

# 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.

**TABLE 1. NEW DRUGS APPROVED BY THE FDA: JULY 20 TO AUGUST 16, 2007**

<i>Generic Name Brand Name (Company) (Date of Approval)</i>	<i>Comparative Agents</i>	<i>Indication</i>	<i>Mechanism of Action Effects</i>	<i>Common Adverse</i>	<i>Dosage Form and Strength</i>	<i>PI</i>
Estradiol <i>EvaMist</i> (KV Pharma- ceutical/ Vivus) (8/07)	Estrogens	Treatment of moderate to severe vasomotor symptoms due to menopause	Mechanism of action unknown: estrogen replacement and stimulation of estrogen receptors	Headache, breast tenderness, nipple pain, nausea, back pain, nasopharyngitis	Spray 1.53 mg/spray	<a href="http://www.fda.gov/cder/foi/label/2007/022014lbl.pdf">http://www.fda.gov/cder/foi/label/2007/022014lbl.pdf</a>
Maraviroc <i>Selzentry</i> (Pfizer) (8/07)	Antiretroviral agents	Combination antiretroviral treatment of adults infected with only CCR5-tropic human immunodeficiency virus 1 (HIV1) who have evidence of viral replication and HIV-1 strains resistant to multiple antiretroviral agents	CCR5 co-receptor antagonists: selectively binds to the human chemokine receptor CCR5 present on the cell membrane, preventing the interaction of HIV-1 gp120 and CCR5 necessary for CCR5-tropic HIV-1 to enter cells	Cough, pyrexia, upper respiratory tract infections, rash, musculo-skeletal symptoms, abdominal pain, dizziness	Tablet 150 and 300 mg	<a href="http://www.fda.gov/cder/foi/label/2007/022128lbl.pdf">http://www.fda.gov/cder/foi/label/2007/022128lbl.pdf</a>

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**TABLE 2. NEW DOSAGE FORMS AND INDICATIONS APPROVED BY THE FDA:  
JULY 20 TO AUGUST 16, 2007**

<i>Generic Name</i>	<i>Brand Name (Company)</i>	<i>Indication</i>	<i>Dosage Form (Date)</i>
<b>New Dosage Forms/ Strength/Route of Administration</b>			
Immune globulin intravenous (human)	<i>Privigen</i> (CSL Behring)	Treatment of primary immunodeficiency and patients with chronic immune thrombocytopenia purpura to rapidly raise platelet counts to prevent bleeding	Injection (7/07)
Omega-3-acid ethyl esters	<i>Lovaza</i> (Reliant Pharmaceuticals)	Name change from <i>Omacor</i> to avoid name-related errors	Capsules (8/07)
Tegaserod	<i>Zelnorm</i> (Novartis)	Reintroduction of tegaserod using a restricted use program: treatment investigational new drug protocol to treat irritable bowel syndrome with constipation and chronic idiopathic constipation in women younger than 55 years of age who meet specific guidelines ( <a href="http://www.zelnorm.com">www.zelnorm.com</a> )	Tablet (7/07)
Tropium chloride	<i>Sanctura XL</i> (Indevus Pharmaceuticals)	Once-daily formulation (60 mg)	Tablet (8/07)

