Current FDA-Related Drug Information

Approvals, Submission, and Important Labeling Changes for US Marketed Pharmaceuticals

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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 me know at bakerdan@wsu.edu.

Table 1. New drugs approved by the US Food and Drug Administration (FDA): October 18, 2012 through November 19, 2012

Omacetaxine mepesuccinate – Synribo (Teva Pharmaceutical)	
<i>Comparative agents:</i>	Bosutinib
<i>Indication:</i>	Treatment of adults with chronic or accelerated phase chronic myeloid leukemia with resistance and/or intolerance to 2 or more tyrosine kinase inhibitors
<i>Mechanism of action:</i>	Unknown, includes inhibition of protein synthesis and is independent of direct Bcr-Abl binding
<i>Common adverse effects:</i>	Thrombocytopenia, anemia, neutropenia, diarrhea, nausea, fatigue, asthenia, injection site reaction, pyrexia, infection, and lymphopenia
<i>Dosage form & strength:</i>	Injection; 3.5 mg single-use vial
<i>Product labeling:</i>	http://www.accessdata.fda.gov/drugsatfda_docs/label/2012/203585lbl.pdf
Perampanel – Fycompa (Eisai)	
<i>Comparative agents:</i>	Anticonvulsants
<i>Indication:</i>	Adjunctive therapy for the treatment of partial-onset seizures with or without secondarily generalized seizures in patients with epilepsy aged 12 years and older
<i>Mechanism of action:</i>	Noncompetitive AMPA glutamate receptor antagonist
<i>Common adverse effects:</i>	Dizziness, drowsiness, fatigue, irritability, falls, upper respiratory tract infection, weight increase, vertigo, loss of muscle coordination (ataxia), gait disturbance, balance disorder, anxiety, blurred vision, stuttering (dysarthria), weakness (asthenia), aggression, and excessive sleep (hypersomnia)
<i>Dosage form & strength:</i>	Tablets: 2, 4, 6, 8, 10, and 12 mg
<i>Product labeling:</i>	http://us.eisai.com/package_inserts/FycompaPI.pdf
Tofacitinib – Xeljanz (Pfizer)	
<i>Comparative agents:</i>	Adalimumab (<i>Humira</i>), infliximab (<i>Remicade</i>), etanercept (<i>Enbrel</i>)
<i>Indication:</i>	Treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to methotrexate; may be used as monotherapy or in combination with methotrexate or other nonbiologic disease-modifying antirheumatic drugs
<i>Mechanism of action:</i>	Inhibitor of Janus kinase (JAK)
<i>Common adverse effects:</i>	Upper respiratory tract infections, headache, diarrhea and nasopharyngitis
<i>Dosage form & strength:</i>	Tablets; 5 mg
<i>Product labeling:</i>	http://labeling.pfizer.com/ShowLabeling.aspx?id=959

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Table 2. New dosage forms and indications approved by the FDA: October 18, 2012 through November 19, 2012

Generic name	Brand name (Company)	Indication and comments
New dosage forms/ strength/route of administration		
Rituximab	<i>Rituxan</i> injection (Genentech, Inc.)	90-minute infusion approved for previously untreated follicular non-Hodgkin lymphoma (NHL) and diffuse large B-cell NHL patients: If patients did not experience a grade 3 or 4 infusion-related adverse event during cycle 1, a 90-minute infusion can be administered in cycle 2 with a glucocorticoid-containing chemotherapy regimen.
New indications		
Calcipotriene / betamethasone dipropionate	<i>Taclonex</i> Topical Suspension (LEO Pharma)	Treatment of body plaque psoriasis for up to 8 weeks
Lidocaine/tetracaine	<i>Plialis</i> (Nuvo Research, Inc. & Galderma)	Use on intact skin in adults to provide local analgesia for superficial aesthetic procedures, such as dermal filler, injection, pulsed dye laser therapy, facial laser resurfacing, and laser-assisted tattoo removal.
Rivaroxaban	<i>Xarelto</i> (Janssen Pharmaceuticals)	Treatment of deep vein thrombosis or pulmonary embolism and to reduce the risk of recurrent deep venous thrombosis and pulmonary embolism following initial treatment

