Diclegis
The FDA has approved Diclegis (doxylamine succinate and pyridoxine hydrochloride) to treat pregnant women experiencing nausea and vomiting. Diclegis is a delayed-release tablet intended for women who have not adequately responded to conservative management of nausea and vomiting during pregnancy, such as dietary and lifestyle modifications. Diclegis is taken daily. Tablets must be taken whole on an empty stomach. The recommended starting dose is two tablets taken at bedtime. If symptoms are not adequately controlled, the dose can be increased to a maximum recommended dose of four tablets daily. Diclegis is marketed by Duchesnay Inc.
For more information, visit: [www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm347087.htm](http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm347087.htm)

Kcentra
The FDA has approved Kcentra (Prothrombin Complex Concentrate, Human) for the urgent reversal of vitamin K antagonist (VKA) anticoagulation in adults with acute major bleeding. Plasma is the only other product in the U.S. approved for this use. Patients receiving chronic anticoagulation therapy with warfarin and other VKA anticoagulants to prevent blood clotting in conditions such as atrial fibrillation or the presence of an artificial heart valve sometimes develop acute bleeding. Like plasma, Kcentra is used in conjunction with the administration of vitamin K to reverse the anticoagulation effect and stop the bleeding. Unlike plasma, Kcentra does not require blood group typing or thawing, so it can be administered more quickly than frozen plasma. Kcentra is associated with the occurrence of blood clots when used as indicated, and carries a boxed warning regarding the risk of blood clots. Kcentra is made from the pooled plasma of healthy donors. It is processed in a way to minimize the risk of transmitting viral and other diseases. The product will be manufactured at CSL Behring's Marburg, Germany facility.
For more information, visit: [www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm350026.htm](http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm350026.htm)

Liptruzet
Merck has announced that the FDA has approved Liptruzet (ezetimibe and atorvastatin) tablets for the treatment of elevated low-density lipoprotein (LDL) cholesterol in patients with primary or mixed hyperlipidemia as adjunctive therapy to diet when diet alone is not enough. Liptruzet contains ezetimibe and atorvastatin. Once-daily Liptruzet treats two sources of cholesterol by inhibiting both the absorption of cholesterol in the digestive tract, through ezetimibe, and the production of cholesterol in the liver, through atorvastatin. Liptruzet became available for wholesalers to order the week of May 6.

Minastrin 24 Fe
Warner Chilcott has announced that the FDA has approved Minastrin 24 Fe (norethindrone acetate and ethinyl estradiol capsules and ferrous fumarate capsules) for the prevention of pregnancy. Minastrin 24 Fe is manufactured for Warner Chilcott by a third party. The Company does not expect to be in a position to commercially launch Minastrin 24 Fe during 2013.
For more information, visit: [http://ir.wcrx.com/releasedetail.cfm?ReleaseID=758063](http://ir.wcrx.com/releasedetail.cfm?ReleaseID=758063)

Procysbi
The FDA has approved Procysbi (cysteamine bitartrate) for the management of nephropathic cystinosis in children and adults. Procysbi was granted orphan product designation because it is intended to treat a rare disease or condition. Procysbi is a delayed-release capsule intended for patients 6 years of age and older. Procysbi is a long-acting formulation that is taken every 12 hours. Procysbi is marketed by Raptor Pharmaceuticals.
For more information, visit: [www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm350091.htm](http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm350091.htm)

Simbrinza
Alcon announced the FDA approval of Simbrinza Suspension, indicated for the reduction of elevated intraocular pressure in patients with primary open-angle glaucoma or ocular hypertension. The new ophthalmic suspension is a fixed-dose combination of a carbonic anhydrase inhibitor (brinzolamide 1.0%) and an alpha-2 adrenergic receptor agonist (brimonidine tartrate 0.2%). Patients are to administer one drop of Simbrinza into the affected eye(s), three times per day.

