April 2014

Drug Information Update

DRUG INFORMATION UPDATE

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NEW GENERICS TO MARKET

GENERIC DRUG NAME	STRENGTH & DOSAGE FORM	GENERIC MANUFACTURER	BRAND NAME	APPROVAL DATE
Capecitabine	150 and 500 mg tablet	Teva USA	Xeloda	3-07-14
Carbidopa	150 mg tablet	Amerigen Pharma	Lodosyn	3-10-14
Atovaquone	750 mg/5 ml oral suspension	Amneal Pharmaceuticals	Mepron	3-19-14
Calipotriene-Betamethasone	0.005-0.064 g ointment	Sandoz	Taclonex	4-1-14
Rifabutin	150 mg capsule	Lupin Pharmaceuticals	Mycobutin	3-26-14
Raloxifene HCL	60 mg tablet	Teva USA	Evista	4-1-14
Lansoprazole-Amoxicillin-Clarithromycin	30-500-500 mg combination pack	Sandoz	Prevpac	3-28-14

NEW DRUG ENTITIES

DESCRIPTION	BRAND NAME	GENERIC NAME	STRENGTH	NOTES
PULMONARY ANTIHYPERTENSIVES, PROSTACYCLINTYPE	ORENITRAM ER	TREPROSTINIL DIOLAMINE	0.25 MG	New Entity
PULMONARY ANTIHYPERTENSIVES, PROSTACYCLINTYPE	ORENITRAM ER	TREPROSTINIL DIOLAMINE	0.125 MG	New Entity
PULMONARY ANTIHYPERTENSIVES, PROSTACYCLINTYPE	ORENITRAM ER	TREPROSTINIL DIOLAMINE	1 MG	New Dosage Form
PULMONARY ANTIHYPERTENSIVES, PROSTACYCLINTYPE	ORENITRAM ER	TREPROSTINIL DIOLAMINE	2.5 MG	New Dosage Form
PROTEIN REPLACEMENT	GLUTASOLVE	GLUTAMINE	15 G	New Strength
VITAMIN B PREPARATIONS	VIRT-CAPS	B COMPLEX & C NO.20/FOLIC ACID	1 MG	New Combination
KERATOLYTICS	KERALAC	UREA	47 %	New Strength
TOPICAL SULFONAMIDES	PLEXION	SULFACETAMIDE SODIUM/SULFUR	9.8%-4.8%	New Strength
ANTIINFLAMMATORY, PHOSPHODIESTERASE-4(PDE4) INHIB.	OTEZLA	APREMILAST	30 MG	New Entity
ANTIINFLAMMATORY, PHOSPHODIESTERASE-4(PDE4) INHIB.	OTEZLA	APREMILAST	20 MG	New Entity
ANTIINFLAMMATORY, PHOSPHODIESTERASE-4(PDE4) INHIB.	OTEZLA	APREMILAST	10 MG	New Entity
ANTIFUNGAL AGENTS	NOXAFIL	POSACONAZOLE	300MG/16.7	New Strength, Route and Dosage Form
VACCINE/TOXOID PREPARATIONS, COMBINATIONS	PENTACEL DTAP-IPV COMPONENT	DIPH,PERTUS (ACEL), TET,POLIO/PF	15-20-20	New Strength

NEW INDICATIONS (EXISTING DRUGS)

Pradaxa

April 8, 2014

FDA approves Pradaxa® for treatment and reduction in risk of recurrent deep vein thrombosis (DVT) and pulmonary embolism (PE)

New indications for Pradaxa® offer U.S. DVT and PE patients a simple treatment option that is aseffective as warfarin with significantly less bleedings.

Almost one in three DVT or PE patients die within three months; DVT-related PE is the leading cause of preventable death in hospital.

FDA approval broadens use of Pradaxa® in the U.S.; Pradaxa® is already approved for stroke prevention in patients with atrial fibrillation.

Ingelheim, Germany, April 8, 2014 – Boehringer Ingelheim today announced that the U.S. Food and Drug Administration (FDA) has approved Pradaxa® (dabigatran etexilate) for the treatment of DVT and PE in patients who have been treated with a parenteral (injectable) anticoagulant for five to 10 days, and to reduce the risk of recurrent DVT and PE in patients who have been previously treated.

Article link:http://www.boehringer-ingelheim.com/news/news_releases/press_releases/2014/08_april_2014_dabigatranetexilate.html
Source website:http://www.boehringer-ingelheim.com/

Topamax®

March 28, 2014

Today, the U.S. Food and Drug Administration approved Topamax (topiramate) for prevention (prophylaxis) of migraine headaches in adolescents ages 12 to 17. This is the first FDA approval of a drug for migraine prevention in this age group. The medication is taken on a daily basis to reduce the frequency of migraine headaches.

Topamax was first approved by the FDA in 1996 to prevent seizures. It was approved for migraine prevention in adults in 2004. “Migraine headaches can impact school performance, social interactions, and family life,” said Eric Bastings, M.D., deputy director of the Division of Neurology Products in the FDA’s Center for Drug Evaluation and Research. “Adding dosing and safety information for the adolescent age group to the drug’s prescribing information will help to inform health care professionals and patients in making treatment choices.”

Article link http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm391026.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery
Source website:http://www.fda.gov/

Xolair®

March 21, 2014

Novartis Announces FDA Approval of Xolair® (omalizumab) for Chronic Idiopathic Urticaria (CIU), a Form of Chronic Hives

First-in-class medicine approved for CIU, a burdensome skin condition that can cause hives, severe itch, and swelling that can last many months and years.

Xolair is approved for CIU patients age 12 years and older who remain symptomatic despite H1-antihistamine treatment, the only previously FDA-approved therapy for CIU.

In clinical studies, Xolair 300 mg and 150 mg significantly improved primary efficacy measure of Itch Severity Score compared to placebo EAST HANOVER, N.J., March 21, 2014 /PRNewswire/ -- Novartis today announced that the US Food and Drug Administration (FDA) approved Xolair® (omalizumab) for the treatment of chronic idiopathic urticaria (CIU), a form of chronic hives.

The new use is for patients 12 years of age and older who remain symptomatic despite treatment with H1-antihistamine therapy. Xolair is not used to treat other forms of urticaria (hives) and is not for use in children less than 12 years of age. Xolair is jointly developed by Genentech and Novartis Pharma AG and is co-promoted by Novartis Pharmaceuticals Corporation with Genentech in the United States.

Article link:http://www.pharma.us.novartis.com/newsroom/pressreleases/137193.shtml
Source website:http://www.pharma.us.novartis.com/

Eliquis®

U.S. FDA Approves Eliquis® (apixaban) To Reduce The Risk Of Blood Clots Following Hip Or Knee Replacement Surgery

March 14, 2014

This approval reflects the continued commitment of the alliance to deliver new treatment options for patients and physicians."

PRINCETON, N.J. & NEW YORK--(BUSINESS WIRE)--Bristol-Myers Squibb Company (NYSE: BMY) and Pfizer Inc. (NYSE: PFE) today announced that the U.S. Food and Drug Administration (FDA) approved a Supplemental New Drug Application (sNDA) for Eliquis (apixaban) for the prophylaxis of deep vein thrombosis (DVT), which may lead to pulmonary embolism (PE), in patients who have undergone hip or knee replacement surgery.

Article link:http://news.bms.com/press-release/us-fda-approves-eliquis-apixabanreduce-risk-blood-clots-following-hip-or-knee-replace&t=635308356960931446
Source website:http://news.bms.com/

FDA NEWS/BULLETINS/ADVISORIES/SAFETY ALERTS

The FDA Enforcement Report

The FDA Enforcement Report is published weekly by the Food and Drug Administration, Department of Health and Human Services. It contains information on actions taken in connection with agency Regulatory activities. This link contains a record of all recalls (Class I, II, and III) for food, drug, biologics, and devices. The report is organized by category and then recall class.

Article link, current week: http://www.accessdata.fda.gov/scripts/enforcement/enforce_rpt-Product-Tabs.cfm?action=Expand+Index&w=02262014&lang=eng
Article link, previous week: http://www.accessdata.fda.gov/scripts/enforcement/enforce_rpt-Product-Tabs.cfm?action=Expand+Index&w=02192014&lang=eng

VPRIV (velaglucerase alfa for injection): Recall - Visible Particulate Matter

[Posted: 3/14/14]

ISSUE: Shire Pharmaceuticals announced a voluntary recall in the United States of one batch, packaged into three lots, of VPRIV due to the presence of visible particulate matter, identified as stainless steel and barium sulfate. The particulate matter was found in a small number of vials in the three packaged lots of VPRIV. A Shire investigation identified the particulate matter root cause as the third party supplier fill finish process.

If infused, there is a possibility of rare but serious adverse events associated with particulate containing barium sulfate.

The following packaged lots were recalled: FEW13-001, FEW13-002, and FED13-006.
These lots were distributed nationwide to hospitals, infusion clinics, patients, and home health agencies in the United States and all have the same NDC code (54092-701-04) and same expiration date of 10/15 (Oct 2015).

BACKGROUND: VPRIV is a hydrolytic lysosomal glucocerebroside-specific enzyme indicated for long-term enzyme replacement therapy (ERT) for pediatric and adult patients with type 1 Gaucher disease. VPRIV is supplied as a sterile, preservative-free, lyophilized powder in single-use vials, for intravenous use.

RECOMMENDATION: Customers should locate and remove all affected product from their facility and/or residence. Affected product should be returned by contacting Shire at 1-888-899-9293 (Monday through Friday between the hours of 8:00am and 5:00pm Eastern Time). Shire has significant quantities of VPRIV to replace any affected product.
Shire does not anticipate any disruption in supply as a result of this voluntary recall.

Article link: http://www.fda.gov/Safety/MedWatch/SafetyInformation/

SafetyAlertsforHumanMedicalProducts

February 2014 Drug Safety Labeling Changes includes 35 products with revisions to Prescribing Information

The MedWatch February 2014 Safety Labeling Changes posting includes 35 products with safety labeling changes to the following sections: BOXED WARNINGS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, ADVERSE REACTIONS and PATIENT PACKAGE INSERT.

The "Summary Page" provides a listing of product names and safety labeling sections revised: http://www.fda.gov/Safety/MedWatch/SafetyInformation/ucm388717.htm

The following drugs had modifications to the BOXED WARNING, CONTRAINDICATIONS, WARNINGS and PRECAUTIONS sections:

Promacta (eltrombopag)
Nizoral (ketoconazole)
Bravelle (urofollitropin for injection, purified)
Juvisync (sitagliptin and simvastatin)
Menopur (menotropins for injection)
Mevacor (lovastatin)
Samsca (tolvaptan)
Vytorin (ezetimibe/simvastatin)
Zocor (simvastatin)
Afinitor (everolimus)
Afinitor Disperz (everolimus tablets for oral suspension)
Agrylin (anagrelide hydrochloride)
Aloxi (palonosetron hydrochloride)
Astagraf XL (tacrolimus extended-release capsules)
Imuran (azathioprine)
Lodosyn (carbidopa)
Simponi Aria (golimumab)
Victrelis (boceprevir)
Zelboraf (vemurafenib)
Biltricide (praziquantel)
Juxtapid (lomitapide)
Nexium (esomeprazole magnesium)
Nexium I.V. (esomeprazole sodium)
Prilosec (omeprazole)
Prilosec (omeprazole magnesium)
Vimovo (naproxen/esomeprazole magnesium)
Xarelto (rivaroxaban)
Zegerid (omeprazole/sodium bicarbonate)

Article link: http://www.fda.gov/Safety

FreeStyle and FreeStyle Flash Blood Glucose Meter by Abbott: Recall - May Produce Mistakenly Low Blood Glucose Results including the OmniPod Insulin Management System with the built-in FreeStyle Blood Glucose Meter

[Posted: 3/16/14]

ISSUE: Abbott is conducting a recall for the FreeStyle Blood Glucose Meter and the FreeStyle Flash Blood Glucose Meter. When used with the Abbott FreeStyle test strips, the FreeStyle Blood Glucose Meter and the FreeStyle Flash Blood Glucose Meter may produce mistakenly low blood glucose results.

BACKGROUND: FreeStyle and FreeStyle Flash Blood Glucose Meters have not been in production since 2010. Abbott began notifying users on Feb. 19, 2014, immediately after the issue was discovered.

RECOMMENDATION: Abbott recommends the following actions for people with meters affected by this recall:

• Immediately contact Abbott Diabetes Care at 1-888-345-5364 to obtain a replacement meter.

• If the only meter available to you is an affected meter, continue to test your blood glucose as recommend by your doctor while you wait for your replacement meter. When using an affected meter, follow the precautions and recommendations in the press release.

• If you have access to an alternative glucose meter, immediately discontinue use of the affected meter and take the necessary steps to continue to monitor your blood sugar with the alternative meter.

• For users of the OmniPod Insulin Management System with the built-in FreeStyle Blood Glucose Meter, refer to the Abbott recommended actions at https://www.abbottdiabetescare.com/press-room/2014/2014-b.html.

Article link :http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm389367.htm

Source website: http://www.fda.gov/

Revatio (sildenafil): Drug Safety Communication - FDA Clarifies Warning About Pediatric Use for Pulmonary Arterial Hypertension

[Posted: 3/31/14]

ISSUE: FDA is clarifying its previous recommendation related to prescribing Revatio (sildenafil) for children with pulmonary arterial hypertension (PAH). Revatio is FDA-approved only to treat PAH in adults, not in children; however, health care professionals must consider whether the benefits of treatment with the drug are likely to outweigh its potential risks for each patient. FDA revised the Revatio drug label in August 2012, adding a warning stating that "use of Revatio, particularly chronic use, is not recommended in children." This recommendation was based on an observation of increasing mortality with increasing Revatio doses in a long-term clinical trial in pediatric patients with PAH. FDA issued a Drug Safety Communication at that time. There may be situations in which the benefit-risk profile of Revatio may be acceptable in individual children, for example, when other treatment options are limited and Revatio can be used with close monitoring.

BACKGROUND: The purpose of the August 2012 recommendation was to raise awareness of clinical trial results showing a higher risk of mortality in pediatric patients taking a high dose of Revatio when compared to pediatric patients taking a low dose. This recommendation was not intended to suggest that Revatio should never be used in children; however, some health care professionals have interpreted this information as a contraindication, and have refused to prescribe or administer the drug.

RECOMMENDATION: The evidence behind FDAs initial recommendation has not changed; this communication is clarifying the strength of the warning communicated in the Revatio drug label.

Article link: http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm391152.htm

Source website: http://www.fda.gov/

Alli (60 mg orlistat capsules) by GlaxoSmithKline: Recall - Product Tampering

[Posted: 3/28/14]

ISSUE: GlaxoSmithKline (GSK) Consumer Healthcare is voluntarily recalling all alli weight loss products from U.S. and Puerto Rico retailers as the company believes that some packages of the product were tampered with and may contain product that is not authentic Alli.
GSK received inquiries from consumers in seven states about bottles of alli that contained tablets and capsules that were not Alli. A range of tablets and capsules of various shapes and colors were reported to be found inside bottles. Additionally, some bottles inside the outer

carton were missing labels and had tamper-evident seals that were not authentic. These tampered products were purchased in retail stores.

BACKGROUND: Alli is for weight loss in overweight adults, 18 years and older when used along with a reduced-calorie and low fat diet. Alli is a turquoise blue capsule with a dark blue band imprinted with the text “60 Orlistat”. It is packaged in a labeled bottle that has an inner foil seal imprinted with the words: “Sealed for Your Protection.”

RECOMMENDATION: Consumers who have product they are unsure or concerned about should not use it. Instead, they should call GSK promptly at 800-671-2554, and a representative will provide further instructions. If they have consumed questionable product, they should also contact their healthcare providers.

Article link: http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm391013.htm

Source website: http://www.fda.gov/

STUDIES and RECENT TOPICS

Experimental Drug May Boost Leukemia Survival, Without Chemo

March 12, 2014

An experimental drug may extend the lives of people with certain hard-to-treat forms of leukemia and lymphoma -- without the need for traditional chemotherapy, according to two studies released Wednesday. The drug, called idelalisib, targets a specific enzyme on white blood cells known as B cells. Researchers found that for people with certain forms of recurrent blood cancers, the drug substantially extended the time that patients lived with no tumor progression.

Article link: http://consumer.healthday.com/cancer-information-5/leukemia-cancer-news-99/experimental-drug-may-boost-leukemia-survival-without-chemo-685735.html
Source website: http://consumer.healthday.com/

Amgen vaccine triggers immune response in advanced melanoma –study

March 14, 2014

An experimental Amgen Inc cancer vaccine used to treat advanced melanoma, the deadliest form of skin cancer, proved effective in a late-stage study in shrinking tumors in a way that suggests the drug triggered the intended systemic immune response, according to data presented on Friday. The vaccine shrank tumors that were directly injected with the drug and tumors around the body that were not injected, according to the data.

Article link: http://www.reuters.com/article/2014/03/14/us-amgen-canceridUSBREA2D1U920140314
Source website: http://www.reuters.com/

Multiple sclerosis patients urge FDA to approve drug

March 14, 2014

In November, the Food and Drug Administration rejected a drug for multiple sclerosis that its sister agencies in Europe, Canada, Mexico and Australia had approved. Doctors and patients who want access to the drug Lemtrada have launched a lobbying campaign to get the regulatory agency to change its mind.

Article link: http://www.usatoday.com/story/news/nation/2014/03/13/multiple-sclerosislemtrada/6345043/
Source website: http://www.usatoday.com/

Intercept says liver disease drug effective in trial

March 16, 2014

Intercept Pharmaceuticals said on Sunday its experimental liver disease drug was effective in a third late-stage clinical trial and that the results set the stage for the company to file for

marketing approval. The drug, obeticholic acid (OCA), is designed to treat primary biliary cirrhosis, a disease in which bile ducts in the liver become damaged, allowing harmful substances to build up and scar liver tissue.

Article link: http://www.reuters.com/article/2014/03/16/us-intercept-pharmaceuticalsidUSBREA2F0UI20140316
Source website: http://www.reuters.com/

Taking ADHD Drugs as a Child Linked to Later Obesity

March 17, 2014

As recent data continues to show higher rates of attention-deficit/hyperactivity disorder (ADHD) among children, parents, doctors and researchers have been eager to better understand what the rising numbers will mean for a generation of kids. With the latest figures suggesting that as many as 11% of youngsters ages 4 to 17 are living with a diagnosis of ADHD in the U.S., some studies have linked the disorder to higher rates of substance abuse and smoking, and now obesity.

Article link: http://time.com/25544/taking-adhd-drugs-as-a-child-linked-to-later-obesity/
Source website: http://time.com/

Roche-backed study finds Tamiflu saved lives in flu pandemic

March 18, 2014

Using Roche's medicine Tamiflu saved lives during the H1N1 swine flu pandemic four years ago, according to a new scientific study published on Wednesday. The pooled analysis of data, involving more than 29,000 patients from 38 countries, was funded by the Swiss drugmaker which hopes the findings will reassure governments about the value of its flu drug following criticism from some doctors.

Article link: http://www.reuters.com/article/2014/03/19/us-roche-tamifluidUSBREA2I00720140319
Source website: http://www.reuters.com/

Is Belphen the Next Blockbuster Diet Drug?

March 18, 2014

Even though there are scant data, obesity researchers and patients have already put a name to a potential new weight-loss craze: Belphen, a combination of lorcaserin (Belviq) and phentermine. The name is a play on Fen-Phen, the wildly popular diet drug that helped patients shed pounds in the 1990s, but at the expense of heart valve problems.

Article link: http://www.medpagetoday.com/Endocrinology/Obesity/44812
Source website: http://www.medpagetoday.com/

Diabetes in Middle Age May Cause Memory Problems Later

March 19, 2014

People who develop type 2 diabetes or high blood pressure in middle age appear more likely to suffer brain damage that can contribute to dementia as they grow older, a new study finds. Diabetes might actually shrink the brain over a long period of time, reducing the size of crucial areas like the hippocampus, which plays an important role in short- and longterm memory, according to the study.

Article link: http://consumer.healthday.com/cognitive-health-information-26/alzheimer-snews-20/diabets-in-midlife-may-lead-to-memory-problems-later-in-life-685964.html
Source website: http://consumer.healthday.com/

Astellas seeks new Xtandi indication

March 19, 2014

Astellas and Medivation have made pursuit of a pre-chemo indication for Xtandi official: the two companies announced Tuesday that they have filed a supplemental New Drug Application with the FDA so the oral drug can be used by metastatic castration-resistant prostate cancer patients earlier in treatment.

Article link: http://www.mmm-online.com/astellas-seeks-new-xtandiindication/article/338943/
Source website: http://www.mmm-online.com/

Roche's Perjeta proves a fast fave with cancer docs, but Kadcyla's a speed Racer

March 19, 2014

Roche's new breast cancer duo, Perjeta and Kadcyla, seemed destined to make a big splash in the oncology market. Now, Decision Resources has the numbers to show just how big that splash has been.

Article link: http://www.fiercepharmamarketing.com/story/roches-perjeta-proves-fastfave-cancer-docs-kadcylas-speed-racer/2014-03-19
Source website: http://www.fiercepharmamarketing.com/

Almost 13 Million More Americans Could Take Statins Under New Guidelines

March 19, 2014

Nearly 13 million more Americans will be eligible to take cholesterol-lowering statin drugs under new guidelines, and most of those additional users will be older than 60, researchers say. The American Heart Association guidelines were released last November and expanded the criteria for statin use to include people with an increased risk of developing heart disease over a 10-year period.

Article link: http://consumer.healthday.com/general-health-information-16/doctor-news-206/almost-13-million-more-americans-could-take-statins-under-new-guidelines-685958.html

Source website: http://consumer.healthday.com/

Poor diagnosis driving global multidrug-resistant TB, WHO warns

March 20, 2014

Half a million people fell sick with dangerous superbug strains of tuberculosis (TB) in 2012, but fewer than one in four were diagnosed, putting the rest at risk of dying due to the wrong medicines or no treatment at all.

Article link: http://www.reuters.com/article/2014/03/20/us-tuberculosisidUSBREA2J0U320140320
Source website: http://www.reuters.com/

Novo Nordisk sees chance of U.S. Tresiba launch before rival products

March 20, 2014

Novo Nordisk should still be able to introduce its long-acting insulin Tresiba on the U.S. market before rival products, despite being hit by a delay, the CEO of the Danish pharmaceutical company said on Thursday. In February 2013, U.S. regulators unexpectedly refused to approve Tresiba until the group conducted extra tests over potential heart risks, dealing a major blow to one of Novo Nordisk's key products as well as to its share price.

Article link: http://finance.yahoo.com/news/novo-nordisk-sees-chance-u-173253213.html
Source website: http://finance.yahoo.com/

More Drug-Resistant Infections Seen in U.S. Children

March 20, 2014

Although still uncommon, certain bacteria may need stronger treatment than oral meds, study says. A growing number of American children are developing infections caused by a worrisome type of antibiotic-resistant bacteria, a new study reports.

Article link: http://www.doctorslounge.com/index.php/news/hd/45342
Source website: http://www.doctorslounge.com/

Hypertension, Obesity Tied to Kidney Cancer

March 24, 2014

Increases in blood pressure and body mass were associated with greater risks of kidney cancer in U.S. men and women, analyses of two large datasets showed. Across increasing categories of systolic blood pressure and body mass index (BMI), the risk of incident kidney cancer rose in women and the risk of death from kidney cancer rose in men (P<0.0001 for both trends), according to Kathleen McTigue, MD, MPH, of the University of Pittsburgh, and colleagues.

Article link: http://www.medpagetoday.com/Cardiology/Hypertension/44906
Source website: http://www.medpagetoday.com/

Penicillin prescriptions risk under-dosing children, say experts

March 25, 2014

Millions of children in the UK are potentially receiving penicillin prescriptions below the recommended dose for common infections, according to new research led jointly by researchers at King's College London, St George's, University of London and Imperial College London. The authors are calling for an urgent review of penicillin dosing guidelines for children -- which at the time of study had not changed in over 50 years -- after discovering wide variation in current prescribing practice.

