**Abbott RealTime HCV Genotype II**

The FDA has approved a test that identifies the genotype of hepatitis C virus (HCV) that a patient is carrying. The Abbott RealTime HCV Genotype II, which can differentiate genotypes 1, 1a, 1b, 2, 3, 4, and 5, using a sample of an infected patient’s blood plasma or serum, will aid healthcare professionals in determining the appropriate approach to treatment. Because the various HCV genotypes respond differently to available drug therapies, knowing the type of HCV a person is infected with can result in better patient outcomes. The Abbott RealTime HCV Genotype II is approved for individuals known to be chronically infected with HCV. It is not approved for use as a diagnostic test or as a screening test for the presence of HCV genetic material in blood, blood products, or tissue donors. It has not been evaluated in newborns or pediatric patients, or in patients with compromised immune systems, such as people with AIDS. The Abbott RealTime HCV Genotype II test is manufactured by Abbott Molecular Inc.

For more information, visit: [www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm357982.htm](http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm357982.htm)

**Brisdelle**

The FDA has approved Brisdelle (paroxetine) to treat moderate to severe hot flashes (vasomotor symptoms) associated with menopause. Brisdelle, which contains the selective serotonin reuptake inhibitor paroxetine mesylate, is currently the only non-hormonal treatment for hot flashes approved by the FDA. The mechanism by which Brisdelle reduces hot flashes is unknown. Brisdelle contains 7.5 mg of paroxetine and is dosed once daily at bedtime. Other medications such as Paxil and Pexeva contain higher doses of paroxetine and are approved for treating conditions such as major depressive disorder, obsessive-compulsive disorder, panic disorder, and generalized anxiety disorder. All medications that are approved for treating depression, including Paxil and Pexeva, have a Boxed Warning about an increased risk of suicide in children and young adults. Because Brisdelle contains the same active ingredient as Paxil and Pexeva, a Boxed Warning about suicidality is included in the Brisdelle label. Brisdelle is marketed by Noven Therapeutics, LLC.

For more information, visit: [www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm359030.htm](http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm359030.htm)

**Rixubis**

The FDA has approved Rixubis (coagulation factor IX [recombinant]) for use in people with hemophilia B who are 16 years of age and older. Rixubis is indicated for the control and prevention of bleeding episodes, perioperative management, and routine use to prevent or reduce the frequency of bleeding episodes. Rixubis is a purified protein produced by recombinant DNA technology. It does not contain human or animal proteins. It is supplied in single-use vials of freeze-dried powder and is administered by intravenous injection after reconstitution with sterile water for injection. When used for the routine prevention of bleeding episodes, it is administered twice weekly. Rixubis is manufactured by Baxter Healthcare Corporation.

For more information, visit: [www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm358918.htm](http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm358918.htm)

**Zubsolv**

Orexo has announced that it has received approval from the FDA for Zubsolv (buprenorphine/naloxone) sublingual tablet CIII. Zubsolv is indicated for use as maintenance treatment for people suffering from opioid dependence and should be used as part of a complete treatment plan to include counseling and psychosocial support. Zubsolv is a once-daily, sublingual tablet with an advanced formulation of buprenorphine and naloxone that fully dissolves within minutes. Orexo US, Inc and its partner Publicis Touchpoint Solutions will launch Zubsolv in September.

**Exelon Patch**
The FDA has expanded the approved indication for Exelon Patch (rivastigmine transdermal system) to include the treatment of people with severe Alzheimer's disease with Exelon Patch 13.3 mg/24h.
For more information, visit: [www.pharma.us.novartis.com/newsroom/pressreleases/137182.shtml](http://www.pharma.us.novartis.com/newsroom/pressreleases/137182.shtml)

**Latuda**
Sunovion Pharmaceuticals Inc. announced that the FDA has approved two new indications for the use of Latuda (lurasidone HCl) as 1) monotherapy and 2) adjunctive therapy with either lithium or valproate, both to treat adult patients with major depressive episodes associated with bipolar I disorder (bipolar depression).

**Mycamine**
Astellas Pharma US, Inc., a US subsidiary of Tokyo-based Astellas Pharma Inc., announced that the FDA has approved its Supplemental New Drug Application for the use of Mycamine (micafungin sodium) for injection by intravenous infusion for the treatment of pediatric patients four months and older with candidemia, acute disseminated candidiasis, *Candida* peritonitis and abscesses, esophageal candidiasis, and prophylaxis of *Candida* infections in patients undergoing hematopoietic stem cell transplants.

