May 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
Eszopiclone	1 mg, 2 mg, and 3 mg tablet	Roxane Labs	Lunesta	4-15-14
Omega-3 Acid Ethyl Esters	1 g capsule	Teva USA	Lovaza	4-09-14
Desvenlafaxine	50 mg and 100 mg tablet ER 24	Macoven Pharmaceutical	Khedezla	4-09-14
Norelgestromin/ Ethin.Estradiol	150-35/24h Patch TDWK	Mylan	OrthoEvra	4-21-14
Emollient Combination No. 43	Cream	Trigen Laboratory	PromiseB	4-18-14
Sevelamer Carbonate	800 mg tablet	Global Pharm	Renvela	4-18-14
Isomethepten/Caf/ Acetaminophen	65-20-325 tablet	Gentex Pharma	Prodrin	1-14-14

NEW DRUG ENTITIES

DESCRIPTION	BRAND NAME	GENERIC NAME	STRENGTH	NOTES
DIAGNOSTIC PREPARATIONS, MISCELLANEOUS	GADAVIST	GADOBUTROL	2 MMOL/2 ML	New Strength
VENOSCLEROSING AGENTS	VARITHENA	POLIDOCANOL	1%	New Dosage Form
TOPICAL PREPARATIONS, ANTIBACTERIALS	ALCORTIN A	HYDROCORTISONE/ IODOQUINE/ALOE#2	2% - 1% - 1%	New Dosage Form
VASODILATORS, CORONARY	NITRONAL	NITROGLYCERIN	25 MG/25 ML	New Dosage Form
VASODILATORS, CORONARY	NITRONAL	NITROGLYCERIN	50 MG/50 ML	New Strength
PRENATAL VITAMIN PREPARATIONS	CITRANATAL 90 DHA	PNV72/IRON, CARB&GLU/FA/DSS/DHA	90-1-300 MG	New Combination
PRENATAL VITAMIN PREPARATIONS	VP CH ULTRA	PNV34/IRON, CARB&FUM/ FA/DSS/DHA	27-1-50 MG	New Combination
PEDIATRIC VITAMIN PREPARATIONS	MULTI-VITAMIN-W-FLUORIDE	PEDI MULTIVIT NO.2 W-FLUORIDE	0.25 MG/ML	New Combination
PEDIATRIC VITAMIN PREPARATIONS	MULTI-VITAMIN-W-FLUORIDE	PEDI MULTIVIT NO.2 W-FLUORIDE	0.5 MG/ML	New Combination
PEDIATRIC VITAMIN PREPARATIONS	MULTI-VITAMIN-FLUOR-IRON	PEDI MV #45/FLUORIDE/IRON	0.25-10/1	New Combination
MULTIVITAMIN PREPARATIONS	MULTIVITAMINS-A,B,D,E,K,ZN	MULTIVITAMIN NO.44/VIT D3/K	1000-800	New Combination
FACTOR IX PREPARATIONS	ALPROLIX	FACTOR IX REC, FC FUSION PROTN	500 UNIT	New Combination
FACTOR IX PREPARATIONS	ALPROLIX	FACTOR IX REC, FC FUSION PROTN	1000 UNIT	New Combination
FACTOR IX PREPARATIONS	ALPROLIX	FACTOR IX REC, FC FUSION PROTN	2000 UNIT	New Combination
FACTOR IX PREPARATIONS	ALPROLIX	FACTOR IX REC, FC FUSION PROTN	3000 UNIT	New Combination
LEPTIN HORMONE ANALOGS	MYALEPT	METRELEPTIN	FNL 5 MG/ML	New Entity
ANTI-INFLAMMATORY/ANTI-ARTHRITICS AGENTS	MONOVISC	HYALURONATE SODIUM, STABILIZED	88 MG/4 ML	New Strength
ANTINEOPLASTIC	ZYKADIA	CERITINIB	150 MG	New Entity

DESCRIPTION	BRAND NAME	GENERIC NAME	STRENGTH	NOTES
SYSTEMIC ENZYME INHIBITORS				
ANTINEOPLASTIC-VEGFR ANTAGONIST	CYRAMZA	RAMUCIRUMAB	100 MG/10 ML	New Entity
ANTINEOPLASTIC-VEGFR ANTAGONIST	CYRAMZA	RAMUCIRUMAB	500 MG/50 ML	New Entity
ALLERGENIC EXTRACTS, THERAPEUTICS	ORALAIR	GR POL-ORC/SW VER/RYE/KENT/TIM	300 IR	New Entity
ALLERGENIC EXTRACTS, THERAPEUTICS	GRASTEK	GRASS POLLEN-TIMOTHY, STD	2800 BAU	New Entity
ALLERGENIC EXTRACTS, THERAPEUTICS	RAGWITEK	WEED POLLEN-SHORT RAGWEED	12 UNIT	New Entity

NEW INDICATIONS (EXISTING DRUGS)

Arzerra®

April 17, 2014

Arzerra®

GSK and Genmab receive FDA approval for Arzerra® (ofatumumab) as first-line treatment in combination with chlorambucil for patients with Chronic Lymphocytic Leukemia (CLL) for whom fludarabine-based therapy is considered inappropriate

GlaxoSmithKline plc (LSE: GSK) and Genmab A/S (OMX: GEN) announced today that the U.S. Food and Drug Administration (FDA) has approved a Supplemental Biologic License Application (sBLA) for the use of Arzerra® (ofatumumab), a CD20-directed cytolytic monoclonal antibody, in combination with chlorambucil for the treatment of previously untreated patients with chronic lymphocytic leukemia (CLL) for whom fludarabine-based therapy is considered inappropriate.

Article link:http://www.gsk.com/media/press-releases/2014/gsk-and-genmab-receive-fdaapproval-for-arzerra-ofatumumab.html
Source website:http://www.gsk.com/

FDA NEWS/BULLETINS/ADVISORIES/SAFETY ALERTS

GenStrip Blood Glucose Test Strips by Shasta Technologies: FDA Safety Communication – May Report False Results

[Posted 04/29/2014]

ISSUE: The FDA is advising people with diabetes and health care professionals to stop using GenStrip Blood Glucose Test Strips because the strips may report incorrect blood glucose levels.

During a recent inspection of Shasta Technologies LLC, the FDA found extensive violations of federal regulations intended to assure the quality of products in the manufacturing of GenStrip Test Strips. FDA found that Shasta Technologies did not have in place many of the requirements of a quality system. Without assurance of an adequate quality system, the FDA believes that the strips could report incorrect blood glucose levels.

BACKGROUND: GenStrip Blood Glucose Test Strips, sold by Shasta Technologies LLC, are "third-party" blood glucose monitoring test strips. Shasta's GenStrips are advertised for use with the LifeScan OneTouch family of glucose meters (e.g. Ultra, Ultra 2 and Ultra Mini).

RECOMMENDATION: Discontinue use of GenStrip Blood Glucose Test Strips. FDA recommends the use of alternative glucose test strips that are designed for use with the LifeScan OneTouch family of glucose meters

Article link:http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm395270.htm
Source website:http://www.fda.gov/

FDA reminds health care professionals to stop dispensing prescription combination drug products with more than 325 mg of acetaminophen

[Posted 04/28/2014]

FDA is reminding health care professionals to stop prescribing and pharmacists to stop dispensing prescription combination drug products that contain more than 325 milligrams (mg) of acetaminophen per tablet, capsule, or other dosage unit. If a pharmacist receives a prescription for a combination product with more than 325 mg of acetaminophen per dosage unit, FDA recommends that they contact the prescriber to discuss a product with a lower dose of acetaminophen. These products are no longer considered safe by FDA and have been voluntarily withdrawn. We encourage pharmacists to return them to the wholesaler or manufacturer.

These products were voluntarily withdrawn by the manufacturers at FDA's request to protect consumers from the risk of severe liver damage, which can result from taking too much acetaminophen.

FDA also asks wholesalers to remove the product codes for all prescription combination drug products containing more than 325 mg of acetaminophen per dosage unit from their ordering systems and return all products to the manufacturers.

Article link:http://www.fda.gov/Drugs/DrugSafety/ucm394916.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery
Source website:http://www.fda.gov/

Epidural Corticosteroid Injection: Drug Safety Communication – Risk of Rare But Serious Neurologic Problems

[Posted 04/23/2014]

Including methylprednisolone, hydrocortisone, triamcinolone, betamethasone, and Dexamethasone

ISSUE: FDA is warning that injection of corticosteroids into the epidural space of the spine may result in rare but serious adverse events, including loss of vision, stroke, paralysis, and death. The injections are given to treat neck and back pain, and radiating pain in the arms and legs. The effectiveness and safety of epidural administration of corticosteroids have not been established, and FDA has not approved corticosteroids for this use.

FDA is requiring the addition of a Warning to the drug labels of injectable corticosteroids to describe these risks.

BACKGROUND: To raise awareness of the risks of epidural corticosteroid injections in the medical community, FDA's Safe Use Initiative convened a panel of experts, including pain management experts to help define the techniques for such injections which would reduce preventable harm. The expert panel's recommendations will be released when they are finalized. FDA will convene an Advisory Committee meeting of external experts in late 2014 to discuss the benefits and risks of epidural corticosteroid injections and to determine if further FDA actions are needed.

RECOMMENDATION: Patients should discuss the benefits and risks of epidural corticosteroid injections with their health care professionals, along with the benefits and risks associated with other possible treatments. See the Drug Safety Communication for a Data Summary and additional information for both patients and healthcare professionals.

Article link:http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm394530.htm
Source website:http://www.fda.gov/

Marcaine (Bupivacaine HCl Injection, USP) 0.25%, 10 ml, Single-Dose, Preservative-Free Vial: Recall – Visible Particulates

[Posted 04/22/2014]

ISSUE: Hospira, Inc. announced a voluntary nationwide recall to the user level for one lot of 0.25% Marcaine (Bupivacaine HCl Injection, USP), 10 mL, Single-dose Vial – Preservative Free (NDC 0409-1559-10), Lot 34-440-DD. The recall is due to a confirmed customer report of discolored solution with visible particles embedded in the glass as well as discolored solution. Hospira has attributed the embedded particulate to a supplier's glass defect.

If the particulate goes undetected and solution is administered, it could block administration of the drug to the patient, causing a delay in therapy. Other risks include local inflammation, mechanical disruption of tissue or immune response to the particulate.

BACKGROUND: Marcaine is packaged 10 units per carton/100 units per case in glass fliptop vials. The impacted lot of Marcaine was distributed December 2013 through January 2014 to wholesalers/distributors, hospitals and clinics nationwide.

Hospira is working with its supplier on implementing corrective and preventive actions.

RECOMMENDATION: Anyone with an existing inventory should immediately stop use and quarantine any affected product. In addition, customers should inform potential users of this product in their organizations of this notification. Hospira will be notifying its direct distributors/customers via a recall letter and will arrange for impacted product to be returned to Stericycle for returns processing. For additional assistance, call Stericycle at 1-877-546-7642 (M-F, 8 a.m. - 5 p.m. ET).

Article link:http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm394464.htm
Source website:http://www.fda.gov/

Lidocaine HCl Injection, USP, by Hospira: Recall – Visible Particulates

[Posted 04/18/2014]

ISSUE: Hospira, Inc. will initiate a voluntary recall of one lot of 1% Lidocaine HCl Injection, USP, 10mg/mL, 30 mL single dose, Preservative - Free to the user level due to a confirmed customer report of orange and black particulate within the solution and embedded within the glass vial. Hospira has identified the particulate as iron oxide. Risk factors associated with the particulate include the potential for particulate to be injected and/or a delay in therapy.

If the particulate or smaller pieces of the particulate that could break off, become free floating within the solution pass through the catheter into the patient, it may result in local inflammation, and/or mechanical disruption of tissue or immune response to the particulate.