TABLE 3. AGENTS PENDING FDA APPROVAL: JULY 20 TO AUGUST 16, 2007

<i>Generic Name (Date)</i>	<i>Brand Name (Company)</i>	<i>Indication</i>	<i>Package Insert or Comments</i>
<b>Approvable Agents</b>			
Sumatriptan/naproxen sodium	<i>Trexima</i> (GlaxoSmithKline)	Treatment of migraine headaches	
<b>Recommended for Approval by an FDA Advisory Panel or the FDA</b>			
Natalizumab (8/07)	<i>Tysabr</i> (Biogen Idec/Elan)	Treatment of patients who have Crohn disease and have failed both tumor necrosis factor inhibitor treatment and are not on immunosuppressive therapy	
<b>Agents not Recommended for Approval OR more information requested by an FDA Advisory Panel or the FDA</b>			
Bifeprunox	(Solvay/Wyeth)	Treatment and maintenance of stability of patients who have schizophrenia	
Fluticasone propionate/salmeterol	<i>Advair</i> (GlaxoSmithKline)	Higher strength formulation (500/50) for the treatment of chronic obstructive pulmonary disease	
<b>Agents Scheduled for Review by an FDA Advisory Panel</b>			
Aprotinin	<i>Trasylol</i> (Bayer Pharmaceuticals)	Prophylactic use to reduce perioperative blood loss and the need for blood transfusion in patients undergoing cardiopulmonary bypass in the course of coronary artery bypass graft surgery who are at increased risk for blood loss and blood transfusion	
Erythropoiesis-stimulating agents	<i>Aranesp, Epogen, Procrit</i> (Amgen)	Treatment of anemia due to chronic renal failure	Review of the risks and benefits associated with the use of this agent for this indication
Over-the-counter (OTC) cough and cold products	Various		Review of the safety and efficacy of over-the-counter cough and cold products marketed for pediatric use
Raltegravir potassium	<i>Isentress</i> (Merck)	Treatment of HIV-1 infection in combination with other antiretroviral agents in treatment-experienced patients with evidence of HIV-1 replication despite ongoing antiretroviral therapy	

**TABLE 4. NEW DRUG APPLICATIONS FILED BY MANUFACTURER: JULY 20 TO AUGUST 16, 2007**

<i>Generic Name Brand Name (Company) (Date)</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>Comments</i>
Cinryze (Lev Pharmaceuticals) (7/07)	None	Acute treatment of hereditary angioedema	C1-esterase inhibitor	NA	Injection	
NA = not available						

**TABLE 5. SUPPLEMENTAL APPLICATIONS FILED BY MANUFACTURER: JULY 20 TO AUGUST 16, 2007**

<i>Generic Name</i>	<i>Generic Name (Company)</i>	<i>Comments</i>
Bivalirudin	Angiomax (Medicines Co)	Immediate treatment of patients with acute coronary syndromes

**TABLE 6. 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>
Ceftriaxone sodium <i>Rocephin</i> (Roche)	<p><b>CONTRAINDICATIONS:</b> Hyperbilirubinemic neonates, especially premature infants—avoid using concurrently with calcium-containing solutions or products in newborns because of the risk of precipitation of ceftriaxone-calcium salt.</p> <p><b>WARNINGS:</b> Ceftriaxone must not be mixed or administered simultaneously with calcium-containing solutions or products, even via different infusion lines.</p> <p>Calcium-containing solutions or products must not be administered within 48 hours of last administration of ceftriaxone.</p> <p>Cases of fatal reactions with calcium-ceftriaxone precipitates in the lungs and kidneys of both term and preterm neonates have been described. In some cases, the infusion lines and times of administration of ceftriaxone and calcium-containing solutions differed.</p>	<a href="http://www.fda.gov/medwatch/SAFETY/2007/May_PI/Rocephin_PI.pdf">http://www.fda.gov/medwatch/SAFETY/2007/May_PI/Rocephin_PI.pdf</a>
Clopidogrel bisulfate <i>Plavix</i> (sanofi- synthelabo/ Bristol-Myers Squibb)	<p><b>WARNINGS:</b> Thrombotic thrombocytopenic purpura (TTP) has been rarely reported following use of <i>Plavix</i>, sometimes after a short exposure (less than 2 weeks). It is characterized by thrombocytopenia, microangiopathic hemolytic anemia (schistocytes [fragmented red blood cells] seen on peripheral smear), neurological findings, renal dysfunction, and fever.</p>	<a href="http://www.fda.gov/medwatch/SAFETY/2007/May_PI/Plavix_PI.pdf">http://www.fda.gov/medwatch/SAFETY/2007/May_PI/Plavix_PI.pdf</a>
<i>(continued)</i>		