Topicort Topical Spray 0.25%
Taro Pharmaceutical Industries Ltd. has reported that it has received approval from the FDA for its Topicort (desoximetasone) Topical Spray, 0.25%. Topicort Topical Spray, 0.25% is a corticosteroid indicated for the treatment of plaque psoriasis in patients 18 years of age or older.
FDA New Indications

Amitiza
Sucampo Pharmaceuticals, Inc. and Takeda Pharmaceuticals USA, Inc. have announced that the FDA has approved Sucampo’s supplemental new drug application for Amitiza (lubiprostone) (24 mcg twice daily) as the first oral medication for the treatment of opioid-induced constipation in adult patients with chronic, non-cancer pain. This is the third indication for Amitiza, which is also approved for the treatment of chronic idiopathic constipation in adults (24 mcg twice daily) and irritable bowel syndrome with constipation in adult women (8 mcg twice daily).
For more information, visit: www.takeda.us/newsroom/press_release_detail.aspx?year=2013&id=272

Sustiva
Bristol-Myers Squibb Company has announced that the FDA has approved a supplemental new drug application (sNDA) for Sustiva (efavirenz), including dosing recommendations for HIV-1 infected pediatric patients three months to three years old and weighing at least 3.5 kg. This approval offers a once-daily option as part of a regimen for this population and includes a “capsule sprinkle” administration method for patients who cannot swallow capsules or tablets.

Vyvanse
Shire has announced that the FDA has approved the prescription medication Vyvanse (lisdexamfetamine dimesylate) Capsules, (CII) as a maintenance treatment in children and adolescents with Attention-Deficit/Hyperactivity Disorder (ADHD). Vyvanse is currently approved as a maintenance treatment in adults with ADHD.
For more information, visit: www.shire.com/shireplc/en/media/shirenws?id=783
Doryx
Warner Chilcott plc has announced that the FDA has approved a 200 mg strength of Doryx (doxycycline hyclate) Delayed-Release Tablets. Doryx Delayed-Release Tablets are a tetracycline-class oral antibiotic. The company anticipates that it will commercially launch Doryx Delayed-Release 200 mg Tablets in July 2013. For more information, visit: http://ir.wcrx.com/releasedetail.cfm?ReleaseID=756218
FDA Alerts

**Kadcyla**
The FDA has notified healthcare professionals that the use of the incorrect nonproprietary name for the breast cancer drug Kadcyla (ado-trastuzumab emtansine) in some medication-related electronic systems poses a risk of mix-up with Herceptin (trastuzumab) and may result in medication errors. The dosing and treatment schedules for Kadcyla and Herceptin, another breast cancer drug, are quite different, so confusion between these products could lead to dosing errors and potential harm to patients. The FDA-approved nonproprietary name for Kadcyla, ado-trastuzumab emtansine, should be used. However, some third-party publications, compendia references, health information systems (eg, electronic health record systems and systems used for pharmacy prescription processing, wholesaler ordering, pharmacy ordering, etc.), and sites on the Internet are incorrectly using the United States Adopted Name (USAN), which is “trastuzumab emtansine,” and omitting the “ado” prefix and hyphen. Use of this truncated version of Kadcyla’s nonproprietary name may cause confusion with Herceptin (trastuzumab). It is important for drug information content publishers to identify drug products by the FDA-approved proprietary (brand) and nonproprietary names that are used in FDA-approved drug labels. This will help prevent medication errors and ensure adverse events are reported for the correct product. No medication errors related to confusion between Kadcyla and Herceptin have been reported to the FDA since approval of Kadcyla on February 22, 2013; however medication errors did occur during the clinical trials that evaluated its safety and efficacy prior to approval.
For more information, visit: [www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm350817.htm](http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm350817.htm)

**OxyContin**
The FDA has approved updated labeling for Purdue Pharma L.P.’s reformulated OxyContin (oxycodone HCl controlled-release) tablets. The new labeling indicates that the product has physical and chemical properties that are expected to make abuse via injection difficult and to reduce abuse via the intranasal route (snorting). Additionally, because original OxyContin provides the same therapeutic benefits as reformulated OxyContin, but poses an increased potential for certain types of abuse, the FDA has determined that the benefits of original OxyContin no longer outweigh its risks and that original OxyContin was withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will not accept or approve any abbreviated new drug applications (generics) that rely upon the approval of original OxyContin. Postmarketing assessments of the impact of reformulated OxyContin on abuse are ongoing, and the FDA will update its evaluation of the effects of reformulated OxyContin on abuse as new data become available.
For more information, visit: [www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm348252.htm](http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm348252.htm)

