache, myalgia, and injection-site reactions (eg, pain, tenderness)	Injection	http://www.fda.gov/cber/label/ixiaro-commercialLB.pdf

TABLE 2. NEW DOSAGE FORMS AND INDICATIONS APPROVED BY THE FDA: MARCH 15 THROUGH APRIL 17, 2009

<i>Generic Name</i>	<i>Brand Name (Company)</i>	<i>Indication and Comments</i>
New Indications		
Escitalopram oxalate	<i>Lexapro</i> (Forest Laboratories)	Acute and maintenance treatment of major depressive disorder in adolescents (12 to 17 years of age)
Olanzapine/Fluoxetine	<i>Symbyax</i> (Eli Lilly)	Acute treatment of treatment-resistant depression
Tigecycline	<i>Tygacil</i> (Wyeth)	Treatment of community-acquired bacterial pneumonia caused by susceptible strains of indicated pathogens in adult patients

TABLE 3. AGENTS PENDING FDA APPROVAL: MARCH 15 THROUGH APRIL 17, 2009

<i>Generic Name</i>	<i>Brand Name (Company)</i>	<i>Indication and Comments</i>
Recommended for Approval by an FDA Advisory Panel or the FDA		
Dronedarone	<i>Multaq</i> (sanofi-aventis)	Delaying symptoms of atrial fibrillation and reducing hospitalization
Rivaroxaban	<i>Xarelto</i> (Bayer Healthcare Pharmaceuticals/ Johnson & Johnson)	Short-term use in preventing deep vein thrombosis and pulmonary embolism in patients undergoing total hip or knee replacement surgery
Saxagliptin	<i>Onglyza</i> (Bristol-Myers Squibb/ AstraZeneca)	Treatment of type 2 diabetes; recommended for approval, but an additional postmarketing study enrolling patients who are older and more ill to look at the cardiovascular risk in these patient populations was recommended
Sertindole	<i>Serdolect</i> (Lundbeck)	Treatment of patients with schizophrenia
Agents Not Recommended for Approval or More Information Requested by an FDA Advisory Panel or the FDA		
Budesonide/Formoterol	<i>Symbicort</i> (AstraZeneca)	More information requested before approval for use as a long-term maintenance drug in the treatment of asthma in children 6 to 11 years of age
Quetiapine	<i>Seroquel XR</i> (AstraZeneca)	Not recommended for approval by the advisory panel as a first-line agent in the treatment of major depressive disorder and generalized anxiety disorder
Agents Scheduled for Review by an FDA Advisory Panel		
Cethromycin	(Advanced Life Sciences)	Outpatient treatment of adults with mild-to-moderate community-acquired pneumonia

TABLE 4. NEW DRUG/BIOLOGICS LICENSE APPLICATIONS FILED BY MANUFACTURER: MARCH 15 THROUGH APRIL 17, 2009

<i>Generic Name Brand Name (Company)</i>	<i>Comparative Agents</i>	<i>Indication</i>	<i>Mechanism of Action</i>	<i>Common Adverse Effects</i>	<i>Dosage Form</i>	<i>Comments</i>
Eslicarbazepine acetate <i>Stedesa</i> (Sepracor)	Carbamazepine, oxcarbazepine	Adjunct treatment of partial-onset seizures in adults with epilepsy	Sodium channel antagonist	Headache, dizziness, and nausea	Tablet	
Ondansetron (MonoSol Rx/ Strativa Pharmaceuticals)	Ondansetron	Prevention of chemotherapy-induced nausea and vomiting, nausea and vomiting associated with radiotherapy, and post-operative nausea and vomiting	Selective 5-HT ₃ receptor antagonist	Headache, diarrhea, malaise/fatigue/constipation, and dizziness	Oral	Dissolving film strip

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TABLE 4. NEW DRUG/BIOLOGICS LICENSE APPLICATIONS FILED BY MANUFACTURER: MARCH 15 THROUGH APRIL 17, 2009 (CONT.)

<i>Generic Name Brand Name (Company)</i>	<i>Comparative Agents</i>	<i>Indication</i>	<i>Mechanism of Action</i>	<i>Common Adverse Effects</i>	<i>Dosage Form</i>	<i>Comments</i>
Pixantrone (Cell Therapeutics)	Doxorubicin	Treatment of relapsed or refractory aggressive non-Hodgkin lymphoma	Major groove binder with an aza-anthracenedione molecular structure	Neutropenia, fever, infection, vomiting, and diarrhea	Intravenous	Beginning of the rolling New Drug Application submission
Pralatrexate (Allos Therapeutics)	None	Treatment of relapsed or refractory peripheral T-cell lymphoma	Antifolate working on cell-expressing replication factor C 1	Thrombocytopenia, mucosal inflammation, neutropenia, and anemia	Intravenous	
Tranexamic acid XP12B (Xanodyne Pharmaceuticals)	Tranexamic acid	Treatment of menorrhagia	Competitive plasmin inhibitor	Headache, nausea, and gastrointestinal distress	Oral, modified release	