**TABLE 6. 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>
Dalteparin sodium injection <i>Fragmin</i> (Eisai/Pfizer)	<b>WARNINGS:</b> Thrombocytopenia In <i>Fragmin</i> clinical trials supporting noncancer indications, platelet counts of less than 100,000/mm <sup>3</sup> and less than 50,000/mm <sup>3</sup> occurred in less than 1% of patients, respectively. In the clinical trial of patients with cancer and acute symptomatic venous thromboembolism treated for up to 6 months in the <i>Fragmin</i> treatment arm, platelet counts of less than 100,000/mm <sup>3</sup> occurred in 13.6% of patients, including 6.5% who also had platelet counts less than 50,000/mm <sup>3</sup> . In the same clinical trial, thrombocytopenia was reported as an adverse event in 10.9% of patients in the <i>Fragmin</i> arm and 8.1% of patients in the oral anti-coagulation arm.	<a href="http://www.fda.gov/medwatch/SAFETY/2007/May_PI/Fragmin_PI.pdf">http://www.fda.gov/medwatch/SAFETY/2007/May_PI/Fragmin_PI.pdf</a>
Emtricitabine and tenofovir disoproxil fumarate <i>Truvada</i> (Gilead Sciences)	<b>BOXED WARNING:</b> Not approved for the treatment of chronic hepatitis B virus (HBV) infection, and the safety and efficacy of <i>Truvada</i> have not been established in patients co-infected with HBV and HIV. <b>WARNINGS:</b> Renal impairment, including cases of acute renal failure and Fanconi syndrome (renal tubular injury with severe hypophosphatemia), has been reported. It is recommended that creatinine clearance (CrCl) be calculated in all patients prior to initiating therapy and as clinically appropriate during therapy with <i>Truvada</i> . Routine monitoring of calculated CrCl and serum phosphorus should be performed in patients at risk for renal impairment. <b>Other</b> <i>Truvada</i> is a fixed-dose combination of emtricitabine and tenofovir disoproxil fumarate. <i>Truvada</i> should not be coadministered with <i>Atripla</i> , <i>Emtriva</i> , or <i>Viread</i> . Due to similarities between emtricitabine and lamivudine, <i>Truvada</i> should not be coadministered with other drugs containing lamivudine, including <i>Combivir</i> (lamivudine/zidovudine), <i>Epivir</i> or <i>Epivir-HBV</i> (lamivudine), <i>Epzicom</i> (abacavir sulfate/lamivudine), or <i>Trizivir</i> (abacavir sulfate/lamivudine/zidovudine).	<a href="http://www.fda.gov/medwatch/SAFETY/2007/May_PI/Truvada_PI.pdf">http://www.fda.gov/medwatch/SAFETY/2007/May_PI/Truvada_PI.pdf</a>
Enoxaparin sodium injection <i>Lovenox</i> (sanofi-aventis)	<b>CONTRAINDICATIONS:</b> Known hypersensitivity to enoxaparin sodium (eg, pruritus, urticaria, anaphylactoid reactions). <b>WARNINGS and PRECAUTIONS:</b> Percutaneous Coronary Revascularization Procedures To minimize the risk of bleeding following the vascular instrumentation during the treatment of unstable angina, non-Q-wave myocardial infarction (MI) and acute ST-segment elevation MI, adhere precisely to the intervals recommended between doses. If a manual compression method is used, sheath should be removed 6 hours after the last intravenous (IV)/subcutaneous <i>Lovenox</i> . If the treatment with enoxaparin sodium is to be continued, the next scheduled dose should be given no sooner than 6 to 8 hours after sheath removal. The site of the procedure should be observed for signs of bleeding or hematoma formation.	<a href="http://www.fda.gov/medwatch/SAFETY/2007/May_PI/Lovenox%20_PI.pdf">http://www.fda.gov/medwatch/SAFETY/2007/May_PI/Lovenox%20_PI.pdf</a>

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**TABLE 6. SIGNIFICANT LABELING CHANGES OR “DEAR HEALTH PROFESSIONAL LETTERS” RELATED TO SAFETY\* (CONT.)**