**Plan B One-Step**
The FDA has announced that it has approved an amended application submitted by Teva Women’s Health, Inc. to market Plan B One-Step (active ingredient levonorgestrel) for use without a prescription by women 15 years of age and older. The product will now be labeled “not for sale to those under 15 years of age *proof of age required* not for sale where age cannot be verified.” Plan B One-Step will be packaged with a product code prompting a cashier to request and verify the customer’s age. A customer who cannot provide age verification will not be able to purchase the product. In addition, Teva has arranged to have a security tag placed on all product cartons to prevent theft. Teva will also make the product available in retail outlets with an onsite pharmacy, where it generally will be available in the family planning or female health aisles. The product will be available for sale during the retailer’s normal operating hours whether the pharmacy is open or not. Teva has indicated that it plans to educate consumers, pharmacy staff, and healthcare professionals about the product’s new status. It has also indicated its willingness to conduct an audit of the age verification practices after the product is approved to ensure that the age limitation is being followed.
For more information, visit: [www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm350230.htm](http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm350230.htm)
Potiga
The FDA is warning the public that the anti-seizure medication Potiga (ezogabine) can cause blue skin discoloration and eye abnormalities characterized by pigment changes in the retina. The FDA does not currently know if these changes are reversible. The FDA is working with the manufacturer to gather and evaluate all available information to better understand these events. The FDA will update the public when more information is available. Pigment changes in the retina have the potential to cause serious eye disease with loss of vision. It is not yet known whether the retinal pigment changes caused by Potiga lead to visual impairment, although several patients have been reported to have impaired visual acuity. In some cases, retinal abnormalities have been observed in the absence of skin discoloration. The skin discoloration in the reported cases appeared as blue pigmentation, predominantly on or around the lips or in the nail beds of the fingers or toes, but more widespread involvement of the face and legs has also been reported. Scleral and conjunctival discoloration, on the white of the eye and inside eyelids, has been observed as well. The skin discoloration generally occurred after four years of treatment with Potiga, but has appeared sooner in some patients. In light of this new safety information, all patients taking Potiga should have a baseline eye exam and periodic eye exams that should include visual acuity testing and dilated fundus photography, and may include fluorescein angiograms, ocular coherence tomography, perimetry, and electroretinograms. Potiga should be discontinued if ophthalmic changes are observed, unless no other treatment options are available. If a patient develops skin discoloration, serious consideration should be given to changing to an alternate medication.
For more information, visit:  
www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm349847.htm

Samsca
The FDA has determined that the drug Samsca (tolvaptan) should not be used for longer than 30 days and should not be used in patients with underlying liver disease because it can cause liver injury, potentially leading to liver transplant or death. An increased risk of liver injury was observed in recent large clinical trials evaluating Samsca for a new use in patients with autosomal dominant polycystic kidney disease. The FDA has worked with the manufacturer to revise the Samsca drug label to include new limitations.
For more information, visit:  
www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm350185.htm

Valproate Sodium, Valproic Acid, Divalproex Sodium
The FDA is advising healthcare professionals and women that the anti-seizure medication valproate sodium and related products, valproic acid and divalproex sodium, are contraindicated and should not be taken by pregnant women for the prevention of migraine headaches. Based on information from a recent study, there is evidence that these medications can cause decreased IQ scores in children whose mothers took them while pregnant. Stronger warnings about use during pregnancy will be added to the drug labels, and valproate’s pregnancy category for migraine use will be changed from "D" (the potential benefit of the drug in pregnant women may be acceptable despite its potential risks) to "X" (the risk of use in pregnant women clearly outweighs any possible benefit of the drug). With regard to valproate use in pregnant women with epilepsy or bipolar disorder, valproate products should only be prescribed if other medications are not effective in treating the condition or are otherwise unacceptable. Valproate products will remain in pregnancy category D for treating epilepsy and manic episodes associated with bipolar disorder. With regard to women of childbearing age who are not pregnant, valproate should not be taken for any condition unless the drug is essential to the management of the woman's medical condition. All non-pregnant women of childbearing age taking valproate products should use effective birth control. Valproate products include: valproate sodium (Depacon), divalproex sodium (Depakote, Depakote CP, and Depakote ER), valproic acid (Depakene and Stavzor), and their generics.
For more information, visit:  
www.fda.gov/Drugs/DrugSafety/ucm350684.htm
0.9% NaCl Injection, USP, 100 mL
Hospira, Inc. has announced that last August it initiated a voluntary nationwide user-level recall of one lot of 0.9% NaCl Injection, USP, 100 mL, Flexible Container, NDC 0409-7984-23. This action was due to one confirmed customer report where four separate particulate issues were identified in four individual flexible containers. The four single particles were identified as follows: polyester fiber, nylon fiber, cotton fiber, and nitrocellulose fiber, respectively. To date, Hospira has not received reports of any adverse events associated with this issue for this lot, and has not identified any quality issues with retention samples for this lot. A recall notification regarding this lot was previously issued to Hospira customers of record on August 31, 2012. The product is used as a source of water and electrolytes and is packaged in a 100 mL flexible container, lot number 05-201-JT (the lot number may be followed by a -01). The affected product has an expiration date of May 1, 2013, and was distributed within the U.S. between May 2011 and August 2011 to wholesalers/distributors, hospitals, and pharmacies. The product was distributed within the following U.S. states: Alaska, Alabama, Arizona, California, Colorado, Florida, Georgia, Hawaii, Iowa, Idaho, Illinois, Indiana, Kansas, Kentucky, Louisiana, Massachusetts, Maryland, Michigan, Missouri, Mississippi, North Carolina, North Dakota, New Jersey, New Mexico, New York, Ohio, Oklahoma, Oregon, Pennsylvania, South Carolina, Tennessee, Texas, Utah, Virginia, Washington, Wisconsin, West Virginia, and Wyoming.
For more information, visit:  [www.fda.gov/Safety/Recalls/ucm349552.htm](http://www.fda.gov/Safety/Recalls/ucm349552.htm)