TABLE 5. SUPPLEMENTAL APPLICATIONS FILED BY MANUFACTURER: MARCH 15 THROUGH APRIL 17, 2009

<i>Generic Name</i>	<i>Brand Name (Company)</i>	<i>Comments</i>
Corticotrophin	<i>H.P. Acthar Gel</i> (Questcor)	Treatment of infantile spasms
Erlotinib	<i>Tarceva</i> (OSI Pharmaceuticals)	First-line maintenance therapy for advanced non-small cell lung cancer in patients who have not progressed following first-line treatment with platinum-based chemotherapy
Lapatinib	<i>Tykerb</i> (GlaxoSmithKline)	First-line regimen combined with antihormonal therapy for hormone-sensitive metastatic breast cancer
Levoleucovorin	<i>Fusilev</i> (Spectrum Pharmaceuticals)	Use in combination with fluorouracil-containing regimens in advanced metastatic colorectal cancer

TABLE 6. SIGNIFICANT LABELING CHANGES OR "DEAR HEALTH CARE PROFESSIONAL" LETTERS RELATED TO SAFETY^a

Generic Name Brand Name (Company)	Warning	Web Site
Abacavir sulfate/lamivudine <i>Epzicom</i> and <i>Trizivir</i> (GlaxoSmithKline)	<p>BOXED WARNING Patients who have the HLA-B*5701 allele are at high risk for experiencing a hypersensitivity reaction to abacavir. Testing for the HLA-B*5701 allele should occur before initiation of therapy. Regardless of HLA-B*5701 status, permanent discontinuation of <i>Epzicom</i> and <i>Trizivir</i> should occur if hypersensitivity cannot be ruled out. Following a hypersensitivity reaction to abacavir, <i>Epzicom</i> and <i>Trizivir</i> should never be restarted; severe symptoms can occur within hours if the drug is restarted, which can result in serious or fatal hypersensitivity reactions.</p> <p>CONTRAINDICATIONS Never restart <i>Epzicom</i> and <i>Trizivir</i> or any other abacavir-containing product following a hypersensitivity reaction to abacavir, regardless of HLA-B*5701 status.</p> <p>WARNINGS Patients who have the HLA-B*5701 allele are at high risk for experiencing a hypersensitivity reaction to abacavir.</p>	<p>http://www.fda.gov/cder/foi/label/2009/021652s0081bl.pdf http://www.fda.gov/cder/foi/label/2009/021205s0211bl.pdf</p>
Bosentan <i>Tracleer</i> (Actelion Pharmaceuticals)	<p>CONTRAINDICATIONS Coadministration of lopinavir/ritonavir and bosentan has resulted in markedly increased plasma concentrations of bosentan. Therefore, concomitant use of <i>Tracleer</i> and lopinavir/ritonavir or other ritonavir-containing HIV regimens is contraindicated.</p> <p>WARNING Decreased sperm counts.</p> <p>PRECAUTIONS Drug Interactions section reworded: Bosentan is metabolized by CYP2C9 and CYP3A4. Inhibition of these enzymes may increase the plasma concentration of bosentan.</p>	<p>http://www.fda.gov/cder/foi/label/2009/021290s0141bl.pdf http://www.fda.gov/cder/foi/label/2009/021290s0151bl.pdf</p>
Ceftriaxone sodium <i>Rocephin</i> (Roche Pharmaceuticals)	<p>WARNINGS Interaction with calcium-containing products: Do not use diluents containing calcium, such as Ringer's solution or Hartmann's solution, to reconstitute <i>Rocephin</i> vials. <i>Rocephin</i> must not be administered simultaneously with calcium-containing, intravenous solutions, including continuous calcium-containing infusions such as parenteral nutrition via Y-site. However, in patients other than neonates, <i>Rocephin</i> and calcium-containing solutions may be administered sequentially if the infusion lines are thoroughly flushed between infusions with a compatible fluid.</p>	<p>http://www.fda.gov/cder/foi/label/2009/050585s0611bl.pdf</p>

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TABLE 6. SIGNIFICANT LABELING CHANGES OR "DEAR HEALTH CARE PROFESSIONAL" LETTERS RELATED TO SAFETY* (CONT.)