Generic Name Brand Name (Company)	Warning	Web Site
Gemifloxacin mesylate <i>Factive</i> (Oscient Pharmaceuticals)	<p><b>WARNINGS: QT Effects</b> No cardiovascular morbidity or mortality attributable to QTc prolongation occurred with <i>Factive</i> treatment in over 8,119 patients, including 707 patients concurrently receiving drugs known to prolong the QTc interval and seven patients with hypokalemia.</p> <p><b>Hypersensitivity Reactions</b> Serious hypersensitivity and/or anaphylactic reactions have been reported in patients receiving fluoroquinolone therapy. Immediately discontinue the drug at the first appearance of a skin rash, jaundice, or any other sign of hypersensitivity and institute supportive measures.</p> <p><b>Clostridium difficile associated Diarrhea (CDAD)</b> CDAD has been reported with use of nearly all antibacterial agents, including <i>Factive</i>, and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon, leading to overgrowth of <i>C. difficile</i>, which produces toxins A and B and contributes to the development of CDAD. If CDAD is suspected or confirmed, ongoing antibiotic use may need to be discontinued if it is not directed against <i>C. difficile</i>. If clinically indicated, institute appropriate fluid and electrolyte management, protein supplementation, antibiotic treatment of <i>C. difficile</i>, as well as surgical evaluation.</p>	<p><a href="http://www.fda.gov/medwatch/SAFETY/2007/May_PI/Factive_PI.pdf">http://www.fda.gov/medwatch/SAFETY/2007/May_PI/Factive_PI.pdf</a></p>
Haloperidol <i>Haldol</i> <i>Decanoate</i> (Janssen Pharmaceutica)	<p><b>WARNINGS: Cardiovascular Effects</b> Cases of sudden death have been reported in psychiatric patients receiving antipsychotic drugs, including <i>Haldol Decanoate</i>. Since QT prolongation has been observed during <i>Haldol Decanoate</i> treatment, it is advised to use caution in patients with QT-prolonging conditions (long QT syndromes, hypokalemia, electrolyte imbalance, drugs known to prolong QT, cardiovascular diseases, family history of QT prolongation). <b>HALDOL DECANOATE MUST NOT BE ADMINISTERED IV.</b></p>	<p><a href="http://www.fda.gov/medwatch/SAFETY/2007/May_PI/Haldol_Decanoate_PI.pdf">http://www.fda.gov/medwatch/SAFETY/2007/May_PI/Haldol_Decanoate_PI.pdf</a></p>
Haloperidol <i>Haldol</i> (Janssen Pharmaceutica)	<p><b>WARNINGS: Cardiovascular Effects</b> Cases of sudden death have been reported in psychiatric patients receiving antipsychotic drugs, including <i>Haldol</i>. Since QT prolongation has been observed during <i>Haldol</i> treatment, it is advised to use caution in patients with QT-prolonging conditions (long QT syndromes, hypokalemia, electrolyte imbalance, drugs known to prolong QT, cardiovascular diseases, family history of QT prolongation). <b>HALDOL MUST NOT BE ADMINISTERED IV.</b></p>	<p><a href="http://www.fda.gov/medwatch/SAFETY/2007/May_PI/Haldol%20Inj_PI.pdf">http://www.fda.gov/medwatch/SAFETY/2007/May_PI/Haldol%20Inj_PI.pdf</a></p>