Article link: http://www.sciencedaily.com/releases/2014/03/140325210637.htm
Source website: http://www.sciencedaily.com/

New Clues to Link Between MS Drug Tysabri and Rare Brain Disease

March 25, 2014

Researchers report that they think they have figured out why patients who take the multiple sclerosis drug Tysabri face a high risk of developing a rare, and sometimes fatal, brain infection. A common virus that can cause the brain disease progressive multifocal leukoencephalopathy (PML) likes to infect and hide in certain blood cells that are triggered to mobilize by Tysabri, the study authors explained. Even more troubling, the researchers discovered that current tests may be missing some who harbor the virus.

Article link: http://consumer.healthday.com/cognitive-health-information-26/brainhealth-news-80/new-clues-to-link-between-ms-drug-tysabri-and-rare-brain-disease-686134.html
Source website: http://consumer.healthday.com/

Nitroglycerin, a Staple of Emergency Rooms, Is in Short Supply

March 25, 2014

The drug nitroglycerin has long been an emergency room staple, a front-line drug that is often the first thing doctors try when a patient shows up with a heart attack. So when Baxter International, the country’s only manufacturer of injectable nitroglycerin, recently told hospitals that it was sharply cutting shipments of the drug, the news sent pharmacists and emergency room doctors into a panic. Hospitals have been struggling for years with intermittent shortages of the drug, but with the latest news, doctors worried they could actually run out.

Article link: http://www.nytimes.com/2014/03/26/business/nitroglycerin-a-staple-ofemergency-rooms-is-in-short-supply.html?partner=rss&emc=rss&_r=1
Source website: http://www.nytimes.com/

FDA staff review recommends against Novartis heart failure drug

March 25, 2014

A drug to treat acute heart failure made by Novartis AG should not be approved because there is insufficient evidence to show it improves symptoms, according to an initial review by the U.S. Food and Drug Administration.

Article link: linkhttp://www.reuters.com/article/2014/03/25/us-novartis-fda-documentsidUSBREA2O0UD20140325
Source website: http://www.reuters.com/

Could half of all breast cancers be prevented?

March 26, 2014
If girls and women of all ages adopted healthier lifestyle behaviors and the highest-risk women took preventive drugs like tamoxifen, the authors of a new report say fully half of breast cancers in the U.S. might be avoided.

Article link: http://www.reuters.com/article/2014/03/26/us-breast-cancersidUSBREA2P12E20140326
Source website: http://www.reuters.com/

US biopharma: 37 new Parkinson's disease medicines now in R&D

March 27, 2014
US biopharmaceutical companies now have 37 new medicines in development for Parkinson's disease – 23 to treat the disease, 11 for related conditions and three diagnostics, according to new industry data.

Article link: http://www.pharmatimes.com/Article/14-03-27/US_biopharma_37_new_Parkinson_s_disease_medicines_now_in_R_D.aspx
Source website: http://www.pharmatimes.com/

Stroke Rounds: BP Control May Cut Second Stroke Risk in Half

March 27, 2014
Stroke patients do a poor job of consistently controlling their blood pressure, but those who do may cut their risk of having another stroke in half, a retrospective analysis found.

Article link: http://www.medpagetoday.com/Cardiology/Hypertension/44973
Source website: http://www.medpagetoday.com/

FDA panel votes against Novartis drug for acute heart failure

March 27, 2014
A drug made by Novartis AG to treat acute heart failure should not be approved because there is insufficient evidence it improves symptoms, a panel of advisers to the U.S. Food and Drug Administration concluded on Thursday.

Article link: http://www.reuters.com/article/2014/03/27/us-novartis-idUSBREA2Q21T20140327
Source website: http://www.reuters.com/

Anti-Anxiety Drugs Tied to Higher Mortality

March 27, 2014

A large study has linked several common anti-anxiety drugs and sleeping pills to an increased risk of death, although it's not certain the drugs were the cause. For more than seven years, researchers followed 34,727 people who filled prescriptions for antianxiety medications like Valium and Xanax, or sleep aids like Ambien, Sonata and Lunesta, comparing them with 69,418 controls who did not.

Article link: http://well.blogs.nytimes.com/2014/03/27/anti-anxiety-drugs-tied-to-higher-mortality/?_php=true&_type=blogs&_php=true&_type=blogs&ref=health&_r=1
Source website: http://well.blogs.nytimes.com/

Antidepressants during pregnancy linked to preterm birth

March 27, 2014

Antidepressant medications taken by pregnant women are associated with increased rates of preterm birth. This finding reinforces the notion that antidepressants should not be used by pregnant women in the absence of a clear need that cannot be met through alternative approaches, say researchers from Brigham and Women's Hospital, Vanderbilt University, MetroWest Medical Center and Tufts Medical Center.

Article link: http://www.sciencedaily.com/releases /2014/03/140327140101.htm?utm_source=feedburner&utm_medium=feed&utm_campaign=Feed%3A+sciencedaily+%28Latest+Science+News+--+ScienceDaily%29
Source website: http://www.sciencedaily.com/

Common Gout Drug Tied to Lower Risk of Early Death in Study

March 28, 2014

A drug often used to treat gout may reduce the risk of premature death in patients with this common form of arthritis, according to a new study. Previous research has associated gout with an increased risk of early death. This study examined how allopurinol -- the most widely used medication for gout -- might affect that risk.
Article link: http://consumer.healthday.com/senior-citizen-information-31/misc-death-and-dyingnews-172/briefs-emb-3-24-gout-drug-death-risk-ard-bumc-release-batch-1198-686146.html
Source website: http://consumer.healthday.com/

MannKind's Inhaled Insulin Tied to Lung Function Concerns

March 28, 2014

MannKind Corp.'s inhaled diabetes drug, found to be effective against Type 2 diabetes, is linked to potential breathing problems that may limit its use in patients with lung diseases, U.S. regulators said. Afrezza, a powdered insulin used through an inhaler, would be the Valencia, California-based company's first marketed product. A Food and Drug Administration staff report today tied the drug to a decline in lung function, bronchial spasms similar to asthma and coughing that caused some patients to stop treatment, according to an online document.

Article link: http://washpost.bloomberg.com/Story?docId=1376-N35BNC6KLVSI01-6MPN9QTK76VAT4QENLGKK88HFT
Source website: http://washpost.bloomberg.com/

Massachusetts bans sale of FDA-approved Zogenix painkiller

March 28, 2014

Officials in Massachusetts have blocked sales of Zogenix's controversial but U.S.-approved painkiller Zohydro, prompting the drugmaker to criticize what it called an "unprecedented action." The state's ban "only serves to unfairly restrict patient access," the company said in a statement late Thursday. "Ultimately, the ban on the prescription medication will add to patient suffering in the state," it added.

Article link: http://www.reuters.com/article/2014/03/28/usa-drugs-opioids-zogenixidUSL1N0MP10S20140328
Source website: http://www.reuters.com/

Pfizer Statement on U.S. FDA Approval of Over-the-Counter Nexium® 24HR

March 28, 2014

Today the U.S. Food and Drug Administration (FDA) approved over-the-counter Nexium® 24HR (esomeprazole 20mg) marking a key step towards providing those who suffer from frequent heartburn broader access to a brand doctors and patients have trusted for years. In 2012, Pfizer acquired exclusive global rights from AstraZeneca to market non-prescription Nexium®. The addition of Nexium® 24HR to the Pfizer Consumer Healthcare portfolio expands the breadth of categories in which we help consumers better manage their health, and extends the value of the world's leading prescription acid blocker brand.

Article link: http://www.pfizer.com/news/press-release/press-releasedetail/pfizer_statement_on_u_s_fda_approval_of_over_the_counter_nexium_24hr
Source website: http://www.pfizer.com/

New Blood Pressure Guidelines May Take Millions of Americans Off Meds

March 29, 2014

About 5.8 million American adults may no longer be prescribed drugs to treat high blood pressure under recently revised guidelines, according to a new study. In February, the Eighth Joint National Committee released controversial guidelines that relaxed blood pressure goals in adults 60 and older from 140/90 to 150/90. The guidelines also eased blood pressure targets for adults with diabetes and kidney disease.

Article link: http://consumer.healthday.com/circulatory-system-information-7/blood-pressure-news-70/new-blood-pressure-guidelines-686243.html

Source website: http://consumer.healthday.com/

Amgen drug lowers cholesterol up to 66 percent in pivotal studies

March 29, 2014

Amgen Inc's drug from a high profile new class of experimental medicines lowered "bad" LDL cholesterol by 55 percent to 66 percent compared with a placebo in a trio of late-stage clinical trials, according to data presented on Saturday.

Article link: http://www.reuters.com/article/2014/03/29/us-heart-amgen-cholesterolidUSBREA2S0IF20140329

Source website: http://www.reuters.com/

Cushing's Drug Lowers BP, Body Weight

March 30, 2014

Patients with Cushing's disease treated with the somatostatin analog pasireotide (Signifor) had improvements in multiple manifestations of hypercortisolism, even if urinary free cortisol (UFC) levels were incompletely controlled, analysis of data from a phase III study showed.

Article link: http://www.medpagetoday.com/Endocrinology/GeneralEndocrinology/45006

Source website: http://www.medpagetoday.com/

Novartis set to close heart drug study early after strong results

March 31, 2014

Swiss drugmaker Novartis is set to end a late-stage clinical trial of a chronic heart failure drug early, following strong interim results. The Basel-based firm said on Monday an independent committee had unanimously recommended it close its PARADIGM-HF study ahead of time after results showed patients receiving its LCZ696 drug lived longer without being hospitalised for heart failure than those who were given the standard care.

Article link: http://in.reuters.com/article/2014/03/31/novartis-heartdrug-studyidINL5N0MS17W20140331

Source website: http://www.reuters.com/

Diabetes Treatment Falls Short as Heart Failure Drug in Study

March 31, 2014

A drug commonly used to treat diabetes does not help prevent heart failure in non-diabetics who've had a heart attack, according to a new study. Researchers said results from the rigorous clinical trial dispute previous findings that showed the drug, metformin, could have a protective effect on the heart.

Article link: http://consumer.healthday.com/diabetes-information-10/diabetes-drug-news-179/diabetes-drug-falls-short-as-heart-failure-drug-686256.html
Source website: http://consumer.healthday.com/

More Research Links Poor Heart Health With Alzheimer's Risk

March 31, 2014

A new study links heart disease with increased odds of developing dementia. Researchers found that artery stiffness -- a condition called atherosclerosis -- is associated with the buildup of beta-amyloid plaque in the brain, a hallmark of Alzheimer's disease.

Article link: http://consumer.healthday.com/senior-citizen-information-31/ misc-aging-news-10/more-research-links-poor-heart-health-with-alzheimer-s-risk-686336.html
Source website: http://consumer.healthday.com/

Aleglitazar No Help Against Coronary Events

March 31, 2014

Treatment with the investigative diabetes drug aleglitazar lowered blood glucose levels in diabetes patients but did not improve cardiovascular outcomes, researchers found. In calculating the impact on the composite endpoint of cardiovascular death, heart attack, or stroke, Michael Lincoff, MD, director of the Cleveland Clinic Coordinating Center for Clinical Research, said 9.5% of patients over the 3-year course of the study experienced the endpoint compared with 10% of patients treated with placebo (P=0.57).

Article link: http://www.medpagetoday.com/Cardiology/Diabetes/45039
Source website: http://www.medpagetoday.com/

UPDATE 2-U.S. FDA advisers back MannKind's inhaled diabetes drug

April 1, 2014

U.S. health advisers on Tuesday recommended approval of MannKind Corp's inhaled diabetes drug, and said the experimental treatment could help some patients, especially those wary of needles typically used with traditional insulin therapy.

Article link: http://www.reuters.com/article/2014/04/01/mannkind-fda-diabetesidUSL1N0MT1W120140401
Source website: http://www.reuters.com/

FDA to speed up approval process for Tetraphase's antibiotic

April 2, 2014

A sign that U.S. regulators are serious about bringing new antibiotics to market quickly came today when Watertown-based Tetraphase Pharmaceuticals said the U.S. Food and Drug Administration has given fast track designation to its most advanced potential drug.

Article link: http://www.bizjournals.com/boston/blog/bioflash/2014/04/fda-to-speed-up-approvalprocess-for-tetraphase-s.html
Source website: http://www.bizjournals.com/

Rare, But Serious, Side Effect Reported With One MS Drug

April 2, 2014

A handful of people taking a medication called Rebif to treat multiple sclerosis have developed a serious condition that causes blood clots to form in small blood vessels throughout the body. In a letter in the March 27 issue of the New England Journal of Medicine, Scottish researchers reported that they found an unexpectedly high number of cases of "thrombotic microangiopathy" in people taking Rebif who suddenly developed severe high blood pressure. The condition is a combination of the clotting disorders hemolytic-uremic syndrome and thrombotic thrombocytopenic purpura (HUS/TTP).

Article link: http://consumer.healthday.com/circulatory-system-information-7/clots-health-news-731/rare-but-serious-side-effect-reported-in-one-ms-medication-686152.html
Source website: http://consumer.healthday.com/

Urine Test Can Uncover BP Med Adherence

April 2, 2014

A simple urine test might help clinicians figure out whether their patients aren't responding to antihypertensive therapy because of true resistance or because of nonadherence, a small study suggested.

Article link: http://www.medpagetoday.com/Cardiology/Hypertension/45089
Source website: http://www.medpagetoday.com/

Experimental Breast Cancer Drug Seems Safe, Effective for Advanced Disease

April 6, 2014

In an early trial, an experimental breast cancer drug stopped disease growth and shrank tumors by more than 30 percent in some patients.The pill, bemaciclib, was safe and well-tolerated by women with breast cancer that had spread, or metastasized, to other parts of the body, according to the results of this phase 1 trial.

Article link: http://consumer.healthday.com/cancer-information-5/breast-cancer-news-94/experimental-breast-cancer-drug-seems-safe-and-effective-686546.html
Source website: http://consumer.healthday.com/

Pain Relievers Tied to Heart Rhythm Disorder

April 9, 2014

A new study found that the popular pain relievers known as nonsteroidal anti-inflammatory drugs, or Nsaids, may increase the risk for the most common type of irregular heartbeat, atrial fibrillation. Dutch researchers followed 8,423 people, average age 69, with normal heart rhythm at the start of the study for an average of 13 years. Over the period, 857 developed atrial fibrillation.

Article link: http://well.blogs.nytimes.com/2014/04/09/pain-relievers-tied-to-heart-rhythmdisorder/?_php=true&_type=blogs&_php=true&_type=blogs&partner=rss&emc=rss&_r=1&
Source website: http://well.blogs.nytimes.com/

Merck hepatitis C drugs shine in easier to treat patients: study

A two-drug combination being tested by Merck & Co to treat hepatitis C cured 98 percent of previously untreated patients without cirrhosis in a midstage clinical trial, providing the latest evidence that the U.S. drugmaker will be highly competitive in the fast evolving field.

Article link: http://www.reuters.com/article/2014/04/10/us-hepatitis-merckidUSBREA390B120140410
Source website: http://www.reuters.com/

Heart Failure Drug Might Help Reduce Hospitalizations

April 9, 2014

A drug often used to treat heart failure patients does little to lower cardiac arrest or death risk among people with a common form of the disease. But it does help reduce hospitalizations, a new study finds.

Article link: http://consumer.healthday.com/general-health-information-16/misc-drugs-news-218/briefs-emb-4-9-5pmet-heart-failure-drug-nejm-bwh-release-batch-1121-686605.html
Source website: http://consumer.healthday.com/

Researchers, regulators and Roche row over stockpiled drug Tamiflu

April 9, 2014

Researchers who have fought for years to get full data on Roche's flu medicine Tamiflu said on Thursday that governments who stockpile it are wasting billions of dollars on a drug whose effectiveness is in doubt. The row has drawn in the drugmaker as well as industry regulators and independent scientists. Supporters of Tamiflu said the researchers' conclusions were flawed and insisted the drug is both safe and effective.

Article link: http://www.reuters.com/article/2014/04/09/us-roche-hldg-tamifluidUSBREA3824K20140409
Source website: http://www.reuters.com/

RECALLS

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
Drugs	Prolifta Dietary Supplement Prolifta, 400mg/capsule, Packaged in 1 and 2 capsule blister packs and 4, 12, and 24 capsule bottles Made in the USA Distributed by: Prolifta LLC 1+877.239.8231 www.proliftaherbal.com.	All lot codes and expiration dates.	Class I	Marketed without an Approved NDA/ANDA: Dietary supplement may contain amounts of an active ingredient found in some FDA-approved drugs for erectile dysfunction (ED) making the dietary supplement an unapproved drug.	Haute Health, LLC
Drugs	PHUK Sexual Enhancement Ultimate Pleasure, 400mg/capsule, packaged in 1 and 2 capsule blister packs and 4,12,24 capsule bottles, Distributed by UME Supplements, INC www.phukherbal.com.	All lot codes and expiration dates.	Class I	Marketed without an Approved NDA/ANDA: Dietary supplement may contain amounts of active ingredients found in some FDA-approved drugs for erectile dysfunction (ED) making the dietary supplement an unapproved drug.	Haute Health, LLC
Drugs	Virilis Pro, 450mg/capsule, Packaged in a 1 and 2 capsule blister packs and 10 capsule bottles, Manufactured for Haute Health Williamstown, NJ 08094 website: http://www.virilispro.com	All lot codes and expiration dates.	Class I	Marketed without an Approved NDA/ANDA: Dietary supplement may contain amounts of active ingredients found in some FDA-approved drugs for erectile dysfunction (ED) making the dietary supplement an unapproved drug.	Haute Health, LLC
Drugs	1% Lidocaine HCl Injection, USP, 10 mg/mL, NDC 0409-4276-01, Hospira, Inc., Lake Forest, IL 60045.	Lot #25090DK; Exp 01/15	Class I	Presence of Particulate Matter: Oxidized stainless steel found in vial of 1% Lidocaine Hydrochloride Injection, USP.	Hospira, Inc.

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
Drugs	Slim Fortune capsules Dietary Supplement. Each bottle contains 30 capsules.	ALL LOTS	Class I	Marketed Without an Approved NDA/ANDA; undeclared Sibutramine	B @ B Trade Inc.
Drugs	Lidiy capsules Dietary Supplement. Each bottle contains 30 capsules	ALL LOTS	Class I	Marketed Without an Approved NDA/ANDA; undeclared Sibutramine	B @ B Trade Inc.
Drugs	Slim Expert softgel capsules Dietary Supplement. One month supply/ 30 softgels. 1 softgel - 650 mg.	ALL LOTS	Class I	Marketed Without an Approved NDA/ANDA; undeclared Sibutramine	B @ B Trade Inc.
Drugs	Vicerex A Powerful And Fast Acting Male Sexual Enhancer, 10 capsules per box, Dietary Supplement. UPC 893490820087 (product numbers may possibly vary for same product identification and same product packaging), distributed by Vicerex.com.	All lots, UPC 893490820087	Class I	Marketed without an Approved NDA/ANDA: Laboratory analysis conducted by the FDA has determined the Vicerex product contains undeclared tadalafil and the Black Ant product contains undeclared sildenafil. Tadalafil and sildenafil are FDA-Approved drugs used to treat male erectile dysfunction (ED), making the Vicerex and the Black Ant products unapproved new drugs.	American Lifestyle.Com
Drugs	Black Ant, 4600 mg x 4. Product is packaged in a small green box with gold lettering on the front, the back side of the box contains mostly foreign character. Within the box there	All lots, UPC 4026666142546 .	Class I	Marketed without an Approved NDA/ANDA: Laboratory analysis conducted by the FDA has determined the Vicerex product contains undeclared tadalafil and the Black	American Lifestyle.Com

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
	are four (4) capsules individually wrapped in black and red plastic with white lettering. UPC 4026666142546 (product numbers may possibly vary for same product identification and same product packaging).			Ant product contains undeclared sildenafil. Tadalafil and sildenafil are FDA-Approved drugs used to treat male erectile dysfunction (ED), making the Vicerex and the Black Ant products unapproved new drugs.	
Drugs	Calcium Gluconate 10% for Injection, SDV 100 mL SDV, PF, Not for Dispensing, For Hospital Administration Only, Rx Formulations, 5949 East University Drive, Mesa, AZ, 85205.	Lot #: 117433@15 Expiration Date: 12/07/2013 Lot #: 117446@8 Expiration Date: 12/12/2013 Lot#: 117923@8 Expiration Date: 12/19/2013	Class I	Non-Sterility: RX Formulation initiated this recall due to a report of microbial contamination found in Calcium Gluconate saturated solution that was observed upon drawing the vial contents into a syringe.	Zions RX Formulations Services LLC dba RX Formuations Serv.
Drugs	Dr. Ming's Chinese Capsule (Ginger 50 mg, Camellia Sinensis 50 mg, Malus Domestica 50 mg, Propetary Blend 300 mg Cynara Scolymus, Hoodia, Siruline, Chitosan, 60-count bottles, Distributed by Natural Products, Doral, FL 33178.	Lot #: 18 04 12, Exp 17 04 14	Class I	Marketed Without An Approved NDA/ANDA: The product contains undeclared sibutramine and phenolphthalein. Sibutramine and phenolphthalein are not currently marketed in the United States, making this product an unapproved new drug.	Slim Beauty USA
Drugs	Magic Slim capsules (Ling Zhi, Ebony, Fox-nut, Tuckahoe, Seman Pruni, Dioscoreae, Wheat Germ, Nature Substance), 60-count bottles.	No lot code information or exp date on packaging.	Class I	Marketed Without An Approved NDA/ANDA: The product contains undeclared sibutramine and phenolphthalein.	Slim Beauty USA

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
				Marketed Without An Approved NDA/ANDA: The product contains undeclared sibutramine and phenolphthalein. Sibutramine and phenolphthalein are not currently marketed in the United States, making this product an unapproved new drug.	
Drugs	Dream Body Slimming Capsule (Chinese bitter orange 24%, Cassia Seed 18%, Aloe 16%, Lotus Leaf Extract 12%, Medical Amylum 30%), 350 mg, 30-count bottles, Made in China (Beijing).	Lot # 20130328, Exp 3/27/15	Class I	Marketed Without An Approved NDA/ANDA: The product contains undeclared sibutramine and . Sibutramine is not currently marketed in the United States, making this product an unapproved new drug.	Slim Beauty USA
Drugs	Magnesium Sulfate 10gm in 250mL Lactated Ringers Bags, Not For Dispensing, For Hospital Administration Only, Rx Formulations, 5949 East University Drive, Mesa, AZ 85205	Lot #: 117037@3 Expiration Date: 12/13/2013 Lot #: 117899@1 Expiration Date: 01/03/2014 Lot #: 118289@7 Expiration Date: 01/09/2014 Lot #: 118078@56 Expiration Date: 01/03/2014 Lot #:118394@29 Expiration Date: 01/09/2014 Lot #: 118338@10 Expiration Date:	Class II	Lack of Assurance of Sterility: The firm expanded the recall to other injectable products due to lack of assurance of sterility from poor aseptic practices observed at the firm.	Zions RX Formulations Services LLC dba RX Formuations Serv.