Chronically, following sequestration, local granuloma formulation may occur.

BACKGROUND: This lot (Lot # 31-427-DK, Expiration Date 1JUL2015) was distributed nationwide to distributors/wholesalers, hospitals and clinics from September 2013 through October 2013.

RECOMMENDATION: Anyone with existing inventory should immediately stop use and quarantine any affected product. In addition, customers should inform potential users of this product in their organizations of this notification. Hospira will be notifying its direct distributors/customers via a recall letter and will arrange for impacted product to be returned to Stericycle for returns processing. For additional assistance, call Stericycle at 1-888-835-2723. For medical inquiries, please contact Hospira Medical Communications at 1-800-615-0187.

Article link:http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm394026.htm
Source website:http://www.fda.gov/

CUBICIN (daptomycin for injection) by Cubist Pharmaceuticals: Recall – Presence of Particulate Matter

[Posted 04/18/2014]

ISSUE: Cubist Pharmaceuticals, Inc. is voluntarily recalling one lot (Lot # 280453F) of CUBICIN (daptomycin for injection) 500 mg to the user level due to the presence of particulate matter, identified as glass particles.

The administration of glass particulate, if present in an intravenous drug, poses a potential safety risk to patients including: thromboembolism, pulmonary emboli, phlebitis, mechanical block of the capillaries or arterioles, activation of platelets, subsequent generation of microthrombi, and emboli. Patients with preexisting condition of trauma or other medical condition that adversely affects the microvascular blood supply are at an increased risk. Administration of a glass particulate can also lead to formation of granulomas, which represent a protective local inflammatory response to the foreign material.

BACKGROUND: Cubicin is an intravenously administered prescription product indicated for the treatment of skin infections and certain blood stream infections. Cubicin was distributed Nationwide to multiple consignees.

RECOMMENDATION: Anyone with an existing inventory of the product lot listed should determine whether they have product from the recalled lot, quarantine and discontinue distribution of this recalled lot of the product and call Cubist at (855) 534-8309 to arrange for return and replacement of the affected lot.

Article link:http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm394025.htm
Source website:http://www.fda.gov/

Propofol Injectable Emulsion, USP by Hospira: Recall – Visible Particulates

[Posted 04/18/2014]

ISSUE: Hospira notified the public of a nationwide recall of seven lots of Propofol Injectable Emulsion, 1%, 200 mg/20 mL (10 mg/mL) to the user level due to a glass defect located on the interior neck of the vial. The defect was identified during a sample inspection where the glass vial contained visible embedded metal particulate. Free-floating metal particulates were also identified in vials upon further analysis.

Injected particulate matter may result in local inflammation, phlebitis, and/or low level allergic response through mechanical disruption of tissue or immune response to the particulate. Capillaries, which may be as small as the size of a red blood cell, may become occluded. Chronically, following sequestration, particulate matter may lead to granulomatous formation, most likely in the lungs. Long term clinically meaningful impact is low if a patient has normal lung function. While extremely rare, embedded stainless steel may put a patient at risk from MRI (strong magnetic field exposure) as particulate, if in the lung, could potentially dislodge and be pulled through tissue.

BACKGROUND: The affected lots were distributed nationwide to distributors/wholesalers, hospitals and clinics from August 2013 through December 2013. On April 2, 2014, Hospira notified its customers via recall letter that the company had implemented corrective actions to the manufacturing process to prevent recurrence. See the Press Release for a listing of affected lot numbers.

RECOMMENDATION: Customers have been advised to check inventory and immediately quarantine any affected product. In addition, customers should inform potential users of this product in their organizations of this notification. Affected product should be returned to Stericycle, which can be contacted at 1-877-272-2158 (M-F, 8 a.m. - 5 p.m. ET).

Article link:http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm393904.htm
Source website:http://www.fda.gov/

FDA MedWatch – March 2014 Drug Safety Labeling Changes includes 30 products with revisions to Prescribing Information

The MedWatch March 2014 Safety Labeling Changes posting includes 30 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/ucm392205.htm

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

Stavzor (Valproic acid)
Xarelto (rivaroxaban)
Diflucan (fluconazole)
Evamist (estradiol transdermal spray)
Sodium Iodide I-131 Therapeutic Solution
Azulfidine (sulfasalazine tablets, USP)
Erwinaze (asparaginase Erwinia chrysanthemi)
Herceptin (trastuzumab)
Jevtana (cabazitaxel)
Miacalcin (calcitonin-salmon)
Nexium (esomeprazole sodium)
Prilosec (omeprazole)
Selzentry (maraviroc)
Revatio (sildenafil)
Ultane (sevoflurane), Ultane NovaPlus (sevoflurane)
Viagra (sildenafil citrate)
Vimovo (naproxen/esomeprazole magnesium)
Xeljanz (tofacitinib)
Xifaxan (rifaximin)

Article link:http://www.fda.gov/Safety/MedWatch/SafetyInformation/ucm392205.htm
Source website:http://www.fda.gov/

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=05072014&lang=eng

Article link, previous week:http://www.accessdata.fda.gov/scripts/ enforcement/enforce_rpt-Product-Tabs.cfm?action=Expand+Index&w=04302014&lang=eng

STUDIES and RECENT TOPICS

FDA Approves Teva's SYNRIBO® (Omacetaxine Mepesuccinate) for Injection for Home Administration

May 5, 2014

New Labeling will Offer People Living with Chronic Myeloid Leukemia (CML) More Treatment Flexibility

Teva Pharmaceutical Industries Ltd. (TEVA) today announced that the U.S. Food and Drug Administration (FDA) has approved SYNRIBO®(omacetaxine mepesuccinate) for injection, for subcutaneous use, to include home administration, and also approved a related Medication Guide and Instructions for Use. With this approval, physicians who treat adults with chronic or accelerated phase CML who are no longer responding to, or who could not tolerate, two or more tyrosine kinase inhibitors (TKIs) will now have the option to allow their patients to administer SYNRIBO® therapy at home. Teva is working to finalize a comprehensive specialty pharmacy support program which will help facilitate successful home administration of SYNRIBO®for HCPs, their patients and caregivers. This program is expected to "go live" as early as possible in the second quarter of 2014.

Article link:http://finance.yahoo.com/news/fda-approves-teva-synribo-omacetaxine-120000339.html
Source website:http://finance.yahoo.com/

FDA questions use of aspirin to prevent first heart attack

May 5, 2014

The U.S. Food and Drug Administration on Monday questioned the value of taking aspirin to try to ward off a first heart attack or stroke in people who have never had cardiovascular problems.

The FDA's statement follows its decision last week to turn down a request by German drugmaker Bayer AG to change the labeling on packages in order to market aspirin's value in preventing heart attacks in people who have never had cardiovascular disease.

Article link:http://news.yahoo.com/fda-questions-aspirin-prevent-first-heart-attack-191836437--finance.html
Source website:http://news.yahoo.com/

Vertex says cystic fibrosis drugs shown to boost lung function

May 1, 2014.

Vertex Pharmaceuticals Inc on Thursday said a combination of its cystic fibrosis drug Kalydeco and an experimental compound was shown to improve lung function in a midstage trial, sending its shares up nearly 8 percent.

Article link:http://www.reuters.com/article/2014/05/01/vertex-idUSL2N0NN1TX20140501
Source website:http://www.reuters.com/

Statins Don't Prevent Kidney Disease Progression, Study Finds

May 1, 2014.

The cholesterol-lowering medications known as statins won't help people with kidney disease avoid dialysis, but the drugs do lower cholesterol in this group, researchers have found.

"Statins had no effect -- neither good nor bad -- on kidney function," study author Dr. Richard Haynes, of the University of Oxford in England, said in an American Society of Nephrology news release.

Article link:http://consumer.healthday.com/diseases-and-conditions-information-37/misckidney-problem-news-432/journal-of-the-american-society-of-nephrology-statins-andkidney-disease-patients-687325.html
Source website:http://consumer.healthday.com/

Everyday Infections May Kill as Antibiotics Lose Potency

April 30, 2014

A post-antibiotic era in which common infections and minor injuries lead to death is a real possibility this century, the World Health Organization said in the first global survey of resistance to antimicrobial drugs.

Article link:http://www.bloomberg.com/news/2014-04-30/common-infections-may-kill-asantibiotics-lose-potency.html
Source website:http://www.bloomberg.com/

Drug Flunks Test in Cancer-Related Fatigue

April 30, 2014

Cancer-related fatigue failed to improve significantly in patients treated with the alertnesspromoting drug modafinil (Provigil), British investigators reported.

Scores on a validated fatigue-assessment questionnaire differed by 2/10 of a point in favor of modafinil, a margin that did not achieve statistical significance. Moreover, twice as many modafinil-treated patients considered the treatment not helpful as compared with placebo group.

Article link:http://www.medpagetoday.com/HematologyOncology/OtherCancers/45507
Source website:http://www.medpagetoday.com/

Another Failed HDL Therapy Trial

April 30, 2014

Despite robust epidemiological evidence suggesting that HDL has a strong protective effect against cardiovascular disease, there has been no good evidence showing that HDL-based therapies are beneficial. Large trials of drugs that raise HDL levels, including niacin and CETP-inhibitors, have failed to demonstrate improvements in outcome. Some observers gleaned hope from several small studies of drugs that mimic HDL activity but these studies have been too small to offer convincing evidence. Now a new study– the largest to ever study an HDL mimetic– has failed to find even a glimmer of benefit.

Article link:http://www.forbes.com/sites/larryhusten/2014/04/30/another-failed-hdl-therapytrial/
Source website:http://www.forbes.com/

Type 2 Diabetes May Shrink the Brain, Study Suggests

April 29, 2014

People with type 2 diabetes may lose more brain volume than is expected as they age, new research indicates.

Surprisingly, this shrinkage doesn't appear to be linked to the damaging effect of diabetes on tiny blood vessels in the brain, but instead by how the brain handles excess sugar, the researchers noted.

Article link:http://consumer.healthday.com/cognitive-health-information-26/brain-healthnews-
80/type-2-diabetes-may-shrink-the-brain-687271.html
Source website:http://consumer.healthday.com/

Amicus Therapeutics rare disease drug effective in trial

April 29, 2014

Amicus Therapeutics Inc said its experimental drug significantly reduced the abnormal accumulation of fat in body cells related to a rare genetic disorder that could lead to heart attack, stroke and kidney failure.

The company, whose shares rose as much as 36 percent, said it would file for U.S. marketing approval based on these results and those from an European trial, expected in the third quarter.

Article link:http://www.reuters.com/article/2014/04/29/us-amicus-study-fatdisorderidUSKBN0DF1PL20140429
Source website:http://www.reuters.com/

Acetaminophen in Rx Drugs: For liver's sake, lower the dose, says FDA

April 28, 2014

Apparently, a Food and Drug Administration warning four months ago was missed by many physicians, pharmacists and patients, so the agency, in an unusual move, saw fit Monday to remind us: Stop writing prescriptions for, stop dispensing prescriptions for, and stop taking prescription medications containing more than 325 milligrams of acetaminophen.

Article link:http://www.latimes.com/science/sciencenow/la-sci-sn-extra-strengthacetaminophen-fda-20140428,0,6108401.story
Source website:http://www.latimes.com/

Higher Doses of Antidepressants Linked to Sucicidal Behavior in Young Patients: Study

April 28, 2014

When prescribing antidepressants for teens and young adults, doctors should not start with high doses of the drugs because it might raise the risk of suicidal behavior, new research suggests.

The study, which was published online April 28 in the journal *JAMA Internal Medicine*, found that younger patients who began treatment with higher-than-recommended doses of antidepressants were more than twice as likely to try to harm themselves as those who were initially treated with the same drugs at lower, recommended doses.