<i>Generic Name Brand Name (Company)</i>	<i>Warning</i>	<i>Web Site</i>
Efalizumab <i>Raptiva</i> (Genentech)	<p>BOXED WARNING Warning: Increased risk of PML, a rapidly progressive viral infection of the central nervous system. Thus, patients taking <i>Raptiva</i> should be monitored frequently. Dosing of <i>Raptiva</i> should be withheld immediately at the first sign or symptom suggestive of PML.</p> <p>CONTRAINDICATIONS Should not be administered to patients in whom PML has been diagnosed.</p> <p>WARNINGS PML is a rapidly progressive infection of the central nervous system caused by the John Cunningham virus that leads to death or severe disability. It appears that the risk of PML increases with prolonged therapy.</p> <p>WITHDRAWN FROM THE MARKET April 8, 2009.</p>	<p>http://www.fda.gov/cder/foi/label/2009/125075s130lbl.pdf http://www.fda.gov/bbs/topics/NEWS/2009/NEW01992.html</p>
Etonogestrel implant <i>Implanon</i> (Organon)	<p>WARNINGS Should be inserted subdermally so that it is palpable after insertion; this will allow for proper removal.</p>	<p>http://www.fda.gov/cder/foi/label/2009/021529s004lbl.pdf</p>
Fludarabine phosphate <i>Fludara</i> (Bayer HealthCare Pharmaceuticals)	<p>BOXED WARNING Updated to include coma, seizures, agitation, and confusion.</p> <p>WARNINGS Severe central nervous system toxicity, including coma; pregnancy category D because of its mechanism of action.</p>	<p>http://www.fda.gov/cder/foi/label/2009/020038s032lbl.pdf</p>
Fluvoxamine maleate <i>Luvox</i> and <i>Luvox CR</i> (BayPharma)	<p>WARNINGS The development of a potentially life-threatening serotonin syndrome or neuroleptic malignant syndrome-like reactions have been reported with SNRIs and SSRIs alone, but also particularly with concomitant use of serotonergic drugs (including triptans) with drugs that impair metabolism of serotonin (including MAOIs) or with antipsychotics or other dopamine antagonists.</p>	<p>http://www.fda.gov/cder/foi/label/2009/021519s001,022033s002lbl.pdf</p>
Heparin (various)	<p>WARNINGS Fatal medication errors: Heparin is supplied in a wide range of strengths. Fatal hemorrhages have occurred in infants and pediatric patients. Thrombocytopenia: Up to 30% incidence rate; thus, a platelet count should be obtained at baseline. Heparin-induced thrombocytopenia and heparin-induced thrombocytopenia and thrombosis: Delayed onset.</p>	<p>http://www.fda.gov/medwatch/safety/2009/feb09.htm#Heparin</p>

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TABLE 6. SIGNIFICANT LABELING CHANGES OR "DEAR HEALTH CARE PROFESSIONAL" LETTERS RELATED TO SAFETY* (CONT.)

<i>Generic Name Brand Name (Company)</i>	<i>Warning</i>	<i>Web Site</i>
Itraconazole <i>Sporanox</i> and <i>Sporanox IV</i> (Janssen)	<p>BOXED WARNING Drug interactions: Sudden death has occurred in patients taking levacetylmethadol (levomethadyl). <i>Sporanox IV</i> cannot be used when administration of sodium chloride injection is contraindicated.</p> <p>CONTRAINDICATIONS Congestive heart failure (new section): Drug interactions with nisoldipine, levacetylmethadol (levomethadyl), and ergot alkaloids.</p> <p>WARNINGS Cardiac dysrhythmias: Levacetylmethadol (levomethadyl). Cardiac disease: It has been shown that itraconazole and calcium channel blockers have a negative inotropic effect and may be associated with the development of congestive heart failure. Treatment of severely neutropenic patients.</p>	<p>http://www.fda.gov/cder/foi/label/2009/020657s011s018s019s0211bl.pdf http://www.fda.gov/cder/foi/label/2009/020083s040s041s0441bl.pdf http://www.fda.gov/cder/foi/label/2009/020966s017s018s0201bl.pdf</p>
Metoprolol succinate <i>Toprol-XL</i> (AstraZeneca)	<p>WARNINGS Pheochromocytoma: If used in the setting of pheochromocytoma, it should be given in combination with an alpha-blocker and only after the alpha-blocker has been initiated.</p>	<p>http://www.fda.gov/cder/foi/label/2009/019962s0381bl.pdf</p>
Mitoxantrone hydrochloride <i>Novantrone</i> (EMD Serono)	<p>BOXED WARNING Cardiotoxicity: Potentially fatal congestive heart failure may occur either during therapy or months to years after termination of therapy. Cardiotoxicity risk increases with cumulative doses and may occur whether or not cardiac risk factors are present.</p> <p>WARNINGS Changes in cardiac function may occur in patients with multiple sclerosis.</p>	<p>http://www.fda.gov/cder/foi/label/2009/019297s030s0311bl.pdf</p>
Nitrofurantoin <i>Furadantin</i> (Sciele Pharma)	<p>CONTRAINDICATIONS Patients with a history of cholestatic jaundice/hepatic dysfunction associated with nitrofurantoin.</p>	<p>http://www.fda.gov/cder/foi/label/2009/009175s0371bl.pdf</p>
Nitrofurantoin monohydrate/macrocrystals <i>Macrodantin</i> and <i>Macrochantin</i> (Procter & Gamble Pharmaceuticals)	<p>CONTRAINDICATIONS Macrochantin is contraindicated in patients with a history of cholestatic jaundice/hepatic dysfunction associated with nitrofurantoin.</p>	<p>http://www.fda.gov/cder/foi/label/2009/020064s0191bl.pdf http://www.fda.gov/cder/foi/label/2009/016620s0681bl.pdf</p>