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
		01/09/2014 Lot #: 118056@46 Expiration Date: 01/02/2014			
Drugs	Potassium Phosphates 4.4mEq/3mM/mL Vials, Not for Dispensing, For Hospital Administration Only, Rx Formulations, 5949 East University Drive, Mesa, AZ 85205	Lot #: 117467@9 Expiration Date: 12/12/2013 Lot #: 117857@2 Expiration Date: 12/15/2013 Lot #: 117740@4 Expiration Date: 12/13/2013	Class II	Lack of Assurance of Sterility: The firm expanded the recall to other injectable products due to lack of assurance of sterility from poor aseptic practices observed at the firm.	Zions RX Formulations Services LLC dba RX Formuations Serv.
Drugs	Oxytocin 30 Units in 500mL Sodium Chloride 0.9% Bags, Not for Dispensing, For Hospital Administration Only, Rx Formulations, 5949 East University Drive, Mesa, AZ 85205	Lot #: 117440@1 Expiration Date: 12/27/2013 Lot #: 117901@2 Expiration Date: 01/03/2014 Lot #: 118291@32 Expiration Date: 01/05/2014 Lot #: 118392@28 Expiration Date: 01/09/2014 Lot #: 117659@66 Expiration Date: 12/26/2013 Lot #: 118348@17 Expiration Date: 01/09/2014 Lot #: 117601@38 Expiration Date: 12/26/2013 Lot #: 117847@13 Expiration Date: 12/29/2013 Lot #: 118058@47 Expiration Date: 01/02/2014	Class II	Lack of Assurance of Sterility: The firm expanded the recall to other injectable products due to lack of assurance of sterility from poor aseptic practices observed at the firm.	Zions RX Formulations Services LLC dba RX Formuations Serv.
Drugs	Sodium Bicarbonate 8.4%, a) 10 mL, b) 20 mL, and c) 22 mL	a) Lot #: 117460@5 Expiration Date:	Class II	Lack of Assurance of Sterility: The firm expanded the recall	Zions RX Formulations Services LLC

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
	units, Not for Dispensing, For Hospital Administration Only, Rx Formulations, 5949 East University Drive, Mesa, AZ 85205	12/12/2013, Lot #: 117911@5 Expiration Date: 12/19/2013, Lot #: 118301@9 Expiration Date: 12/25/2013 b) Lot #: 117462@6 Expiration Date: 12/12/2013, Lot #: 117916@6 Expiration Date: 12/19/2013, Lot #: 118305@10 Expiration Date: 12/25/2013 c) Lot #: 118011@23 Expiration Date: 12/18/2013, Lot #: 118092@63 Expiration Date: 12/18/2013, Lot #: 118401@31 Expiration Date: 12/25/2013, Lot #: 118013@24 Expiration Date: 12/18/2013, Lot #: 118094@64 Expiration Date: 12/18/2013, Lot #: 118403@32 Expiration Date: 12/25/2013		to other injectable products due to lack of assurance of sterility from poor aseptic practices observed at the firm.	dba RX Formuations Serv.
Drugs	Bupivacaine 3%, 300 mL units, Not for Dispensing, For Hospital Administration Only, Rx Formulations, 5949 East University Drive, Mesa, AZ 85205	Lot #: 117456@3 Expiration Date: 12/12/2013 Lot #: 117907@3 Expiration Date: 12/19/2013 Lot #: 118297@8 Expiration Date:	Class II	Lack of Assurance of Sterility: The firm expanded the recall to other injectable products due to lack of assurance of sterility from poor aseptic practices observed at the firm.	Zions RX Formulations Services LLC dba RX Formuations Serv.

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
		12/25/2013			
Drugs	Vitamin B-12 injections, a) 1 mL and b) 30 mL units, Not for Dispensing, For Hospital Administration Only, Rx Formulations, 5949 East University Drive, Mesa, AZ 85205	a) Lot#118954@2 Exp. Date: 03/09/2014, Lot# 118917@2 Exp. Date: 03/06/2014; b) Lot #: 119379@24 Exp. Date: 01/19/2014, Lot#: 118815@27 Exp. Date: 03/03/2014	Class II	Lack of Assurance of Sterility: The firm expanded the recall to other injectable products due to lack of assurance of sterility from poor aseptic practices observed at the firm.	Zions RX Formulations Services LLC dba RX Formuations Serv.
Drugs	etomidate injection, USP, 2 mg/mL, packaged in a) 20 mg/10 mL (2 mg/mL), 10 mL Single Dose Vials (NDC 0069-0006-02), 10 x 10 mL vials per carton (NDC 0069-0006-01) and b) 40 mg/20 mL (2 mg/mL) 20 mL Single Dose Vials (NDC 0069-0006-04), 10 x 20 mL vials per carton (NDC 0069-0006-03), Rx only, Distributed by Pfizer Labs; Division of Pfizer Inc., New York, NY 10017.	Lot #: a) 5000983, 5000986, Exp 08/14; 5001023, Exp 09/14; b) 5000927, 5000931, 5000936, 5000942, 06/14; 5001012, 5001040, Exp 09/14; 5001071, Exp 10/14	Class II	Presence of Particulate Matter: Potential for small black particles to be present in individual vials, the potential for missing lot number and/or expiry date on the outer carton and the potential for illegible/missing lot number and expiry on individual vials.	Agila Specialties Private Ltd.
Drugs	Pleo Not OINTMENT 3X, 30 g Tube, Topical Homeopathic Medicine, OTC Only. Made in Germany, Distributed by: SANUM USA Corp.,1465 Slater Road, Fernadale, WA 98248; Manufactured	Batch # 03051, EXP: April 2014; Batch # 13072, EXP: June 2015; Batch #21033, EXP: April 2016.	Class II	Penicillin Cross Contamination	Terra-Medica Inc.

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
	By: SANUM-Kehlbeck GmbH & Co. KG. NDC: 49807-2305-1.				
Drugs	Pleo Not SUPPOSITORIES 3X, 10 Suppository Cartons, Homeopathic Medicine, OTC Only. Made in Germany, Distributed by: SANUM USA Corp.,1465 Slater Road, Fernadale, WA 98248; Manufactured By: SANUM-Kehlbeck GmbH & Co. KG. NDC: 49807-2304-1.	Batch # 1080, EXP: July 2015; Batch # 1102, EXP: Septempber 2017.	Class II	Penicillin Cross Contamination	Terra-Medica Inc.
Drugs	Pleo Not CAPSULES 4X, 20 Tablet Cartons, Oral Homeopathic Fever Reducer/ Cough Suppressant/ Decongestant Medicine, OTC Only. Made in Germany, Distributed by: SANUM USA Corp.,1465 Slater Road, Fernadale, WA 98248; Manufactured By: SANUM-Kehlbeck GmbH & Co. KG. NDC: 49807-2303-1.	Batch # 14010, EXP: December 2014; Batch # 11080, EXP: August 2015; Batch # 12092, EXP: July 2017.	Class II	Penicillin Cross Contamination	Terra-Medica Inc.
Drugs	Pleo Not TABLETS 5X, 20 Tablet Cartons, Oral Homeopathic Medicine, OTC Only. Made in Germany, Distributed by: SANUM USA Corp.,1465 Slater Road, Fernadale, WA 98248; Manufactured By: SANUM-Kehlbeck GmbH & Co. KG. NDC:	Batch # 15070, EXP: June 2015; Batch # 24072, EXP: June 2017.	Class II	Penicillin Cross Contamination	Terra-Medica Inc.

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
	49807-2302-1.				
Drugs	Pleo Not DROPS, 5X, 10 mL Bottles, Oral Homeopathic Medicine, OTC Only. Made in Germany, Distributed by: SANUM USA Corp.,1465 Slater Road, Fernadale, WA 98248; Manufactured By: SANUM-Kehlbeck GmbH & Co. KG. NDC: 49807-2301-1.	Batch # 21049, EXP: March 2014; Batch # 13059; EXP: April 2014; Batch # 09080, EXP: July 2015; Batch #15100; EXP: September 2015; Batch # 24092; EXP: August 2017.	Class II	Penicillin Cross Contamination	Terra-Medica Inc.
Drugs	Pleo Not PORTABLE SIPS, 5X, 10 x 1mL Cartons, Oral Homeopathic Medicine, OTC Only. Made in Germany, Distributed by: SANUM USA Corp.,1465 Slater Road, Fernadale, WA 98248; Manufactured By: SANUM-Kehlbeck GmbH & Co. KG. NDC: 49807-2306-1. Pleo Not PORTABLE SIPS, 5X, 50 x 1mL Cartons, Oral Homeopathic Medicine, OTC Only. Made in Germany, Distributed by: SANUM USA Corp.,1465 Slater Road, Fernadale, WA 98248; Manufactured By: SANUM-Kehlbeck GmbH & Co. KG. NDC: 49807-2306-2.	(10 x 1mL): Batch # 07099, EXP: August 2014; Batch # 15090; EXP: August 2015; Batch # 06120, EXP: November 2015; Batch #19023; EXP: January 2018. (50 x 1ml) Portable Sips: Batch # 07099, EXP: August 2014; Batch # 15090; EXP: August 2015; Batch # 1110, EXP: October 2015; Batch #6120; EXP: November 2015;Batch # 19023; EXP January 2018.	Class II	Penicillin Cross Contamination	Terra-Medica Inc.
Drugs	Pleo Not PORTABLE SIPS, 6X, 10 x 1mL Cartons, Oral Homeopathic	(10 x 1mL) Batch # 25050, EXP: April 2015. (50 x 1mL): Batch #	Class II	Penicillin Cross Contamination	Terra-Medica Inc.

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
	Medicine, OTC Only. Made in Germany, Distributed by: SANUM USA Corp.,1465 Slater Road, Fernadale, WA 98248; Manufactured By: SANUM-Kehlbeck GmbH & Co. KG. NDC: 49807-2308-1. Pleo Not PORTABLE SIPS, 6X, 50 x 1mL Cartons, Oral Homeopathic Medicine, OTC Only. Made in Germany, Distributed by: SANUM USA Corp.,1465 Slater Road, Fernadale, WA 98248; Manufactured By: SANUM-Kehlbeck GmbH & Co. KG. NDC: 49807-2308-2 .	25050, EXP: April 2015.			
Drugs	Pleo Not PORTABLE SIPS 7X,10 x 1 mL Cartons, Oral Homeopathic Medicine, OTC Only. Made in Germany, Distributed by: SANUM USA Corp., 1465 Slater Road, Ferndale, WA 98248. Manufactured by: Sanum-Kehlbeck GmbH & Co. KG. NDC: 49807-2310-1. Pleo Not PORTABLE SIPS 7X, 50 x 1 mL Cartons, Oral Homeopathic Medicine, OTC Only. Made in Germany, Distributed by: SANUM USA Corp., 1465 Slater Road,	(10 x 1 mL) Portable Sips: Batch # 20010, EXP: December 2014. (50 x 1ml) Portable Sips: Batch # 20010, EXP: December 2014.	Class II	Penicillin Cross Contamination	Terra-Medica Inc.

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
	Ferndale, WA 98248. Manufactured by: Sanum-Kehlbeck GmbH & Co. KG. NDC: 49807-2310-2.				
Drugs	Pleo Nota- Quent DROPS 5X, 10 mL Bottles, Homeopathic Medicine, OTC Only. Made in Germany, Manufactured by: Sanum-Kehlbeck GmbH & Co. KG, Hoya, Germany. Distributed by: SANUM USA Corp., 1465 Slater Road, Ferndale, WA 98248. NDC: 49807-0031-1.	Batch #04062 , EXP: May 2017; Batch #06062 , EXP: May 2017.	Class II	Penicillin Cross Contamination	Terra-Medica Inc.
Drugs	Pleo Quent SUPPOSITORIES 3X, 10 Suppository Cartons, Oral Homeopathic Medicine, OTC Only. Made in Germany for: SANUM USA Copr, 1456 Slater Road, Ferndale, WA 98248 by Sanum-Kehlbeck GmbH & Co. KG. NDC: 49807-2904-1.	Batch # 2089; EXP: June 2014; Batch #3031 , EXP: June 2016.	Class II	Penicillin Cross Contamination	Terra-Medica Inc.
Drugs	Pleo Quent CAPSULES 4X, 20 Capsule Cartons, Oral Homeopathic Medicine, OTC Only. Made in Germany for: SANUM USA Copr, 1456 Slater Road, Ferndale, WA 98248 by Sanum-Kehlbeck GmbH & Co. KG NDC: 49807-2902-1.	Batch # 25030; EXP: April 2015; Batch # 27101, EXP: Sept 2016.	Class II	Penicillin Cross Contamination	Terra-Medica Inc.
Drugs	Pleo Quent DROPS 5X, 10 mL Bottles, Oral Homeopathic	Batch # 15129; EXP: November 2014; Batch	Class II	Penicillin Cross Contamination	Terra-Medica Inc.

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
	Medicine, OTC Only. Made in Germany for: SANUM USA Copr, 1456 Slater Road, Ferndale, WA 98248 by Sanum-Kehlbeck GmbH & Co. KG. NDC: 49807-2901-1.	#12040, EXP: March 2015; Batch #01081, EXP: August 2016.			
Drugs	Pleo Quent PORTABLE SIPS 5X, 10 x 1 ml Cartons, Oral Homeopathic Medicine, OTC Only. Made in Germany for: SANUM USA Copr, 1456 Slater Road, Ferndale, WA 98248 by Sanum-Kehlbeck GmbH & Co. KG. NDC: 49807-2905-1. Pleo Quent PORTABLE SIPS 5X, 50 x 1 ml Cartons, Oral Homeopathic Medicine, OTC Only. Made in Germany for: SANUM USA Copr, 1456 Slater Road, Ferndale, WA 98248 by Sanum-Kehlbeck GmbH & Co. KG. NDC: 49807-2905-2.	10 x 1 ml: Batch # 13090; EXP: August 2015. 50 x 1 ml: Batch #13090, EXP: August 2015.	Class II	Penicillin Cross Contamination	Terra-Medica Inc.
Drugs	Pleo Fort SUPPOSITORIES 3X, 10 Suppository Carton, Homeopathic Digestive Aid Medicine, OTC Only. Made in Germany for: SANUM USA Copr, 1456 Slater Road, Ferndale, WA 98248 by Sanum-Kehlbeck GmbH & Co. KG. NDC: 49807-1106-1.	Batch # 3110; EXP: October 2015; Batch # 1112; EXP: October 2017.	Class II	Penicillin Cross Contamination	Terra-Medica Inc.
Drugs	Pleo Fort CAPSULES	Batch # 24030;	Class II	Penicillin Cross	Terra-Medica

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
	4X, 20 Capsule Cartons Homeopathic Digestive Aid Medicine, OTC Only. Made in Germany for: SANUM USA Copr, 1456 Slater Road, Ferndale, WA 98248 by Sanum-Kehlbeck GmbH & Co. KG. NDC: 49807-1103-1.	EXP: February 2015; Batch # 14062; EXP: May 2017.		Contamination	Inc.
Drugs	Pleo Fort PORTABLE SIPS 5X, 10 x 1 mL Carton. Oral Homeopathic Medicine, OTC Only. Made in Germany for: SANUM USA Copr, 1456 Slater Road, Ferndale, WA 98248 by Sanum-Kehlbeck GmbH & Co. KG. NDC: 49807-1105-1. Pleo Fort PORTABLE SIPS 5X, 50 x 1 mL Carton. Oral Homeopathic Medicine, OTC Only. Made in Germany for: SANUM USA Copr, 1456 Slater Road, Ferndale, WA 98248 by Sanum-Kehlbeck GmbH & Co. KG. NDC: 49807-1105-2.	10 x 1 ml Cartons: Batch # 15030; EXP: February 2015; Batch # 12122; EXP: November 2017. 50 x 1 ml: Batch # 15030; EXP: February 2015; Batch # 12122; EXP: November 2017.	Class II	Penicillin Cross Contamination.	Terra-Medica Inc.
Drugs	Pleo-Fort DROPS 5X, 10ml bottle, Homeopathic Digestive Aid Medicine, OTC Only. Made in Germany for: SANUM USA Copr, 1456 Slater Road, Ferndale, WA 98248 by Sanum-Kehlbeck GmbH & Co. KG. NDC:	Batch # 23109; EXP: September 2014; Batch # 08030; EXP: February 2015; Batch # 12032; EXP: February 2017; Batch # 26043; EXP: March 2018.	Class II	Penicillin Cross Contamination	Terra-Medica Inc.

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
	49807-1101-1.				
Drugs	Pleo Fort TABLETS 5X, 20 Tablet Carton, Homeopathic Digestive Aid Medicine, OTC Only. Made in Germany. Distributed by: SANUM USA Corp., 1465 Slater Road, Ferndale WA 98248. Manufactured by: Sanum-Kehlbeck GmbH & Co. KG. NDC: 49807-1102-1.	Batch # 27100; EXP: September 2015; Batch # 29100; EXP: October 2015; Batch # 25013; EXP: January 2018.	Class II	Penicillin Cross Contamination	Terra-Medica Inc.
Drugs	Pleo Ex SUPPOSITORIES 3X, 10 Suppository Packages; Homeopathic Antifungal Medicine, OTC Only. Made in Germany. Distributed by: SANUM USA Corp., 1465 Slater Road, Ferndale, WA 98248. Manufactured by: Sanum-Kehlbeck GmbH & Co. KG. NDC: 49807-1001-1.	Batch # 2011; EXP: December 2015; Batch # 2081, EXP: July 2016; Batch # 3063, EXP: May 2018; Batch # 1013, EXP: February 2018.	Class II	Penicillin Cross Contamination	Terra-Medica Inc.
Drugs	Pleo Ex DROPS 5X, 10 ml bottles, Homeopathic Antifungal Medicine, OTC Only. Made in Germany for: SANUM USA Corp., 1465 Slater Road, Ferndale, WA 98248 by Sanum-Kehlbeck GMbH & Co. KG. NDC: 49807-1003-1.	Batch # 07011; EXP: December 2015; Batch # 09043, EXP: March 2108.	Class II	Penicillin Cross Contamination	Terra-Medica Inc.
Drugs	Pleo Ex PORTABLE SIPS 5X, 10 x 1 mL, Oral Homeopathic Medicine, OTC Only.	10 x 1 mL: Batch # 09020; EXP: January 2015; Batch # 03052,	Class II	Penicillin Cross Contamination	Terra-Medica Inc.

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
	Made in Germany. Distributed by: SANUM USA Corp. 1465 Slator Road, Ferndale, WA 98248. Manufactured by: Sanum-Kehlbeck GmbH & Co. KG, NDC: 49807-1005-1. PLEO--EX Portable Sips 5X, 50 x 1 mL, Oral Homeopathic Medicine, OTC Only. Made in Germany. Distributed by: SANUM USA Corp. 1465 Slator Road, Ferndale, WA 98248. Manufactured by: Sanum-Kehlbeck GmbH & Co. KG, NDC: 49807-1005-2.	EXP: April 2017. 50 x 1 mL: Batch # 09020; EXP: January 2015; Batch # 03052, EXP: April 2017.			
Drugs	Pleo Stolo DROPS 6X, 10ml Bottle; Homeopathic Anti-Inflammatory Medicine, OTC Only. Made in Germany for: SANUM USA Copr, 1456 Slater Road, Ferndale, WA 98248 by Sanum-Kehlbeck GmbH & Co. KG. NDC: 49807-0011-1.	Batch # 08060; EXP: May 2015; Batch # 07119, EXP: August 2014; Batch # 03043, EXP: May 2018.	Class II	Penicillin Cross Contamination	Terra-Medica Inc.
Drugs	Rantidine Tablets USP, 150 mg, 500-count bottles, Rx only, Manufactured by: Shasun Pharmaceuticals Limited, Unit-II R.S. No 32 33 & 34, Shasun Road, Periyakalapet, Puducherry, - 605 014, India; Manufactured	Lot 12AN118A, Exp 10/14	Class II	Presence of Foreign Tablets/Capsules: Recall is due to a pharmacist complaint of a "foreign material", identified as Metoprolol Tartrate Tablet USP 50 mg, found co-mingled in a bottle of Ranitidine Tablets	Glenmark Generics Inc., USA

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
	for: Glenmark Generics Inc, USA, Mahwah, NJ 07430, UPC 3 68462 24805 8, NDC 68462-248-05.			USP 150 mg.	
Drugs	Ritalin HCl (methylphenidate HCl) USP, 10 mg, 100 tablets per Bottle, Rx only, Mfd. by: Novartis Pharmaceuticals Corp. Suffern, NY 10901, Dist. by: Novartis Pharmaceuticals Corp. East Hanover, New Jersey 07936, NDC 0078-0440-05	Lot #: F0126	Class III	Labeling: Incorrect or Missing Package Insert; The back of the Medication Guide attached to the Package Insert for Ritalin Tablets was printed with information related to Ritalin SR (Sustained Release) Tablets. Both products, Ritalin Tablets and Ritalin SR Tablets utilize a combined Package Insert. The individual Medication Guides are attached to the Package Insert via a perforation. Although the two products contain the same active ingredient, methylphenidate, the Medication Guides are not identical because the two products contain different excipients.	Novartis Pharmaceuticals Corp.

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
Drugs	Duloxetine Delayed-Release Capsules, USP, 20 mg, Rx Only, 60 capsules per Bottle,	Lot #: 48D001, Exp. 5/2015; 48D002, Exp. 9/2015	Class II	Failed Tablet/Capsule Specifications: Teva Pharmaceuticals USA, is voluntarily recalling certain lots of Duloxetine DR Capsules USP, 20 mg, 30 mg & 60 mg due to a customer complaint trend regarding capsule breakage.	Teva Pharmaceuticals USA
Drugs	Duloxetine Delayed-Release Capsules, USP, 30 mg, Rx Only, 30 Capsules per Bottle,	Lot #: 49D001, Exp. 4/2015; 49D002, Exp. 6/2015; 49D003, Exp. 7/2015; 49D004, 49D005, 49D006, Exp. 9/2015; 49D007, Exp. 10/2015	Class II	Failed Tablet/Capsule Specifications: Teva Pharmaceuticals USA, is voluntarily recalling certain lots of Duloxetine DR Capsules USP, 20 mg, 30 mg & 60 mg due to a customer complaint trend regarding capsule breakage.	Teva Pharmaceuticals USA
Drugs	Duloxetine Delayed-Release Capsules, USP, 60 mg, Rx Only, 30 Capsules per Bottle,	Lot #: 50D003, Exp. 2/2015; 50D004, 50D005, Exp. 3/2015; 50D006, Exp. 5/2015; 50D010, Exp. 6/2015; 50D028, Exp. 9/2015; 50D029, 50D031, Exp. 10/2015; 50D032, 50D033, Exp.	Class II	Failed Tablet/Capsule Specifications: Teva Pharmaceuticals USA, is voluntarily recalling certain lots of Duloxetine DR Capsules USP, 20 mg, 30 mg & 60 mg due to a customer complaint trend regarding capsule breakage.	Teva Pharmaceuticals USA

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
		11/2015			
Drugs	HydrOXYzine HCl Tablets, USP 25 mg, 100 Tablet Blister, Rx	Lot 120407, Exp 01/14; Lot 121337 Exp 03/14; Lot 122054, Exp 05/14; Lot 122598, Exp 06/14; Lot 130125, Exp 12/14	Class II	Good Manufacturing Practices Deviations: The product has an active pharmaceutical ingredient from an unapproved source.	American Health Packaging
Drugs	HydrOXYzine HCl Tablets, USP 50 mg, 100 Tablet Blister, Rx	Lot 120757, Exp. 02/14; Lot 121104, Exp 03/14; Lot 122055, Exp 05/14; Lot 123038, Exp 07/14; Lot 125115, Exp 11/14	Class II	Good Manufacturing Practices Deviations: The product has an active pharmaceutical ingredient from an unapproved source.	American Health Packaging
Drugs	Suprax, Cefixime for Oral Suspension USP 500 mg/5 ml, 10mL (when reconstituted),	Lot #s: F300737 Exp. February 2015, F300743 Exp. February 2015	Class III	Failed Impurities/Degradation Specifications: Product did not meet specification in total impurities at the 9-month stability station.	Lupin Pharmaceuticals Inc.
Drugs	Suprax, Cefixime for Oral Suspension USP, 500 mg/5 ml, 20 mL (when reconstituted),	Lot #s: F300736 Exp. February 2015, F300740 Exp. February 2015, F300741 Exp. February 2015	Class III	Failed Impurities/Degradation Specifications: Product did not meet specification in total impurities at the 9-month stability station.	Lupin Pharmaceuticals Inc
Drugs	DermOtic Oil (fluocinolone acetonide) 0.01% Ear Drops, 20 mL bottle, Rx only Manufactured and Distributed by: Hill Dermaceuticals, Inc. Sanford, Florida	12H028B exp. 01/14	Class III	Subpotent Drug: The active ingredient, fluocinolone acetonide, was found to be subpotent during the firm's routine testing.	Hill Dermaceuticals, Inc.