Article link:http://consumer.healthday.com/mental-health-information-25/depression-news-

176/higher-doses-of-antidepressants-may-raise-risk-of-suicidal-behavior-in-youngerpatients-study-687266.html
Source website:http://consumer.healthday.com/

Death Rates From Pancreatic Cancer Continue To Climb: Most Other Cancers Declining In Europe

April 25, 2014

Based on a new study published in the journal Annals of Oncology on April 23, death rates in Europe from pancreatic cancer continue to increase in both men and women in 2014–lung cancer is noted to be increasing in females as well.

Article link:http://www.forbes.com/sites/robertglatter/2014/04/25/death-rates-frompancreatic-cancer-continue-to-climb-most-other-cancers-declining-in-europe/
Source website:http://www.forbes.com/

Cholesterol drug users may use pills as a license to overeat

April 25, 2014

People who take the common cholesterol-lowering drugs known as statins may feel a false sense of security and eat a bit more, according to a new study.

Researchers found that U.S. adults taking statins in 1999-2000 were eating fewer calories than people not taking the drugs, but statin users were eating about the same amount as non-users by 2009-2010.

Article link:http://www.reuters.com/article/2014/04/25/us-cholesterol-drugidUSBREA3O1YK20140425
Source website:http://www.reuters.com/

ADHD Drug Ritalin Boosted Self-Control in Tests

April 25, 2014

Ritalin, a drug used to treat attention-deficit/hyperactivity disorder, may help people maintain self-control so they can stick to a diet or a boring project, a new study suggests.

Despite the findings, you shouldn't start using Ritalin to assist your self-control, the study authors cautioned. Ritalin is a powerful psychiatric drug that should only be taken with a prescription.

Article link:http://consumer.healthday.com/kids-health-information-23/attention-deficitdisorder-adhd-news-50/adhd-drug-tried-in-tests-of-self-control-687127.html

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

Clostridium Difficile - Novel but Controversial Technique

April 24, 2014

Researchers have announced a breakthrough that may make it even easier to treat patients infected with Clostridium difficile (C. diff) using a novel but controversial technique involving fecal matter. And while the news is fantastic for patients, it presents challenges for the US Food and Drug Administration's (FDA) current regulatory policies.

Article link:http://www.raps.org/focus-online/news/news-article-view/article/4912/fdasfrozen-poop-problem.aspx
Source website:http://www.raps.org/

Novartis lung drug not inferior to GSK's Seretide, study shows

April 25, 2014

Patients taking Novartis' inhaled medicine Onbrez Breezhaler for chronic lung disease had benefits similar to those taking GlaxoSmithKline's Seretide, the Swiss drugmaker said on Friday, citing a late stage study.

Article link:http://www.reuters.com/article/2014/04/25/us-novartis-lungidUSBREA3O0D920140425
Source website:http://www.reuters.com/

Working with a pharmacist benefits stroke patients: study

April 24, 2014

People who recently had a minor stroke are more likely to get their cholesterol and blood pressure under control if they see a pharmacist periodically as compared to a nurse, a new study found.

Keeping cholesterol and blood pressure in check is important because high levels can boost a patient's risk of having a heart attack, a bigger stroke or even of dying. But these risk factors tend to be poorly controlled.

Article link:http://www.reuters.com/article/2014/04/24/us-working-with-a-pharmacistidUSBREA3N1H420140424
Source website:http://www.reuters.com/

Statin users may see drug as a free pass

April 24, 2014

Millions of Americans are prescribed statins to lower cholesterol and prevent cardiovascular diseases. A new study shows users' diets may have changed from those who used them 10 years earlier.

People taking statins to reduce cholesterol may feel a false sense of security and overindulge in unhealthy foods, according to a new study.

Article link:http://www.usatoday.com/story/news/nation/2014/04/24/statin-users-healthydiets/
8095167/
Source website:http://www.usatoday.com/

Not all older adults want emergency stroke drug: study

April 22, 2014

About one-quarter of older adults would not want to receive clot-busting medication for a stroke if they arrived at the hospital unable to make the decision themselves, a new survey found.

The medication, tissue plasminogen activator, or tPA, typically does not save a patient's life following a stroke. But people who receive tPA or similar drugs tend to have better mental functioning after a stroke and are more likely to be able to live independently, according to Dr. Winston Chiong.

Article link:http://www.reuters.com/article/2014/04/22/us-older-adultsidUSBREA3L1M920140422
Source website:http://www.reuters.com/

AbbVie's files all-oral HCV drug with FDA

April 22, 2014

AbbVie filed a New Drug Application (NDA) with FDA today, for its all-oral HCV combo drug in adults with chronic genotype 1 HCV infection. The regimen consists of ABT-450/ritonavir, ombitasvir (ABT-267) and dasabuvir (ABT-333).

The investigational drug combo has demonstrated SVR12 (cure) rates of over 95% in trials.

Article link:http://www.mmm-online.com/abbvies-files-all-oral-hcv-drug-withfda/article/343726/#
Source website:http://www.mmm-online.com/

Boehringer lines up biosimilars of major drugs

Boehringer Ingelheim plans to make biosimilar versions of the drugs Humira, Avastin and MabThera/Rituxan as part of its ambitions in biopharmaceuticals.

Speaking to journalists at the company's annual conference in Germany, chairman Andreas Barner confirmed that all these compounds are in advanced stages of development, demonstrating Boehringer's commitment to the growing biosimilars market.

Article link:http://www.pmlive.com/pharma_news/boehringer_lines_up_biosimilars_of_major_drugs_561324
Source website:http://www.pmlive.com/

What Sarepta Needs To Do Next To Get Its Muscular Dystrophy Drug Approved

April 21, 2014

In a second dramatic reversal for a promising treatment for a terrible disease, Sarepta Therapeutics SRPT +2.62% announced that it will file an application with the Food and Drug Administration for its drug eteplirsen, to treat Duchenne muscular dystrophy that is caused by a specific mutation, by the end of 2014. The news should please both investors and patient advocates who have campaigned for the drug's approval.

Article link:http://www.forbes.com/sites/matthewherper/2014/04/21/digging-in-to-sareptasfda-victory/
Source website:http://www.forbes.com/

New Drugs May Help Prevent Migraines

April 22, 2014

Two experimental drugs may help prevent migraines in people who suffer multiple attacks a month, according to preliminary findings from a pair of clinical trials.

The drugs, one given by IV and one by injection, are part of a new approach to preventing migraine headaches. They are "monoclonal antibodies" that target a tiny protein called the calcitonin gene-related peptide (CGRP) -- which recent research has implicated in triggering migraine pain.

Article link:http://consumer.healthday.com/head-and-neck-information-17/headacheshealth-news-345/new-drugs-may-help-prevent-migraines-687057.html
Source website:http://consumer.healthday.com/

VA, California Panels Urge Costly Hepatitis C Drugs For Sickest Patients

April 17, 2014

Doctors should consider expensive new hepatitis C drugs for patients with advanced liver disease, including those awaiting transplants, but ask most others to wait for drugs in development, the Department of Veterans Affairs said Wednesday.

Article link:http://www.kaiserhealthnews.org/Stories/2014/April/17/hepatitis-c-sovaldipanels-urge-approval.aspx
Source website:http://www.kaiserhealthnews.org/

Potential New Treatment for Alcoholism: Ezogabine

April 17, 2014

A relatively new anti-seizure drug may help alcoholics quit drinking, according to a new study.

Researchers at Boston University School of Medicine found that ezogabine had the potential to reduce alcohol consumption amongst alcoholics by reducing the desire to drink.

Article link:http://www.forbes.com/sites/melaniehaiken/2014/04/17/potential-newtreatment-for-alcoholism-epilepsy-drug-ezogabine/
Source website:http://www.forbes.com/

Children prescribed codeine despite safety concerns

April 21, 2014

Although significant concerns have been raised about the safety and benefits of codeinecontaining medications for children, there's been only a slight decline in hospital emergency department prescriptions for the drugs over the past decade, a new study finds.

Article link:http://www.usatoday.com/story/news/nation/2014/04/21/codeine-prescriptionschildren-emergency-rooms/7866439/
Source website:http://www.usatoday.com/

Study finds adverse respiratory outcomes for older people with COPD taking benzodiazepine

April 17, 2014

A group of drugs commonly prescribed for insomnia, anxiety and breathing issues "significantly increase the risk" that older people with chronic obstructive pulmonary disease, or COPD, need to visit a doctor or Emergency Department for respiratory reasons, new research has found.

Article link:http://www.sciencedaily.com/releases/2014/04/140417090830.htm

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

Stroke Rounds: Depression Tied to Worse Stroke Outcomes

April 17, 2014

Depression was found to be a significant and independent risk factor for poor stroke outcomes in a study from the U.K., and recovery from depression within a year did not alter long-term risk.

Article link:http://www.medpagetoday.com/Neurology/Strokes/45302
Source website:http://www.medpagetoday.com/

FDA wants stronger warning labels for long-acting opioids

April 17, 2014

The U.S. Food and Drug Administration is requiring labels of all long-acting opioids to say they should be used strictly for patients in severe pain, a response to surging overdoses and deaths each year from the widely used pain medicines.

Article link:http://in.reuters.com/article/2014/04/17/opioids-fda-idINL2N0N90X720140417
Source website:http://in.reuters.com/

FDA Grants Fast Track Status To Amgen Heart Failure Drug

April 17, 2014

Amgen announced yesterday that its new chronic heart failure drug ivabradine had been granted fast track status by the FDA. The company said the fast track designation, which is for drugs that treat serious conditions and fill an umet medical need, will aid the development and speed the review of the drug.

Article link:http://www.forbes.com/sites/larryhusten/2014/04/17/fda-grants-fast-trackstatus-to-amgen-heart-failure-drug/
Source website:http://www.forbes.com/

Info may prompt seniors to taper off sleeping pills

April 17, 2014

Older people are willing and able to get themselves off medications like sleeping pills once they're informed of the potential harms, according to a new Canadian study.

"Even among patients who have been taking sleeping pills for 30 years, many of them in their 80s and 90s were able to get off the sleeping pills once they realized that these pills could cause

falls, memory problems and car accidents," lead author Dr. Cara Tannenbaum of the University of Montreal told Reuters Health.

Article link:http://www.reuters.com/article/2014/04/17/us-sleeping-pillsidUSBREA3G1YP20140417
Source website:http://www.reuters.com/

Diabetes complications show significant decline in past two decades

April 16, 2014

Diabetes is becoming increasingly common in the United States, but the risks of complications from the blood sugar disease have declined since 1990, according to a new study.

Better preventive care for adults with diabetes contributed to a 68 percent drop in their risk of heart attacks and a 64 percent drop in deaths from high blood sugar.

Article link:http://www.reuters.com/article/2014/04/16/us-diabetes-complicationsidUSBREA3F1V220140416
Source website:http://www.reuters.com/

Misdiagnoses Common Among U.S. Outpatients: Review

April 17, 2014

At least 5 percent of American adults -- 12 million people -- are misdiagnosed in outpatient settings every year, and half of these errors could be harmful, a new study indicates.

The findings, from an analysis of data from several published studies, should lead to greater efforts to monitor and reduce the number of misdiagnoses that occur in primary care, said Dr. Hardeep Singh, at Baylor College of Medicine, and colleagues.

Article link:http://health.yahoo.net/news/s/hsn/misdiagnoses-common-among-u-soutpatients-review
Source website:http://health.yahoo.net/

Informed Patients Question Unnecessary Prescriptions

Apri 16, 2014

Well-informed patients might make better choices about what prescriptions they take, according to the evaluation of an educational intervention aimed at encouraging seniors to discontinue sleeping pill use published online April 14 in JAMA Internal Medicine.

