

## Current FDA-Related Drug Information

# New Drugs Approved by the FDA Agents Pending FDA Approval Supplemental Applications Filed by Manufacturer Significant Labeling Changes

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

TABLE 1. NEW DRUGS APPROVED BY THE FDA: DECEMBER 20, 2006 TO JANUARY 19, 2007

Generic Name	Brand Name (Company)	Indication/Comment	Dosage Form (Date)
<b>New Dosage Forms/ Strength/Route of Administration</b>			
Antihemophilic factor/von Willebrand factor complex	<i>Alphanate</i> (Grifols)	Dual inactivated (solvent detergent and heat treatment) antihemophilic factor/von Willebrand factor complex for the treatment of congenital von Willebrand disease in connection with surgery or other invasive procedures	Injection (2/07)
Azacitidine	<i>Vidaza</i> (Pharmion Corporation)	Approved for intravenous (IV) administration over a period of 10 to 40 minutes; previously only approved for subcutaneous administration	Injection (1/07)
L-thyroxin	<i>Tirosint</i> (Institut Biochimique)	Softgel capsule that is supposed to assure stability across the manufacturing process and uniform distribution of the active molecule among the capsules	Capsule (2/07)
Orlistat	<i>Alli</i> (GlaxoSmith Kline)	Over-the-counter availability of a lower strength formulation (60 mg) as a weight-loss agent in combination with a reduced-calorie, low-fat diet	Capsule (2/07)
<b>New Indications</b>			
Drospirenone 3 mg/ethinyl estradiol 20 mcg	<i>YAZ</i> (Berlex)	Treatment of moderate acne vulgaris in women who desire an oral contraceptive for birth control	Tablet (1/07)
Fondaparinux sodium	<i>Arixtra</i> (GlaxoSmith Kline)	Treatment of patients with unstable angina or non-ST segment elevation myocardial infarction (MI) and ST-segment elevation MI	Injection (2/07)

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**TABLE 2. AGENTS PENDING FDA APPROVAL: DECEMBER 20, 2006 TO JANUARY 19, 2007**

<i>Generic Name (Date)</i>	<i>Brand Name (Company)</i>	<i>Indication</i>	<i>Package Insert or Comments</i>
<b>Approvable Agents</b>			
Desvenlafaxine succinate (1/07)	<i>Pristiq</i> (Wyeth)	Treatment for adult patients with major depressive disorder	Pending items are issues that are related to a manufacturing facility, plans to educate health care providers and patients, and postmarketing studies
<b>Agents Scheduled for Review by an FDA Advisory Panel</b>			
Maraviroc	(Pfizer)	Treatment of antiretroviral-experienced patients with chemokine (c-c motif) receptor 5 tropic human immunodeficiency virus	

**TABLE 3. SUPPLEMENTAL APPLICATIONS FILED BY MANUFACTURER: DECEMBER 20, 2006 TO JANUARY 19, 2007**

<i>Generic Name (Date)</i>	<i>Brand Name (Company)</i>	<i>Comments</i>
Sitagliptin phosphate	<i>Januvia</i> (Merck)	Two applications were filed; use in the initial treatment of patients with type 2 diabetes mellitus (DM) and the other for add-on therapy with metformin for glycemic control in patients with type 2 DM

**TABLE 4. SIGNIFICANT LABELING CHANGES OR "DEAR HEALTH PROFESSIONAL LETTERS" RELATED TO SAFETY**

<i>Generic Name Brand Name (Company)</i>	<i>Warning</i>	<i>Web Site</i>
Darbepoetin alfa <i>Aranesp</i> (Amgen)	The drug is ineffective in reducing red blood cell transfusions or fatigue in patients with cancer who have anemia that is not due to concurrent chemotherapy. In addition, darbepoetin alfa therapy may be associated with a higher mortality in this patient population.	<a href="http://www.fda.gov/medwatch/safety/2007/Aranesp_DHCP_012707.htm">http://www.fda.gov/medwatch/safety/2007/Aranesp_DHCP_012707.htm</a>
Estradiol/norethindrone acetate <i>Activella</i> (Novo Nordisk)	Updated sections: BOXED WARNING : Cardiovascular WARNINGS: Cardiovascular disorders, stroke, coronary heart disease, venous thromboembolism, malignant neoplasms, dementia	<a href="http://www.fda.gov/medwatch/safety/2006/Dec_Pls/Activella_PI.pdf">http://www.fda.gov/medwatch/safety/2006/Dec_Pls/Activella_PI.pdf</a>
Heparin (Baxter)	Heparin sodium injection 10,000 units/mL, and HEP-LOCK U/P 10 units/mL. The blue labeling used on these products could cause them to be mistaken for each other. Death has occurred as a result of the higher dosage heparin sodium injection 10,000 units/mL inadvertently administered to an infant instead of the lower dosage of HEP-LOCK U/P 10 units/mL.	<a href="http://www.fda.gov/medwatch/safety/2007/heparin_DHCP_02-06-2007.pdf">http://www.fda.gov/medwatch/safety/2007/heparin_DHCP_02-06-2007.pdf</a>