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
	32773 NDC 28105-160-20				
Drugs	Derma-Smoothe/FS fluocinolone acetonide 0.01% Topical Oil (Scalp Oil), 4 fl. oz., Rx only. Manufactured and Distributed by: Hill Dermaceuticals, Inc. Sanford, Florida 32773 NDC 28105-149-04	12J030C exp. 03/14, 12L041C exp. 05/14	Class III	Subpotent Drug: The active ingredient, fluocinolone acetonide, was found to be subpotent during the firm's routine testing.	Hill Dermaceuticals, Inc.
Drugs	Derma-Smoothe/FS fluocinolone acetonide 0.01% Topical Oil (Body Oil) 4 fl. oz., Rx only Manufactured and Distributed by: Hill Dermaceuticals, Inc. Sanford, Florida 32773 NDC 28105-150-04	13D010A exp. 10/14.	Class III	Subpotent Drug: The active ingredient, fluocinolone acetonide, was found to be subpotent during the firm's routine testing.	Hill Dermaceuticals, Inc.
Drugs	ROYAL PHARMACEUTICALS Derma-Smoothe/FS fluocinolone acetonide 0.01% Topical Oil (Body Oil) 4 fl. oz., Rx only Manufactured by: Hill Dermaceuticals, Inc. for: Royal Pharmaceuticals NDC 68791-101-04	13E013A exp. 11/14.	Class III	Subpotent Drug: The active ingredient, fluocinolone acetonide, was found to be subpotent during the firm's routine testing.	Hill Dermaceuticals, Inc.
Drugs	Derma-Smoothe/FS fluocinolone acetonide 0.01% (Scalp Oil), 4 fl.oz., Rx	13E014A exp. 11/14, 13F02C exp 12/14.	Class III	Subpotent Drug: The active ingredient, fluocinolone acetonide, was found to be subpotent during the firm's routine testing.	Hill Dermaceuticals, Inc.
Drugs	S DermOtic Oil fluocinolone acetonide 0.01% (Ear Drops), 20 ml, Rx only	13F015B exp. 12/14, 13G023B exp. 01/15	Class III	Subpotent Drug: The active ingredient, fluocinolone acetonide, was found	Hill Dermaceuticals, Inc.

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
				to be subpotent during the firm's routine testing.	
Drugs	Fluocinolone acetonide 0.01% Topical Oil (Scalp Oil), 4 fl.oz., Rx only	13F015C exp. 12/14.	Class III	Subpotent Drug: The active ingredient, fluocinolone acetonide, was found to be subpotent during the firm's routine testing.	Hill Dermaceuticals, Inc.
Drugs	Fluocinolone Acetonide 0.01% Topical Oil (Body Oil), 4 fl.oz., Rx only	13F016A exp. 12/14.	Class III	Subpotent Drug: The active ingredient, fluocinolone acetonide, was found to be subpotent during the firm's routine testing.	Hill Dermaceuticals, Inc.
Drugs	Fluocinolone Acetonide 0.01% Oil EAR DROPS, 20 ml, Rx	13F017B exp. 12/14, 13F020B exp 12/14	Class III	Subpotent Drug: The active ingredient, fluocinolone acetonide, was found to be subpotent during the firm's routine testing.	Hill Dermaceuticals, Inc
Drugs	QVAR® (beclomethasone dipropionate HFA), C4 INHALATION AEROSOL	lot 120088, exp.3/2014, NDC 59310-202-40, 40 mcg,8.7g / 120 metered inhalations, lot 120491, exp. 10/2014, NDC 59310-175-41,40 mcg,7.3g / 100 metered inhalations	Class III	Failed Impurity/Degradation Specification; for 17-BMP at the 9 and 18 month stability time point	Teva Pharmaceuticals USA
Drugs	Tivicay (dolutegravir) Tablets 50 mg, 30 Tablet Bottles, Rx	Lot #: 3ZP2210 Sub-lot A, Expiry: 10/15	Class III	Cross Contamination with Other Products: Product contains Promecta (eltrombopag).	Viiv Healthcare Company

CURRENT DRUG SHORTAGES

Methylene Blue Injection

January 27, 2014

Reason for the Shortage

- Akorn had methylene blue on back order due to increased demand for the product.
- American Regent has methylene blue on back order due to manufacturing delays.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=27
Source link: http://www.ashp.org

Indigo Carmine Injection

January 27, 2014

Reason for the Shortage

- American Regent had temporarily suspended manufacture of most drug products in April, 2011.
- American Regent resumed manufacturing in Shirley, New York in early-May, 2011.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=861
Source link: http://www.ashp.org

Morrhuate Sodium Injection

February 3, 2014

Reason for the Shortage

- American Regent had temporarily suspended manufacture of most drug products in April, 2011.
- American Regent resumed manufacturing in Shirley, New York in early-May, 2011.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=903
Source link: http://www.ashp.org

Caffeine and Ergotamine Tartrate

February 3, 2014

Reason for the Shortage

- Sandoz states the shortage is due to a change in the raw material plant location.
- Sandoz is the only manufacturer of caffeine and ergotamine tablets.

- Cypress discontinued their caffeine and ergotamine tablets in February, 2011 and West-Ward discontinued their product in April, 2010.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=880
Source link: http://www.ashp.org

Azathioprine Injection

February 3, 2014

Reason for the Shortage

- Ben Venue has stopped production in its plant in Bedford, Ohio and will close in early 2014. Ben Venue supplies multiple sterile injectable products for Bedford Laboratories. Supplies of product that has already been manufactured will continue to be released until inventory is depleted. Bedford Laboratories has a small number of products manufactured elsewhere that are not affected by this closure.
- There are no other manufacturers of azathioprine injection.
- The oral presentations are not affected by this shortage.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=935
Source link: http://www.ashp.org

Esmolol Injection

February 5, 2014

Reason for the Shortage

- Ben Venue has stopped production in its plant in Bedford, Ohio and will close in early 2014. Ben Venue supplies multiple sterile injectable products for Bedford Laboratories. Supplies of product that has already been manufactured will continue to be released until inventory is depleted. Bedford Laboratories has a small number of products manufactured elsewhere that are not affected by this closure.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=833
Source link: http://www.ashp.org

Vitamin A Injection

February 10, 2014

Reason for the Shortage

- Hospira is changing manufacturing sites from a 3rd party manufacturer to in-house manufacturing. This has caused a delay in production.
- Hospira is the sole manufacturer of vitamin A injection.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=704
Source link: http://www.ashp.org

Sodium Acetate Injection

February 10, 2014

Reason for the Shortage

- American Regent had temporarily suspended distribution of most drug products including all sodium acetate presentations in April, 2011.
- American Regent resumed manufacturing in Shirley, New York in early-May, 2011.
- American Regent has discontinued sodium acetate 2 mEq/mL 100 mL vials.
- Fresenius Kabi (formerly APP) had sodium acetate on shortage due to increased demand.
- Hospira had sodium acetate on shortage due to manufacturing delays.
- Baxter discontinued sodium acetate in June, 2008.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=762
Source link: http://www.ashp.org

Methyldopate Injection

February 10, 2014

Reason for the Shortage

- American Regent had temporarily suspended manufacture of most drug products in April, 2011.
- American Regent resumed manufacturing in Shirley, New York in early-May, 2011.
- There are no other suppliers of methyldopate injection.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=844
Source link: http://www.ashp.org

Hydroxyzine Injection

February 10, 2014

Reason for the Shortage

- American Regent has hydroxyzine injection on shortage due to manufacturing delays.
- American Regent is the sole supplier of hydroxyzine injection.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=829
Source link: http://www.ashp.org

Droperidol Injection

February 10, 2014

Reason for the Shortage

- American Regent droperidol injection on back order due to manufacturing delays.
- Hospira has droperidol on back order due to shortage of raw material.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=818
Source link: http://www.ashp.org

Chromium (Chromic Chloride) Injection

February 10, 2014

Reason for the Shortage

- Hospira has chromium (chromic chloride) injection on shortage due to manufacturing delays.
- American Regent had temporarily suspended distribution of most drug products including chromium (chromic chloride) injection in April, 2011.
- American Regent resumed manufacturing in Shirley, New York in early-May, 2011.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=943
Source link: http://www.ashp.org

Amino Acid Products

February 11, 2014

Reason for the Shortage

- Baxter was unable to provide a reason for the shortage.
- Braun had several amino acid products on back order due to manufacturing delays.
- Hospira had several amino acid products on back order due to manufacturing delays.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=671
Source link: http://www.ashp.org

Indomethacin Injection

February 14, 2014

Reason for the Shortage

- Indomethacin for injection is on nationwide back order due to manufacturing issues.
- Lundbeck sold several products to Recordati in January 2013 including Indocin IV and NeoProfen IV. Recordati is not currently manufacturing Indocin IV but NeoProfen is available.
- Ben Venue has stopped production in its plant in Bedford, Ohio and will close in early 2014. Ben Venue supplies multiple sterile injectable products for Bedford Laboratories. Supplies of product that has already been manufactured will continue to be released until inventory is depleted. Bedford Laboratories has a small number of products manufactured elsewhere that are not affected by this closure.
- Fresenius Kabi (formerly APP) had indomethacin injection on shortage due to increase demand for the product.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=596
Source link: http://www.ashp.org

Cyclosporine Injection

February 14, 2014

Reason for the Shortage

- Perrigo acquired Paddock Laboratories in July 2011. Perrigo discontinued cyclosporine injection in late-November, 2011.
- Bedford has cyclosporine injection on shortage due to manufacturing delays. Bedford anticipates full availability of each presentation the company reintroduces to market.
- Ben Venue has stopped production in its plant in Bedford, Ohio and will close in early 2014. Ben Venue supplies multiple sterile injectable products for Bedford Laboratories. Supplies of product that has already been manufactured will continue to be released until inventory is depleted. Bedford Laboratories has a small number of products manufactured elsewhere that are not affected by this closure.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=948
Source link: http://www.ashp.org

Furosemide Injection

February 18, 2014

Reason for the Shortage

- Fresenius Kabi (formerly APP) has furosemide injection on shortage due to increased demand for the product.
- American Regent had temporarily suspended manufacture of most drug products including furosemide in April, 2011.
- American Regent resumed manufacturing in Shirley, New York in early-May, 2011.
- Hospira has furosemide on shortage due to manufacturing delays.
- Wockhardt has discontinued all furosemide injection presentations.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=636
Source link: http://www.ashp.org

Dactinomycin Injection

February 20, 2014

Reason for the Shortage

- Ben Venue has stopped production in its plant in Bedford, Ohio and will close in early 2014. Ben Venue supplies multiple sterile injectable products for Bedford Laboratories. Supplies of product that has already been manufactured will continue to be released until inventory is depleted. Bedford Laboratories has a small number of products manufactured elsewhere that are not affected by this closure, but dactinomycin is not one of these products.
- Recordati acquired several products from Lundbeck in January 2013 including Cosmegen.
- Cosmegen can be ordered through wholesalers or ASD Healthcare at 1-800-746-6273

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=1064
Source link: http://www.ashp.org

Acyclovir Injection

February 21, 2014

Reason for the Shortage

- Fresenius Kabi (formerly APP) is not manufacturing acyclovir lyophilized powder to concentrate on supplying the solution for injection.

- Ben Venue has stopped production in its plant in Bedford, Ohio and will close in early 2014. Ben Venue supplies multiple sterile injectable products for Bedford Laboratories. Supplies of product that has already been manufactured will continue to be released until inventory is depleted. Bedford Laboratories has a small number of products manufactured elsewhere that are not affected by this closure.
- AuroMedics introduced acyclovir injection in February 2014.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=467
Source link: http://www.ashp.org

Haloperidol Decanoate Injection

February 24, 2014

Reason for the Shortage

- Teva products are on shortage due to manufacturing delays.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=526
Source link: http://www.ashp.org

Lomustine Capsules

February 24, 2014

Reason for the Shortage

- Bristol-Myers Squibb discontinued CeeNu capsules.
- NextSource Biotechnology took over distribution of lomustine capsules in April 2013 and is now the sole supplier of lomustine capsules.
- Due to the critical shortage of lomustine, FDA is allowing NextSource Biotechnology to import product. Initial shipments of lomustine capsules will include an unapproved trade name, CCNSB. Future supplies will only include the non-proprietary name

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=1023
Source link: http://www.ashp.org

Iron Sucrose Injection

February 24, 2014

Reason for the Shortage

- American Regent could not provide a reason for the shortage.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=1057
Source link: http://www.ashp.org

Potassium Acetate Injection

February 26, 2014

Reason for the Shortage

- Hospira states the shortage was due to manufacturing delays.
- Hospira and American Regent discontinued potassium acetate 2 meq/mL 100 mL bulk packages.
- American Regent had temporarily suspended manufacture of most drug products including potassium acetate in April, 2011.
- American Regent resumed manufacturing in Shirley, New York in early-May, 2011.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=668
Source link: http://www.ashp.org

Levocarnitine Injection

February 26, 2014

Reason for the Shortage

- American Regent has levocarnitine injection on back order due to manufacturing delays.
- Ben Venue has stopped production in its plant in Bedford, Ohio and will close in early 2014. Ben Venue supplies multiple sterile injectable products for Bedford Laboratories. Supplies of product that has already been manufactured will continue to be released until inventory is depleted. Bedford Laboratories has a small number of products manufactured elsewhere that are not affected by this closure.
- Teva could not provide a reason for the shortage.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=968
Source link: http://www.ashp.org

Calcium Chloride Injection

February 26, 2014

Reason for the Shortage

- American Regent had temporarily suspended distribution of most drug products including calcium chloride in April, 2011.
- American Regent resumed manufacturing in Shirley, New York in early-May, 2011.
- American Regent has issued a statement that one lot (Lot #2476) of calcium chloride has a potential for particulate formation due to interaction with the rubber from the stoppers. Do not use if any particles are present. The product was inspected and no particulates were seen prior to the release. A filter is required for withdrawal from the vial and administration as a precautionary measure.
- Hospira has calcium chloride on shortage due to manufacturing delays.

- Amphastar had product on shortage due to increased demand for the product.
- FDA, in cooperation with Amneal-Agila LLC, is allowing temporary importation of calcium chloride 100 mg/mL 10 mL syringes. These are the same concentration and size as the Hospira Ansyr syringes. These can be ordered by calling Amneal-Agila customer service at 1-866-525-7270. Further information can be found online. A comparison chart between the Hospira calcium chloride Ansyr syringes and the calcium chloride syringes from Amneal-Agila can be found online.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=941
Source link: http://www.ashp.org

Ascorbic Acid Injection

February 26, 2014

Reason for the Shortage

- American Regent had temporarily suspended distribution of most drug products in April, 2011.
- American Regent resumed manufacturing in Shirley, New York in early-May, 2011.
- Hospira has discontinued all presentations of Cenolate injection and all supplies were depleted as of early-February, 2010.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=934
Source link: http://www.ashp.org

Ammonium Molybdate Injection

February 26, 2014

Reason for the Shortage

- American Regent has ammonium molybdate injection on shortage due to manufacturing delays.
- American Regent is the sole supplier of ammonium molybdate injection.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=1003
Source link: http://www.ashp.org

Nimodipine Capsules

February 27, 2014

Reason for the Shortage

- Caraco cannot provide a reason for the shortage.
- Teva discontinued nimodipine capsules in early-March, 2013.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=970
Source link: http://www.ashp.org

Methotrexate Tablets

February 27, 2014

Reason for the Shortage

- Major discontinued methotrexate tablets in 2013.
- Mylan could not provide a reason for the shortage.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=961
Source link: http://www.ashp.org

Doxazosin Tablets

February 27, 2014

Reason for the Shortage

- Teva discontinued all unit-dose presentations in November, 2012.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=586
Source link: http://www.ashp.org

Vitamin E Aqueous Oral Solution

March 3, 2014

Reason for the Shortage

- Hospira is changing manufacturing sites from a 3rd party manufacturer to in-house manufacturing. This has caused a delay in production.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=965
Source link: http://www.ashp.org

Vinblastine Injection

March 3, 2014

Reason for the Shortage

- Ben Venue has stopped production in its plant in Bedford, Ohio and will close in early 2014. Ben Venue supplies multiple sterile injectable products for Bedford Laboratories. Supplies of product that has already been manufactured will continue to be released until inventory is depleted. Bedford Laboratories has a small number of products manufactured elsewhere that are not affected by this closure.1

- Fresenius Kabi (formerly APP) had their product in short supply due to increased demand for the product and a manufacturing delay.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=883
Source link: http://www.ashp.org

Nicardipine Hydrochloride Injection

March 3, 2014

Reason for the Shortage

- Teva recalled 4 lots nicardipine injection because the product did not meet purity specifications. The recalled lots are 31302508B, 31302510B, 31302957B, 31303195B.
- Teva discontinued nicardipine injection in September, 2010.
- American Regent had temporarily suspended distribution of all drug products in April, 2011.
- American Regent resumed manufacturing in Shirely, New York in early-May, 2011.
- Mylan Institutional could not provide a reason for the shortage.
- Wockhardt has nicardipine on shortage due to an FDA import alert.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=31
Source link: http://www.ashp.org

Mecasermin Injection

March 3, 2014

Reason for the Shortage

- Ipsen Pharmaceuticals states the shortage is due to a manufacturing delay and raw material shortage.
- Additional information is available here and here.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=1058
Source link: http://www.ashp.org

Liotrix Tablets

March 3, 2014

Reason for the Shortage

- Thyrolar tablets from Forest Laboratories are on back order due to manufacturing changes.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=24
Source link: http://www.ashp.org

Doxapram Injection

March 3, 2014

Reason for the Shortage

- Ben Venue has stopped production in its plant in Bedford, Ohio and will close in early 2014. Ben Venue supplies multiple sterile injectable products for Bedford Laboratories. Supplies of product that has already been manufactured will continue to be released until inventory is depleted. Bedford Laboratories has a small number of products manufactured elsewhere that are not affected by this closure.
- West-Ward had Dopram on shortage due to manufacturing delays.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=877
Source link: http://www.ashp.org

Chloramphenicol Sodium Succinate Injection

March 3, 2014

Reason for the Shortage

- Fresenius Kabi has chloramphenicol injection on back order due to a raw material shortage.
- Fresenius Kabi is the sole supplier of chloramphenicol injection.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=1068
Source link: http://www.ashp.org

Butorphanol Injection

March 3, 2014

Reason for the Shortage

- Apotex discontinued butorphanol injection in 2008.
- Ben Venue has stopped production in its plant in Bedford, Ohio and will close in early 2014. Ben Venue supplies multiple sterile injectable products for Bedford Laboratories. Supplies of product that has already been manufactured will continue to be released until inventory is depleted. Bedford Laboratories has a small number of products manufactured elsewhere that are not affected by this closure.
- Hospira states the shortage was due to manufacturing delays.
- West-Ward discontinued butorphanol injection in early 2012.
- Sandoz discontinued Stadol injection in 2010.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=939
Source link: http://www.ashp.org

Buprenorphine Injection

March 3, 2014

Reason for the Shortage

- Ben Venue has stopped production in its plant in Bedford, Ohio and will close in early 2014. Ben Venue supplies multiple sterile injectable products for Bedford Laboratories. Supplies of product that has already been manufactured will continue to be released until inventory is depleted. Bedford Laboratories has a small number of products manufactured elsewhere that are not affected by this closure.
- American Regent has recently upgraded their manufacturing plant. Product will become available in stages as production resumes.
- Hospira had buprenorphine on shortage due to API constraints and increased demand.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=938
Source link: http://www.ashp.org

Levothyroxine Oral Tablets

March 4, 2014

Reason for the Shortage

- Pfizer is in communication with FDA about the availability of Levoxyl oral tablets.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=1013
Source link: http://www.ashp.org

Benztropine Injection

March 4, 2014

Reason for the Shortage

- American Regent has benztropine injection on back order due to manufacturing delays.
- Fresenius Kabi USA recalled benztropine injection due to potential for glass particles in the vials. Product may have been under APP or Nexus labels. Detailed information on the recall can be found online.
- West-Ward had benztropine injection on back order due to increased demand for the product.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=1042
Source link: http://www.ashp.org

Allopurinol Injection

March 4, 2014

Reason for the Shortage

- Ben Venue has stopped production in its plant in Bedford, Ohio and will close in early 2014. Ben Venue supplies multiple sterile injectable products for Bedford Laboratories. Supplies of product that has already been manufactured will continue to be released until inventory is depleted. Bedford Laboratories has a small number of products manufactured elsewhere that are not affected by this closure.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=998
Source link: http://www.ashp.org

Alcohol Dehydrated Injection (Ethanol)

March 4, 2014

Reason for the Shortage

- American Regent had temporarily suspended manufacture of most drug products in April, 2011.
- American Regent resumed manufacturing in Shirley, New York in early-May, 2011.
- Hospira and Consolidated Midland discontinued all injectable alcohol dehydrated products.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=778
Source link: http://www.ashp.org

Sufentanil Injection

March 5, 2014

Reason for the Shortage

- West-Ward had sufentanil on shortage due to manufacturing delays.
- Hospira has sufentanil on shortage due to manufacturing delays.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=823
Source link: http://www.ashp.org

Reserpine Oral Tablets

March 5, 2014

Reason for the Shortage

- Sandoz said the shortage is due to a delay in obtaining raw materials.
- There are no other manufacturers of reserpine tablets.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=975
Source link: http://www.ashp.org

Denileukin Diftitox Injection

March 5, 2014

Reason for the Shortage

- Eisai is working to resolve a manufacturing problem.
- Eisai is the sole manufacturer of denileukin diftitox.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=1009
Source link: http://www.ashp.org

Clarithromycin Immediate Release Tablets

March 5, 2014

Reason for the Shortage

- Ranbaxy has an import ban on their products.
- Apotex import ban has been lifted, but the company has not resumed production of clarithromycin immediate-release tablets.
- Mylan discontinued clarithromycin tablets in 2013.
- Teva could not provide a reason for the shortage.
- UDL discontinued clarithromycin 500 mg 100 count unit-dose in May 2013.
- Wockhardt has clarithromycin tablets on shortage due to regulatory delays.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=945
Source link: http://www.ashp.org

Buprenorphine Sublingual Tablets

March 5, 2014

Reason for the Shortage

- Teva could not provide a reason for the shortage.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=1030
Source link: http://www.ashp.org

Bumetanide Tablets

March 5, 2014

Reason for the Shortage

- Mylan Institutional cannot provide a reason for the shortage.
- Sandoz cannot provide a reason for the shortage.
- Teva cannot provide a reason for the shortage.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=1073
Source link: http://www.ashp.org

Neostigmine Bromide Tablets

March 6, 2014

Reason for the Shortage

- Valeant could not provide a reason for the shortage.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=1060
Source link: http://www.ashp.org

Naproxen Oral Suspension

March 6, 2014

Reason for the Shortage

- Roxane discontinued their naproxen oral suspension in June 2013.
- Genentech could not provide a reason for the shortage.
- Palmetto acquired naproxen 25 mg/mL oral suspension in June 2013. Pharmacy wholesalers can contact Palmetto to obtain product.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=1055
Source link: http://www.ashp.org

Terbutaline Sulfate Injection

March 10, 2014

Reason for the Shortage

- Ben Venue has stopped production in its plant in Bedford, Ohio and will close in early 2014. Ben Venue supplies multiple sterile injectable products for Bedford Laboratories. Supplies of product that has already been manufactured will continue to be released until inventory is depleted. Bedford Laboratories has a small number of products manufactured elsewhere that are not affected by this closure.
- Akorn has discontinued terbutaline injection.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=808
Source link: http://www.ashp.org

Erythromycin Lactobionate Injection

March 10, 2014

Reason for the Shortage

- Hospira has Erythrocin 500 mg vials on shortage due to manufacturing delays.1
- Hospira is the sole supplier of erythromycin lactobionate.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=546
Source link: http://www.ashp.org