Table 3. Agents pending FDA approval: October 18, 2012 through November 19, 2012

Generic name	Brand name (Company)	Indication and comments
Complete response letter: more information required		
Lixivaptan	(Cornerstone Therapeutics)	Additional clinical and nonclinical information was requested to support its application for the treatment of symptomatic hypervolemic and euvoletic hyponatremia associated with heart failure and syndrome of inappropriate antidiuretic hormone.
Treprostinil diethanolamine extended-release tablets	(United Therapeutics Corporation)	Clinical importance of the 6-minute walk distance effect size shown in the studies with the extended-release formulation was questioned by the FDA.
Recommended for approval by an FDA advisory panel		
Insulin degludec	<i>Tresidba</i> (Novo Nordisk)	Treatment of diabetes
Insulin degludec/aspart	<i>Ryzodeg</i> (Novo Nordisk)	Treatment of diabetes
Lomitapide	(Aegerion)	Homozygous familial hypercholesterolemia used as an adjunct to a low-fat diet and other lipid-lowering therapies; FDA advisory panel voted 13:2 for approval.

Table 4. New drug / biologics license applications filed by manufacturer: October 18, 2012 through November 19, 2012

Generic name Brand name (Company)	Comparative agents	Indication	Mechanism of action	Common adverse effects	Dosage form or route	Comments
Macitentan <i>Opsumit</i> (Actelion)	Bosentan	Treatment of patients with pulmonary arterial hypertension	Dual endothelin receptor antagonist	Nasopharyngitis, headache, and anemia	Oral	–

Table 5. Significant labeling changes or “Dear Health Professional” letters related to safety^a

Generic Name Brand Name (Company)	Warning
All HMG CoA reductase inhibitors (statin)	<p>WARNINGS AND PRECAUTIONS</p> <p>Skeletal Muscle</p> <ul style="list-style-type: none"> There have been rare reports of immune-mediated necrotizing myopathy (IMNM), an autoimmune myopathy, associated with (statin) use. IMNM is characterized by proximal muscle weakness and elevated serum creatine kinase, which persist despite discontinuation of statin treatment; muscle biopsy showing necrotizing myopathy without significant inflammation; improvement with immunosuppressive agents. <p>http://www.fda.gov/Safety/MedWatch/SafetyInformation/ucm327852.htm</p>
Ambrisentan <i>Letairis</i> (Gilead)	<p>CONTRAINDICATIONS</p> <p>Idiopathic Pulmonary Fibrosis</p> <ul style="list-style-type: none"> Contraindicated in patients with idiopathic pulmonary fibrosis (IPF) including IPF patients with pulmonary hypertension (WHO group 3). <p>ADVERSE REACTIONS</p> <p>Postmarketing Experience</p> <ul style="list-style-type: none"> Asthenia, dizziness, and fatigue <p>http://www.fda.gov/Safety/MedWatch/SafetyInformation/ucm233391.htm</p>
Bosentan <i>Tracleer</i> (Actelion Pharmaceuticals Ltd)	<p>WARNINGS AND PRECAUTIONS</p> <p>Patients with Pre-existing Hepatic Impairment</p> <ul style="list-style-type: none"> Not recommended in patients with moderate or severe liver impairment. In addition, initiation should generally be avoided in patients with elevated aminotransferases (> 3 x upper limit of normal [ULN]) prior to drug initiation because monitoring hepatotoxicity in these patients may be more difficult. <p>USE IN SPECIFIC POPULATIONS</p> <ul style="list-style-type: none"> In patients with moderate hepatic impairment (Child-Pugh class B), the systemic exposures to bosentan and its active metabolite increased significantly. Tracleer should generally be avoided in patients with moderate or severe liver impairment. <p>http://www.fda.gov/Safety/MedWatch/SafetyInformation/ucm327930.htm</p>
Brimonidine tartrate/timolol maleate <i>Combigan</i> (Allergan)	<p>CONTRAINDICATIONS</p> <p>Neonates and Infants (under the age of 2 years)</p> <ul style="list-style-type: none"> <i>Combigan</i> is contraindicated in neonates and infants (under the age of 2 years). <p>WARNINGS AND PRECAUTIONS</p> <p>Ocular Hypersensitivity</p> <ul style="list-style-type: none"> Ocular hypersensitivity reactions have been reported with brimonidine tartrate ophthalmic solutions 0.2%, with some reported to be associated with an increase in intraocular pressure. <p>ADVERSE REACTIONS</p> <p>Postmarketing Experience</p> <ul style="list-style-type: none"> Hypersensitivity In infants, apnea, bradycardia, coma, hypotension, hypothermia, hypotonia, lethargy, pallor, respiratory depression, and somnolence have been reported. <p>OVERDOSAGE</p> <ul style="list-style-type: none"> Symptoms of brimonidine overdose have been reported in neonates, infants, and children receiving brimonidine ophthalmic solutions as part of medical treatment of congenital glaucoma or by accidental oral ingestion <p>http://www.fda.gov/Safety/MedWatch/SafetyInformation/ucm327514.htm</p>