**Vibativ**
The FDA has expanded the approved use of the antibiotic Vibativ (telavancin) to treat patients with hospital-acquired and ventilator-associated bacterial pneumonia (HABP/VABP) caused by *Staphylococcus aureus*. Vibativ should be used for the treatment of HABP/VABP only when alternative treatments are not suitable. Vibativ was approved in 2009 to treat complicated skin and skin structure infections. It is marketed by Theravance, Inc.
For more information, visit: [www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm358209.htm](http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm358209.htm)

**Xgeva**
The FDA has expanded the approved use of Xgeva (denosumab) to treat adults and some adolescents with giant cell tumor of the bone (GCTB), a rare and usually non-cancerous tumor. Xgeva is a monoclonal antibody that binds to RANKL, a protein essential for maintenance of healthy bone. RANKL is also present in GCTB. Xgeva is intended for patients whose GCTB cannot be surgically removed (unresectable) or when surgery is likely to result in severe morbidity, such as loss of limbs or joint removal. It should only be used in adolescents whose bones have matured. The FDA reviewed Xgeva under its priority review program, which provides for an expedited review of drugs. Xgeva was granted orphan product designation because it is intended to treat a rare disease or condition. Xgeva was approved in 2010 to prevent fractures when cancer has spread to the bones. It is marketed by Amgen.
For more information, visit: [www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm356528.htm](http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm356528.htm)
**AFX Introducer System**

On May 13, 2013, Endologix, Inc. initiated a recall of AFX Introducer System Model S17-45 due to reports of the dilator breaking during procedures. The AFX Introducer System is intended to help introduce catheters and other medical devices into blood vessels during procedures with minimal blood loss. This recalled product was distributed and manufactured from April 1, 2013 through April 30, 2013 and distributed in the US only in Florida, Indiana, Michigan, New Hampshire, New Jersey, and New York. Affected lot numbers include 1079840, 1079843, 1079844, and 1079845. On May 13, 2013, Endologix sent its customers an Urgent Medical Device Recall Notice letter stating "Do not use or further distribute any affected product."

For more information, visit:
www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm357563.htm

**Benztropine Mesylate Injection**

Fresenius Kabi USA is voluntarily recalling four lots of Benztropine Mesylate Injection, USP, 2 mg/2 mL (1 mg/mL) in 2 mL single dose vials due to the potential presence of glass particles (glass delamination) in the vials. The defect discovered in this product was noted as visible particulate. However, the process of glass delamination may result in formation of visible and subvisible particles. No adverse events, patient reactions, or customer complaints have been reported to date. The product is manufactured by Allergy Laboratories, Inc. and distributed by Fresenius Kabi USA. The product may appear with "APP" or "Nexus Pharmaceuticals" labels. Recalled lot numbers include 030712, 071212, 090512, and 111412.

For more information, visit:
www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm359330.htm

**Estarylla**

Sandoz is conducting a voluntary nationwide recall to the retailer level of one lot of its Estarylla (norgestimate and ethinyl estradiol) tablets in the US, following a customer report of a placebo tablet present in a row of active tablets on one pack. Estarylla is indicated for the prevention of pregnancy in women who elect to use oral contraceptives as a method of contraception. Sandoz is not aware of any reports to date of related adverse events. An internal medical assessment concludes that the probability of adverse health events is minimal, as the packaging flaw is easily visible and the risk of pregnancy occurring after non-administration of one blue tablet is low. The lot number, expiration date, and NDC code of the recalled lot is: LF01213A, expiration date 02/2014, NDC 00781-4058-15. It is supplied in cartons containing 3 blister cards of 28 tablets each. This lot was distributed to the US market only. Estarylla is manufactured for Sandoz by a third party manufacturer.

For more information, visit: www.fda.gov/Safety/Recalls/ucm359613.htm

**Medtronic Xomed, Inc. NIM Trivantage EMG Endotracheal Tube**

The FDA has notified healthcare professionals of a Class I Recall of the Medtronic Xomed, Inc. NIM Trivantage EMG Endotracheal Tube. The NIM Trivantage Endotracheal Tube is used by healthcare professionals to continuously monitor the laryngeal muscles during surgery. The device keeps the patient's airway open for ventilation and for electromyography (EMG) monitoring of the laryngeal muscles when connected to an appropriate EMG monitor. The firm received complaints of "cuff leak" or "cuff deflation" occurring when the inflation valve cap is inappropriately removed (pulled off, instead of snapped-off sideways). This requires the physician to re-inflate or replace the deflated tube to ensure the continued breathing support of the patient. Use of this recalled product can result in serious adverse health consequences, including death. On March 14, 2013, the firm sent an "URGENT Product Recall Notification" letter to its customers. Customers were instructed to return any affected devices still in their possession.