Sulfamethoxazole/Trimethoprim Injection

March 11, 2014

Reason for the Shortage

- Sulfamethoxazole/trimethoprim injection was on backorder due to manufacturing problems and a recall.
- Teva is the sole supplier of sulfamethoxazole/trimethoprim injection.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=613
Source link: http://www.ashp.org

Rifampin for Injection

March 11, 2014

Reason for the Shortage

- Ben Venue has stopped production in its plant in Bedford, Ohio and will close in early 2014. Ben Venue supplies multiple sterile injectable products for Bedford Laboratories. Supplies of product that has already been manufactured will continue to be released until inventory is depleted. Bedford Laboratories has a small number of products manufactured elsewhere that are not affected by this closure.
- Pfizer had rifampin injection on back order due to a manufacturing issue resulting in potential for product discoloration and possible impurities or potency issues. This information is addressed in a Dear Healthcare Professional letter.
- Akorn discontinued rifampin in September 2013 due to shortage of raw material.
- Mylan Institutional acquired rifampin injection from Pfizer on December 7, 2013.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=350
Source link: http://www.ashp.org

Tiopronin Tablets

March 12, 2014

Reason for the Shortage

- Mission Pharmacal anticipates Thiola will be on shortage in 2nd quarter 2014 due to raw materials being discontinued

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=1067
Source link: http://www.ashp.org

Intravenous Fat Emulsion

March 12, 2014

Reason for the Shortage

- Hospira recalled several lots of Liposyn II and Liposyn III presentations.
- Hospira has discontinued the Liposyn II presentations because the raw material is unavailable.
- Hospira has Liposyn III on shortage due to manufacturing delays.
- Baxter had Intralipid presentations on intermittent back order due to increased demand.
- FDA, in cooperation with Baxter and Fresenius Kabi, is allowing temporary importation of UK Intralipid 20% in Biofine containers. Although these are manufactured by Fresenius Kabi they will be ordered through Baxter. There are several differences between the US and UK products. The key differences include the different container and location of the port. The product label for the UK Intralipid presentation can be found online.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=651
Source link: http://www.ashp.org

Ethambutol Tablets

March 12, 2014

Reason for the Shortage

- VersaPharm states the reason for the shortage is change in manufacturing facility.
- X-Gen could not provide a reason for the shortage.
- G&W Laboratories discontinued ethambutol tablets in mid-April 2013.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=982
Source link: http://www.ashp.org

Doxorubicin Injection

March 12, 2014

Reason for the Shortage

- Ben Venue has stopped production in its plant in Bedford, Ohio and will close in early 2014. Ben Venue supplies multiple sterile injectable products for Bedford Laboratories. Supplies of product that has already been manufactured will continue to be released until inventory is depleted. Bedford Laboratories has a small number of products manufactured elsewhere that are not affected by this closure.
- Teva had doxorubicin on shortage due to manufacturing issues.
- Pfizer has doxorubicin on shortage due to shipping delays.
- Sagent introduced doxorubicin injection in November 2013.
- Mylan Institutional acquired doxorubicin lyophilized powder from Pfizer on December 6, 2013.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=464
Source link: http://www.ashp.org

Dexmethylphenidate Hydrochloride

March 12, 2014

Reason for the Shortage

- Teva cannot provide a reason for the shortage.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=1079
Source link: http://www.ashp.org

Cephalexin Oral Suspension

March 12, 2014

Reason for the Shortage

- Orchid/Karalax discontinued all cephalexin oral suspension products in the 3rd Quarter of 2013.
- Ranbaxy has an import ban on their cephalexin oral suspension products.
- Carlsbad Technology, Inc. discontinued all cephalexin oral suspension products in late-2012 due manufacturing cost and shortage or raw materials.
- Teva could not provide a reason for the shortage.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=1043
Source link: http://www.ashp.org

Black Widow Antivenin (Latrodectus Mactans)

March 12, 2014

Reason for the Shortage

- Merck has low inventory of Antivenin Latrodectus Mactans.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=670
Source link: http://www.ashp.org

Procainamide Hydrochloride Injection

March 13, 2014

Reason for the Shortage

- Hospira has procainamide injection on shortage due to manufacturing delays.
- There are no other manufacturers of procainamide injection.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=868
Source link: http://www.ashp.org

Nalbuphine Injection

March 13, 2014

Reason for the Shortage

- Endo discontinued Nubain in 2008.
- Teva discontinued all nalbuphine injections in July, 2010.
- Hospira has nalbuphine on shortage due to manufacturing delays.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=665
Source link: http://www.ashp.org

Trace Elements Injection

March 14, 2014

Reason for the Shortage

- American Regent has trace element injection on back order due to manufacturing delays.
- American Regent is the sole supplier of FDA-approved combined trace elements.
- In cooperation with FDA, Fresenius Kabi USA is providing Addamel N (adult trace element injection) and Peditrace (pediatric trace element injection) to the US market to help alleviate the shortage. Addamel N and Peditrace are manufactured in an FDA-

approved facility in Norway by Fresenius Kabi AG, the parent company of Fresenius Kabi, USA.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=785
Source link: http://www.ashp.org

Fluconazole Injection

March 14, 2014

Reason for the Shortage

- Teva has fluconazole injection on shortage due to manufacturing delays.
- West-Ward has fluconazole injection on shortage due to manufacturing delays.
- Ben Venue has stopped production in its plant in Bedford, Ohio and will close in early 2014. Ben Venue supplies multiple sterile injectable products for Bedford Laboratories. Supplies of product that has already been manufactured will continue to be released until inventory is depleted. Bedford Laboratories has a small number of products manufactured elsewhere that are not affected by this closure.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=644
Source link: http://www.ashp.org

Cidofovir Injection

March 14, 2014

Reason for the Shortage

- Gilead recalled one lot of Vistide on February 4, 2013, due to particulate matter in some vials.
- Mylan Institutional launched cidofovir injection in mid-March 2013.
- Heritage could not provide a reason for the shortage.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=994
Source link: http://www.ashp.org

Aminophylline Injection

March 14, 2014

Reason for the Shortage

- American Regent had temporarily suspended distribution of most drug products in April, 2011.
- American Regent resumed manufacturing in Shirley, New York in early-May, 2011.
- Hospira states that the shortage is due to manufacturing delays.
- Hospira discontinued aminophylline ampules in September, 2011.
- Theophylline injection is available from BBraun and may be affected by this shortage.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=705
Source link: http://www.ashp.org

Aminocaproic Acid Injection

March 14, 2014

Reason for the Shortage

- American Regent has aminocaproic acid on shortage due to manufacturing delays.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=789
Source link: http://www.ashp.org

Rabies Immune Globulin

March 17, 2014

Reason for the Shortage

- Sanofi Pasteur states the reason for the shortage is increased demand and manufacturing delay.
- Grifols had HyperRab on back order due to increased demand.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=331
Source link: http://www.ashp.org

Methylprednisolone Acetate Injection

March 17, 2014

Reason for the Shortage

- Sandoz and Teva could not provide a reason for the shortage.
- Pfizer had Depo-Medrol injection on shortage due to manufacturing delay.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=923
Source link: http://www.ashp.org

Citric acid and Potassium Citrate Oral

March 17, 2014

Reason for the Shortage

- Cypress Pharmaceuticals has Cytra-K crystals on back order due to a raw material supply issue.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=1080

Source link: http://www.ashp.org

Sodium Chloride 0.45%% Injection Bags

March 18, 2014

Reason for the Shortage

- Baxter has 0.45% sodium chloride on shortage due to increased demand.
- BBraun had 0.45% sodium chloride on allocation due to increased demand.
- Hospira cited increased demand as the reason for the shortage.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=1083
Source link: http://www.ashp.org

Heparin Sodium Injection

March 18, 2014

Reason for the Shortage

- FDA has issued import bans against 22 Chinese manufacturers of heparin due to inadequate good manufacturing practices (GMPs).
- West-Ward obtained five presentations of the heparin sodium injection from Baxter in September, 2011. Baxter only retained two large volume heparin presentations. All other Baxter presentations have been discontinued.
- Fresenius Kabi (formerly APP) reports that heparin products are on back order due to increased demand for the product.
- Hospira states the shortage of heparin vials is due to manufacturing delays.
- Covidien and B. Braun could not provide a reason for the shortage.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=387
Source link: http://www.ashp.org

Ephedrine Injection

March 18, 2014

Reason for the Shortage

- Sandoz and Akorn cannot provide a reason for the shortage.
- Hospira discontinued ephedrine in March, 2011.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=351
Source link: http://www.ashp.org

Water-Miscible Oral Multiple Vitamins

March 20, 2014

Reason for the Shortage

- Source CF could not provide a reason for the shortage.
- Axcan Pharma discontinued ADEKs chewable tablets in May 2011.
- Macoven discontinued AKEDamins in early-2014.
- Standard multivitamins are not affected by this shortage.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=991
Source link: http://www.ashp.org

Topiramate Sprinkle Capsules

March 20, 2014

Reason for the Shortage

- Teva could not provide a reason for the shortage.
- Mylan recently discontinued topiramate sprinkle capsules.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=1088
Source link: http://www.ashp.org

Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis (Tdap) Vaccine

March 20, 2014

Reason for the Shortage

- Sanofi-Pasteur has Adacel is in short supply due to manufacturing delays. This product is also known as adult tetanus toxoid, reduced diphtheria toxoid and acellular pertussis (Tdap) vaccine.
- GlaxoSmithKline has available Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine (Boostrix). The 1 count Boostrix syringe is no longer made.
- Adult Tetanus and Diphtheria Toxoids Adsorbed (Td) (Tenivac, Sanofi-Pasteur) is not affected by this shortage.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=1051
Source link: http://www.ashp.org

Multiple Vitamins for Infusion

March 20, 2014

Reason for the Shortage

- Hospira states the shortage is due to manufacturing delays.
- Baxter states the reason for the shortage is manufacturing delays. Sandoz manufacturers Infuvite pediatric for Baxter. In February, 2012 Sandoz notified Baxter it was suspending production of the Infuvite pediatric 5 mL vials indefinitely. Infuvite pediatric 50 mL vials will continue to be available.
- Baxter discontinued NDC 54643-5649-02 in March 2012.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=831
Source link: http://www.ashp.org

Mercaptopurine Tablets

March 20, 2014

Reason for the Shortage

- Mylan and Teva could not provide a reason for the shortage.
- Roxane states the reason for the shortage was increased demand.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=997
Source link: http://www.ashp.org

Loteprednol Etabonate 0.5% Ophthalmic Suspension

March 20, 2014

Reason for the Shortage

- Valeant Pharmaceuticals discontinued Lotemax 0.5% ophthalmic suspension in February 2014 because of the anticipated release of the generic product in April 2014.
- Valeant Pharmaceuticals acquired Bausch & Lomb in August 2013.
- Supplies of Alrex (loteprednol 0.2% ophthalmic suspension) and Zylet (loteprednol 0.5% and tobramycin 0.3% ophthalmic suspension) are not affected and continue to be available.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=1089
Source link: http://www.ashp.org

Ketorolac Tromethamine Injection

March 20, 2014

Reason for the Shortage

- American Regent discontinued all ketorolac injection presentations in 2010.
- Fresenius Kabi (formerly APP) states the shortage was due to manufacturing delays.
- Baxter could not provide a reason for the shortage.
- Cura filed for bankruptcy in 2010.
- Hospira has ketorolac on shortage due to manufacturing delays for quality improvement activities and increased demand for the product.
- Ben Venue has stopped production in its plant in Bedford, Ohio and will close in early 2014. Ben Venue supplies multiple sterile injectable products for Bedford Laboratories. Supplies of product that has already been manufactured will continue to be released until inventory is depleted. Bedford Laboratories has a small number of products manufactured elsewhere that are not affected by this closure. West-Ward has ketorolac injection on shortage due to manufacturing delays.
- FDA imposed an import ban in mid-2013 on several Wockhardt products including ketorolac.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=593
Source link: http://www.ashp.org

Cytarabine Injection

March 20, 2014

Reason for the Shortage

- Fresenius Kabi (formerly APP) has cytarabine on shortage due to increased demand.
- Ben Venue has stopped production in its plant in Bedford, Ohio and will close in early 2014. Ben Venue supplies multiple sterile injectable products for Bedford Laboratories. Supplies of product that has already been manufactured will continue to be released until inventory is depleted. Bedford Laboratories has a small number of products manufactured elsewhere that are not affected by this closure.
- Mylan Institutional acquired cytarabine injection from Pfizer on December 6, 2013.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=413
Source link: http://www.ashp.org

Cefpodoxime

March 20, 2014

Reason for the Shortage

- Ranbaxy has an import ban on all solid medications including cefpodoxime.
- Aurobindo could not provide a reason for the shortage.
- Pfizer has discontinued Vantin.
- Sandoz could not provide a reason for the shortage.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=793
Source link: http://www.ashp.org

Secretin Injection

March 21, 2014

Reason for the Shortage

- ChiRhoClin is qualifying a new manufacturing site.
- ChiRhoStim 40 mcg vials have not been launched.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=913
Source link: http://www.ashp.org

Bumetanide Injection

March 21, 2014

Reason for the Shortage

- Ben Venue has stopped production in its plant in Bedford, Ohio and will close in early 2014. Ben Venue supplies multiple sterile injectable products for Bedford Laboratories. Supplies of product that has already been manufactured will continue to be released until inventory is depleted. Bedford Laboratories has a small number of products manufactured elsewhere that are not affected by this closure.
- Baxter discontinued bumetanide 0.25 mg/mL 2 mL vial in early-2011.
- West-Ward acquired several Baxter products including bumetanide in mid-2011. Bumetanide was on shortage because demand exceeded supply.
- Hospira has bumetanide on shortage due to manufacturing delays.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=674
Source link: http://www.ashp.org

Atracurium Injection

March 21, 2014

Reason for the Shortage

- Ben Venue has stopped production in its plant in Bedford, Ohio and will close in early 2014. Ben Venue supplies multiple sterile injectable products for Bedford Laboratories. Supplies of product that has already been manufactured will continue to be released until inventory is depleted. Bedford Laboratories has a small number of products manufactured elsewhere that are not affected by this closure.
- Hospira launched atracurium in mid-2013.
- Sagent had atracurium on shortage due to increased demand.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=872
Source link: http://www.ashp.org

Tuberculin Purified Protein Derivate for Intradermal Injection

March 24, 2014

Reason for the Shortage

- Sanofi Pasteur states the shortage is due to production delays
- JHP states the shortage was due to increased demand for the product.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=973
Source link: http://www.ashp.org

Thiotepa for Injection

March 24, 2014

Reason for the Shortage

- Ben Venue has stopped production in its plant in Bedford, Ohio and will close in early 2014. Ben Venue supplies multiple sterile injectable products for Bedford Laboratories. Supplies of product that has already been manufactured will continue to be released until inventory is depleted. Bedford Laboratories has a small number of products manufactured elsewhere that are not affected by this closure.
- FDA is allowing temporary importation of Tepadina (thiotepa), from Adienne Srl in Italy. Product may be ordered directly through Adienne Srl. The solution is similar in formulation to US thiotepa. The main differences between the two products are listed below:
- Tepadina comes in 15 mg and 100 mg vials while the US thiotepa from Bedford only comes in a 15 mg vial. Reconstitution of the products should still yield a final concentration of 10 mg/mL and therefore use caution in choosing vial size and volume of diluent.

- Tepadina is indicated for different uses and therefore different dosing regimens are on the Europe labeling compared to US labeling, but it is the same product as in the US.
- The bar coding for the Italian product will not provide correct information to bar code readers since the manufacturing code is not an NDC number. More information on the product packaging and ordering procedures can be found online.
- There are no other manufacturers of thiotepa for injection.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=589
Source link: http://www.ashp.org

Isosorbide Dinitrate Immediate Release Tablets

March 24, 2014

Reason for the Shortage

- Sandoz and West-Ward could not provide a reason for the shortage.
- Major discontinued isosorbide dinitrate 5 mg immediate release tablets in April 2012. Major discontinued isosorbide dinitrate 10 mg immediate release tablets in April 2013. Major discontinued isosorbide dinitrate 20 mg immediate release tablets in June 2013.
- West-Ward discontinued several isosorbide dinitrate immediate release tablet presentations in December 2013.

Article link: http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=909
Source link: http://www.ashp.org

Empty Evacuated Containers

March 24, 2014

Reason for the Shortage

- Hospira is changing the type of stoppers used for empty evacuated containers, and will not have containers available until the transition is complete.
- Baxter has empty evacuated containers on shortage due to supply constraints.
- B. Braun has evacuated glass containers on shortage due to increased demand for the product and raw material constraints.

Article link:http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=983
Source link: http://www.ashp.org

Doxorubicin Liposomal Injection

March 24, 2014

Reason for the Shortage

- Janssen Products, LP states the shortage is due to manufacturing issues. Janssen Products, LP has updates with information about the shortage on the Doxil website that is updated regularly.1-3
- Janssen is working to transition Doxil manufacturing to additional suppliers. A temporary solution to this shortage was to use areas of the Ben Venue Laboratories facility available for production and other partners to complete the manufacturing process. FDA exercised regulatory discretion and approved additional lots of 2 mg/mL 10 mL (20 mg) vials.
- Ben Venue has stopped production in its plant in Bedford, Ohio and will close in early 2014. Ben Venue supplies multiple sterile injectable products for Bedford Laboratories. Supplies of product that has already been manufactured will continue to be released until inventory is depleted. Bedford Laboratories has a small number of products manufactured elsewhere that are not affected by this closure.
- Caraco launched generic doxorubicin liposomal injection in mid-March 2013 and can supply the market with their presentations.

Article link:http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=806
Source link: http://www.ashp.org

Choline Magnesium Trisalicylate

March 24, 2014

Reason for the Shortage

- Caraco has discontinued their product. Product was recently seized by US Marshals due to good manufacturing practice violations (see news release for more information).
- Marlex could not provide a reason for their shortage.

Article link:http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=556
Source link: http://www.ashp.org

Amphotericin B Cholesteryl Sulfate Complex Injection

March 24, 2014

Reason for the Shortage

- Kadmon had acquired Three Rivers Pharmaceuticals in October 2010 and Amphotec was part of the product portfolio.

- Kadmon recently sold Amphotec to Alkopharma. Alkopharma is the sole supplier of amphotericin b cholesteryl sulfate lipid complex. The contracted manufacturer of Amphotec was Ben Venue Laboratories.
- Ben Venue has stopped production in its plant in Bedford, Ohio and will close in early 2014. Ben Venue supplies multiple sterile injectable products for Bedford Laboratories. Supplies of product that has already been manufactured will continue to be released until inventory is depleted. Bedford Laboratories has a small number of products manufactured elsewhere that are not affected by this closure.
- The shortage of amphotericin b cholesteryl sulfate lipid complex is not affecting other amphotericin formulations.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=894
Source link: http://www.ashp.org

Amikacin Injection

March 24, 2014

Reason for the Shortage

- Ben Venue has stopped production in its plant in Bedford, Ohio and will close in early 2014. Ben Venue supplies multiple sterile injectable products for Bedford Laboratories. Supplies of product that has already been manufactured will continue to be released until inventory is depleted. Bedford Laboratories has a small number of products manufactured elsewhere that are not affected by this closure.
- Hospira discontinued amikacin in May, 2010 due to a raw material shortage.
- Teva's product was unavailable due to manufacturing delays.
- Sandoz discontinued Amikin injection in 2006.
- Heritage launched amikacin injection in March 2014.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=501
Source link: http://www.ashp.org

Sodium Chloride 0.45% Injection Bags

March 25, 2014

Reason for the Shortage

- Baxter has 0.45% sodium chloride on shortage due to increased demand.
- BBraun had 0.45% sodium chloride on allocation due to increased demand.
- Hospira cited increased demand as the reason for the shortage.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1083
Source link: http://www.ashp.org

Granisetron Hydrochloride Injection

March 25, 2014

Reason for the Shortage

- Akorn discontinued granisetron 0.1 mg/mL 1 mL vials in August, 2011.
- Apotex and Baxter discontinued their granisetron hydrochloride presentations.
- Fresenius Kabi states the shortage is due to manufacturing delays.
- Bedford discontinued granisetron in May, 2011 to concentrate on the manufacturing of other products.
- Roche discontinued Kytril 0.1 mg/mL and 1 mg/mL 1 mL vials in October, 2009. They discontinued the 1 mg/mL 4 mL vials in July 2010.
- Teva states the shortage is due to manufacturing delays.
- Wockhardt discontinued granisetron hydrochloride injection 0.1 mg/mL 1 mL vials in early, 2010.
- FDA imposed an import ban in mid-2013 on several Wockhardt products including granisetron 1 mg/mL 1 mL and 4 mL vials.
- Sagent had granisetron on shortage due to increased demand.
- Sandoz had granisetron on shortage due to increased demand.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=633
Source link: http://www.ashp.org

Echothiophate Powder for Ophthalmic Solution

March 25, 2014

Reason for the Shortage

- Pfizer has Phospholine Iodide in short supply due to shipping delays.
- Pfizer is the only manufacturer of echothiophate powder for ophthalmic solution (Phospholine Iodide)

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=85
Source link: http://www.ashp.org

Copper Injection

March 25, 2014

Reason for the Shortage

- American Regent had temporarily suspended manufacture of most drug products in April, 2011.