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**TABLE 6. 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>
Levofloxacin <i>Levaquin</i> (Ortho-McNeil Pharmaceutical)	<p><b>WARNINGS: CDAD</b></p> <p>CDAD has been reported with use of nearly all antibacterial agents, including <i>Levaquin</i>, and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon, leading to overgrowth of <i>C. difficile</i>. <i>C. difficile</i> produces toxins A and B, which contribute to CDAD development.</p> <p>If CDAD is suspected or confirmed, ongoing antibiotic use not directed against <i>C. difficile</i> may need to be discontinued. Institute appropriate fluid and electrolyte management, protein supplementation, antibiotic treatment of <i>C. difficile</i>, and surgical evaluation as clinically indicated.</p>	<a href="http://www.fda.gov/medwatch/SAFETY/2007/May_PI/Levaquin_PI.pdf">http://www.fda.gov/medwatch/SAFETY/2007/May_PI/Levaquin_PI.pdf</a>
Lopinavir/ ritonavir <i>Kaletra Oral Solution</i> (Abbott Laboratories)	Warning regarding the risk of accidental overdose in pediatric patients.	<a href="http://www.fda.gov/medwatch/safety/2007/Kaletra_DHCP.pdf">http://www.fda.gov/medwatch/safety/2007/Kaletra_DHCP.pdf</a>
Methamphetamine hydrochloride <i>Desoxyn</i> (Ovation Pharmaceuticals)	<p>Box Warning regarding serious cardiovascular events, including sudden death.</p> <p>Sections added to the Warning Section:</p> <ul style="list-style-type: none"> <li>• Sudden Death and Pre-existing Structural Cardiac Abnormalities or other Serious Heart Problems</li> <li>• Psychiatric Adverse Events</li> <li>• Long-Term Suppression of Growth</li> <li>• Seizures</li> <li>• Visual Disturbance</li> </ul>	<a href="http://www.fda.gov/medwatch/SAFETY/2007/May_PI/Desoxyn_PI.pdf">http://www.fda.gov/medwatch/SAFETY/2007/May_PI/Desoxyn_PI.pdf</a>
Moxifloxacin hydrochloride <i>Avelox</i> (Bayer Health Care & Schering- Plough)	<p><b>WARNINGS: Hypersensitivity Reactions</b></p> <p>Other serious and sometimes fatal events, some due to hypersensitivity, have been rarely reported in patients receiving therapy with quinolones. These events may be severe and generally occur following the administration of multiple doses. The drug should be immediately discontinued at the first appearance of a skin rash, jaundice, or any other sign of hypersensitivity, and supportive measures should be instituted.</p> <p><b>WARNINGS: CDAD</b></p> <p>CDAD has been reported with use of nearly all antibacterial and may range in severity from mild diarrhea to fatal colitis, with antibacterial agents alters the normal flora of the colon, leading to overgrowth of <i>C. difficile</i>.</p> <p><i>C. difficile</i> produces toxins A and B, which contribute to the development of CDAD.</p> <p>If CDAD is suspected or confirmed, ongoing antibiotic use not directed against <i>C. difficile</i> may need to be discontinued. Institute appropriate fluid and electrolyte management, protein supplementation, antibiotic treatment of <i>C. difficile</i>, and surgical evaluation as clinically indicated.</p>	<a href="http://www.fda.gov/medwatch/SAFETY/2007/May_PI/Avelox_PI.pdf">http://www.fda.gov/medwatch/SAFETY/2007/May_PI/Avelox_PI.pdf</a>

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**TABLE 6. 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>
Nalidixic acid <i>NegGram</i> (sanofi-aventis)	<p><b>WARNINGS: CDAD</b>                      CDAD has been reported with use of nearly all antibacterial agents and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of <i>C. difficile</i>.  <i>C. difficile</i> produces toxins A and B, which contribute to the development of CDAD.                      If CDAD is suspected or confirmed, ongoing antibiotic use not directed against <i>C. difficile</i> may need to be discontinued. Institute appropriate fluid and electrolyte management, protein supplementation, antibiotic treatment of <i>C. difficile</i>, and surgical evaluation as clinically indicated.</p>	<p><a href="http://www.fda.gov/medwatch/SAFETY/2007/May_PI/NegGram_Caplets_PI.pdf">http://www.fda.gov/medwatch/SAFETY/2007/May_PI/NegGram_Caplets_PI.pdf</a></p>
Ofloxacin <i>Floxin</i> tablet (Ortho-McNeil Pharmaceutical)	<p><b>WARNINGS: CDAD</b>                      CDAD has been reported with use of nearly all antibacterial agents and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon, leading to overgrowth of <i>C. difficile</i>.  <i>C. difficile</i> produces toxins A and B which contribute to the development of CDAD.                      If CDAD is suspected or confirmed, ongoing antibiotic use not directed against <i>C. difficile</i> may need to be discontinued. Institute appropriate fluid and electrolyte management, protein supplementation, antibiotic treatment of <i>C. difficile</i>, and surgical evaluation as clinically indicated.</p>	<p><a href="http://www.fda.gov/medwatch/SAFETY/2007/May_PI/Floxin_PI.pdf">http://www.fda.gov/medwatch/SAFETY/2007/May_PI/Floxin_PI.pdf</a></p>
Peginterferon alfa-2b <i>PEG-INTRON</i> (Schering)	<p><b>WARNINGS: Neuropsychiatric Events</b>                      Life-threatening or fatal neuropsychiatric events, including suicide, suicidal and homicidal ideation, depression, relapse of drug addiction/overdose, and aggressive behavior sometimes directed towards others have occurred in patients with and without a previous psychiatric disorder during PEG-INTRON treatment and follow-up.</p>	<p><a href="http://www.fda.gov/medwatch/SAFETY/2007/May_PI/PegIntron_PI.pdf">http://www.fda.gov/medwatch/SAFETY/2007/May_PI/PegIntron_PI.pdf</a></p>
Ritonavir <i>Norvir</i> (Abbott Laboratories)	<p><b>WARNINGS: Drug Interactions</b>                      Tipranavir coadministered with ritonavir 200 mg has been associated with reports of clinical hepatitis and hepatic decompensation including some fatalities.</p>	<p><a href="http://www.fda.gov/medwatch/SAFETY/2007/May_PI/Norvir_PI.pdf">http://www.fda.gov/medwatch/SAFETY/2007/May_PI/Norvir_PI.pdf</a></p>
Somatropin (rDNA origin) injection <i>Norditropin</i> (Novo Nordisk)	<p><b>CONTRAINDICATIONS: Acute Critical Illness</b>                      Treatment with pharmacologic amounts of somatropin is contraindicated in patients with acute critical illness.  <b>Prader-Willi Syndrome in Children</b>                      Contraindicated in patients with Prader-Willi syndrome who are severely obese, have a history of upper airway obstruction or sleep apnea, or have severe respiratory impairment.  <b>Hypersensitivity</b>                      Localized reactions are the most common hypersensitivity reactions.</p>	