For more information, visit: www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm358172.htm

**Recombivax HB Adult Formulation**

Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., initiated a voluntary recall of Recombivax HB Adult Formulation, Lot Number J001183, due to the potential for a limited number of cracked vials to be present in the lot. Merck's investigation concluded that for certain vials in the affected lot, the potential exists for a crack to have occurred in the vial. If the vial was cracked, the integrity of the vial and the sterility of any product remaining in the vial could not be assured. Lot Number J001183 of Recombivax HB Adult Formulation is the only lot impacted by the recall and was distributed solely within the US. The lot was distributed by Merck between March 12, 2013 and May 2, 2013. There is adequate inventory to replace recalled product at this time. If product from this lot has been administered, revaccination is not necessary.

For more information, visit: www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm359493.htm
Rugby Label Enteric Coated 81 mg Aspirin Tablets
Advance Pharmaceutical Inc. announced that it is conducting a voluntary nationwide recall to the user level of the over-the-counter drug product, Rugby label Enteric Coated Aspirin Tablets, 81 mg, Lot 13A026. Advance Pharmaceutical Inc. first initiated the recall on June 17, 2013, after receiving a complaint about a bottle labeled as Enteric Coated Aspirin Tablets, 81 mg, actually containing Acetaminophen 500-mg tablets. Rugby label Enteric Coated Aspirin is indicated for the temporary relief of minor aches and pains and is packaged in bottles of 120 tablets with NDC 0536-3086-41 and UPC 3 0536-3086-41 9. The affected lot of Enteric Coated Aspirin Tablets is Lot 13A026 with Expiration Date 01-2015. The lot was manufactured and packaged by Advance Pharmaceutical Inc. under the label of Rugby Laboratories. Rugby Laboratories (Major Pharmaceuticals) distributed the product nationwide to wholesalers and retailers. Advance Pharmaceutical Inc. notified Rugby Laboratories of the recall by email and overnight mail, and is arranging for return of all recalled bottles.
For more information, visit:
www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm357924.htm

Symbios GOPump and GOBlock Kits
The FDA and Symbios are informing the public of a recall of all GoPump Rapid Recovery System kits and GOBlock Kits manufactured with flow control components assembled prior to July 2012. The affected products may have excessively high flow rates. As a result, medications could be delivered too quickly from the balloon to the surgical site and cause patient toxicity due to the rapid influx of medication. This can lead to serious illness, including seizure, abnormal heart rhythms, and death. Elderly patients and patients with low body mass are at high risk of these complications. Customers who purchased the affected devices were notified about the problem by letter dated May 10, 2013, and follow-up letters were sent on May 14, 2013 and May 30, 2013 notifying customers of additional recalled lots. Symbios is working to secure all affected product and have it returned.
For more information, visit:
www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm356516.htm

V60 Ventilators
Respironics California, Inc. has initiated a recall on the V60 ventilator because of an issue with the software on the V60 Power Management Board Assembly. If a component fails on the Power Management Board Assembly, it may cause ventilator support to be lost with potentially no audible alarm from the ventilator. This recalled product may cause serious adverse health consequences, including death. The recalled products were distributed from November 16, 2009 through March 28, 2013. On June 3, 2013, Philips Healthcare sent a "MEDICAL DEVICE CORRECTION" letter to all customers who received the V60 Ventilators. The letter described the product, the problem, and the actions to be taken.
For more information, visit:
www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm358040.htm

Zydus Pharmaceuticals Warfarin 2 mg Tablets
Zydus Pharmaceuticals USA Inc. is voluntarily recalling one lot of warfarin 2 mg Tablets, Lot #MM5767, expiration date June 2014 to the retail level. Four tablets of warfarin 2 mg Tablets, Lot MM5767, have been found to be oversized in one product complaint. Ingestion of a greater than intended dose of warfarin could lead to an increased pharmacological effect. As a result, patients would be more likely to develop bleeding as an adverse reaction, and in some patients that bleeding into a critical organ (mostly the central nervous system) could be fatal. The risk of bleeding is increased if overdosing is repeated continuously on a daily basis. The product is packaged in HDPE Bottle of 1000’s count, which may have been dispensed to patients in smaller bottles. The only lot affected of warfarin 2 mg Tablets being recalled is Lot MM5767. The product can be identified by its NDC #6838205310. The product was distributed nationwide in the US to wholesalers/distributors, retailers and mail order providers, from November 2012 to December 2012.
For more information, visit:
www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm356519.htm
Hydroxyethyl Starch Solutions

Hydroxyethyl starch (HES) solutions are used for the treatment of hypovolemia when plasma volume expansion is desired. Recent data have associated the use of these products with an increased risk of severe adverse events when used in certain patient populations. The FDA has analyzed recent data that indicate an increased risk of (i) mortality and renal injury requiring renal replacement therapy in critically ill adult patients, including patients with sepsis and those admitted to the ICU; and (ii) excess bleeding, particularly in patients undergoing open heart surgery in association with cardiopulmonary bypass. The FDA has concluded that HES solutions should not be used in critically ill adult patients, including patients with sepsis and those admitted to the ICU, and a Boxed Warning to include the risk of mortality and severe renal injury is warranted. In addition, the FDA has reviewed a meta-analysis of studies conducted in patients undergoing open heart surgery in association with cardiopulmonary bypass and has determined that an additional warning about excessive bleeding is needed in the Warnings and Precautions Section of the package insert.