- American Regent resumed manufacturing in Shirley, New York in early-May, 2011.
- Hospira has cupric chloride on shortage due to manufacturing delays.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=946
Source link: http://www.ashp.org

Testosterone Enanthate Injection

March 27, 2014

Reason for the Shortage

- Watson could not provide a reason for the shortage.
- Endo discontinued brand name Delatestryl in 2011.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1045
Source link: http://www.ashp.org

Rocuronium Injection

March 27, 2014

Reason for the Shortage

- Merck (formerly Schering-Plough) acquired Zemuron from Organon on July 1, 2008. The 5 mL vials were on back order at the time the company acquired the product. Some generic products have had intermittent supply problems due to increased demand for product.
- Merck (formerly Schering-Plough) discontinued Zemuron 10 mg/mL 10 mL multidose vials in the 3rd Quarter of 2013.
- Mylan Institutional (formerly Bioniche) acquired multiple products from Generamedix, including rocuronium. Mylan Institutional states the reason for the shortage was increased demand.
- Hospira has rocuronium on shortage due to manufacturing delays.
- Teva has rocuronium on shortage due to manufacturing delays.
- APP and Sagent cited increased demand as the reason for this shortage.
- The Medicines Company launched rocuronium in early 2014.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=434
Source link: http://www.ashp.org

Phenytoin Injection

March 27, 2014

Reason for the Shortage

- West-Ward had phenytoin on shortage due to manufacturing delays.
- Hospira has phenytoin ampules on shortage due to increased demand for the product. Hospira discontinued phenytoin Carpuject syringes in August 2013 for business reasons.
- X-Gen Pharmaceuticals has phenytoin on shortage due to manufacturing delays.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=740
Source link: http://www.ashp.org

Mesna Injection

March 27, 2014

Reason for the Shortage

- Teva has a shortage of mesna injection due to manufacturing delays.
- Ben Venue has stopped production in its plant in Bedford, Ohio and will close in early 2014. Ben Venue supplies multiple sterile injectable products for Bedford Laboratories. Supplies of product that has already been manufactured will continue to be released until inventory is depleted. Bedford Laboratories has a small number of products manufactured elsewhere that are not affected by this closure.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=642
Source link: http://www.ashp.org

Mannitol Injection

March 27, 2014

Reason for the Shortage

- Hospira had mannitol injection on shortage due to manufacturing delays.
- Fresenius Kabi had mannitol injection on shortage due to increased demand for the product.
- American Regent had temporarily suspended manufacture of most drug products in April, 2011.
- American Regent resumed manufacturing in Shirley, New York in early-May, 2011.
- Baxter could not provide a reason for the shortage.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=863
Source link: http://www.ashp.org

aspirin Tablets (Buffered)

March 27, 2014

Reason for the Shortage

- Novartis has temporarily suspended manufacture of multiple drug products that were manufactured at the Lincoln facility including Bufferin and Ascriptin Tablets.
- Novartis voluntarily recalled all lots of Bufferin Tablets with expiration dates of December 20, 2013 or earlier.
- Novartis divested the rights for all Bufferin products to Ducere Pharma in early-2013.
- Ducere Pharma re-introduced Bufferin tablets in late 2013.
- Medique Products discontinued their buffered aspirin presentations in May, 2012.
- Major states the shortage was due to increased demand for the product.
- Teva discontinued their buffered aspirin products late 2009 and early 2010.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=950
Source link: http://www.ashp.org

Vecuronium Bromide Injection

March 28, 2014

Reason for the Shortage

- Hospira states the shortage is due to manufacturing delays.
- Teva states the shortage is due to manufacturing delays.
- Pfizer sold vecuronium injection to Mylan Institutional in December 2013.
- Ben Venue has stopped production in its plant in Bedford, Ohio and will close in early 2014. Ben Venue supplies multiple sterile injectable products for Bedford Laboratories. Supplies of product that has already been manufactured will continue to be released until inventory is depleted. Bedford Laboratories has a small number of products manufactured elsewhere that are not affected by this closure.
- Sagent temporarily suspended the manufacture of vecuronium 10 mg and 20 mg vials.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=490
Source link: http://www.ashp.org

Sterile Empty Vials

March 28, 2014

Reason for the Shortage

- Hospira states the shortage is due to manufacturing delays.
- Fresenius Kabi (formerly APP) reduced production of sterile empty vials to permit increased production of drug products affected by critical shortages.
- Sterile empty vials may be available from medical supply distributors.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=890
Source link: http://www.ashp.org

Calcium Gluconate Injection

March 28, 2014

Reason for the Shortage

- American Regent has calcium gluconate on shortage due to manufacturing delays.
- Fresenius Kabi (formerly APP) has calcium gluconate on shortage due to increase demand for the product.
- American Regent has issued a statement that all lots of calcium gluconate may contain glass particles and filters must be used. Do not use if there are visible glass particles and filter all other product.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=48
Source link: http://www.ashp.org

Selenium Injection

March 31, 2014

Reason for the Shortage

- American Regent had temporarily suspended distribution of most drug products including selenium injection in April, 2011.
- American Regent resumed manufacturing in Shirley, New York in early-May, 2011.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=784
Source link: http://www.ashp.org

Polymyxin B Sulfate Injection

March 31, 2014

Reason for the Shortage

- Fresenius Kabi (formerly APP) could not provide a reason for the shortage.
- Ben Venue has stopped production in its plant in Bedford, Ohio and will close in early 2014. Ben Venue supplies multiple sterile injectable products for Bedford Laboratories. Supplies of product that has already been manufactured will continue to be released until inventory is depleted. Bedford Laboratories has a small number of products manufactured elsewhere that are not affected by this closure.
- Sagent suspended manufacturing of Polymyxin B sulfate injection in October, 2012.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=784
Source link: http://www.ashp.org

Ondansetron Injection

March 31, 2014

Reason for the Shortage

Ondansetron 2 mg/mL vials

- Caraco temporarily discontinued ondansetron injection.
- West-Ward acquired Baxter's ondansetron vials for injection. West-Ward discontinued the ondansetron 20 mL vials in October, 2011 and discontinued ondansetron 2 mg/mL vials in packages of 5 in Spring, 2012.
- BD launched ondansetron 2 mg/mL prefilled syringes in September 2013.
- Ben Venue has stopped production in its plant in Bedford, Ohio and will close in early 2014. Ben Venue supplies multiple sterile injectable products for Bedford Laboratories. Supplies of product that has already been manufactured will continue to be released until inventory is depleted. Bedford Laboratories has a small number of products manufactured elsewhere that are not affected by this closure.
- Hospira has ondansetron on shortage due to manufacturing delays.
- Mylan Institutional acquired ondansetron injection from Pfizer on December 7, 2013.
- Teva is temporarily discontinuing ondansetron 20 mL injection. The company does not have plans to manufacture additional product after the short-dated product is depleted.
- West-Ward had ondansetron on back order due to increased demand.
- Wockhardt has ondansetron injection on shortage due to an FDA import alert.

Ondansetron 32 mg/50 mL premixed bags

- All presentations of ondansetron 32 mg/50 mL premixed bags have been discontinued.

- Single-dose IV ondansetron 32 mg is no longer recommended due to an increased potential for QT prolongation and has been removed from the Zofran product labeling. The maximum dose for chemotherapy-induced nausea should not exceed 16 mg. FDA is working with manufacturers to voluntarily recall all ondansetron 32 mg premixed bags from the market by early 2013. Oral ondansetron dosing is not affected by the new recommendations, including the 24 mg oral dose for chemotherapy-induced nausea and vomiting.
- Baxter has discontinued and recalled their ondansetron premixed bags.
- Bedford discontinued their ondansetron premixed bags in December, 2012.
- Hospira discontinued their ondansetron premixed bags in December, 2012. Product has not been available on the market for several years.
- Claris recalled all lots of their ondansetron premixed bags in mid-2010.
- Claris discontinued their ondansetron premixed bags in June 2013.
- Pfizer discontinued their ondansetron premixed bags in January, 2012.
- Teva discontinued their ondansetron premixed bags in late-November, 2012. Product has not shipped since early 2010.
- West-Ward has discontinued their ondansetron premixed bags.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1040
Source link: http://www.ashp.org

Neostigmine Methylsulfate Injection

March 31, 2014

Reason for the Shortage

- Fresenius Kabi, USA (formerly APP) said the reason for the shortage is increased demand for the product.
- American Regent had temporarily suspended manufacture of most drug products in April, 2011.
- American Regent resumed manufacturing in Shirley, New York in early-May, 2011, but some products are still affected.
- West-Ward said the reason for the shortage was increased demand for the product.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=311
Source link: http://www.ashp.org

Mitomycin Injection

March 31, 2014

Reason for the Shortage

- Ben Venue has stopped production in its plant in Bedford, Ohio and will close in early 2014. Ben Venue supplies multiple sterile injectable products for Bedford Laboratories. Supplies of product that has already been manufactured will continue to be released until inventory is depleted. Bedford Laboratories has a small number of products manufactured elsewhere that are not affected by this closure.
- Accord states the reason for the shortage was increased demand.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=433
Source link: http://www.ashp.org

Methazolamide Tablets

March 31, 2014

Reason for the Shortage

- Sandoz cannot provide a reason for the shortage.
- Perrigo acquired Neptazane tablets and methazolamide tablets from Fera.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=901
Source link: http://www.ashp.org

Labetalol Injection

March 31, 2014

Reason for the Shortage

- Ben Venue has stopped production in its plant in Bedford, Ohio and will close in early 2014. Ben Venue supplies multiple sterile injectable products for Bedford Laboratories. Supplies of product that has already been manufactured will continue to be released until inventory is depleted. Bedford Laboratories has a small number of products manufactured elsewhere that are not affected by this closure.
- Hospira has labetalol on shortage due to manufacturing delays and increased demand.
- Apotex discontinued their 4 mL vials (NDC 60505-0717-00) in February, 2010. The company could not provide a reason for the discontinuation.
- Sagent suspended production on labetalol 5 mg/mL 20 mL vials in July 2013.

- Sagent suspended production on labetalol 5 mg/mL 20 mL vials in July 2013 and 40 mL vials in February 2014.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=397
Source link: http://www.ashp.org

Haemophilus B Conjugate Vaccine

March 31, 2014

Reason for the Shortage

- Sanofi Pasteur had ActHIB in short supply due to the shortage of other combination vaccines (eg, Pentacel®).
- GlaxoSmithKline cannot provide a reason for the shortage of Hiberix but it has not been manufactured since 2011.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1052
Source link: http://www.ashp.org

Dihydroergotamine Mesylate Injection

March 31, 2014

Reason for the Shortage

- Ben Venue has stopped production in its plant in Bedford, Ohio and will close in early 2014. Ben Venue supplies multiple sterile injectable products for Bedford Laboratories. Supplies of product that has already been manufactured will continue to be released until inventory is depleted. Bedford Laboratories has a small number of products manufactured elsewhere that are not affected by this closure.
- Valeant cannot provide a reason for the shortage of dihydroergotamine mesylate injection.
- Paddock states the reason for the shortage is manufacturing delay.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1050
Source link: http://www.ashp.org

Chorionic Gonadotropin (Human) Injection

March 31, 2014

Reason for the Shortage

- Merck (formerly Schering-Plough) states their product is on allocation to prevent use in the gray market.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=382
Source link: http://www.ashp.org

Papaverine Injection

April 1, 2014

Reason for the Shortage

- Bedford and Sandoz have discontinued their papaverine presentations.
- American Regent, the sole supplier of papaverine injection, had temporarily suspended distribution of all drug products in April, 2011.
- American Regent resumed manufacturing in Shirley, New York in early-May, 2011.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=382
Source link: http://www.ashp.org

Dobutamine Injection

April 1, 2014

Reason for the Shortage

- Baxter had dobutamine on back order due to increased demand and manufacturing constraints.
- Ben Venue has stopped production in its plant in Bedford, Ohio and will close in early 2014. Ben Venue supplies multiple sterile injectable products for Bedford Laboratories. Supplies of product that has already been manufactured will continue to be released until inventory is depleted. Bedford Laboratories has a small number of products manufactured elsewhere that are not affected by this closure.
- Hospira has dobutamine on shortage due increased demand for the product.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=929
Source link: http://www.ashp.org

Dimercaprol Injection

April 1, 2014

Reason for the Shortage

- Akorn cannot provide a reason for the shortage.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1086
Source link: http://www.ashp.org

Adenosine Injection

April 1, 2014

Reason for the Shortage

- Akorn launched adenosine 3 mg/mL 2 mL vials 25 count in April 2013.
- Astellas had Adenoscan on back order due to increased demand. This back order is now resolved. Adenoscan is used for diagnostic purposes as an adjunct to thallium-201 myocardial perfusion scintigraphy. Adenocard and generic adenosine products are labeled for use in paroxysmal supraventricular tachycardia.
- Ben Venue has stopped production in its plant in Bedford, Ohio and will close in early 2014. Ben Venue supplies multiple sterile injectable products for Bedford Laboratories. Supplies of product that has already been manufactured will continue to be released until inventory is depleted. Bedford Laboratories has a small number of products manufactured elsewhere that are not affected by this closure.
- Sagent has adenosine syringes on shortage because the company is transferring suppliers of raw materials. The current supplier has exited the market.
- Teva has discontinued their adenosine injection.
- Wockhardt discontinued their adenosine 3 mg/mL 2 mL and 4 mL syringes.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=976
Source link: http://www.ashp.org

Levothyroxine Sodium Injection

April 2, 2014

Reason for the Shortage

- Fresenius Kabi (formerly APP) could not provide a reason for the shortage of the 500 mcg vial.
- Fresenius Kabi (formerly APP) launched levothyroxine 200 mcg vials in mid-2013.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=343
Source link: http://www.ashp.org

Ceftazidime Injection

April 2, 2014

Reason for the Shortage

- Pfizer discontinued all of its ceftazidime injection products in late-November, 2011.
- West-Ward discontinued all of its ceftazidime injection products in January 2012.
- Hospira had ceftazidime on shortage due to manufacturing delays.
- Covis purchased all rights to Fortaz from GlaxoSmithKline. Covis began changing NDC numbers in December 2012.
- Sagent had ceftazidime injection on shortage due to increased demand for the product.
- WG Critical Care launched ceftazidime 1 gram vials in July 2013 and product is available at wholesalers. Ceftazidime 2 gram and 6 gram presentations were launched in August 2013.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=869
Source link: http://www.ashp.org

Zinc Injection

April 3, 2014

Reason for the Shortage

- Hospira states the shortage of zinc chloride injection is due to manufacturing delays.
- Hospira is the only manufacturer of zinc chloride injection.
- American Regent had temporarily suspended manufacture of most drug products in April, 2011.
- American Regent resumed manufacturing in Shirley, New York in early-May, 2011.
- FDA is allowing temporary importation of zinc gluconate trihydrate 1 mg/mL 10 mL vials from Aguettant Laboratories in France. This product is being distributed through Baxter Healthcare. The labeling will come in the original container which is in French. Information translated into English along with a table comparing the US and French products can be found in the Dear Healthcare Professional Letter.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=777
Source link: http://www.ashp.org

Vincristine Injection

April 3, 2014

Reason for the Shortage

- Hospira states the shortage is due to manufacturing delays.
- Teva states vincristine injection is on allocation due to increased demand.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=777
Source link: http://www.ashp.org

Vasopressin Injection

April 3, 2014

Reason for the Shortage

- American Regent had temporarily suspended manufacture of most drug products including vasopressin injection in April, 2011.
- American Regent resumed manufacturing in Shirley, New York in early-May, 2011.
- American Regent recalled 17 lots of vasopressin in August, 2011 due to potential for decreased potency.
- JHP has Pitressin on shortage due to increased demand for the product.
- Fresenius Kabi (formerly APP) had vasopressin on shortage due to increased demand for the product.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=795
Source link: http://www.ashp.org

Prednisone Tablets

April 3, 2014

Reason for the Shortage

- Cadista states the shortage is due to a raw materials shortage.
- Perrigo discontinued prednisone tablets in 2013.
- Roxane and Watson could not provide a reason for the shortage.
- Qualitest discontinued prednisone 20 mg tablets in August 2013.
- West-Ward states the reason for the shortage is manufacturing delays.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=930
Source link: http://www.ashp.org

Phenobarbital Tablets

April 3, 2014

Reason for the Shortage

- West-Ward states the reason for the shortage is manufacturing delay.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1061
Source link: http://www.ashp.org

Oxytocin Injection

April 3, 2014

Reason for the Shortage

- Fresenius Kabi, USA (formerly APP) states the shortage is due to increased demand.
- JHP could not provide a reason for the shortage.
- West-Ward states the shortage is due to stock becoming short-dated.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=876
Source link: http://www.ashp.org

Methotrexate Injection

April 3, 2014

Reason for the Shortage

- Ben Venue has stopped production in its plant in Bedford, Ohio and will close in early 2014. Ben Venue supplies multiple sterile injectable products for Bedford Laboratories. Supplies of product that has already been manufactured will continue to be released until inventory is depleted. Bedford Laboratories has a small number of products manufactured elsewhere that are not affected by this closure.
- Sandoz recalled two lots of methotrexate 40 mL preservative-free vials in May 2013 due to discover of particulate matter during routine quality control inspection.
- Mylan Institutional acquired methotrexate injection from Pfizer on December 6, 2013.
- Bioniche was acquired by Mylan Institutional in September, 2011.
- Teva discontinued methotrexate 4 mL vials in October 2013 due to business reasons.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=26
Source link: http://www.ashp.org

Ketamine Injection

April 3, 2014

Reason for the Shortage

- Ben Venue has stopped production in its plant in Bedford, Ohio and will close in early 2014. Ben Venue supplies multiple sterile injectable products for Bedford Laboratories. Supplies of product that has already been manufactured will continue to be released until inventory is depleted. Bedford Laboratories has a small number of products manufactured elsewhere that are not affected by this closure.
- JHP and Mylan Institutional could not provide a reason for the shortage.
- Hospira states the ketamine shortage is due to manufacturing delays.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=592
Source link: http://www.ashp.org

Epinephrine Injection

April 3, 2014

Reason for the Shortage

- American Regent has epinephrine on shortage due to manufacturing delays.
- Hospira has epinephrine syringes on shortage due to manufacturing delays.
- JHP states the reason for the shortage was due to increased demand.
- JHP discontinued three epinephrine presentations in late-2013.
- Amphastar states the shortage was due to increased demand. Amphastar changed the NDC numbers of their epinephrine products in November 2012.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=685
Source link: http://www.ashp.org

Dexrazoxane Injection

April 3, 2014

Reason for the Shortage

- Ben Venue has stopped production in its plant in Bedford, Ohio and will close in early 2014. Ben Venue supplies multiple sterile injectable products for Bedford Laboratories. Supplies of product that has already been manufactured will continue to be released until inventory is depleted. Bedford Laboratories has a small number of products manufactured elsewhere that are not affected by this closure.
- Biocodex USA acquired Totect from Apricus Pharmaceuticals in April 2013.
- Apricus Pharmaceuticals acquired Topotarget USA in late 2011.

- Topotarget worked with FDA to extend the expiration date of specific batch numbers of Totect to 36 months. Information regarding this extension and the batch numbers can be found in four Dear Healthcare Customer letters available online.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=415
Source link: http://www.ashp.org

Daunorubicin Hydrochloride Injection

April 3, 2014

Reason for the Shortage

- Ben Venue has stopped production in its plant in Bedford, Ohio and will close in early 2014. Ben Venue supplies multiple sterile injectable products for Bedford Laboratories. Supplies of product that has already been manufactured will continue to be released until inventory is depleted. Bedford Laboratories has a small number of products manufactured elsewhere that are not affected by this closure.
- Teva states the reason for the shortage is demand exceeding available supply.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1007
Source link: http://www.ashp.org

Carboplatin Solution for Injection

April 3, 2014

Reason for the Shortage

- Bedford discontinued carboplatin in May, 2011 to concentrate on the manufacturing of other products.
- Teva has carboplatin injection on shortage due to manufacturing delays.
- Fresenius Kabi has carboplatin on shortage due to increased demand for the product.
- Sandoz has carboplatin on shortage due to manufacturing delays.
- Sagent launched carboplatin in November 2013.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1005
Source link: http://www.ashp.org

Barium Sulfate Oral Suspension

April 3, 2014

Reason for the Shortage

- Bracco Diagnostics states the reason for the shortage is manufacturing delay, as well as increased demand. Bracco Diagnostics has provided a customer letter detailing the reason for the shortage and barium sulfate presentations affected.
- Bracco discontinued multiple products in August 2013 in order to streamline their product portfolio. Table 1 summarizes the barium products that were discontinued. Bracco has provided an updated product portfolio detailing the product changes and the recommended alternate products.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=963
Source link: http://www.ashp.org

Ticarcillin Clavulanate

April 4, 2014

Reason for the Shortage

- GlaxoSmithKline could not provide a reason for the shortage.
- GlaxoSmithKline discontinued Timentin 3.1 gram ADD-Vantage vials in late-2012.
- Baxter could not provide a reason for the shortage.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=802
Source link: http://www.ashp.org

Chloroprocaine Injection

April 4, 2014

Reason for the Shortage

- Ben Venue has stopped production in its plant in Bedford, Ohio and will close in early 2014. Ben Venue supplies multiple sterile injectable products for Bedford Laboratories. Supplies of product that has already been manufactured will continue to be released until inventory is depleted. Bedford Laboratories has a small number of products manufactured elsewhere that are not affected by this closure.
- Hospira discontinued chloroprocaine injection in January, 2012 due to inability to obtain raw materials. All supply was depleted in January.
- Fresenius Kabi (formerly APP) has transitioned from 1 count presentations to 25 count sizes. All 1 count presentations were depleted in early 2012.

- Fresenius Kabi (formerly APP) had Nesacaine on shortage from depletion of raw materials due increased demand for the product.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=849
Source link: http://www.ashp.org

Ezetimibe and Atorvastatin Tablets

April 7, 2014

Reason for the Shortage

- In January 2014, Merck recalled all Liptruzet lots from wholesalers due to packaging defects in the outer laminate foil pouches.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1084
Source link: http://www.ashp.org

Ethiodized Oil

April 7, 2014

Reason for the Shortage

- Savage / Nycomed Laboratories is no longer manufacturing Ethiodol solution for injection due to a marketing decision.
- Guerbet recently acquired the Ethiodol New Drug Application from Savage / Nycomed. The company is working with FDA to resume manufacturing of this product.2,3 In cooperation with FDA, Guerbet is providing Lipiodol Ultra-Fluide to the US market. Lipiodol Ultra-Fluide and Ethiodol are similar products. However, Lipiodol Ultra-Fluide is different from Ethiodol in that iodine content is expressed differently. Ethiodol iodine content is 37% weight/weight (475 mg/mL) and Lipiodol is 48% weight/volume (480 mg/mL)

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=618
Source link: http://www.ashp.org

Doxycycline Capsules and Tablets

April 7, 2014

Reason for the Shortage

- Actavis states the reason for the shortage is supply and demand.
- Teva discontinued their doxycycline presentations in May 2013.

- Major discontinued most doxycycline presentations in February 2013. The company could not provide a reason for the discontinuation.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=977
Source link: http://www.ashp.org

Desmopressin Injection

April 7, 2014

Reason for the Shortage

- Teva and Hospira have desmopressin injection on shortage due to manufacturing delays.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1010
Source link: http://www.ashp.org

Calcitriol Injection

April 7, 2014

Reason for the Shortage

- Akorn has calcitriol injection on shortage due to increased demand for the product.
- American Regent has calcitriol on back order due to manufacturing delays.
- Abbott discontinued Calcijex in April 2012.
- West-Ward discontinued their calcitriol injection in May, 2011.
- Calcitriol capsule and oral solution presentations are available from multiple manufacturers.
- Fresenius Kabi (formerly APP) discontinued calcitriol injection in January 2014.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=940
Source link: http://www.ashp.org

Bupivacaine Injection

April 7, 2014

Reason for the Shortage

- Fresenius Kabi (formerly APP) has Sensorcaine on shortage due to increased demand for the product.
- Hospira has Marcaine and bupivacaine on shortage due to manufacturing delays.
- AuroMedics introduced bupivacaine injection in February 2014.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=864
Source link: http://www.ashp.org

BCG Vaccine Live Intravesical

April 7, 2014

Reason for the Shortage

- Sanofi Pasteur states the reason for the shortage is manufacturing delay.
- Tice BCG vaccine intradermal for tuberculosis (Merck, NDC 00052-0603-02) is available from wholesalers by drop shipment only.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=915
Source link: http://www.ashp.org

Leucovorin Calcium Injection

April 8, 2014

Reason for the Shortage

- Ben Venue has stopped production in its plant in Bedford, Ohio and will close in early 2014. Ben Venue supplies multiple sterile injectable products for Bedford Laboratories. Supplies of product that has already been manufactured will continue to be released until inventory is depleted. Bedford Laboratories has a small number of products manufactured elsewhere that are not affected by this closure.
- Teva has leucovorin on shortage due to manufacturing delays.
- Fresenius Kabi (formerly APP) has leucovorin on shortage due to increase demand.
- Fusilev (levoleucovorin) and leucovorin oral tablets are not affected by the shortage.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=488
Source link: http://www.ashp.org

Isoniazid Tablets

April 8, 2014

Reason for the Shortage

- Versapharm could not provide a reason for the shortage.
- West-Ward discontinued isoniazid tablets in late-November 2013.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=985
Source link: http://www.ashp.org

Pentostatin Injection

April 9, 2014

Reason for the Shortage

- Ben Venue has stopped production in its plant in Bedford, Ohio and will close in early 2014. Ben Venue supplies multiple sterile injectable products for Bedford Laboratories. Supplies of product that has already been manufactured will continue to be released until inventory is depleted. Bedford Laboratories has a small number of products manufactured elsewhere that are not affected by this closure.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=874
Source link: http://www.ashp.org

Methylergonovine Maleate

April 9, 2014

Reason for the Shortage

- Akorn could not provide a reason for the shortage of methylergonovine maleate injection.
- American Regent has methylergonovine maleate injection on back order due to manufacturing delays.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=906
Source link: http://www.ashp.org

Lidocaine with Epinephrine Injection

April 9, 2014

Reason for the Shortage

- Hospira has lidocaine with epinephrine presentations on shortage due to manufacturing delays.
- Fresenius Kabi (formerly APP) had Xylocaine with epinephrine presentations on shortage due to increased demand for the product.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=860
Source link: http://www.ashp.org

Lactated Ringer's Injection Bags

April 9, 2014

Reason for the Shortage

- Baxter has lactated ringer's on shortage due to increased demand.
- BBraun has lactated ringer's on allocation due to increased demand.
- Hospira cites increased demand as the reason for the shortage

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1078
Source link: http://www.ashp.org