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Table 5. Significant labeling changes or “Dear Health Professional” letters related to safety^a (CONT.)

Generic Name Brand Name (Company)	Warning
Certolizumab pegol <i>Cimzia</i> (UCB, Inc.)	<p>WARNINGS AND PRECAUTIONS</p> <p>Hepatitis B Virus (HBV) Reactivation</p> <ul style="list-style-type: none"> • Use of tumor necrosis factor (TNF) blockers has been associated with reactivation of HBV in patients who are chronic carriers of this virus. In some instances, HBV reactivation occurring in conjunction with TNF blocker therapy has been fatal. The majority of reports have occurred in patients concomitantly receiving other medications that suppress the immune system, which may also contribute to HBV reactivation. • Test patients for HBV infection before initiating treatment with <i>Cimzia</i>. For patients who test positive for HBV infection, consultation with a physician with expertise in the treatment of hepatitis B is recommended. Adequate data are not available on the safety or efficacy of treating patients who are carriers of HBV with antiviral therapy in conjunction with TNF blocker therapy to prevent HBV reactivation. Patients who are carriers of HBV and require treatment with <i>Cimzia</i> should be closely monitored for clinical and laboratory signs of active HBV infection throughout therapy and for several months following termination of therapy. • In patients who develop HBV reactivation, discontinue <i>Cimzia</i> and initiate effective antiviral therapy with appropriate supportive treatment. The safety of resuming TNF blocker therapy after HBV reactivation is controlled is not known. <p>http://www.fda.gov/Safety/MedWatch/SafetyInformation/ucm327828.htm</p>

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Table 5. Significant labeling changes or “Dear Health Professional” letters related to safety^a (CONT.)

Generic Name Brand Name (Company)	Warning
Duloxetine hydrochloride <i>Cymbalta</i> (Lilly)	<p>CONTRAINDICATIONS</p> <p>Monoamine Oxidase Inhibitors (MAOIs)</p> <ul style="list-style-type: none"> • The use of MAOIs intended to treat psychiatric disorders with <i>Cymbalta</i> or within 5 days of stopping treatment with <i>Cymbalta</i> is contraindicated because of an increased risk of serotonin syndrome. The use of <i>Cymbalta</i> within 14 days of stopping an MAOI intended to treat psychiatric disorders is also contraindicated. • Starting <i>Cymbalta</i> in a patient who is being treated with MAOIs such as linezolid or intravenous methylene blue is contraindicated because of an increased risk of serotonin syndrome. <p>WARNINGS AND PRECAUTIONS</p> <p>Serotonin Syndrome</p> <ul style="list-style-type: none"> • The development of a potentially life-threatening serotonin syndrome has been reported with selective norepinephrine reuptake inhibitors (SNRIs) and selective serotonin reuptake inhibitors (SSRIs), including <i>Cymbalta</i>, alone but particularly with concomitant use of other serotonergic drugs (including triptans, tricyclic antidepressants, fentanyl, lithium, tramadol, tryptophan, buspirone, and St. John’s wort) and with drugs that impair metabolism of serotonin (in particular, MAOIs, both those intended to treat psychiatric disorders and others, such as linezolid and intravenous methylene blue). • Serotonin syndrome symptoms may include mental status changes (eg, agitation, hallucinations, delirium, and coma), autonomic instability (eg, tachycardia, labile blood pressure, dizziness, diaphoresis, flushing, hyperthermia), neuromuscular symptoms (eg, tremor, rigidity, myoclonus, hyperreflexia, incoordination), seizures, and/or gastrointestinal symptoms (eg, nausea, vomiting, diarrhea). Patients should be monitored for the emergence of serotonin syndrome. • The concomitant use of <i>Cymbalta</i> with MAOIs intended to treat psychiatric disorders is contraindicated. <i>Cymbalta</i> should also not be started in a patient who is being treated with MAOIs such as linezolid or intravenous methylene blue. There may be circumstances when it is necessary to initiate treatment with an MAOI such as linezolid or intravenous methylene blue in a patient taking <i>Cymbalta</i>. <i>Cymbalta</i> should be discontinued before initiating treatment with the MAOI. • If concomitant use of <i>Cymbalta</i> with other serotonergic drugs including triptans, tricyclic antidepressants, fentanyl, lithium, tramadol, buspirone, tryptophan, and St. John’s wort is clinically warranted, patients should be made aware of a potential increased risk for serotonin syndrome, particularly during treatment initiation and dose increases. Treatment with <i>Cymbalta</i> and any concomitant serotonergic agents should be discontinued immediately if the above events occur and supportive symptomatic treatment should be initiated. <p>Discontinuation of Treatment with <i>Cymbalta</i></p> <ul style="list-style-type: none"> • Discontinuation symptoms have been systematically evaluated in patients taking duloxetine. Following abrupt or tapered discontinuation in placebo-controlled clinical trials, the following symptoms occurred at 1% or greater and at a significantly higher rate in duloxetine-treated patients compared to those discontinuing from placebo: dizziness, headache, nausea, diarrhea, paresthesia, irritability, vomiting, insomnia, anxiety, hyperhidrosis, and fatigue. <p>http://www.fda.gov/Safety/MedWatch/SafetyInformation/ucm319241.htm</p>