For more information, visit: www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm358349.htm

Olmesartan Medoxomil

The FDA is warning that the blood pressure drug olmesartan medoxomil (marketed as Benicar, Benicar HCT, Azor, Tribenzor, and generics) can cause intestinal problems known as sprue-like enteropathy. Symptoms of sprue-like enteropathy include severe, chronic diarrhea with substantial weight loss. The FDA has approved changes to the labels of these drugs to include this concern. Sprue-like enteropathy has not been detected with ARB drugs other than olmesartan. The FDA will continue to evaluate the safety of olmesartan-containing products and will communicate again if additional information becomes available. Healthcare professionals should tell patients to contact them if they develop severe, chronic diarrhea with substantial weight loss while taking an olmesartan-containing product, even if it takes months to years for symptoms to develop.

For more information, visit: www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm359528.htm

Plan B One-Step

The FDA announced that it has approved the use of Plan B One-Step (levonorgestrel) as a nonprescription product for all women of child-bearing potential. This action complies with the April 5, 2013 order of the United States District Court in New York to make levonorgestrel-containing emergency contraceptives available as an OTC product without age or point-of-sale restrictions. Plan B One-Step is an emergency contraceptive intended to reduce the chance of pregnancy following unprotected sexual intercourse or a known or suspected contraceptive failure (eg, condom). Plan B One-Step is a single-dose pill (1.5 mg tablet) that is effective in decreasing the chance of pregnancy and should be taken as soon as possible within three days after unprotected sex. On June 10, 2013, the agency notified a United States District Court judge in New York of its intent to comply with the court’s April 5, 2013 order instructing the FDA to make levonorgestrel-containing emergency contraceptives available as an OTC product without age or point-of-sale restrictions. To comply, the FDA asked Teva Women’s Health, the manufacturer of Plan B One-Step, to submit a supplemental application seeking approval of the one-pill product to be made available without any restrictions. The agency has fulfilled its commitment to the court by promptly completing its review and approval of the supplemental application.

For more information, visit: www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm358082.htm

Sprycel

Bristol-Myers Squibb Company and Otsuka America Pharmaceutical, Inc. have announced that the FDA has approved an update to the Sprycel (dasatinib) product labeling. The labeling now includes three-year efficacy and safety data in patients with newly diagnosed Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase (CP) and five-year data in CP Ph+ CML patients who are resistant or intolerant to Gleevec (imatinib mesylate). Sprycel is a kinase inhibitor indicated for the treatment of adults with newly diagnosed CP Ph+ CML.


For more information, visit: www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm355986.htm

Human Immune Globulin Products

The FDA has analyzed recent data that has strengthened the association between the use of intravenous, subcutaneous, and intramuscular human immune globulin products and the risk of thrombosis. The FDA is requiring manufacturers to add information on thrombosis to the current Boxed Warning in the labels of all intravenous human immune globulin products and to add a Boxed Warning to the labels of all subcutaneous and intramuscular human immune globulin products to highlight the risk of thrombosis and to add information on its mitigation. A retrospective analysis of data from a large health claims-related database, as well as continued postmarketing adverse event reports of thrombosis have strengthened the evidence for an association between the use of intravenous, subcutaneous, and intramuscular human immune globulin products and the risk of thrombosis. This information necessitates a Boxed Warning for the entire class of products.

For more information, visit: www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ucm355986.htm

For more information, visit: www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm358349.htm

For more information, visit: www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm359528.htm

For more information, visit: www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm358082.htm

Zyprexa Relprevv
The FDA is investigating two unexplained deaths in patients who received an intramuscular injection of the antipsychotic drug Zyprexa Relprevv (olanzapine pamoate). The patients died 3-4 days after receiving an appropriate dose of the drug, well after the 3-hour post-injection monitoring period required under the Zyprexa Relprevv Risk Evaluation and Mitigation Strategy (REMS). Both patients were found to have very high olanzapine blood levels after death. High doses of olanzapine can cause delirium, cardiopulmonary arrest, cardiac arrhythmias, and reduced level of consciousness ranging from sedation to coma. The FDA is providing this information to healthcare professionals while it continues its investigation. If therapy with Zyprexa Relprevv is started or continued in patients, healthcare professionals should follow the REMS requirements and drug label recommendations. At this time, the FDA is continuing to evaluate these deaths and will provide an update when more information is available.
For more information, visit: www.fda.gov/Drugs/DrugSafety/ucm356971.htm