Atorvastatin Tablets

April 9, 2014

Reason for the Shortage

- In November 2012, Ranbaxy voluntarily recalled 41 lots of atorvastatin tablets due to possible contamination with very small glass particles. Ranbaxy resumed supply of atorvastatin tablets in late-March 2013.
- Ranbaxy has atorvastatin on shortage due to manufacturing delay.
- Apotex and Mylan Institutional could not provide a reason for the shortage.
- Watson discontinued all atorvastatin presentations in February 2013.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=989
Source link: http://www.ashp.org

Tetracycline Capsules

April 10, 2014

Reason for the Shortage

- Due to the shortage, combination products that contain oral tetracycline may be affected as well.
- Heritage launched tetracycline capsules in October 2013.
- Teva states tetracycline capsules are unavailable due to a raw material shortage.
- Watson discontinued tetracycline capsules in October 2013. The company could not provide a reason for the discontinuation.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=816
Source link: http://www.ashp.org

Technetium Tc99m Albumin Aggregated Injection

April 10, 2014

Reason for the Shortage

- Technetium Tc99m Albumin Aggregated Kit is in short supply due to manufacturing delays, according to FDA.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1053
Source link: http://www.ashp.org

Synthetic Conjugated Estrogen

April 10, 2014

Reason for the Shortage

- Teva could not provide a reason for the shortage.
- Premarin is not affected by this shortage.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1087
Source link: http://www.ashp.org

Sodium Thiosulfate Injection

April 10, 2014

Reason for the Shortage

- American Regent has recently upgraded their manufacturing plant. Product will become available in stages as production resumes.
- Hope Pharmaceutical received FDA approval of their sodium thiosulfate product in February, 2012. Hope Pharmaceutical has the only FDA approved product of sodium thiosulfate.
- Hope also has Nithiodote available, a combination of sodium thiosulfate and sodium nitrite.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=766
Source link: http://www.ashp.org

Propofol Injection

April 10, 2014

Reason for the Shortage

- Hospira had propofol on shortage due to manufacturing delays.1
- Sagent is distributing propofol presentations from Teva.2,4
- Fresenius Kabi (formerly APP) is transitioning all presentations to Diprivan in mid-2013. They will no longer make generic propofol once the current supply is depleted. Diprivan 25 counts are transitioning to 10 count sizes.3
- In cooperation with FDA, Fresenius Kabi was providing Propoven 10 mg/mL injection to the US market again to help alleviate the shortage. They are no longer importing Propoven due to increased supply of product supplied in the US. Propoven is manufactured in FDA-approved facilities by Fresenius Kabi AG, the parent company of Fresenius Kabi, USA.6 Propoven is different from Diprivan in that it is preservative-free and contains medium-chain triglycerides as well as long-chain triglycerides. (Diprivan contains only long-chain triglycerides and also contains EDTA).5,6 Fresenius Kabi has a Dear Healthcare professional letter at .5,6 Report any offers to sell Propoven by an entity other than Fresenius Kabi to drugshortages@fda.hhs.gov.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=573
Source link: http://www.ashp.org

Octreotide Injection

April 10, 2014

Reason for the Shortage

- Fresenius Kabi (formerly APP) reports that the shortage is due to increased demand for the product.
- Ben Venue has stopped production in its plant in Bedford, Ohio and will close in early 2014. Ben Venue supplies multiple sterile injectable products for Bedford Laboratories. Supplies of product that has already been manufactured will continue to be released until inventory is depleted. Bedford Laboratories has a small number of products manufactured elsewhere that are not affected by this closure.
- Sandoz discontinued octreotide injection in 2nd quarter 2013.
- Teva has octreotide on shortage due to manufacturing delays.
- Wockhardt has octreotide on back order due to an import ban.
- Sandostatin LAR presentations from Novartis are not affected by this shortage.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=803
Source link: http://www.ashp.org

Mirtazapine Tablets

April 10, 2014

Reason for the Shortage

- Actavis (Watson) cannot provide a reason for the shortage.
- Greenstone discontinued all remaining mirtazapine presentations in December 2013.
- Sandoz discontinued their mirtazapine presentations in early-2014.
- Teva discontinued various unit dose presentations throughout 2013, including mirtazapine. Teva could not provide a reason for the shortage.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1066
Source link: http://www.ashp.org

Metoprolol Injection

April 10, 2014

Reason for the Shortage

- American Regent had temporarily suspended manufacture of most drug products including metoprolol in April, 2011.1 The company Regent resumed manufacturing in Shirley, New York in early-May, 2011.
- Fresenius Kabi (formerly APP) and Hospira state the shortage was due to increased demand for the product.
- Ben Venue has stopped production in its plant in Bedford, Ohio and will close in early 2014. Ben Venue supplies multiple sterile injectable products for Bedford Laboratories. Supplies of product that has already been manufactured will continue to be released until inventory is depleted. Bedford Laboratories has a small number of products manufactured elsewhere that are not affected by this closure, metoprolol is not one of these medications.
- Sagent had metoprolol injection on shortage due to increased demand for the product.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=813
Source link: http://www.ashp.org

Haloperidol Lactate Injection

April 10, 2014

Reason for the Shortage

- Ben Venue has stopped production in its plant in Bedford, Ohio and will close in early 2014. Ben Venue supplies multiple sterile injectable products for Bedford Laboratories. Supplies of product that has already been manufactured will continue to be released

until inventory is depleted. Bedford Laboratories has a small number of products manufactured elsewhere that are not affected by this closure.
- Teva has haloperidol lactate on shortage due to manufacturing delays.
- Mylan Institutional acquired haloperidol lactate injection from Pfizer on December 6, 2013.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=527
Source link: http://www.ashp.org

Amifostine Injection

April 10, 2014

Reason for the Shortage

- Caraco could not provide a reason for the shortage.
- Medimmune discontinued brand name Ethyol 500 mg injection in August, 2009.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=980
Source link: http://www.ashp.org

Tobramycin Injection

April 11, 2014

Reason for the Shortage

- Teva has tobramycin solution for injection on shortage due to manufacturing delays.
- Hospira has tobramycin on shortage due to manufacturing delays.
- Fresenius Kabi has tobramycin solution for injection on shortage due to increased demand.
- Pfizer acquired tobramycin injection from Akorn in early-May, 2011.
- Pfizer divested tobramycin injection to Mylan Institutional on December 6, 2013.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=701
Source link: http://www.ashp.org

Sincalide Injection

April 11, 2014

Reason for the Shortage

- Bracco Diagnostics has Kinevac on shortage due to manufacturing delays.
- There are no approved alternatives to Kinevac for the labeled indications.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1032

Source link: http://www.ashp.org

Propranolol Injection

April 11, 2014

Reason for the Shortage

- Ben Venue has stopped production in its plant in Bedford, Ohio and will close in 2014. Ben Venue supplies multiple sterile injectable products for Bedford Laboratories. Bedford Laboratories has a small number of products manufactured elsewhere that are not affected by this closure.
- Fresenius Kabi has propranolol injection available but with short-expiration dating.
- Sandoz cannot provide a reason for the shortage.
- West-Ward has propranolol injection on shortage due to manufacturing delays.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1091
Source link: http://www.ashp.org

Propranolol Injection

April 11, 2014

Reason for the Shortage

- Ben Venue has stopped production in its plant in Bedford, Ohio and will close in 2014. Ben Venue supplies multiple sterile injectable products for Bedford Laboratories. Bedford Laboratories has a small number of products manufactured elsewhere that are not affected by this closure.
- Fresenius Kabi has propranolol injection available but with short-expiration dating.
- Sandoz cannot provide a reason for the shortage.
- West-Ward has propranolol injection on shortage due to manufacturing delays.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1091
Source link: http://www.ashp.org

Pancuronium Injection

April 11, 2014

Reason for the Shortage

- Teva discontinued their pancuronium presentations in May, 2010.1
- Hospira's product is on back order due to manufacturing delays and retesting of raw material. Hospira is the only manufacturer of pancuronium.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=851

Source link: http://www.ashp.org

Methocarbamol Injection

April 11, 2014

Reason for the Shortage

- West-Ward states the reason for the shortage was due to manufacturing delays.
- There are no other manufacturers of methocarbamol injection.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=920
Source link: http://www.ashp.org

Diltiazem Injection

April 11, 2014

Reason for the Shortage

- Ben Venue has stopped production in its plant in Bedford, Ohio and will close in early 2014. Ben Venue supplies multiple sterile injectable products for Bedford Laboratories. Supplies of product that has already been manufactured will continue to be released until inventory is depleted. Bedford Laboratories has a small number of products manufactured elsewhere that are not affected by this closure.
- Hospira states the reason for the shortage is manufacturing delay.
- West-Ward has diltiazem injection on shortage due to manufacturing delays.
- Teva discontinued all diltiazem presentations in March, 2011.
- Biovail discontinued Cardizem Lyo-Ject in 2007 due to business reasons.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=217
Source link: http://www.ashp.org

Chlorothiazide Oral Suspension

April 11, 2014

Reason for the Shortage

- Salix could not provide a reason for the shortage.
- Salix are the sole suppliers of chlorothiazide oral suspension.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1076
Source link: http://www.ashp.org

Cefuroxime Sodium Injection

April 11, 2014

Reason for the Shortage

- Sagent states manufacture of cefuroxime 1.5 gram was suspended in March, 2013. No further production is planned.
- Hospira discontinued cefuroxime 1.5 gram and 7.5 gram vials in January, 2013.
- Covis launched the new NDC numbers in August 2013.
- BBraun discontinued their cefuroxime solution in December 2013.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=990
Source link: http://www.ashp.org

Calcium Acetate Capsules

April 11, 2014

Reason for the Shortage

- Fresenius Medical cannot provide a reason for the shortage.
- Hawthorne states the reason for the shortage was manufacturing delay.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1002
Source link: http://www.ashp.org

Acetylcysteine Inhalation Solution

April 11, 2014

Reason for the Shortage

- American Regent had temporarily suspended distribution of most drug products in April, 2011.
- American Regent resumed manufacturing in Shirley, New York in early-May, 2011.
- Roxane Labs discontinued acetylcysteine inhalation solution in April 2014. The product had previously been on shortage due to manufacturing delays.
- Hospira had acetylcysteine inhalation solution on shortage due to increased demand for the product.
- Fresenius Kabi (formerly APP) states the reason for the shortage is increased demand.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=932
Source link: http://www.ashp.org

Ampicillin Sulbactam

April 23, 2014

Reason for the Shortage

- AuroMedics Pharma launched new product in mid-June, 2012.
- Hospira states that ampicillin sulbactam vials are on back order due to manufacturing delay.
- Mylan Institutional discontinued ampicillin sulbactam injection in late 2013.
- Sagent had ampicillin sulbactam vials on allocation due to increased demand for the product.
- Sandoz cannot provide a reason for the shortage.
- WG Critical Care launched ampicillin sulbactam 1.5 gram vials in March 2014.
- West-Ward acquired several Baxter products in early 2011.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=805
Source link: http://www.ashp.org

Dexmedetomidine

April 23, 2014

Reason for the Shortage

- Hospira states the reason for the shortage is manufacturing delay.
- There are no other manufacturers of dexmedetomidine injection.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1092
Source link: http://www.ashp.org

Memantine Hydrochloride

April 23, 2014

Reason for the Shortage

- Forest cannot provide a reason for the shortage of Namenda XR capsules.
- Forest plans to discontinue all Namenda immediate-release tablets on August 15, 2014. Forest will continue to market Namenda oral solution and Namenda XR extended-release capsules. Forest states the reason for discontinuing the Namenda immediate-release tablets is to focus on the Namenda XR extended-release capsules.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1082
Source link: http://www.ashp.org

Morphine Injections

April 23, 2014

Reason for the Shortage

- Fresenius Kabi (formerly APP) states the shortage is due to a change in manufacturing sites.
- Hospira states the shortage is due to manufacturing delays.
- Hospira discontinued preservative-containing Carpuject syringes in August, 2012 and replaced them with preservative-free Carpuject syringes.
- West-Ward states the shortage was due to increased demand for product. West-Ward changed old Baxter to new West-Ward NDC codes in early 2012.
- IMS (Amphastar) discontinued morphine 1 mg/mL 10 mL Luer-lock syringes in March, 2012 due to low demand for the product.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=664
Source link: http://www.ashp.org

Nitroglycerin Injection

April 23, 2014

Reason for the Shortage

- American Regent has recently upgraded their manufacturing plant. Product will become available in stages as production resumes.
- Hospira states the shortage is due to manufacturing delays.
- Hospira discontinued nitroglycerin in Dextrose 5%, 40 mg/100 mL, 500 mL glass bottles (NDC 00409-1484-03) in 2010.
- Baxter has nitroglycerin premixes on shortage due to a raw material supply issue.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=786
Source link: http://www.ashp.org

Piperacillin Tazobactam Injection

April 23, 2014

Reason for the Shortage

- Hospira has piperacillin/tazobactam on shortage due to manufacturing delays.
- Pfizer has Zosyn on shortage due to manufacturing delays

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1075
Source link: http://www.ashp.org

Prochlorperazine Edisylate Injection

April 23, 2014

Reason for the Shortage

- Ben Venue has stopped production in its plant in Bedford, Ohio and will close in early 2014. Ben Venue supplies multiple sterile injectable products for Bedford Laboratories. Supplies of product that has already been manufactured will continue to be released until inventory is depleted. Bedford Laboratories has a small number of products manufactured elsewhere that are not affected by this closure.
- Heritage launched prochlorperazine 5 mg/mL 2 mL vials in January 2014.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1063
Source link: http://www.ashp.org

Promethazine Injection

April 23, 2014

Reason for the Shortage

- Teva states the shortage is due to manufacturing delays.
- West-Ward states the shortage was due to manufacturing delays. The company has also changed the NDC numbers for products that were formerly Baxter products.
- Hospira states the shortage is due to manufacturing delays.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=654
Source link: http://www.ashp.org

Sufentanil Injection

April 23, 2014

Reason for the Shortage

- West-Ward had sufentanil on shortage due to manufacturing delays.
- Hospira has sufentanil on shortage due to manufacturing delay

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=823
Source link: http://www.ashp.org

Sulfacetamide and Prednisolone Ophthalmic Ointment

April 23, 2014

Reason for the Shortage

- Allergan states the reason for shortage was difficulty in obtaining the raw materials needed for manufacturing.
- Allergan is the sole supplier of sulfacetamide 10% and prednisolone 0.2% ophthalmic ointment and ophthalmic suspension.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1033
Source link: http://www.ashp.org

Atropine Sulfate Injection

April 22, 2014

Reason for the Shortage

- American Regent had temporarily suspended manufacture of most drug products in April, 2011.
- American Regent resumed manufacturing in Shirley, New York in early-May, 2011.
- Hospira states the shortage is due to manufacturing delays.
- Amphastar had atropine on shortage due to increased demand.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=814
Source link: http://www.ashp.org

Cyanocobalamin Injection

April 22, 2014

Reason for the Shortage

- American Regent had temporarily suspended manufacture of most drug products including cyanocobalamin injection in April, 2011.
- American Regent resumed manufacturing in Shirley, New York in early-May, 2011.

- Fresenius Kabi (formerly APP) has cyanocobalamin injection on shortage due to increased demand for the product.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=947
Source link: http://www.ashp.org

Hydrocortisone Sodium Succinate Injection

April 22, 2014

Reason for the Shortage

- Hospira has A-Hydrocort on shortage due to requirements related to good manufacturing practices.
- Pfizer had Solu-Cortef on shortage due to manufacturing delays.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=925
Source link: http://www.ashp.org

Lissamine Green Ophthalmic Strips

April 22, 2014

Reason for the Shortage

- Hub Pharmaceuticals had temporarily stopped supplying Lissamine green ophthalmic strips. This is an unapproved drug, however there has not been any action taken by FDA in relation to this drug. FDA has information available on drug shortages and unapproved drugs.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1090
Source link: http://www.ashp.org

Magnesium Sulfate Injection

April 22, 2014

Reason for the Shortage

- American Regent had temporarily suspended distribution of most drug products including magnesium sulfate injection in April, 2011.
- American Regent resumed manufacturing in Shirley, New York in early-May, 2011.

- Fresenius Kabi (formerly APP) has magnesium sulfate injection on shortage due to increased demand for the product.
- Hospira has magnesium sulfate injection on shortage due to manufacturing delays.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=757
Source link: http://www.ashp.org

Mupirocin Calcium 2% Nasal Ointment

April 22, 2014

Reason for the Shortage

- GlaxoSmithKline cannot provide a reason for the shortage.
- Mupirocin cream is not affected by this shortage.
- Mupirocin 22 gram tubes are not affected by this shortage.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1094
Source link: http://www.ashp.org

Thiothixene Capsules

April 22, 2014

Reason for the Shortage

- Pfizer discontinued Navane (thiothixene) 2 mg, 10 mg, and 20 mg presentations in the fall of 2011. The Navane 5 mg presentation was discontinued previously.
- Sandoz discontinued all thiothixene presentations in early-2012.
- Mylan discontinued thiothixene 10 mg capsules in 1000 count in the first half of 2011 and discontinued thiothixene 2 mg and 5 mg capsules in 1000 count in early-April, 2012.
- Mylan cannot provide a reason for the shortage.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=835
Source link: http://www.ashp.org

Torsemide Injection

April 22, 2014

Reason for the Shortage

- Roche discontinued Demadex injection for business reasons. Demadex tablets are not affected by this shortage.
- Bedford has approval for torsemide injection, but has not yet launched the product.
- American Regent had temporarily suspended distribution of most drug products presentations in April, 2011.
- American Regent resumed manufacturing in Shirley, New York in early-May, 2011.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=344
Source link: http://www.ashp.org

Caffeine Citrate Injection and Oral Solution

April 21, 2014

Reason for the Shortage

- American Regent had temporarily suspended manufacture of most drug products in April, 2011.
- American Regent resumed manufacturing in Shirley, New York in early-May, 2011.
- Ben Venue has stopped production in its plant in Bedford, Ohio and will close in 2014. Ben Venue supplies multiple sterile injectable products for Bedford Laboratories. Supplies of product that has already been manufactured will continue to be released until inventory is depleted. Bedford Laboratories has a small number of products manufactured elsewhere that are not affected by this closure.
- Perrigo cannot provide a reason for the shortage.
- Sagent states the reason for the shortage is increased demand.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=862
Source link: http://www.ashp.org

Ciprofloxacin Injection

April 21, 2014

Reason for the Shortage

- Claris had recalled all lots of their ciprofloxacin premixed bags. More information can be found online.
- Pfizer discontinued ciprofloxacin injection in 2010.
- Teva discontinued all ciprofloxacin injection in September, 2011.
- Bedford discontinued ciprofloxacin injection in May, 2011 to concentrate on the manufacturing of other products.
- Bayer took over Cipro IV from Merck in 2011.

- Hospira and Sagent could not provide a reason for the shortage

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=944
Source link: http://www.ashp.org

Cisatracurium Injection

April 21, 2014

Reason for the Shortage

- Sandoz could not provide a reason for the shortage.
- Nimbex injection is on shortage due to increased demand.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1072
Source link: http://www.ashp.org

Dacarbazine Injection

April 21, 2014

Reason for the Shortage

- Teva had dacarbazine on back order due to manufacturing delays.1
- Ben Venue has stopped production in its plant in Bedford, Ohio and will close in 2014. Ben Venue supplies multiple sterile injectable products for Bedford Laboratories. Supplies of product that has already been manufactured will continue to be released until inventory is depleted. Bedford Laboratories has a small number of products manufactured elsewhere that are not affected by this closure.2

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=949
Source link: http://www.ashp.org

Diphtheria, Tetanus Toxoid, and Acellular Pertussis and Inactivated Poliovirus and Haemophilus B Conjugate Vaccine (DTaP - IPV/Hib)

April 21, 2014

Reason for the Shortage

- Sanofi Pasteur states the reason for the shortage is manufacturing delay, which will reduce supplies below current demand.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=921
Source link: http://www.ashp.org

Diphtheria, Tetanus Toxoid, and Acellular Pertussis Vaccine (DTaP)

April 21, 2014

Reason for the Shortage

- Sanofi Pasteur states the reason for the Daptacel shortage is manufacturing delay.
- Sanofi Pasteur discontinued Tripedia in 2011.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=922
Source link: http://www.ashp.org

Fluorometholone Ophthalmic Ointment

April 21, 2014

Reason for the Shortage

- Allergan had FML ophthalmic ointment on shortage due to problems obtaining raw materials.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1034
Source link: http://www.ashp.org

Fluorouracil Injection

April 21, 2014

Reason for the Shortage

- Fresenius Kabi (formerly APP) states fluorouracil is on allocation to prevent excessive purchases.
- Teva has fluorouracil on allocation due to increased demand.
- Mylan Institutional temporarily discontinued their fluorouracil injection in May 2013.
- Mylan Institutional acquired fluorouracil injection from Pfizer on December 6, 2013.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=798
Source link: http://www.ashp.org

Hydromorphone Hydrochloride Injection

April 21, 2014

Reason for the Shortage

- Hospira had hydromorphone injection on shortage due to manufacturing delays.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=856
Source link: http://www.ashp.org

Caffeine and Sodium Benzoate Injection

April 17, 2014

Reason for the Shortage

- American Regent had temporarily suspended manufacture of multiple drug products including caffeine and sodium benzoate injection in April, 2011.1
- American Regent resumed manufacturing in Shirley, New York in early-May, 2011.1
- American Regent is the sole manufacturer of caffeine and sodium benzoate injection.
- Caffeine citrate injection is not affected by this shortage.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=817
Source link: http://www.ashp.org

Alprostadil Products

April 16, 2014

Reason for the Shortage

- Bedford discontinued alprostadil in May, 2011 to concentrate on the manufacturing of other products.
- Auxilium could not provide a reason for the shortage.
- Teva's product is on long-term back order due to manufacturing difficulties.
- Pfizer's Caverject Impulse is on back order while the product is reformulated. The company has discontinued Caverject injection 10 mcg lyophilized powder and 20 mcg/mL solution for injection. Prostin VR Pediatric was on back order for unknown reasons.
- Actient has acquired several products from Schwarz (UCB) including Edex cartridges in 2010.
- Auxilium acquired Actient's urology products including Edex cartridges in April 2013.
- Meda Pharmaceuticals has acquired Muse from Vivus.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=474
Source link: http://www.ashp.org

Bupivacaine with epinephrine Injection

April 16, 2014
Reason for the Shortage

- Fresenius Kabi (formerly APP) has Sensorcaine with epinephrine on shortage due to increased demand for the product.
- Hospira has bupivacaine with epinephrine and Marcaine with epinephrine on shortage due to manufacturing delays.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=937
Source link: http://www.ashp.org

Ciprofloxacin Immediate-Release Tablets

April 16, 2014

Reason for the Shortage

- Ranbaxy has an FDA import ban on several of their products manufactured in India.
- Carlsbad Technology discontinued ciprofloxacin tablets in 2014.
- Marlex is unable to provide a reason for their shortage.
- Major discontinued their ciprofloxacin immediate-release tablets in February, 2010.
- Teva discontinued their ciprofloxacin immediate-release tablet, unit dose presentations in June, 2010.
- Schering has discontinued all Cipro immediate-release tablet presentations.
- UDL has discontinued all ciprofloxacin immediate-release 250 mg unit-dose tablets.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=572
Source link: http://www.ashp.org

Dexamethasone Sodium Phosphate

April 16, 2014

Reason for the Shortage

- American Regent voluntarily recalled all dexamethasone sodium phosphate due to the presence of particulate matter in the solution and discontinued manufacture of all dexamethasone 4 mg/mL presentations in March, 2011.
- American Regent had temporarily suspended distribution of most drug products including dexamethasone in April, 2011.
- American Regent resumed manufacturing in Shirley, New York in early-May, 2011.
- Fresenius Kabi (formerly APP) states the dexamethasone sodium phosphate shortage was due to supply and demand issues.
- Baxter could not provide a reason for the shortage. Baxter sold several products to West-Ward in mid-2011.
- West-Ward had dexamethasone sodium phosphate injection on shortage due to increased demand.
- Pfizer divested all dexamethasone presentation to Mylan Institutional on December 6, 2013.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=572
Source link: http://www.ashp.org

Dopamine Injection

April 16, 2014

Reason for the Shortage

- B Braun discontinued their dopamine premix in November 2012 due to raw material supply issues.
- Hospira states the shortage is due to manufacturing delays.
- American Regent has recently upgraded their manufacturing plant. Product will become available in stages as production resumes.
- Baxter has dopamine on allocation due to increased demand.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=88
Source link: http://www.ashp.org

Etomidate Injection

April 16, 2014

Reason for the Shortage

- Ben Venue has stopped production in its plant in Bedford, Ohio and will close in early 2014. Ben Venue supplies multiple sterile injectable products for Bedford Laboratories. Supplies of product that has already been manufactured will continue to be released until inventory is depleted. Bedford Laboratories has a small number of products manufactured elsewhere that are not affected by this closure.
- Hospira states etomidate injection was in short supply due to manufacturing delays.
- American Regent had temporarily suspended distribution of most drug products including etomidate injection in April, 2011.
- American Regent resumed manufacturing in Shirley, New York in early-May, 2011.
- Mylan Institutional acquired etomidate injection from Pfizer on December 6, 2013. Mylan Institutional divested some presentations of etomidate injection to JHP Pharmaceuticals in April 2014.
- Mylan recalled 10 lots of etomidate injection with the Pfizer label in February 2014. The recall was due to the presence of particulate matter and missing lot numbers and expiration dates on the vials.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=419
Source link: http://www.ashp.org

Fentanyl Injection

April 16, 2014

Reason for the Shortage

- West-Ward acquired Baxter's fentanyl injection products in May, 2011. The company began changing NDC numbers in July, 2012.
- West-Ward states the shortage was due to a manufacturing delay for the fentanyl 50 mcg/mL 20 mL ampules. The 20 mL vials were in short supply due to increased demand.
- Hospira states the shortage is due to increased demand and manufacturing delays including quality improvement activities. Hospira is increasing production of the ampules to help meet the demand.
- Akorn launched Sublimaze injection in late-March, 2012.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=647
Source link: http://www.ashp.org

Fludarabine Injection

April 16, 2014

Reason for the Shortage

- Fresenius Kabi, USA (formerly APP) had fludarabine lyophilized powder for injection on shortage due to focus on supplying solution for injection.
- Fresenius Kabi, USA had fludarabine solution for injection on shortage due to increased demand.
- Teva has fludarabine on shortage due to manufacturing delays.
- Sagent had fludarabine on shortage due to manufacturing delays.
- Hospira had fludarabine on shortage due to manufacturing delays.
- Sandoz had fludarabine on back order due to manufacturing delays.
- Mylan Institutional temporarily discontinued fludarabine injection in late-April 2013.
- Genzyme discontinued Fludara in July, 2012.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=648
Source link: http://www.ashp.org

Glycopyrrolate Injection

April 16, 2014

Reason for the Shortage

- West-Ward had glycopyrrolate on shortage due to increased demand for the product. West-Ward has increased production to meet market demand.
- American Regent had temporarily suspended manufacture of most drug products in April, 2011.
- American Regent resumed manufacturing in Shirley, New York in early-May, 2011.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=385
Source link: http://www.ashp.org

Midazolam Injections

April 16, 2014

Reason for the Shortage

- West-Ward acquired Baxter's midazolam injection products in May, 2011.
- Ben Venue has stopped production in its plant in Bedford, Ohio and will close in early 2014. Ben Venue supplies multiple sterile injectable products for Bedford Laboratories.