Article link:http://www.physiciansbriefing.com/Article.asp?AID=686789
Source website:http://www.physiciansbriefing.com/

FDA Formally Withdraws Approval for Second Generic Version of Popular Antidepressant

April 11, 2014

This week the US Food and Drug Administration (FDA) formally—and quietly—withdrew a generic version of GlaxoSmithKline's Wellbutrin XL (bupropion) 300 mg following a determination that the drug was not bioequivalent to its originator.

Article link:http://www.raps.org/focus-online/news/news-article-view/article/4881/fdaformally-withdraws-approval-for-second-generic-version-of-popular-antidepre.aspx
Source website:http://www.raps.org/

Idea of New Attention Disorder Spurs Research, and Debate

April 11, 2014

With more than six million American children having received a diagnosis of attention deficit hyperactivity disorder, concern has been rising that the condition is being significantly misdiagnosed and overtreated with prescription medications.

Article link:http://www.nytimes.com/2014/04/12/health/idea-of-new-attention-disorderspurs-research-and-debate.html?ref=health
Source website:http://www.nytimes.com/

Blood Test Aims to Predict Breast Cancer's Return

April 15, 2014

A new blood test may one day help predict the recurrence of breast cancer and also a woman's response to breast cancer treatment, researchers report.

"We are able to do this with literally a spoonful of serum [blood]," said study co-author Saraswati Sukumar, who is co-director of the breast cancer program at the Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins University School of Medicine, in Baltimore.

Article link:http://www.bloomberg.com/news/2014-03-31/teva-gets-supreme-court-hearingon-generic-copaxone-delay.html
Source website: http://www.bloomberg.com/

Nearly 10 Percent of U.S. Adults Now Have Diabetes: Study

April 14, 2014

The percentage of Americans with diabetes has doubled since 1988, with nearly one in 10 adults now diagnosed with the blood-sugar disease, researchers report.In the late 1980s and early 1990s, the rate of diagnosed and undiagnosed diabetes was 5.5 percent of the U.S. population. By 2010, that number had risen to 9.3 percent. That means 21 million American adults had confirmed diabetes in 2010, according to the researchers.

Article link:http://health.usnews.com/health-news/articles/2014/04/14/nearly-10-percent-ofus-adults-now-have-diabetes-study
Source website: http://health.usnews.com/

Sleep Apnea May Be Linked to Poor Bone Health

April 15, 2014

People with sleep apnea, a common sleep disorder, may be at increased risk for the bonethinning disease osteoporosis, especially women and older people, a new study suggests. Sleep apnea causes repeated, brief interruptions in breathing during sleep. Untreated sleep apnea can increase a person's risk of heart disease, heart attack and stroke.

Article link:http://consumer.healthday.com/diseases-and-conditions-information-37/miscdiseases-and-conditions-news-203/sleep-disorder-may-be-linked-to-poor-bone-health-686780.html
Source website: http://consumer.healthday.com/

Cancer in “Miracle” Patients Studied Anew for Disease Clues

April 11, 2014

The history of oncology is rife with reports of patients with advanced cancer who staged miraculous recoveries.

Now scientists are starting to use sophisticated DNA sequencing technology to determine if these “exceptional responders” carry gene variations that can lead to new treatment approaches, better targeted therapies or even the re-emergence of experimental drugs once deemed failures.

Article link:http://www.bloomberg.com/news/2014-04-11/cancer-miracle-patients-studiedanew-for-disease-clues.html
Source website: http://www.bloomberg.com/

Rheumatoid Arthritis May Harm Kidneys

April 11, 2014

People with rheumatoid arthritis may be at increased risk for kidney disease and require close monitoring, a new study suggests.

Researchers looked at 813 people with rheumatoid arthritis and an equal number of people without the condition. Over 20 years, the rheumatoid arthritis patients had a 25 percent risk of developing chronic kidney disease, compared with a 20 percent risk for those in the general population.

Article link:http://consumer.healthday.com/bone-and-joint-information-4/rheumatoidarthritis-news-43/rheumatoid-arthritis-may-take-toll-on-kidneys-686714.html
Source website:http://consumer.healthday.com/

Intercept's liver disease drug proves highly effective in study

April 12, 2014

A drug being developed by Intercept Pharmaceuticals Inc led to significant improvement in signs of a rare liver disease that primarily affects middle-aged women, likely reducing the risk of need for liver transplant and of death, according to results of a late-stage clinical trial presented on Saturday.

Article link:http://www.reuters.com/article/2014/04/12/us-liver-interceptidUSBREA3B04220140412
Source website:http://www.reuters.com/

Study ties breathing problems, asthma to bone loss

April 11, 2014

People with asthma-related breathing problems may be at increased risk for bone loss, according to a new study.
The study examined the records of more than 7,000 adults in Seoul, Korea, and found those with a certain characteristic of asthma had significantly lower bone density in a region of their spine than those without asthma symptoms.

Article link:http://www.reuters.com/article/2014/04/11/us-breathing-problemsidUSBREA3A1TK20140411?feedType=RSS&feedName=healthNews
Source website:http://www.reuters.com/

RECALLS

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
Drugs	Adipotrim XT, New Powerful Formula, 30 rapid release capsules per bottle, Dietary Supplement, www.adipotrim.com	Lot #: 052012, Exp 10/2015	Class I	Marketed Without an Approved NDA/ANDA: FDA lab results found undeclared API Fluoxetine in this dietary supplement.	Deseo Rebajar
Drugs	Cefoxitin for Injection and Dextrose Injection, 1 g in Duplex, 50 mL Container, Catalog No. 3123-11, For IV Use Only, Single Use, Sterile, Rx Only, B Braun Medical Inc, Irvine CA 92614-5895, NDC 0264-3123-11	Lot# H3E507, Exp 11/14	Class I	Presence of Particulate Matter: B. Braun Medical Inc. is recalling several injectable products due to visible particulate matter found in reserve sample units.	B. Braun Medical Inc
Drugs	0.9 % Sodium Chloride Injection USP in PAB 50 mL partial fill in 100 mL PAB Container, Catalog No. S8004-5384, Rx Only, B Braun Medical Inc., Irvine CA 92614-5895, NDC 0264-1800-31	Lot# J2P912, Exp 02/14	Class I	Presence of Particulate Matter: B. Braun Medical Inc. is recalling several injectable products due to visible particulate matter found in reserve sample units.	B. Braun Medical Inc
Drugs	Ceftriaxone for Injection and Dextrose Injection, 1 g in Duplex, 50 mL Container, Catalog Number 3153-11, For IV Use Only, Single Dose, Sterile, Rx Only, B Braun Medical Inc., Irvine CA 92614-5895	Lot# H3B702, Exp 02/15	Class I	Presence of Particulate Matter: B. Braun Medical Inc. is recalling several injectable products due to visible particulate matter found in reserve sample units.	B. Braun Medical Inc
Drugs	Cefepime for Injections USP and Dextrose Injection USP, 1 g in Duplex, 50 mL Container, Catalog Number 3193-11, For	Lot# H2L712, Exp 09/14	Class I	Presence of Particulate Matter: B. Braun Medical Inc. is recalling several injectable products due to visible	B. Braun Medical Inc

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
	IV Use Only, Single Dose, Sterile, Rx Only, B Braun Medical Inc., Irvine CA 92614-5895, NDC 0264-3193-11			particulate matter found in reserve sample units.	
Drugs	Cefazolin for Injection USP and Dextrose Injections USP, 1 g in Duplex, 50 mL Container, Catalog Number 3103-11, For IV Use Only, Sterile, Single Dose, Rx Only, B Braun Medical Inc., Irvine CA 92614-5895, NDC 0264-3103-11	Lot# H2S725, H2S726, Exp 07/14; H3D724, Exp 11/14; H3E724, Exp 12/14; Lot# H3H507, Exp 01/15	Class I	Presence of Particulate Matter: B. Braun Medical Inc. is recalling several injectable products due to visible particulate matter found in reserve sample units.	B. Braun Medical Inc
Drugs	Cefazolin for Injection USP and Dextrose Injection USP, 2 g in Duplex, 50 mL Container, Catalog Number 3105-11, Rx Only, B Braun Medical Inc., Irvine CA 92614, NDC 0264-3105-11	Lot# H2S723, Exp 07/14; H3H711, Exp 01/15	Class I	Presence of Particulate Matter: B. Braun Medical Inc. is recalling several injectable products due to visible particulate matter found in reserve sample units.	B. Braun Medical Inc
Drugs	0.9 % Sodium Chloride Injection USP, 1000 mL, Catalog No. S4000-SS, Rx Only, Sterile, Single Dose Container, B Braun Medical Inc., Irvine, CA 92614-5895, NDC 0264-4000-55	Lot# J0B003, Exp 02/14	Class I	Presence of Particulate Matter: B. Braun Medical Inc. is recalling several injectable products due to visible particulate matter found in reserve sample units.	B. Braun Medical Inc
Drugs	6.9% FreAmine HBC (Amino Acid Injection), partial fill container 750 mL in a 1000 mL container, Catalog No. S9350-58SS, Sterile, Single dose container, Rx Only, B Braun Medical Inc., Irvine, CA 92614-5895, NDC 0264-9350-	Lot# J2H002, Exp 06/14; J2S018, Exp 12/14	Class I	Presence of Particulate Matter: B. Braun Medical Inc. is recalling several injectable products due to visible particulate matter found in reserve sample units.	B. Braun Medical Inc

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
	55				
Drugs	15% Amino Acids Injection PBP Glass, 1000 mL, Catalog No. S3200-SS, Pharmacy Bulk Package, Not For Direct Infusion, For Intravenous Use, Sterile, Single Dose Container, Rx Only, B Braun Medical Inc., Irvine, CA 92614-5895, NDC 0264-3200-55	Lot# J2J012, Exp 01/14; J3B002, Exp 08/14	Class I	Presence of Particulate Matter: B. Braun Medical Inc. is recalling several injectable products due to visible particulate matter found in reserve sample units.	B. Braun Medical Inc
Drugs	TrophAmine (10% Amino Acid Injection), 500 mL Container, Rx Only, Catalog No. S9341-SS, Sterile, Single Dose Container, B Braun Medical Inc., Irvine CA 92614-5895, NDC 0264-9341-55	Lot# J3A028, Exp 07/14	Class I	Presence of Particulate Matter: B. Braun Medical Inc. is recalling several injectable products due to visible particulate matter found in reserve sample units.	B. Braun Medical Inc
Drugs	ProcalAmine (3% Amino Acid and 3% Glycerin Injection with Electrolytes) 1000 mL Container, Rx Only, Catalog No. S9050, Sterile, Single Dose Container, B Braun Medical Inc., Irvine CA 92614-5895, NDC 0264-1915-07	Lot# J3B007, Exp 08/14	Class I	Presence of Particulate Matter: B. Braun Medical Inc. is recalling several injectable products due to visible particulate matter found in reserve sample units.	B. Braun Medical Inc
Drugs	Hyperlyte CR (Multi-Electrolyte Concentrate), 20 mL/dose, 250 mL Container, Catalog No. S9432, Rx Only, Sterile, B Braun Medical Inc., Irvine CA 92614-5895, In Canada Dist by: B Braun Medical Inc., Scarborough, Ontario	Lot# J3B007, Exp 08/14	Class I	Presence of Particulate Matter: B. Braun Medical Inc. is recalling several injectable products due to visible particulate matter found in reserve sample units.	B. Braun Medical Inc

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
	M1H 2W4, NDC 0264-1943-20, Canada DIN 01924311				
Drugs	Human Chorionic Gonadotropin, EP (HCG) in 5 mu. 2 mu, and 1 mu packages, For use and distribution in prescription compounding, manufacturing, processing or repacking only in accordance with FDA regulations and applicable law. Potency 5489.6IU/mg. Packed by Medisca, Inc. Irving, TX, 75063, USA NDC 38779-2673-1, NDC 38779-2673-2, and NDC 38779-2673-6. Lot Numbers 101751/A, Exp: 05/16, CAS: 9002-61-3; 101752/A, Exp: 05/16, CAS 9002-61-3; and 101799/A, Exp: 05/16, CAS: 9002-61-3	Lot Numbers 101751/A, Exp: 05/16, CAS: 9002-61-3; 101752/A, Exp: 05/16, CAS 9002-61-3; and 101799/A, Exp: 05/16, CAS: 9002-61-3. NDC 38779-2673-1, NDC 38779-2673-2, and NDC 38779-2673-6.	Class I	Labeling: Label Error on Declared Strength; Firm states that erroneous potency information was found on the label.	Medisca Inc.
Drugs	Lidocaine HCl Injection, USP, 2%, 20 mg per mL, packaged in 5-mL single-dose vials, 10 vials per box, Rx Only, Hospira, Inc., Lake Forest, IL. 60045, NDC 0409-2066-05.	Lot 32135DD; Exp 08/15	Class I	Presence of Particulate Matter-Confimed customer complaint of particulates embedded in glass container and in contact with product solution.	Hospira Inc.
Drugs	Dianeal PD-2 Peritoneal Dialysis Solution with 1.5% Dextrose, 6000 mL Ambu-Flex II container, Rx only,	Lot number: C903799, Exp 05/15	Class I	Non-Sterility: Complaints of leaks and particulate matter identified as mold in the solution bag and the	Baxter Healthcare Corp.