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TABLE 6. SIGNIFICANT LABELING CHANGES OR "DEAR HEALTH CARE PROFESSIONAL" LETTERS RELATED TO SAFETY* (CONT.)

<i>Generic Name Brand Name (Company)</i>	<i>Warning</i>	<i>Web Site</i>
Sodium phosphate monobasic monohydrate, USP, and sodium phosphate dibasic anhydrous, USP <i>OsmoPrep</i> (Salix Pharmaceuticals)	BOXED WARNING There have been rare but serious reports of acute phosphate nephropathy in patients who received oral sodium phosphate products for colon cleansing before colonoscopy. Some cases have resulted in permanent impairment of renal function and some patients required long-term dialysis. Although some cases have occurred in patients without identifiable risk factors, patients at increased risk for acute phosphate nephropathy may include those with increased age, hypovolemia, increased bowel transit time (such as bowel obstruction), active colitis, or baseline kidney disease and those using medications that affect renal perfusion or function (such as diuretics, angiotensin-converting enzyme inhibitors, angiotensin receptor blockers, and, possibly, nonsteroidal anti-inflammatory drugs).	http://www.fda.gov/cder/foi/label/2009/021892s0031bl.pdf
Sodium phosphate monobasic monohydrate, USP, and sodium phosphate dibasic anhydrous, USP <i>Visicol</i> (Salix Pharmaceuticals)	BOXED WARNING There have been rare but serious reports of acute phosphate nephropathy in patients who received oral sodium phosphate products for colon cleansing before colonoscopy. Some cases have resulted in permanent impairment of renal function, and some patients required long-term dialysis. Although some cases have occurred in patients without identifiable risk factors, patients at increased risk for acute phosphate nephropathy may include those with increased age, hypovolemia, increased bowel transit time (such as bowel obstruction), active colitis, or baseline kidney disease and those using medications that affect renal perfusion or function (such as diuretics, angiotensin-converting enzyme inhibitors, angiotensin receptor blockers, and, possibly, nonsteroidal anti-inflammatory drugs).	http://www.fda.gov/cder/foi/label/2009/021097s0131bl.pdf
Stavudine <i>Zerit</i> (Bristol-Myers Squibb Company)	WARNINGS Hepatic impairment and toxicity may occur with didanosine and hydroxyurea; thus, this combination should be avoided.	http://www.fda.gov/cder/foi/label/2009/020413s025,020412s0331bl.pdf

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TABLE 6. SIGNIFICANT LABELING CHANGES OR "DEAR HEALTH CARE PROFESSIONAL" LETTERS RELATED TO SAFETY* (CONT.)

<i>Generic Name Brand Name (Company)</i>	<i>Warning</i>	<i>Web Site</i>
Tacrolimus <i>Prograf</i> (Astellas Pharma)	<p>WARNINGS Nephrotoxicity: Can cause nephrotoxicity, particularly when used in high doses. Neurotoxicity: Can cause neurotoxicity, particularly when used in high doses, and it has been reported that patients taking tacrolimus may develop posterior reversible encephalopathy syndrome. Latent viral infections: Patients who are immunosuppressed are at increased risk for opportunistic infections.</p> <p>PRECAUTIONS At a given mycophenolate mofetil dose, mycophenolic acid exposure is higher with <i>Prograf</i> coadministration than with cyclosporine coadministration.</p> <p>ADVERSE REACTIONS Urogenital: BK virus nephropathy. Postmarketing/Nervous system: Posterior reversible encephalopathy syndrome, PML.</p>	http://www.fda.gov/cder/foi/label/2009/050708s034,050709s026lbl.pdf

*Practitioners are encouraged to check the FDA's MEDWATCH Web site (<http://www.fda.gov/medwatch/safety.htm>) for updated information; HIV = human immunodeficiency virus; MAOI = monoamine oxidase inhibitor; PML = progressive multifocal leukoencephalopathy; SNRI = serotonin norepinephrine reuptake inhibitor; SSRI = serotonin selective reuptake inhibitor.