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**TABLE 6. 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>
Somatropin (rDNA origin) (cont.)	<p>WARNINGS and PRECAUTIONS: Acute Critical Illness Increased mortality has been reported in patients with acute critical illness due to complications following open heart surgery, abdominal surgery, multiple accidental trauma, or those with acute respiratory failure who have been treated with pharmacologic amounts of somatropin.</p> <p>Neoplasms Patients should be monitored carefully for potential malignant transformation of skin lesions (ie, increased growth of pre-existing nevi).</p> <p>Fluid Retention Fluid retention during somatropin replacement therapy in adults may frequently occur.</p> <p>Progression of Pre-existing Scoliosis in Pediatric Patients Skeletal abnormalities, including scoliosis, are commonly seen in untreated patients with Turner syndrome and Noonan syndrome.</p>	<p><a href="http://www.fda.gov/medwatch/SAFETY/2007/May_PI/Norditropin%20_PI.pdf">http://www.fda.gov/medwatch/SAFETY/2007/May_PI/Norditropin%20_PI.pdf</a></p>
Tenofovir disoproxil fumarate <i>Viread</i> (Gilead Sciences)	<p>BOXED WARNING: <i>Viread</i> is not approved for the treatment of chronic hepatitis B virus (HBV) infection and the safety and efficacy of <i>Viread</i> have not been established in patients co-infected with HBV and HIV.</p> <p>WARNINGS: Renal impairment, including cases of acute renal failure and Fanconi syndrome (renal tubular injury with severe hypophosphatemia), has been reported. It is recommended that CrCl be calculated in all patients prior to initiating therapy and as clinically appropriate during therapy with <i>Viread</i>. Routine monitoring of calculated CrCl and serum phosphorus should be performed in patients at risk for renal impairment.</p> <p>Other <i>Viread</i> is a fixed-dose combination of emtricitabine and tenofovir disoproxil fumarate. <i>Viread</i> should not be coadministered with <i>Atripla</i> or <i>Emitriva</i>. Due to similarities between emtricitabine and lamivudine, <i>Viread</i> should not be used in combination with the fixed-dose combination products <i>Truvada</i> or <i>Atripla</i>, since it is a component of these products.</p>	<p><a href="http://www.fda.gov/medwatch/SAFETY/2007/May_PI/Viread_PI.pdf">http://www.fda.gov/medwatch/SAFETY/2007/May_PI/Viread_PI.pdf</a></p>