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Table 5. Significant labeling changes or “Dear Health Professional” letters related to safety^a (CONT.)

Generic Name Brand Name (Company)	Warning
Esomeprazole – all formulations (AstraZeneca)	<p>WARNINGS AND PRECAUTIONS</p> <p>Interaction with Clopidogrel</p> <ul style="list-style-type: none"> • Avoid concomitant use of esomeprazole/omeprazole with clopidogrel. Clopidogrel is a prodrug. Inhibition of platelet aggregation by clopidogrel is entirely due to an active metabolite. The metabolism of clopidogrel to its active metabolite can be impaired by use with concomitant medications, such as esomeprazole, that inhibit CYP2C19 activity. Concomitant use of clopidogrel with 40 mg esomeprazole/omeprazole reduces the pharmacological activity of clopidogrel. When using esomeprazole/omeprazole, consider alternative anti-platelet therapy. <p>DRUG INTERACTIONS</p> <p>Effects on Hepatic Metabolism/Cytochrome P-450 pathways</p> <ul style="list-style-type: none"> • Clopidogrel: Clopidogrel is metabolized to its active metabolite in part by CYP2C19. Concomitant use of esomeprazole/omeprazole 40 mg results in reduced plasma concentrations of the active metabolite of clopidogrel and a reduction in platelet inhibition. Avoid concomitant administration of esomeprazole/omeprazole with clopidogrel. When using esomeprazole/omeprazole, consider use of alternative antiplatelet therapy. <p>http://www.fda.gov/Safety/MedWatch/SafetyInformation/ucm327922.htm</p>
Fenofibrate <i>Fenoglide</i> (Santarus)	<p>WARNINGS and PRECAUTIONS</p> <p>Mortality and Coronary Heart Disease Morbidity</p> <ul style="list-style-type: none"> • The effect of <i>Fenoglide</i> on coronary heart disease morbidity and mortality and noncardiovascular mortality has not been established. <p>Skeletal Muscle</p> <ul style="list-style-type: none"> • Observational studies indicate that the risk for rhabdomyolysis is increased when fibrates, in particular gemfibrozil, are co-administered with an HMG-CoA reductase inhibitor (statin). The combination should be avoided unless the benefit of further alterations in lipid levels is likely to outweigh the increased risk of this drug combination. <p>Paradoxical Decreases in High-Density Lipoprotein (HDL) Cholesterol Level</p> <ul style="list-style-type: none"> • Reports of severe decreases in HDL cholesterol levels (as low as 2 mg/dL) occurring in diabetic and nondiabetic patients initiated on fibrate therapy. The decrease in HDL cholesterol is mirrored by a decrease in apolipoprotein A1. <p>DRUG INTERACTION</p> <p>Colchicine</p> <ul style="list-style-type: none"> • Cases of myopathy, including rhabdomyolysis, have been reported with fenofibrates co-administered with colchicine, and caution should be exercised when prescribing fenofibrate with colchicine. <p>http://www.fda.gov/Safety/MedWatch/SafetyInformation/ucm327867.htm</p>

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Table 5. Significant labeling changes or “Dear Health Professional” letters related to safety^a (CONT.)