Supplies of product that have already been manufactured will continue to be released until inventory is depleted. Bedford Laboratories has a small number of products manufactured elsewhere that are not affected by this closure.
- Hospira has midazolam on shortage due to manufacturing delays and demand exceeding supply due to current market conditions.
- Hospira discontinued midazolam 5 mg/mL 1 mL iSecure syringes in July 2011.
- Fresenius Kabi (formerly APP) had midazolam on shortage due to increased demand.
- Due to low demand, Akorn is focusing on other medications that are in greater need of supply.
- FDA imposed an import ban in mid-2013 on several Wockhardt products including midazolam injection.
- Medicines Company launched midazolam injection in early 2014.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=858
Source link: http://www.ashp.org

Milrinone Injection

April 16, 2014

Reason for the Shortage

- Fresenius Kabi (formerly APP) states the reason for the shortage was increased demand for the product.
- West-Ward acquired Baxter's milrinone injection vials in May 2011.
- West-Ward states the shortage is due to manufacturing delays.
- Baxter had milrinone premixed bags on shortage due to increased demand.
- Ben Venue has stopped production in its plant in Bedford, Ohio and will close in early 2014. Ben Venue supplies multiple sterile injectable products for Bedford Laboratories. Supplies of product that has already been manufactured will continue to be released until inventory is depleted. Bedford Laboratories has a small number of products manufactured elsewhere that are not affected by this closure.
- Apotex, Bioniche, and Teva discontinued milrinone 1 mg/mL vials.
- Sanofi-Aventis discontinued Primacor injection.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=741
Source link: http://www.ashp.org

Olanzapine Injection

April 16, 2014

Reason for the Shortage

- American Regent states the reason for the shortage is manufacturing delay.
- Sandoz states the reason for the shortage is increased demand.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1093
Source link: http://www.ashp.org

Phenylephrine Hydrochloride Injection

April 16, 2014

Reason for the Shortage

- Sandoz discontinued the phenylephrine 1 mL presentations prior to 2011.
- Hospira discontinued their Neo-Synephrine injections in May, 2010.
- Teva discontinued their phenylephrine injections in mid-December, 2010.
- American Regent has phenylephrine injection on shortage due to increased demand for the product.
- Sandoz could not provide a reason for the phenylephrine injection shortage.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=184
Source link: http://www.ashp.org

Reteplase Injection

April 16, 2014

Reason for the Shortage

- Cornerstone Therapeutics acquired EKR Therapeutics in June 2012. EKR Therapeutics had previously purchased Retavase from PDL BioPharma. Cornerstone is seeking FDA approval of a new supplier of the active pharmaceutical ingredient for Retevase.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=569
Source link: http://www.ashp.org

Succinylcholine chloride Injection

April 16, 2014

Reason for the Shortage

- Hospira had Quelicin on shortage due to manufacturing delays.
- Sandoz had Anectine on shortage due to extra quality reviews.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=582
Source link: http://www.ashp.org

Succinylcholine chloride Injection

April 16, 2014

Reason for the Shortage

- Hospira had Quelicin on shortage due to manufacturing delays.
- Sandoz had Anectine on shortage due to extra quality reviews.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=582
Source link: http://www.ashp.org

Vancomycin Hydrochloride Injection

April 16, 2014

Reason for the Shortage

- Hospira has vancomycin on shortage due to increased demand.
- Fresenius Kabi (formerly APP) has vancomycin injection on shortage due to increased demand.
- Sagent has vancomycin on shortage due to increased demand.
- Akorn has sold their vancomycin products to Pfizer and stopped distributing on April 29, 2011.
- Mylan Institutional acquired vancomycin injection from Pfizer on December 6, 2013.
- Mylan Institutional (formerly Bioniche) has acquired multiple products from Generamedix, including vancomycin hydrochloride.
- Mylan Institutional discontinued two vancomycin presentations in September 2013.
- Pfizer acquired multiple products from Akorn, including vancomycin hydrochloride in early-May, 2011.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=132
Source link: http://www.ashp.org

Cefazolin Injection

April 15, 2014

Reason for the Shortage

- Fresenius Kabi, BBraun, and WG Critical Care have cefazolin on shortage due to increased demand.
- Apotex and Sandoz have cefazolin on shortage due to manufacturing delays.
- Hospira has cefazolin on shortage due to manufacturing delays and increased demand.
- Sagent has cefazolin on shortage due to increased demand and shipping delays.
- West-ward could not provide a reason for the shortage.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=987
Source link: http://www.ashp.org

Cefotaxime Injection

April 15, 2014

Reason for the Shortage

- Fresenius Kabi discontinued all cefotaxime presentations in April 2011.
- Hospira had Claforan on shortage due to manufacturing delays.
- Baxter could not provide a reason for the shortage.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=826
Source link: http://www.ashp.org

Dextrose 5% Injection Large Volume Bags

April 15, 2014

Reason for the Shortage

- Baxter states the shortage is due to increased demand.
- BBraun had 5% dextrose on allocation due to increased demand.
- Hospira states the shortage is due to increased demand and manufacturing delays.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1081
Source link: http://www.ashp.org

Leuprolide Acetate 14-Day Kit

April 15, 2014

Reason for the Shortage

- Sandoz states the shortage was due to increased demand.
- Sandoz relaunched Leuprolide 1 mg/0.2 mL 2.8 mL injection in late-January, 2013. The product has a new NDC number.
- Teva states the shortage is due to manufacturing delays.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=737
Source link: http://www.ashp.org

Lidocaine Injection

April 15, 2014

Reason for the Shortage

- Hospira has lidocaine presentations on shortage due to manufacturing delays.
- Fresenius Kabi, USA (formerly APP) has Xylocaine and lidocaine presentations on shortage due to increased demand for the product.
- Amphastar had lidocaine 2% emergency syringes on shortage due to increased demand for the product.
- BBraun had lidocaine and dextrose premixed bags on shortage due to increased demand for the product.
- Baxter discontinued two lidocaine and dextrose premixed bag presentations in March, 2012.
- AuroMedics introduced lidocaine injection in February 2014.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=747
Source link: http://www.ashp.org

Lorazepam injectable presentations

April 15, 2014

Reason for the Shortage

- Bedford discontinued lorazepam in May, 2011 to concentrate on the manufacturing of other products.
- West-Ward acquired Baxter's lorazepam injection products in May, 2011. NDC numbers for the lorazepam and Ativan products were changed in April, 2012.
- West-Ward has Ativan on back order due to increase surplus of the lorazepam presentations.
- Hospira states lorazepam vials are on shortage due to increased demand and manufacturing delays. The 1 mL iSecure syringes were discontinued in September 2011.
- Akorn has increased production to help meet demand.
- Amphastar had lorazepam 2 mg/mL vials on shortage due to increased demand.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=859
Source link: http://www.ashp.org

Methylphenidate Hydrochloride

April 15, 2014

Reason for the Shortage

- Mallinckrodt states the shortage was due to delay in obtaining raw materials. The company has stopped using the trade name Methylin and all products are now marketed as methylphenidate immediate-release or extended-release tablets with new NDC numbers.
- Sandoz states that the shortage is due to delay in obtaining raw materials.
- Teva introduced generic methylphenidate extended release capsules (CD) in late-September 2012, and these capsules are AB-rated to Metadate CD capsules.
- UCB states methylphenidate IR tablets were on shortage due to supply and demand.
- Actavis (formerly Watson) says the methylphenidate IR tablets are on shortage due to supply constraints.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=752
Source link: http://www.ashp.org

Norepinephrine Injection

April 15, 2014

Reason for the Shortage

- Ben Venue has stopped production in its plant in Bedford, Ohio and will close in early 2014. Ben Venue supplies multiple sterile injectable products for Bedford Laboratories. Supplies of product that has already been manufactured will continue to be released until inventory is depleted. Bedford Laboratories has a small number of products manufactured elsewhere that are not affected by this closure.
- Claris cannot provide a reason for the norepinephrine shortage.
- Teva temporarily discontinued norepinephrine in June 2010.
- Hospira has Levophed on shortage due manufacturing delays.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=712
Source link: http://www.ashp.org

Paclitaxel Injection

April 15, 2014

Reason for the Shortage

- Fresenius Kabi (formerly APP) had paclitaxel on shortage due to increase demand for the product.
- Ben Venue has stopped production in its plant in Bedford, Ohio and will close in early 2014. Ben Venue supplies multiple sterile injectable products for Bedford Laboratories. Supplies of product that has already been manufactured will continue to be released until inventory is depleted. Bedford Laboratories has a small number of products manufactured elsewhere that are not affected by this closure.
- Teva had paclitaxel on shortage due to manufacturing delays.
- Sandoz has paclitaxel on back order due to a raw material shortage.
- Hospira had paclitaxel on back order due to increased demand for the product.
- Sagent had paclitaxel on shortage due to increased demand for the product.
- Pfizer launched paclitaxel 100 mg and 300 mg vials in March, 2012 and launched the 30 mg vials in April, 2012.
- Mylan Institutional acquired paclitaxel injection from Pfizer on December 7, 2013.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=790
Source link: http://www.ashp.org

Pantoprazole Tablets

April 15, 2014

Reason for the Shortage

- Actavis, Aurobindo, Mylan, and Torrent could not provide a reason for the shortage.
- FDA imposed an import ban in mid-2013 on several Wockhardt products including pantoprazole.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=979
Source link: http://www.ashp.org

Potassium Chloride Injection

April 15, 2014

Reason for the Shortage

- Hospira states the reason for the shortage is manufacturing delays.
- Fresenius Kabi and Baxter could not provide a reason for the shortage.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=696
Source link: http://www.ashp.org

Potassium Phosphate Injection

April 15, 2014

Reason for the Shortage

- American Regent has potassium phosphate injection on back order due to manufacturing delays.
- American Regent has issued a statement that all lots of potassium phosphate may contain glass particles and filters must be used. Do not use if there are visible glass particles and filter all other product.
- Hospira has potassium phosphate 15 mL vials on shortage due to increased demand.
- In cooperation with FDA, Fresenius Kabi USA (formerly APP) is providing Glycophos (sodium glycerophosphate) injection to the US market to help alleviate the shortage. Glycophos is manufactured in an FDA-approved facility in Norway by Fresenius Kabi AG.
- Fresenius Kabi, USA (formerly APP) launched potassium phosphate injection in November 2013.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=709
Source link: http://www.ashp.org

Sodium Chloride 0.9% Injection Bags

April 15, 2014

Reason for the Shortage

- Baxter has 0.9% sodium chloride on shortage due to increased demand.
- BBraun had 0.9% sodium chloride on allocation due to increased demand.
- Hospira cites increased demand as the reason for the shortage.
- In cooperation with the FDA, Fresenius Kabi is providing 0.9% sodium chloride to the US market to help alleviate the national shortage. This 0.9% sodium chloride is manufactured in an FDA-approved facility in Norway by Fresenius Kabi AG, the parent company of Fresenius Kabi USA, LLC. There will be presentations available with Scandinavian and Australian/English labels and the package insert is the same for all imported presentations.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=993
Source link: http://www.ashp.org

Sodium Phosphate Injection

April 15, 2014

Reason for the Shortage

- American Regent has sodium phosphate injection on back order due to manufacturing delays.
- American Regent has issued a statement that all lots of sodium phosphate have potential for crystallization. Do not use if any particles are present.
- Hospira has sodium phosphate injection on shortage due to manufacturing delays.
- In cooperation with FDA, Fresenius Kabi USA is providing Glycophos (sodium glycerophosphate) injection to the US market to help alleviate the shortage. Glycophos is manufactured in an FDA-approved facility in Norway by Fresenius Kabi AG, the parent company of Fresenius Kabi USA.
- Fresenius Kabi launched sodium phosphate injection in mid-January 2014.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=770
Source link: http://www.ashp.org

Sumatriptan Succinate Injection

April 15, 2014

Reason for the Shortage

- Sagent states the reason for the shortage is increased demand.
- JHP could not provide a reason for the shortage.
- GlaxoSmithKline could not provide a reason for the shortage.
- Pfizer has had Alsuma on shortage since September 2013 due to manufacturing issues.
- Teva has temporarily suspended the production of sumatriptan injection

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1085
Source link: http://www.ashp.org

Tamoxifen Tablets

April 15, 2014

Reason for the Shortage

- Teva and Mylan could not provide a reason for the shortage.
- Actavis could not provide a reason for the shortage.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1071
Source link: http://www.ashp.org

Tesamorelin Injection

April 15, 2014

Reason for the Shortage

- EMD Serono states Egrifta is on shortage due to manufacturing delays.
- The 1 mg vials were discontinued in May 2013.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1065
Source link: http://www.ashp.org

Tranexamic Acid Injection

April 15, 2014

Reason for the Shortage

- Fresenius Kabi (formerly APP) has tranexamic acid injection on shortage due to increased demand for the product.
- Mylan Institutional cannot provide a reason for the shortage.
- X-Gen has tranexamic acid on shortage due to increased demand.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1049
Source link: http://www.ashp.org

Ammonium Chloride Injection

April 14, 2014

Reason for the Shortage

- Hospira states the shortage of ammonium chloride is due to manufacturing delays.
- Hospira is the sole manufacturer of ammonium chloride injection.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=933
Source link: http://www.ashp.org

Azithromycin Injection

April 14, 2014

Reason for the Shortage

- Apotex and Fresenius Kabi could not provide a reason for the shortage.
- Hospira has azithromycin injection on shortage due to increased demand.
- Sagent had azithromycin injection on shortage due to increased demand.
- Pfizer discontinued Zithromax 500 mg vial with Vial-Mate Adaptor in January 2013.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=936
Source link: http://www.ashp.org

Dibucaine Ointment

April 14, 2014

Reason for the Shortage

- Perrigo and Fougera cannot provide a reason for the shortage.
- Geritrex introduced dibucaine 1% ointment in March 2014.
- Novartis divested the rights for all Nupercainal ointment products to Ducere Pharma in 2013.
- These products are available Over-The-Counter.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1074
Source link: http://www.ashp.org

Dipyridamole Injection

April 14, 2014

Reason for the Shortage

- Bedford discontinued dipyridamole injection in May, 2011 to concentrate on the manufacturing of other products.
- Teva has temporarily discontinued their 2 mL and 10 mL products in order to increase the package sizes.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=465
Source link: http://www.ashp.org

Electrolyte Concentrate

April 14, 2014

Reason for the Shortage

- American Regent had temporarily suspended distribution of most drug products including Nutrilyte and Nutrilyte II in April, 2011.
- American Regent resumed manufacturing in Shirley, New York in early-May, 2011.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1054
Source link: http://www.ashp.org

Enalaprilat Injection

April 14, 2014

Reason for the Shortage

- Ben Venue has stopped production in its plant in Bedford, Ohio and will close in 2014. Ben Venue has stopped production in its plant in Bedford, Ohio and will close in early 2014. Ben Venue supplies multiple sterile injectable products for Bedford Laboratories. Supplies of product that has already been manufactured will continue to be released until inventory is depleted. Bedford Laboratories has a small number of products manufactured elsewhere that are not affected by this closure.
- West-Ward has enalaprilat injection on shortage due to manufacturing delays.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=587
Source link: http://www.ashp.org

Famotidine Injection

April 14, 2014

Reason for the Shortage

- Ben Venue has stopped production in its plant in Bedford, Ohio and will close in early 2014. Ben Venue supplies multiple sterile injectable products for Bedford Laboratories. Supplies of product that has already been manufactured will continue to be released until inventory is depleted. Bedford Laboratories has a small number of products manufactured elsewhere that are not affected by this closure.
- West-Ward states the shortage is due to manufacturing delays.
- Oral famotidine products are not affected by this shortage.
- Pfizer launched famotidine injections in March, 2012.
- Mylan Institutional acquired famotidine injections from Pfizer on December 6, 2013.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=810
Source link: http://www.ashp.org

Fenoldopam Mesylate Injection

April 14, 2014

Reason for the Shortage

- Hospira has Corlopam on shortage due to manufacturing delays.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1031
Source link: http://www.ashp.org

Fosphenytoin Injection

April 14, 2014

Reason for the Shortage

- Akorn discontinued fosphenytoin injection in 2011.
- Fresenius Kabi states the shortage is due to manufacturing delays.
- American Regent discontinued fosphenytoin injection in late-2010.
- Bedford discontinued fosphenytoin in May, 2011 to concentrate on the manufacturing of other products.
- Hospira states the shortage is due to manufacturing delays.
- Pfizer discontinued the Cerebyx 500 mg presentation in September, 2009 and the 1 gram presentation in early-February, 2010.
- Pfizer launched Cerebyx 2 mL and 10 mL vials in October 2013.
- Teva, Apotex, Baxter, GeneraMedix, and Wockhardt have discontinued their fosphenytoin presentations.
- West-Ward had fosphenytoin on shortage due to manufacturing delays.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=127
Source link: http://www.ashp.org

Gentamicin injection

April 14, 2014

Reason for the Shortage

- Hospira has gentamicin on shortage due to manufacturing delays.
- Fresenius Kabi (formerly APP) had gentamicin on shortage due to increased demand. Fresenius Kabi discontinued their 10 mg/mL 2 mL multi-dose vial in mid-2011.
- Baxter has gentamicin on shortage due to increased demand.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=728
Source link: http://www.ashp.org

Iron Dextran Injection

April 14, 2014

Reason for the Shortage

- American Regent cannot provide a reason for the shortage.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1069
Source link: http://www.ashp.org

Methylprednisolone Sodium Succinate Injection

April 14, 2014

Reason for the Shortage

- Hospira discontinued all methylprednisolone sodium succinate products in January 2013 due to raw material issues.
- Bedford discontinued methylprednisolone in May, 2011 to concentrate on the manufacturing of other products.
- Pfizer has Solu-Medrol on shortage due to manufacturing delays.
- Fresenius Kabi (formerly APP) has methylprednisolone sodium succinate on shortage due to priority of other medications.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1077
Source link: http://www.ashp.org

Sodium Chloride Concentrated Solution for Injection

April 14, 2014

Reason for the Shortage

- American Regent discontinued 23.4% sodium chloride 30 mL and 100 mL presentations in 2012.
- Baxter discontinued their sodium chloride 250 mL presentation in 2008.
- Fresenius Kabi (formerly APP) has sodium chloride concentrated solution on shortage due to increased demand. Fresenius Kabi discontinued 14.6% sodium chloride 20 mL vials in February 2013.
- Hospira has 14.6% and 23.4% sodium chloride solutions for injection on shortage due to manufacturing delays. Hospira discontinued sodium chloride 14.6% solution 250 mL vials in February 2011.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=724
Source link: http://www.ashp.org

Testosterone Cypionate Intramuscular Injection

April 14, 2014

Reason for the Shortage

- Paddock has testosterone on back order due to increased demand and shipping delays from their contract manufacturer.
- West-Ward had testosterone cypionate on shortage due to manufacturing delays.
- Sandoz discontinued testosterone cypionate 200 mg/mL 1 mL and 10 mL vials in September 2011. Sandoz discontinued final presentation in first half of 2012.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=638
Source link: http://www.ashp.org

NEW DRUGS COMING TO MARKET

PRODUCT	MFR	ROUTE	INDICATION	PHARMACOLOGY	MARKET RELEASE
Tedizolid	Trius Therapeutics	PO,IV	Skin and soft tissue infections	Second-generation oxazolidinone antibacterial agent with activity against drug-resistant Gram-positive infections	NDA filed 10/22/2013; QIDP designation by the FDA 1/2013; FDA priority review with FDA action date of 6/20/2014
Dalbavancin (Dalvance)	Durata	IV	Treat methicillin-resistant Staphylococcus	Second-generation lipoglycopeptide agent that belongs to the same class as vancomycin, once-weekly IV	NDA re-filed 9/26/2013; FDA action date 5/26/14
Epanova	Omthera	PO	Hypertriglyceridemia	Omega-3 fatty acid	NDA filed 7/13; FDA action date 5/5/14
Bupropion SR and naltrexone SR (Contrave)	Orexigen Therapeutics	PO	Obesity	Sustained release combination of atypical antidepressant & opioid receptor antagonist	NDA re-submitted 12/2013; FDA action date 6/10/2014
Vedolizumab (Entyvio)	Takeda	SC, IV	Crohn's disease, ulcerative colitis	Humanized monoclonal antibody that acts as an α4β7 integrin inhibitor	BLA filed 6/13; Priority review; FDA action date 2/18/14 (ulcerative colitis) and 6/18/14 (Crohn's disease)
Ferric citrate (Zerenex)	Keryx	PO	Hyperphosphatemia	Small-molecule phosphate binder	NDA filed 8/2013; FDA action date 6/7/2014