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
	Baxter Healthcare Corporation, Deerfield, IL 60015, Product Code L5B9710, NDC 0941-0411-11			overpouch.	
Drugs	Fluoxetine Capsules, USP, 20 mg, 30-count bottles, Rx only, Distributed by: Wal-Mart, Bentonville, AR 72716; Manufactured by: TEVA PHARMACEUTICALS USA, Sellersville, PA 18960; Packaged by: Legacy Pharmaceutical Packaging LLC, Earth City, MO 63045, NDC 68645-130-54, UPC 3 68645 13054 5.	Lot numbers: 131328, Exp 08/15; 131634, Exp 09/15; and 131833, Exp 11/15	Class II	Chemical Contamination: The recalling firm received notice that their supplier is recalling capsules due to complaints of capsules having an unusual odor.	Legacy Pharmaceutical Packaging
Drugs	Fluoxetine Capsules USP, 20 mg, packaged in a) 100-count bottles (NDC 50111-648-01), b) 500-count bottles (NDC 50111-648-02), c) 1000-count bottles (NDC 50111-648-03), and d) 2000-count bottles (NDC 50111-648-44), Rx only, Manufactured in Poland By: Pliva Krakow Pharmaceutical Company S.A., Krakow, Poland; Manufactured For: Teva Pharmaceuticals USA, Sellersville, PA 18960.	Lot #: a) 6A211150, 6A211151, 6A211152, 6A211153, 6A211154, Exp 11/15; 6A212083, 6A212084, 6A212085, 6A212086, Exp 12/15; b) 6A211143, 6A211145, 6A211146, 6A211147, Exp 11/15; c) 6A209116, 6A209117, 6A209118, 6A209119, 6A209120, Exp 09/15; 6A211139,	Class II	Chemical Contamination: Recall due to a customer complaint trend regarding capsule odor.	Teva Pharmaceuticals USA

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
		6A211140, 6A211141, Exp 11/15; 6A212087, Exp 12/15; d) 6A209124, Exp 09/15; 6A211144, 6A211148, 6A211149, Exp 11/15			
Drugs	Fluoxetine Capsules USP, 10 mg, 100-count bottles, Rx only, Manufactured in Poland By: Pliva Krakow Pharmaceutical Company S.A., Krakow, Poland; Manufactured For: Teva Pharmaceuticals USA, Sellersville, PA 18960, NDC 50111-647-01, UPC 3 50111-647-01 5.	Lot #: 6A211158, 6A211159, 6A211163, Exp 11/15	Class II	Chemical Contamination: Recall due to a customer complaint trend regarding capsule odor.	Teva Pharmaceuticals USA
Drugs	Lupron Depot (Leuprolide Acetate for Depot Suspension) Single Dose Administration Kit with prefilled dual-chamber syringe, 22.5 mg for 3-month administration, Rx only, Manufactured for: AbbVie Inc., North Chicago, IL 60064; by: Takeda Pharmaceutical Company Limited, Osaka, Japan 540-8645; NDC 0074-3346-03, UPC 3 00743 34603 9.	Lot #: 1014204, Exp 10/11/15; 1014485, Exp 12/11/16; and 1015007, Exp 12/06/16	Class II	Defective Delivery System: Some Lupron Depot Kits may contain a syringe with a potentially defective LuproLoc needle stick protection device	AbbVie Inc

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
Drugs	Lupron Depot (Leuprolide Acetate for Depot Suspension) Single Dose Administration Kit with prefilled dual-chamber syringe, 45 mg for 6-month administration, Rx only, Manufactured for: AbbVie Inc., North Chicago, IL 60064; by: Takeda Pharmaceutical Company Limited, Osaka, Japan 540-8645; NDC 0074-3473-03, UPC 3 00743 47303 2.	Lot # 1013976, Exp 09/25/15	Class II	Defective Delivery System: Some Lupron Depot Kits may contain a syringe with a potentially defective LuproLoc needle stick protection device	AbbVie Inc
Drugs	LUPRON DEPOT-PED (Leuprolide Acetate for Depot Suspension) Single Dose Administration Kit with prefilled dual-chamber syringe, 11.25 mg for 3-month administration, Rx only, Manufactured for: AbbVie Inc., North Chicago, IL 60064; by: Takeda Pharmaceutical Company Limited, Osaka, Japan 540-8645; NDC 0074-3779-03, UPC 3 00743 77903 5.	Lot #:1013566, Exp 12/08/16	Class II	Defective Delivery System: Some Lupron Depot Kits may contain a syringe with a potentially defective LuproLoc needle stick protection device.	AbbVie Inc
Drugs	Lupron Depot (leuprolide acetate for depot suspension) Single Dose Administration Kit with prefilled dual-chamber syringe,	Lot #: 1013906, Exp 09/21/16	Class II	Defective Delivery System: Some Lupron Depot Kits may contain a syringe with a potentially defective LuproLoc needle stick	AbbVie Inc

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
	11.25 mg for 3-Month administration, Rx only, Manufactured for: AbbVie Inc., North Chicago, IL 60064; by: Takeda Pharmaceutical Company Limited, Osaka, Japan 540-8645; NDC 0074-3663-03, UPC 3 00743 66303 7.			protection device.	
Drugs	Lupron Depot (Leuprolide Acetate for Depot Suspension) Single Dose Administration Kit with prefilled dual-chamber syringe, 7.5 mg for 1-month administration, Rx only, Manufactured for: AbbVie Inc., North Chicago, IL 60064; by: Takeda Pharmaceutical Company Limited, Osaka, Japan 540-8645; NDC 0074-3642-03, UPC 3 00743 64203 2.	Lot #: 1012381, 1012383, Exp 08/22/16	Class II	Defective Delivery System: Some Lupron Depot Kits may contain a syringe with a potentially defective LuproLoc needle stick protection device.	AbbVie Inc
Drugs	Venlafaxine Hydrochloride Extended-Release Tablets, 150 mg, packaged in a) 30-count bottles (NDC 41616-758-83, UPC 3 41616 75883 2); and b) 90-count bottles (NDC 41616-758-81, UPC 3 41616 75881 8), Rx only, Distributed by: Caraco Pharmaceutical	Lot #: a) JKL3354A, Exp 04/14; JKL5444A, Exp 08/14; JKL5457B, JKL5445A, Exp 09/14; JKL5840A, Exp 10/14; JKL6588A, Exp 11/14; b) JKL3354B, Exp 04/14;	Class II	Failed Dissolution Specifications: Stability results found the product did not meet the drug release dissolution specifications.	Caraco Pharmaceutical Laboratories, Ltd.

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
	Laboratories, Ltd., 1150 Elijah McCoy Drive, Detroit, MI 48202; Manufactured at: Sun Pharmaceutical Ind. Ltd., Halol-Baroda Highway, Halol-389 350, Gujarat, India.	JKL5444B, Exp 08/14; JKL5457C, JKL5445B, Exp 09/14; JKL5840B, Exp 10/14.			
Drugs	Venlafaxine Hydrochloride Extended-Release Tablets, 37.5 mg, packaged in a) 30-count bottles (NDC 41616-760-83, UPC 3 41616 76083 5); and b) 90-count bottles (NDC 41616-760-81, UPC 3 41616 76081 1), Rx only, Distributed by: Caraco Pharmaceutical Laboratories, Ltd., 1150 Elijah McCoy Drive, Detroit, MI 48202; Manufactured at: Sun Pharmaceutical Ind. Ltd., Halol-Baroda Highway, Halol-389 350, Gujarat, India.	Lot #: a) JKL4344A, Exp 07/14; JKL5460A, Exp 10/14; JKL5458A, Exp 11/14; b) JKL4344B, Exp 07/14; JKL5460B, Exp 10/14; JKL5458B, Exp 11/14.	Class II	Failed Dissolution Specifications: Stability results found the product did not meet the drug release dissolution specifications.	Caraco Pharmaceutical Laboratories, Ltd.
Drugs	GLYBURIDE and METFORMIN HYDROCHLORIDE Tablets USP, 5mg/500mg, 500 count bottle, Manufactured In INDIA By: EMCURE PHARMACEUTICALS LTD harmaceuticals Ltd., Hinjwadi, Pune, India, Manufactured For: TEVA	TE36018, Exp. 06/15	Class II	This recall was initiated because laboratory testing was not followed in accordance with GMP requirements.	Teva Pharmaceuticals USA

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
	PHARMACEUTICALS USA, Sellersville, PA 18960, NDC: 0093-5712-05				
Drugs	INDOMETHACIN Capsules USP, 25 mg 100 count bottle, Rx only , Manufactured In INDIA By: EMCURE PHARMACEUTICALS LTD harmaceuticals Ltd., Hinjwadi, Pune, India, Manufactured For: TEVA PHARMACEUTICALS USA, Sellersville, PA 18960, NDC 0093-4029-01	TE32134, Exp. 02/15	Class II	This recall was initiated because laboratory testing was not followed in accordance with GMP requirements.	Teva Pharmaceuticals USA
Drugs	INDOMETHACIN Capsules USP, 50 mg, a) 100 count bottle, (NDC 0093-4030-01), b) 500 count bottle, (NDC 0093-4030-05), Manufactured In INDIA By: EMCURE PHARMACEUTICALS LTD harmaceuticals Ltd., Hinjwadi, Pune, India, Manufactured For: TEVA PHARMACEUTICALS USA, Sellersville	TE38139, Exp. 08/16, TE39022, Exp. 09/16,	Class II	This recall was initiated because laboratory testing was not followed in accordance with GMP requirements.	Teva Pharmaceuticals USA
Drugs	METHYLDOPA Tablets USP, 500 mg, 100 count bottle, Rx only, Manufactured In INDIA By: EMCURE PHARMACEUTICALS LTD harmaceuticals Ltd., Hinjwadi, Pune, India, Manufactured For: TEVA PHARMACEUTICALS USA, Sellersville, PA	TE36053A,TE36063A, Exp. 06/16	Class II	This recall was initiated because laboratory testing was not followed in accordance with GMP requirements.	Teva Pharmaceuticals USA