Generic Name Brand Name (Company)	Warning
Ipilimumab <i>Yervoy</i> (Bristol Myers Squibb)	<p>USE IN SPECIFIC POPULATIONS</p> <p>Pregnancy</p> <ul style="list-style-type: none"> In pregnant cynomolgus monkeys treated with ipilimumab every 3 weeks from the onset of organogenesis in the first trimester through parturition, at exposure levels either 2.6 or 7.2 times higher by area under the curve (AUC) than the exposures at the clinical dose of 3 mg/kg of ipilimumab, found no treatment-related adverse effects on reproduction during the first 2 trimesters of pregnancy. Beginning in the third trimester, the ipilimumab-treated groups experienced higher incidences of severe toxicities including abortion, stillbirth, and premature delivery (with corresponding lower birth weight) and higher incidences of infant mortality in a dose-related manner compared to controls. <p>Nursing Mothers</p> <ul style="list-style-type: none"> In monkeys treated at dose levels resulting in exposures 2.6 and 7.2 times higher than those in humans at the recommended dose, ipilimumab was present in milk at concentrations of 0.1 and 0.4 mcg/mL, representing a ratio of up to 0.3% of the serum concentration of the drug. Because many drugs are secreted in human milk and because of the potential for serious adverse reactions in nursing infants from <i>Yervoy</i>, a decision should be made whether to discontinue nursing or to discontinue <i>Yervoy</i>, taking into account the importance of <i>Yervoy</i> to the mother. <p>Hepatic Impairment</p> <ul style="list-style-type: none"> No dose adjustment is needed for patients with mild hepatic impairment (total bilirubin [TB] >1.0 x to 1.5 x ULN or aspartate aminotransferase [AST] >ULN). <i>Yervoy</i> has not been studied in patients with moderate (TB >1.5 x to 3.0 x ULN and any AST) or severe (TB >3 x ULN and any AST) hepatic impairment. <p>http://www.fda.gov/Safety/MedWatch/SafetyInformation/ucm328023.htm</p>
Meclizine hydrochloride (various)	<p>PRECAUTIONS</p> <p>Hepatic Impairment</p> <ul style="list-style-type: none"> As meclizine undergoes metabolism, hepatic impairment may result in increased systemic exposure of the drug. Treatment with meclizine should be administered with caution in patients with hepatic impairment. <p>Renal Impairment</p> <ul style="list-style-type: none"> Due to a potential for drug/metabolite accumulation, meclizine should be administered with caution in patients with renal impairment and in the elderly as renal function generally declines with age. <p>Drug Interactions</p> <ul style="list-style-type: none"> There may be increased central nervous system (CNS) depression when meclizine is administered concurrently with other CNS depressants, including alcohol, tranquilizers, and sedatives. Based on in vitro evaluation, meclizine is metabolized by CYP2D6. Therefore there is a possibility for a drug interaction between meclizine and CYP2D6 inhibitors. <p>http://www.fda.gov/Safety/MedWatch/SafetyInformation/ucm327678.htm</p>
Mirtazapine <i>Remeron</i> & <i>Remeron SolTab</i> (Organon)	<p>CONTRAINDICATIONS</p> <ul style="list-style-type: none"> Starting <i>Remeron</i> in a patient who is being treated with MAOIs such as linezolid or intravenous methylene blue is also contraindicated because of an increased risk of serotonin syndrome. <p>WARNINGS</p> <ul style="list-style-type: none"> There may be circumstances when it is necessary to initiate treatment with an MAOI such as linezolid or intravenous methylene blue in a patient taking <i>Remeron</i>. <i>Remeron</i> should be discontinued before initiating treatment with the MAOI. <p>http://www.fda.gov/Safety/MedWatch/SafetyInformation/ucm327848.htm</p>

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Table 5. Significant labeling changes or “Dear Health Professional” letters related to safety^a (CONT.)