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**TABLE 6. SIGNIFICANT LABELING CHANGES OR “DEAR HEALTH PROFESSIONAL LETTERS” RELATED TO SAFETY\* (CONT.)**

Generic Name Brand Name (Company)	Warning	Web Site
Thiazolidinedione antidiabetic drugs Pioglitazone <i>Actos</i> (Takeda) Rosiglitazone <i>Avandia</i> (GlaxoSmithKline) plus all combination products	Class warning for all thiazolidinedione class of antidiabetic drugs: observe patients carefully for the signs and symptoms of heart failure, including excessive, rapid weight gain, shortness of breath, and edema after starting drug therapy.	<a href="http://www.fda.gov/bbs/topics/NEWS/2007/NEW01683.html">http://www.fda.gov/bbs/topics/NEWS/2007/NEW01683.html</a>
Tigecycline <i>Tygacil</i> (Wyeth)	WARNINGS: CDAD CDAD has been reported with use of nearly all antibacterial agents and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon, leading to overgrowth of <i>C. difficile</i> . <i>C. difficile</i> produces toxins A and B, which contribute to the development of CDAD. If CDAD is suspected or confirmed, ongoing antibiotic use not directed against <i>C. difficile</i> may need to be discontinued. Institute appropriate fluid and electrolyte management, protein supplementation, antibiotic treatment of <i>C. difficile</i> , and surgical evaluation as clinically indicated.	<a href="http://www.fda.gov/medwatch/SAFETY/2007/May_PI/Tygacil_PI.pdf">http://www.fda.gov/medwatch/SAFETY/2007/May_PI/Tygacil_PI.pdf</a>
Tinidazole <i>Tindamax</i> (Mission Pharmaceutical)	BOXED WARNING: Warning/potential risk for carcinogenicity. CONTRAINDICATIONS • In patients with a previous history of hypersensitivity to tinidazole or other nitroimidazole derivatives • In breast-feeding mothers: interruption of breast-feeding is recommended during tinidazole therapy and for 3 days following the last dose WARNINGS and PRECAUTIONS: Vaginal Candidiasis The use of tinidazole may result in Candida vaginitis. Drug Resistance Prescribing in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.	<a href="http://www.fda.gov/medwatch/SAFETY/2007/May_PI/Tindamax%20_PI.pdf">http://www.fda.gov/medwatch/SAFETY/2007/May_PI/Tindamax%20_PI.pdf</a>
Tipranavir <i>Aptivus</i> (Boehringer Ingelheim)	WARNINGS: Effects on Platelet Aggregation and Coagulation Aptivus/ritonavir should be used with caution in patients who may be at risk of increased bleeding from trauma, surgery, other medical conditions, or those who are receiving medications known to increase the risk of bleeding such as antiplatelet agents and anticoagulants, or those who are taking supplemental high doses of vitamin E. Tipranavir may inhibit human platelet aggregation. Coadministration with vitamin E increases the bleeding effects of tipranavir.	<a href="http://www.fda.gov/medwatch/SAFETY/2007/May_PI/Aptivus_PI.pdf">http://www.fda.gov/medwatch/SAFETY/2007/May_PI/Aptivus_PI.pdf</a>

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"DEAR HEALTH PROFESSIONAL LETTERS" RELATED TO SAFETY\***

<i>Generic Name Brand Name (Company)</i>	<i>Warning</i>	<i>Web Site</i>
Ziprasidone Hydrochloride <i>Geodon</i> (Pfizer)	WARNINGS: QT Prolongation and Risk of Sudden Death Although torsades de pointes has not been observed in association with the use of ziprasidone at recommended doses in an increased risk, there have been rare postmarketing reports (in the presence of multiple confounding factors).	<a href="http://www.fda.gov/medwatch/SAFETY/2007/May_PI/Geodon_PI.pdf">http://www.fda.gov/medwatch/ SAFETY/2007/May_PI/Geodon_ PI.pdf</a>
*Practitioners are encouraged to check the Food and Drug Administration's MedWatch Web site ( <a href="http://www.fda.gov/med-watch/safety.htm">http://www.fda.gov/med- watch/safety.htm</a> ) for updated information.		