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
	18960, NDC 0093-2932-01				
Drugs	Phosphatidylcholine Solution for Injection, 50 mg/ mL, 50 mL Vial, Rx Only, Not for Resale. John Hollis Pharmacy, 110 20th Avenue N, Nashville, TN 37203.	Lot #: 41652, Expiry: 8/2/14; Lot #: 41668, Expiry: 7/13/14	Class II	Labeling: Incorrect Expiration Date; Expiration date is earlier than listed on vial.	John W Hollis Inc
Drugs	Polidocanol 3% Solution, 50 mL Vial, Rx Only, Not for Resale. John Hollis Pharmacy, 110 20th Avenue N, Nashville, TN 37203.	Lot #: 641:07, Expiry: 8/11/14	Class II	Presence of Particulate Matter	John W Hollis Inc
Drugs	Potassium Chloride for Inj. Concentrate, USP, 40 mEq (2 mEq/mL), 20 mL Single-dose Fliptop Vial, For IV use, Rx only, Hospira, Inc., Lake Forest, IL 60045 USA	Lot 22-127-DK	Class II	Presence of Particulate; red and black particulate within the solution and embedded within the plastic vial identified as iron oxide	Hospira Inc.
Drugs	0.9% Sodium Chloride Irrigation, USP, 1000 mL,Not for Injection, Manufactured by Baxter Healthcare Corporation, Deerfield, IL 60015, USA, NDC 0338-0048-04.	Lot # GI09272; Exp 09/16	Class II	Presence of Particulate Matter: Nylon fibers found in a bottle of 0.9% sodium chloride for irrigation.	Baxter Healthcare Corp.
Drugs	Sevoflurane, USP (Inhalation Anesthetic), Rx Only, 250 mL Amber Bottle. Manufactured By: Piramal Critical Care, 3950 Schelden Circle, Bethlehem, PA 18017. NDC: 66794-015-25.	Lot #: S2611I28 (exp 9/16), S2511I14 (exp 9/16), S2531I16 (exp 9/16), S2721J21 (exp 10/16), S2871K03 (exp 11/16), S2881K03 (exp 11/16), and	Class II	Failed pH Specifications: product was too acidic.	Piramal Critical Care, Inc.

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
		S2931K07 (exp 11/16).			
Drugs	Papaverine 60 mg, Phentolamine 4 mg, and Atropine 0.3 mg Solution, 10 mL Vial, Rx Only. Not for Resale. John Hollis Pharmacy, 110 20th Avenue N, Nashville, TN 37203.	Lot #: 1905, Expiry: 4/30/14	Class II	Labeling: Incorrect Expiration Date; Expiration date is earlier than listed on vial.	John W Hollis Inc
Drugs	Metformin Hydrochloride Tablets USP 500 mg, 500 tablets Rx Only, Manufactured by Blu Caribe Dorado PR 00646. Distributed by Blu Pharmaceuticals Franklin NY 42134 NDC 24658-290-05	Lot # 13E0008F3P8V; Exp. 03/15	Class II	Defective container: Product distributed without inner seal on bottles.	Blu Pharmaceuticals Inc
Drugs	Metformin Hydrochloride Tablets USP 1000 mg, 500 tablets Rx Only, Manufactured by Blu Caribe Dorado PR 00646. Distributed by Blu Pharmaceuticals Franklin NY 42134, NDC 24658-0292-05	Lot # 13E0014F1P8V; Exp. 04/15	Class II	Defective container: Product distributed without inner seal on bottles.	Blu Pharmaceuticals Inc
Drugs	Metoprolol Succinate Extended-Release Tablets, USP, 50 mg, 30-count bottle, Rx only, Manufactured by: Wockhardt Limited, Mumbai, India; Distributed by: Wockhardt USA LLC., 20 Waterview Blvd., Parsippany, NJ 07054, USA; NDC 64679-735-09, UPC 3 64679 73509 1.	Lot #: LN10686, LN10687, LN10688, LN10707, LN10708, Exp 02/15	Class II	Failed Dissolution Specifications: failure of dissolution test observed at nine month time point.	Wockhardt Usa Inc.

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
Drugs	Mangiacotti - Lemon Verbena Hand Sanitizer Spray, alcohol free, 0.5 fl. Oz., 15 mL spray bottle, UPC 870678005306, Active Ingredient Benzalkonium Chloride 0.1%, Dist by: Mangiacotti, Attleboro, MA 02703.	Lot Code: 13348	Class II	Microbial Contamination of Non-Sterile Products: Elevated counts of bacteria was found, Serratia liquefaciens.	Mangiacotti
Drugs	Mangiacotti - Lavender Hand Sanitizer Spray, alcohol free, 0.5 fl Oz. 15 mL spray bottle, UPC 870678005313, Active Ingredient Benzalkonium Chloride 0.1%, Dist by: Mangiacotti, Attleboro, MA 02703 .	Lot Code: 13348	Class II	Microbial Contamination of Non-Sterile Products: Elevated counts of bacteria was found, Serratia liquefaciens.	Mangiacotti
Drugs	Mangiacotti - Ocean Hand Sanitizer Spray, alcohol free, 0.5 fl Oz. 15 mL spray bottle, UPC 870678005320, Active Ingredient Benzalkonium Chloride 0.1%, Dist By: Mangiacotti, Attleboro, MA 02703.	Lot Code: 13350	Class II	Microbial Contamination of Non-Sterile Products: Elevated counts of bacteria was found, Serratia liquefaciens.	Mangiacotti
Drugs	Mangiacotti - Clementine Hand Sanitizer Spray, alcohol free, 0.5 fl Oz. 15 mL spray bottle, UPC 870678005337, Active Ingredient Benzalkonium Chloride 0.1%, Dist By: Mangiacotti, Attleboro, MA 02703.	Lot Code: 13350	Class II	Microbial Contamination of Non-Sterile Products: Elevated counts of bacteria was found, Serratia liquefaciens.	Mangiacotti
Drugs	Mangiacotti -	Lot Code: 13350	Class II	Microbial	Mangiacotti

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
	Pomegranate Hand Sanitizer Spray, alcohol free, 0.5 fl Oz. 15 mL spray bottle, UPC 870678005344, Active Ingredient Benzalkonium Chloride 0.1%, Dist By: Mangiacotti, Attleboro, MA 02703			Contamination of Non-Sterile Products: Elevated counts of bacteria was found, Serratia liquefaciens.	
Drugs	Mangiacotti - Ginger Lime Hand Sanitizer Spray, alcohol free, 0.5 fl Oz. 15 mL spray bottle, UPC 870678005351, Active Ingredient Benzalkonium Chloride 0.1%, Dist By: Mangiacotti, Attleboro, MA 02703.	Lot Code: 13351	Class II	Microbial Contamination of Non-Sterile Products: Elevated counts of bacteria was found, Serratia liquefaciens.	Mangiacotti
Drugs	Polidocanol 1% Solution, 50 mL Vial, Rx Only, Not for Resale. John Hollis Pharmacy, 110 20th Avenue N, Nashville, TN 37203	Lot #: 565:27, Expiry: 5/31/14	Class III	Labeling: Incorrect Expiration Date; Expiration date is earlier than listed on vial.	John W Hollis Inc
Drugs	Cetirizine Hydrochloride Chewable Tablets, 5 mg, 30 count bottle, OTC Manufactured by Sun Pharma, Gujarat, India, NDC 47335-343-83	JKM2067A Exp. 07/14, JKM2068A Exp.10/14, JKM2069A Exp. 01/15, JKM6399A Exp. 04/15	Class III	Failed Impurities/Degradation Specifications: Stability testing found the product may not meet the drug release specification through expiry.	Caraco Pharmaceutical Laboratories, Ltd.
Drugs	Children's Cetirizine Hydrochloride Chewable Tablets, 10 mg, 30 count bottle, OTC, Manufactured by Sun Pharma, Gujarat, India, Distributed Chain Drug Consortium, Boca	JKM2070A Exp. 07/14, JKM2071A Exp.10/14, JKM2072A Exp. 01/15, JKM2072B Exp. 01/15, JKM6400A Exp.	Class III	Failed Impurities/Degradation Specifications: Stability testing found the product may not meet the drug release specification through expiry.	Caraco Pharmaceutical Laboratories, Ltd.

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
	Raton, FL, NDC 47335-344-83	04/15			
Drugs	Risperidone Oral Solution, 1 mg/mL, 30 mL bottle, Rx only, Manufactured by Apotex Inc., Toronto, Ontario, Canada M9L 1T9, Manufactured for Apotex Corp., Weston, FL 33326, NDC 60505-0380-1.	Lot #: KD4855, Exp 06/14	Class III	Failed Impurities/Degradation Specifications: Out of Specification for an impurity at the 18 month stability time point.	Apotex Inc.
Drugs	Maximum Strength/Non-Drowsy Tussin DM Adult Maximum Strength, Cough Cold, Dextromethorphan HBr, USP, 10 mg (Cough Suppressant) , Guaifenesin, USP, 200 mg (Expectorant), 4, 8 fl oz bottles , OTC only, labeled as A) CareOne 8 fl oz bottle, Distributed by American Sales Company, Lancaster, NY 14086, UPC 341520339677, B) Our Family 4 fl oz bottle, Distributed by Nash Finch Company, NFC Brands, MPLS, MN 55435, UPC 070253579523, C) Premier Value 4, 8 fl oz bottle, Distributed by Chain Drug Consortium, LLC., Boca Raton, FL 33431, 4 fl oz UPC 840986024719; 8 fl oz UPC 840986024726, NDC 68016-177-XX, D)	Lot #: 73762, 80030, 82053, 83032, 73768, 76414, 78222, 78441, 140423, 140494, 142396,145460, 145959, 73831, 73832, 78440, 79819, 82606, 80969, 140530, 142413, 145461, 74163; Exp 06/14 Lot #:148820, 149396, 149995, 150208, 150422, 150599, 151023, 151071,151337, 148931,151072. ; Exp 08/15	Class III	Presence of Precipitate; white substance confirmed as Guaifenesin, an active ingredient was observed in some bottles.	Aaron Industries Inc

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
	Rexall 4 fl oz bottle, Packaged for Dolencorp, LLC, Goodlettsville, TN 37072, UPC 715256714044, E) Safeway 4 fl oz, Distributed by Safeway INC, Pleasanton, CA 94566-0009, UPC 321130763581; F) Select Brand 4, 8 fl oz, Distributed by Select Brand Distributers, Pine Bluff, AR 71603, 4 fl oz UPC 015127024303; 8 fl oz UPC 015127024310.				
Drugs	Children's Triacting Night Time Cold & Cough with PE (diphenhydramine hcl and phenylephrine hcl), Grape Flavor, For Ages 6 to 11, 4 fl oz Bottles, liquid. Labeled A) aaron health KIDS, Manufactured by: Aaron Industries, P.O. Box 801, Lynwood, CA 90262. UPC: 7 15256 72204 9. B) FAMILY wellness, Distributed By: Family Dollar Services, Inc., 10401 Monroe Rd, Matthews, NC 28105. UPC: 0 32251 03394 0. C) Good Neighbor Pharmacy. Distributed By: AmerisourceBergen, 1300 Morris Drive, Chesterbrook, PA	Lot # (expiry): Aaron Health A) 73825 (6/14), 74141 (6/14), 74830 (6/14), 74898 (7/14), 75339 (7/14), 75455 (7/14), 78531 (9/14), 79050 (9/14), 79267 (10/14), 80017 (7/14), 80781 (7/14), 81121 (10/14), 82178 (10/14). FAMILY wellness B) 82312 (10/14), 82500 (10/15), 133197 (1/15), 140385 (1/15), 141937 (2/15), 142669 (2/15), 143201 (2/15), 143656 (2/15), 145268 (2/15), 146058	Class III	Presence of Precipitate: Small amounts of diphenydramine and mannitol precipitated out of solution.	P&L Developments, LLC