(continued)

**TABLE 4. SIGNIFICANT LABELING CHANGES OR  
“DEAR HEALTH PROFESSIONAL LETTERS” RELATED TO SAFETY (CONT.)**

<i>Generic Name Brand Name (Company)</i>	<i>Warning</i>	<i>Web Site</i>
Indinavir sulfate <i>Crixivan</i> (Merck)	CONTRAINDICATIONS: Alprazolam has been added to the list of CYP3A4 metabolized drugs that are inhibited by indinavir, which can result in elevated plasma concentrations of the inhibited drug.	<a href="http://www.fda.gov/medwatch/safety/2006/Dec_PIs/Crixivan_PI.pdf">http://www.fda.gov/medwatch/safety/2006/Dec_PIs/Crixivan_PI.pdf</a>
Rotavirus, live, oral, pentavalent vaccine <i>RotaTeq</i> (Merck)	There have been 28 postmarketing reports of intussusception following the administration of the vaccine.	<a href="http://www.fda.gov/cber/safety/phnrota021307.htm">http://www.fda.gov/cber/safety/phnrota021307.htm</a>
Telithromycin <i>Ketek</i> (Sanofi-Aventis)	Acute bacterial sinusitis and acute bacterial exacerbations of chronic bronchitis are no longer approved indications for telithromycin therapy. The warning section has been updated on the risk of hepatotoxicity, loss of consciousness, and visual disturbances. BOXED WARNING: Contraindicated in patients with myasthenia gravis.	<a href="http://www.fda.gov/bbs/topics/NEWS/2007/NEW01561.html">http://www.fda.gov/bbs/topics/NEWS/2007/NEW01561.html</a>
Topical anesthetic drugs	HEALTH WARNING: Application of large amounts of topical anesthetics by the patient to their skin can result in high levels of these products in the blood causing life-threatening side effects, such as an irregular heartbeat, seizures, and death.	<a href="http://www.fda.gov/cder/drug/advisory/topical_anesthetics.htm">http://www.fda.gov/cder/drug/advisory/topical_anesthetics.htm</a>
Trastuzumab <i>Herceptin</i> (Genentech)	BOXED WARNING: <b>Cardiomyopathy</b> Risk and severity of left ventricular cardiac dysfunction and congestive heart failure is highest in patients who received trastuzumab concurrently with anthracycline-containing chemotherapy regimens. Discontinuation of therapy should be considered if the patient develops a clinically significant decrease in their left ventricular function. <b>Infusion Reactions/Pulmonary Toxicity</b> Trastuzumab administration can result in serious infusion reactions and pulmonary toxicity.	<a href="http://www.fda.gov/medwatch/safety/2006/Nov_PIs/Herceptin_PI.pdf">http://www.fda.gov/medwatch/safety/2006/Nov_PIs/Herceptin_PI.pdf</a>
Valsartan <i>Diovan</i> and <i>Diovan HCT</i> (Novartis)	WARNINGS: There have been reports of spontaneous abortion, oligohydramnios, and newborn renal dysfunction when pregnant women have inadvertently taken valsartan. ADVERSE REACTIONS: There are very rare reports of thrombocytopenia.	<a href="http://www.fda.gov/medwatch/safety/2006/Nov_PIs/Diovan_PI.pdf">http://www.fda.gov/medwatch/safety/2006/Nov_PIs/Diovan_PI.pdf</a>
Voriconazole <i>Vfend IV</i> (Pfizer)	PRECAUTION and CONTRAINDICATIONS: Efavirenz has been added to the list of drugs that can significantly decrease the plasma concentration of voriconazole, and voriconazole can decrease the plasma concentrations of efavirenz if standard recommended doses are utilized. The dose of both medications needs to be adjusted if concomitant therapy is to be used.	<a href="http://www.fda.gov/medwatch/safety/2006/Dec_PIs/Vfend_PI.pdf">http://www.fda.gov/medwatch/safety/2006/Dec_PIs/Vfend_PI.pdf</a>
*Practitioners are encouraged to check the Food and Drug Administration’s MedWatch website ( <a href="http://www.fda.gov/med-watch/safety.htm">http://www.fda.gov/med-watch/safety.htm</a> ) for updated information.		