Generic Name Brand Name (Company)	Warning
Omeprazole – all formulations (various)	<p>WARNINGS AND PRECAUTIONS</p> <p>Interaction with Clopidogrel</p> <ul style="list-style-type: none"> • Avoid concomitant use of esomeprazole/omeprazole with clopidogrel. Clopidogrel is a prodrug. Inhibition of platelet aggregation by clopidogrel is entirely due to an active metabolite. The metabolism of clopidogrel to its active metabolite can be impaired by use with concomitant medications, such as esomeprazole, that inhibit CYP2C19 activity. Concomitant use of clopidogrel with 40 mg esomeprazole/omeprazole reduces the pharmacological activity of clopidogrel. When using esomeprazole/omeprazole, consider alternative antiplatelet therapy. <p>DRUG INTERACTIONS</p> <p>Effects on Hepatic Metabolism/Cytochrome P-450 pathways</p> <ul style="list-style-type: none"> • Clopidogrel: Clopidogrel is metabolized to its active metabolite in part by CYP2C19. Concomitant use of esomeprazole/omeprazole 40 mg results in reduced plasma concentrations of the active metabolite of clopidogrel and a reduction in platelet inhibition. Avoid concomitant administration of esomeprazole/omeprazole with clopidogrel. When using esomeprazole/omeprazole, consider use of alternative antiplatelet therapy. <p>http://www.fda.gov/Safety/MedWatch/SafetyInformation/ucm327922.htm</p>
Pemetrexed for injection <i>Alimta</i> (Lilly)	<p>WARNINGS AND PRECAUTIONS</p> <p>Requirement for Premedication and Concomitant Medication to Reduce Toxicity</p> <ul style="list-style-type: none"> • Vitamin supplementation: Prior to treatment with <i>Alimta</i>, initiate supplementation with oral folic acid and intramuscular vitamin B12 to reduce the severity of hematologic and gastrointestinal toxicity of <i>Alimta</i>. Do not substitute oral vitamin B12 for intramuscular vitamin B12. • Corticosteroids: Administer dexamethasone the day before, the day of, and the day after <i>Alimta</i> administration <p>Required Laboratory Monitoring</p> <ul style="list-style-type: none"> • Complete blood count and renal function tests obtained at the beginning of each cycle and as needed. Do not initiate a cycle of treatment unless the absolute neutrophil count (ANC) is ≥ 1500 cells/mm³, the platelet count is $\geq 100,000$ cells/mm³, and creatinine clearance is ≥ 45 mL/min. <p>http://www.fda.gov/Safety/MedWatch/SafetyInformation/ucm327519.htm</p>
Tocilizumab <i>Actemra</i> (Genentech, Inc.)	<p>WARNINGS AND PRECAUTIONS</p> <p>Hypersensitivity reactions, including anaphylaxis, have occurred in patients who received premedication.</p> <p>http://www.fda.gov/Safety/MedWatch/SafetyInformation/ucm327824.htm</p>
Topiramate <i>Topamax</i> – all formulations (Janssen Pharmaceuticals)	<p>WARNINGS AND PRECAUTIONS</p> <ul style="list-style-type: none"> • <i>Topamax</i> with concomitant valproic acid (VPA): to convey that the hyperammonemia developed in response to treatment with both <i>Topamax</i> and VPA together. <p>http://www.fda.gov/Safety/MedWatch/SafetyInformation/ucm195797.htm</p>
Tricyclic antidepressants – dibenzazepine clomipramine, imipramine, and nortriptyline (various)	<p>CONTRAINDICATIONS</p> <ul style="list-style-type: none"> • Starting these drugs in a patient who is being treated with linezolid or intravenous methylene blue is also contraindicated because of an increased risk of serotonin syndrome. <p>WARNINGS</p> <p>Serotonin Syndrome</p> <ul style="list-style-type: none"> • The development of a potentially life-threatening serotonin syndrome has been reported with drugs that impair metabolism of serotonin (in particular, MAOIs, both those intended to treat psychiatric disorders and also others, such as linezolid and intravenous methylene blue). • These drugs should not be started in a patient who is being treated with MAOIs such as linezolid or intravenous methylene blue. <p>http://www.fda.gov/Safety/MedWatch/SafetyInformation/ucm327699.htm</p>

^aPractitioners are encouraged to check the FDA’s MEDWATCH Web site (<http://www.fda.gov/medwatch/safety.htm>) for updated information.