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
	19087. NDC: 24385-121-25. D) Pedia Care. Distributed by Medtech Products Inc., Irvington, NY 10533. UPC: 8 14832 01354 7. E) Quality Choice. Distributed by Quality Choice, Novi, MI 48376-0995. NDC: 63868-0368-04. F) Safeway. Distributed by Safeway Inc. P.O. Box 99, Pleasanton, CA 94566. NDC: 21130-152-04. G) Well at Walgreens. Distributed By: Walgreen Co, 200 Wilmot Rd., Deerfield, IL 60015. NDC: 0363-0152-04.	(2/15), 146406 (2/15), 146963 (2/15), 147613 (3/15), 148105 (3/15), 148297 (7/15), 148809 (3/15), 149149 (8/15), 149317 (8/15), 149411 (8/15), 149814 (8/15), 149815 (8/15), 150305 (8/15), 150673 (8/15), 151039 (9/15), 151573 (9/15), 151762 (9/15), 152798 (9/15), 153206 (9/15), 153207 (9/15), 153514 (9/15), 154024 (9/15), 155380 (1/16). Good Neighbor Pharmacy C)141202 (2/15),145249 (2/15), 146425 (2/15). Pedia Care D) 73242 (5/14), 73243 (5/14), 73244 (5/14), 73824 (6/14), 74206 (6/14), 74207 (6/14), 74303 (6/14), 74460 (6/14), 78805 (9/14), 79265 (10/14), 79266 (10/14), 79573 (9/14), 80456 (6/14), 80457 (7/14), 83746 (1/15), 133196			

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
		(1/15), 144273 (2/15), 154090 (9/15). Quality Choice E) 79355 (6/14), 133193 (1/15), 149447 (8/15), 152870 (8/15). Safeway F) 74899 (7/14), 75103 (7/14), 78803 (9/14), 79089 (9/14), 79349 (6/14), 79671 (10/14), 80599 (10/14), 81263 (7/14), 81960 (10/14), 82047 (10/14), 83726 (1/15), 133194 (1/15), 140252 (1/15), 141023 (2/15), 141692 (2/15), 142148 (2/15), 142316 (2/15), 143399 (2/15), 145170 (2/15), 145826 (1/15), 145828 (1/15), 145829 (2/15), 147961 (3/15), 150302 (2/15), 150304 (7/15), 150549 (8/15), 150866 (9/15), 151650 (8/15), 151651 (9/15), 151906 (9/15), 154922 (1/16), 154923 (1/16). Well at Walgreens G) 73671 (5/14), 73898 (6/14), 74459 (6/14),			

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
		74900 (7/14), 75306 (7/14), 75671 (7/14), 76022 (7/14), 78804 (9/14), 79264 (5/14), 79325 (6/14), 79747 (6/14), 8188401 (7/14), 8195301 (7/14), 8195401 (9/14), 8195501 (10/14), 8200601 (10/14), 8257301 (10/14), 8282601 (10/14), 8374501 (10/14), 13319201 (1/16), 13319501 (1/16), 14096601 (2/15), 14165601 (2/15), 14193601 (2/15), 14726901 (3/15), 14755501 (3/15), 14812901 (3/15), 14824701 (3/15), 14829601 (7/15), 14914401 (8/15), 15074701 (9/15),			

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
		15434701 (11/15).			
Drugs	Glytone Acne, acne treatment facial cleanser, 2% Salicylic Acid, 200 mL/6.7 FL Oz Bottle, Distributed by Genesis Pharmaceuticals, Inc. a subsidiary of Pierre Fabre, Parsippany, NJ 07054, UPC 3 04760-00413-2	Lot 54, Exp: 1/14/2016	Class III	Failed Stability Specifications: Out of specification results for viscosity in one lot of Glytone Acne Treatment Facial Cleanser.	Genesis Pharmaceutical , Inc.
Drugs	Liptruzet (ezetimibe and atorvastin) tablets,10 mg/10 mg, a) 30 count blister (NDC 66582-320-30), b) 90 count blister (NDC 66582-320-54), Rx only, Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc, Whitehouse Station, NJ 08889	a) Liptruzet 10/10mg, 30 count, 346380,353183, Exp. 07/14 b) Liptruzet 10/10mg, 90 count 346381, 350264, Exp 07/14; 357235, Exp. 12/14.	Class III	Defective Container; some of the outer laminate foil pouches allowed in air and moisture, which could potentially decrease the effectiveness or change the characteristics of the product.	Merck & Co Inc
Drugs	Liptruzet (ezetimibe and atorvastin) tablets,10 mg/20 mg, a) 30 count blister (NDC 66582-321-30), b) 90 count blister (NDC 66582-321-54), Rx only, Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc, Whitehouse Station, NJ 08889	a) Liptruzet 10/20mg 30 count, 346353, 346354, Exp. 06/14; 351809, Exp. 07/14, 360530, Exp. 12/14. b) Liptruzet 10/20mg, 90 count, 346387, Exp. 06/14; 353185, Exp.12/14.	Class III	Defective Container; some of the outer laminate foil pouches allowed in air and moisture, which could potentially decrease the effectiveness or change the characteristics of the product.	Merck & Co Inc
Drugs	Liptruzet (ezetimibe and atorvastin) tablets,10 mg/40 mg, a) 30 count blister (NDC 66582-322-30), b) 90 count blister	a) Liptruzet 10/40mg 30 count, 346304, 346342, 350256, 353107,	Class III	Defective Container; some of the outer laminate foil pouches allowed in air and moisture, which could potentially	Merck & Co Inc

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
	(NDC 66582-322-54), Rx only, Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc, Whitehouse Station, NJ 08889	353108, 353109, Exp. 06/14; 353110, Exp.12/14 b) Liptruzet 10/40mg 90 count 346382, Exp. 06/14; 353186, Exp.12/14.		decrease the effectiveness or change the characteristics of the product.	
Drugs	Liptruzet (ezetimibe and atorvastin) tablets,10 mg/80 mg, a) 30 count blister (NDC 66582-323-30), b) 90 count blister (NDC 66582-323-54), Rx only, Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc, Whitehouse Station, NJ 08889	a) Liptruzet 10/80mg 30 count, 346379, 350257, Exp.07/14; 353591, Exp. 06/15. b) Liptruzet 10/80mg 90 count, 346383, 371072, Exp. 06/15.	Class III	Defective Container; some of the outer laminate foil pouches allowed in air and moisture, which could potentially decrease the effectiveness or change the characteristics of the product.	Merck & Co Inc
Drugs	Azathioprine Tablets USP, 50 mg, 100 count bottle, Rx only, Roxanne Laboratories, Inc., Columbus, Ohio, 43216, NDC 0054-4084-25	Lot 261983A Exp.11/15	Class III	Labeling: Incorrect or Missing Lot and/or Exp Date: This recall is being conducted because the product was given 36 month expiration dates instead of the filed 24 months.	Boehringer Ingelheim Roxane Inc
Drugs	Mercaptopurine Tablets USP, 50 mg, 25 count bottle, Rx only, Roxanne Laboratories, Inc., Columbus, Ohio, 43216, NDC 0054-4581-11	Lot 261997A Exp 02/16; 262214V, 359283V Exp. 05/16	Class III	Labeling: Incorrect or Missing Lot and/or Exp Date: This recall is being conducted because the product was given 36 month expiration dates instead of the filed 24 months.	Boehringer Ingelheim Roxane Inc

CURRENT DRUG SHORTAGES

Amikacin Injection

April 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=638
Source link:http://www.ashp.org

Cefpodoxime

April 24, 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/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=638
Source link:http://www.ashp.org

Ceftazidime Injection

April 24, 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=638
Source link:http://www.ashp.org

Cytarabine Injection

April 24, 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/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=638
Source link:http://www.ashp.org

Doxycycline Capsules and Tablets

April 24, 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=638

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

Ethiodized Oil

April 24, 2014

Reason for the Shortage

- Savage / Nycomed Laboratories is no longer manufacturing Ethiodol solution for injection due to a marketing decision.
- In cooperation with FDA, Guerbet is providing Lipiodol Ultra-Fluide to the US market.2,3 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).
- Guerbet received FDA approval of Lipiodol in April 2014.

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

Haloperidol Decanoate Injection

April 24, 2014

Reason for the Shortage

- Teva products are on shortage due to manufacturing delays.

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

Methylene Blue Injection

April 24, 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/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=638
Source link:http://www.ashp.org

Methylprednisolone Acetate Injection

April 24, 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/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=638
Source link:http://www.ashp.org

Mirtazapine Tablets

April 24, 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=638
Source link:http://www.ashp.org

Atorvastatin Tablets

April 25, 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=638
Source link:http://www.ashp.org

Bupivacaine Injection

April 25, 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=638
Source link:http://www.ashp.org

Cefotetan Disodium Injection

April 25, 2014

Reason for the Shortage

- Fresenius Kabi states the reason for the shortage is manufacturing delay.

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

Chromium (Chromic Chloride)

April 25, 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/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=638
Source link:http://www.ashp.org

Copper Injection

April 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=638
Source link:http://www.ashp.org

Erythromycin Lactobionate Injection

April 25, 2014

Reason for the Shortage

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

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

Mannitol Inhalation Capsules

April 25, 2014

Reason for the Shortage

- Pharmaxis states the reason for the shortage is manufacturing delay.
- There are no other manufacturers of mannitol inhalation capsules.

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

Selenium Injection

April 25, 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=638
Source link:http://www.ashp.org

Sincalide Injection

April 25, 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=638
Source link:http://www.ashp.org

Zinc Injection

April 25, 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=638
Source link:http://www.ashp.org

Ondansetron Injection

April 28, 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 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. Mylan Institutional temporarily discontinued ondansetron 2 mg/mL injectable products in Februrary 2014.
- 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=638
Source link:http://www.ashp.org

Propofol Injection

April 28, 2014

Reason for the Shortage

- Hospira had propofol on shortage due to manufacturing delays.
- Sagent is distributing propofol presentations from Teva.
- 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.
- 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. 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). 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=638
Source link:http://www.ashp.org

Rabies Immune Globulin

April 28, 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/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=638
Source link: http://www.ashp.org

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

April 28, 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/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=638
Source link:http://www.ashp.org

Isotretinoin Oral Capsules

April 29, 2014

Reason for the Shortage

- Teva and VersaPharm could not provide a reason for the shortage
- Mylan and Dr Reddy's state the shortage is due to increased demand for the products

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

Bumetadine Tablets

April 30, 2014

Reason for the Shortage

- Mylan Institutional discontinued bumetanide tablets in March 2014
- Sandoz cannot provide a reason for the shortage.
- Teva cannot provide a reason for the shortage.

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

Caffeine and Ergotamine Tartrate

April 30, 2014

Reason for the Shortage

- Sandoz states the shortage was 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/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=638
Source link:http://www.ashp.org

Epinephrine Injection

April 30, 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=638
Source link:http://www.ashp.org

Milrinone Injection

April 30, 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=638
Source link:http://www.ashp.org

Nalbuphine Injection

April 30, 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/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=638
Source link:http://www.ashp.org

Nimodipine Capsules

April 30, 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/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=638
Source link:http://www.ashp.org

Sodium Chloride 0.9% Injection Bags

April 30, 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. There will be presentations available with Scandinavian and Australian/English labels and the package insert is the same for all imported presentations
- In cooperation with the FDA, Baxter is providing imported 0.9% sodium chloride to the US market to help alleviate the national shortage. This 0.9% sodium chloride in Viaflo containers is manufactured in Spain by Baxter.