Anticoagulant Citrate Phosphate Dextrose Solution
Fenwal has initiated a voluntary Urgent Product Recall of one lot (FM13A15027) of Product Code 4R1584, Anticoagulant Citrate Phosphate Dextrose Solution, USP (CPD) BLOOD-PACK unit. Fenwal has identified a labeling issue with this batch of Product Code 4R1584 in which the platelet container is incorrectly labeled as “AS-1 Red Blood Cell Adenine-Saline added.” To date, there is only one reported occurrence of this incident and no safety concerns have been raised.
For more information, visit:  [www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm350275.htm](http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm350275.htm)

FreeStyle Insulinx Blood Glucose Meters
Abbott has announced that in the U.S. it is initiating a voluntary recall of FreeStyle Insulinx Blood Glucose Meters. The company has determined that at extremely high blood glucose levels of 1024 mg/dL and above, the FreeStyle Insulinx Meter will display and store in memory an incorrect test result that is 1024 mg/dL below the measured result. For example, at a blood glucose value of 1066 mg/dL, the meter will display and store a value of 42 mg/dL (1066 mg/dL - 1024 mg/dL = 42 mg/dL). No other Abbott blood glucose meters are impacted by this issue.
For more information, visit:  [www.fda.gov/Safety/Recalls/ucm348391.htm](http://www.fda.gov/Safety/Recalls/ucm348391.htm)

NuVision Pharmacy Lyophilized HcG 5000 IU-5 mL and Sermorelin/GHRH6-5 mL
NuVision Pharmacy is voluntarily recalling all unexpired lots of lyophilized compounds HcG 5000 IU-5 mL and Sermorelin/GHRH6-5 mL to the user level. The recall is being initiated due to a lack of sterility assurance and concerns associated with the quality control processes identified during the FDA inspection. In the event a sterile product is compromised, patients are at risk for serious and possible life-threatening infections. To date, NuVision Pharmacy has received no reports of injury or illness associated with the use of their sterile products. However, out of abundance of caution and in the interest of their patients, NuVision Pharmacy has decided to voluntarily proceed with this recall process. These products were supplied to the offices of licensed medical professionals. NuVision Pharmacy’s sterile products covered under this recall were distributed nationwide.
For more information, visit:  [www.fda.gov/Safety/Recalls/ucm348095.htm](http://www.fda.gov/Safety/Recalls/ucm348095.htm)

Piperacillin and Tazobactam for Injection
Apopex Corp. has announced that it is conducting, on behalf of the manufacturer Hospira, Inc., a voluntary nationwide recall of 15 lots of Piperacillin and Tazobactam for Injection, USP 40.5 grams, NDC number 60505-0773-00, to the hospital/healthcare provider/user level. The impacted lots of Piperacillin and Tazobactam for Injection, USP 40.5 grams may show precipitation/crystallization in IV bag or IV line after reconstitution. Hospira has stated that administration of precipitated Piperacillin/Tazobactam in an IV bag or IV line may result in local reactions such as phlebitis; renal impairment; end-organ embolism and ischemia; and/or vasculitis. In addition, the precipitation of the drug may not allow delivering a needed therapeutic dose of piperacillin and tazobactam, thus resulting in inadequate treatment of the targeted infection. This could result in adverse health consequences that could range from transient and minor impairment or complaints to permanent impairment of a body function or permanent damage to a body structure. Hospira has not received any reports of adverse events related to this recall.
For more information, visit:  [www.fda.gov/Safety/Recalls/ucm349976.htm](http://www.fda.gov/Safety/Recalls/ucm349976.htm)