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

Aminophylline Injection

May 1, 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/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=638
Source link:http://www.ashp.org

Azathioprine Injection

May 1, 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/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=638
Source link:http://www.ashp.org

Calcium Gluconate Injection

May 1, 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=638
Source link:http://www.ashp.org

Clarithromycin Immediate-Release Tablets

May 1, 2014

Reason for the Shortage

- Ranbaxy has an import ban on their products.
- Apotex import ban has been lifte, but the company is not marketing clarithromycin immediate-release tablets in the U.S.
- 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/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=945
Source link:http://www.ashp.org

Doxazosin Tablets

May 1, 2014

Reason for the Shortage

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

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

Droperidol Injection

May 1, 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/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=818
Source link:http://www.ashp.org

Intravaneous Fat Emulsion

May 1, 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/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=651
Source link:http://www.ashp.org

Labetalol Injection

May 1, 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

Morrhuate Sodium Injection

May 1, 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/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=903
Source link:http://www.ashp.org

Multiple Vitamins for Infusion

May 1, 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/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=831
Source link:http://www.ashp.org

Nicardipine Hydrochloride Injection

May 1, 2014

Reason for the Shortage

- Cornerstone Therapeutics discontinued Cardene ampules in March 2014. The company could not provide a reason for the discontinuation
- 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/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=31
Source link:http://www.ashp.org

Phenylephrine Hydrochloride Injection

May 1, 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

Rocuronium Injection

May 1, 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.[1] 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

Trace Elements Injection

May 1, 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/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=785
Source link:http://www.ashp.org

Vecuronium Bromide Injection

May 1, 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 2014. Ben Venue supplies multiple sterile injectable products for Bedford Laboratories. Suppliers 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

Vitamin A Injection

May 1, 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/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=704
Source link:http://www.ashp.org

Buprenorphine Injection

May 5, 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.
- 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/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=938
Source link:http://www.ashp.org

Buprenorphine Sublingual Tablets

May 5, 2014

Reason for the Shortage

- Teva could not provide a reason for the shortage.

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

Ciprofloxacin Injection

May 5, 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

Clindamycin Injection

May 5, 2014

Reason for the Shortage

- Pfizer states the Cleocin Add-Vantage vials are on shortage due to manufacturing delays.
- Hospira has clindamycin injection on shortage due to manufacturing delays.
- Akorn launched clindamycin injection in June 2013.
- Sandoz has clindamycin injection on shortage due to increased demand.
- Sagent has clindamycin injection on allocation due to increased demand.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1029
Source link:http://www.ashp.org

Nitroglycerin Injection

May 5, 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.
- In cooperation with FDA, Arbor Pharmaceuticals is importing glyceryl trinitrate (Nitronal) injection to the US market to help alleviate the national shortage. This glyceryl trinitrate is manufactured in an FDA-approved facility in Germany by Pohl Boskamp. Glyceryl trinitrate is another name for nitroglycerin

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

Oxytocin Injection

May 5, 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

Pantoprazole Tablets

May 5, 2014

Reason for the Shortage

- Actavis, Aurobindo, Mylan, Teva, 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

Fosphenytoin Injection

May 6, 2014

Reason for the Shortage

- Akorn discontinued fosphenytoin injection in 2011.
- Fresenius Kabi recalled numerous lots of fosphenytoin due to particulate matter potentially from glass delamination and consistent with glass particulates observed in samples. Fresenius Kabi has a letter discusiing the lot numbers and what to do with affected product
- 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.

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

Hydroxyzine Injection

May 6, 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/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=829
Source link:http://www.ashp.org

Methyldopate

May 6, 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/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=844
Source link:http://www.ashp.org

Promethazine Injection

May 6, 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

Acetylcysteine Inhalation Solution

May 7, 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 has acetylcysteine inhalation solution on shortage due to manufacturing delay
- Fresenius Kabi (formerly APP) states the reason for the shortage was increased demand

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

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

Chlorothiazide Oral Suspension

May 7, 2014

Reason for the Shortage

- Salix is the sole supplier of chlorothiazide oral suspension

Article link:

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

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

Citric acid and Potassium Citrate Oral

May 7, 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/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1080

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

Dactinomycin Injection

May 7, 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/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1064
Source link:http://www.ashp.org

Desmopressin Injection

May 7, 2014

Reason for the Shortage

- Teva and Hospira have desmopressin injection on shortage due to manufacturing delays.
- Sanofi could not provide a reason for the shortage

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

Dexpanthenol Injection

May 7, 2014

Reason for the Shortage

- American Regent has dexpanthenol injection on shortage due to manufacturing delays
- There are no other suppliers of dexpanthenol injection

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1103
Source link:http://www.ashp.org

Dibucaine Ointment

May 7, 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

Doxorubicin Liposomal Injection

May 7, 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.
- Jansen 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 and additional lot 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

Heparin Sodium Injection

May 7, 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/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=387
Source link:http://www.ashp.org

Lidocaine Injection

May 7, 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 has 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=859
Source link:http://www.ashp.org

Naproxen Oral Suspension

May 7, 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/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1055
Source link:http://www.ashp.org

Sodium Acetate Injection

May 7, 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/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=762
Source link:http://www.ashp.org

Acyclovir Suspension

May 8, 2014

Reason for the Shortage

- Hi-Tech discontinued acyclovir suspension in April 2014
- Actavis could not provide a reason for the shortage

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1018
Source link:http://www.ashp.org

Acyclovir Injection

May 8, 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/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=467
Source link:http://www.ashp.org

Aminocaproic Acid Injection

May 8, 2014

Reason for the Shortage

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

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

Benztropine Injection

May 8, 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

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

Calcium Chloride Injection

May 8, 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

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

Esmolol Injection

May 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.

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

Lactated Ringer's Injection Bags

May 8, 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

Midazolam Injections

May 8, 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

Octreotide Injection

May 8, 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

Paclitaxel Injection

May 8, 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 has paclitaxel on shortage due to manufacturing delay
- Sagent has paclitaxel on shortage due to manufacturing delay
- 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

Phenytoin Injection

May 8, 2014

Reason for the Shortage

- 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

Potassium Acetate Injection

May 8, 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/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=668
Source link:http://www.ashp.org

Vincristine Injection

May 8, 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=42

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

Gentamicin Injection

May 9, 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

Methylprednisonlone Sodium Succinate Injection

May 9, 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

Pancuronium Injection

May 9, 2014

Reason for the Shortage

- Teva discontinued their pancuronium presentations in May, 2010.
- 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

Papaverine Injection

May 9, 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=781
Source link:http://www.ashp.org

Procainamide Hydrochloride Injection

May 9, 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/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=868
Source link:http://www.ashp.org

Sodium Chloride Concentrated Solution for Injection

May 9, 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

Sterile Empty Vials

May 9, 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

Sufentanil Injection

May 9, 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/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=823
Source link:http://www.ashp.org

Tamoxifen Tablets

May 9, 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

Alcohol Dehydrated Injection (Ethanol)

May 12, 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/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=778
Source link:http://www.ashp.org

Amiodarone Hydrochloride Injection

May 12, 2014

Reason for the Shortage

- Hospira has amiodarone injection on shortage due to manufacturing delays.
- Fresenius Kabi has amiodarone injection on shortage due to increased demand.
- West-Ward stated the reason for the shortage is demand exceeding supply due to current market conditions

Article link:http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=358
Source link:http://www.ashp.org

Bupivacaine with Epinephrine Injection

May 12, 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

Cefazolin Injection

May 12, 2014

Reason for the Shortage

- Fresenius Kabi, BBraun, West-Ward, 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.

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

Chorionic Gonadotropin (Human) Injection

May 12, 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

Cidofovir Injection

May 12, 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

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

Cyclosporine Injection

May 12, 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/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=948
Source link:http://www.ashp.org

Dexamethasone Sodium Phosphate

May 12, 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=751
Source link:http://www.ashp.org

Doxorubicin Injection

May 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/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=464
Source link:http://www.ashp.org

Ketorolac Tromethamine Injection

May 12, 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/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=593
Source link:http://www.ashp.org

Lidocaine with Epinephrine Injection

May 12, 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

Magnesium Sulfate Injection

May 12, 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

Methocarbamol Injection

May 12, 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

Methotrexate Tablets

May 12, 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/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=961
Source link:http://www.ashp.org

Metronidazole Injection

May 12, 2014

Reason for the Shortage

- Hospira has metronidazole injection on back order due to manufacturing delays.
- Baxter is allocating metronidazole injection due to increased demand for the product.

Article link:http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=643
Source link:http://www.ashp.org

Neostigmine Methylsulfate Injection

May 12, 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

Norepinephrine Injection

May 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.
- 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

Potassium Phosphate Injection

May 12, 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 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

Propranolol Injection

May 12, 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 had propranolol injection available but with short-expiration dating
- Sandoz cannot provide a reason for the shortage
- West-Ward had 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

Sodium Chloride 0.45% Injection Bags

May 12, 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

Sodium Phosphate Injection

May 12, 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. Glycopho is manufactured in an FDA-approved facility in Norway by Fresenius Kabi AG
- 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

Terbutaline Sulfate Injection

May 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.
- Akorn has discontinued terbutaline injection.

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

Tiopronin Tablets

May 12, 2014

Reason for the Shortage

- Mission Pharmacal has Thiola on shortage due to raw materials being discontinued

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

Tuberculin Purified Protein Derivative for Intradermal Injection

May 12, 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/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=973
Source link:http://www.ashp.org

Water-Miscible Oral Multiple Vitamins

May 12, 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.
- Libertas plans to launch softgel capsules in mid-June 2014

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

Bumetanide Injection

May 13, 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. Suppliers 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/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=674
Source link:http://www.ashp.org

Diltiazem Injection

May 13, 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.

- 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

Dimercaprol Injection

May 13, 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

Enalaprilat Injection

May 13, 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

Ephedrine Injection

May 13, 2014

Reason for the Shortage

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

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

Fludarabine Injection

May 13, 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

Thiothixene Capsules

May 13, 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

Barium Sulate Oral Suspension

May 14, 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

Ceftriaxone Sodium Injection

May 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.
- Fresenius Kabi and West-Ward state the reason for the shortage is increased demand.
- Hospira states the reason for the shortage is manufacturing delay.
- Sandoz and WG Critical Care cannot provide a reason for the shortage.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1101
Source link:http://www.ashp.org

Cephalexin Oral Suspension

May 14, 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/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1043
Source link:http://www.ashp.org

Dexmethylphenidate Hydrochloride

May 14, 2014

Reason for the Shortage

- Teva cannot provide a reason for the shortage

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

Echothiophate Powder for Ophthalmic Solution

May 14, 2014

Reason for the Shortage

- 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

Empty Evacuated Containers

May 14, 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

Fluconazole Injection

May 14, 2014

Reason for the Shortage

- Teva has fluconazole injection on shortage due to manufacturing delays.
- Pfizer has fluconazole injection on shortage due to manufacturing delays related to labeling changes
- 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 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=644
Source link:http://www.ashp.org

Indomethacin Injection

May 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/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=596
Source link:http://www.ashp.org

Methotrexate Injection

May 14, 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. Suppliers 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.
- Mylan Institutional divested three presentations of methotrexate injection to Intas (Accord Healthcare) in April 2014
- 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

Neostigmine Bromide Tablets

May 14, 2014

Reason for the Shortage

- Valeant discontinued Prostigmin tablets on March 12, 2014
- There are no other manufacturers of neostigmine bromide tablets

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

Piperacillin Tazobactam Injection

May 14, 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

Succinylcholine Chloride Injection

May 14, 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

May 14, 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

Vasopressin Injection

May 14, 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 had 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

Adenosine Injection

May 15, 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 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.
- 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

Atracurium Injection

May 15, 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.
- Hospira launched atracurium in mid-2013
- Sagent has atracurioum on allocation due to manufacturing delays

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

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

Caffeine Citrate Injection and Oral Solution

May 15, 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.
- Paddock discontinued caffeine citrate injection and oral solution in May 2014.
- 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

Olanzapine Injection

May 15, 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

Prednisone Tablets

May 15, 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

Testosterone Enanthate Injection

May 15, 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

Carboplatin Solution for Injection

May 16, 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

Ethambutol Tablets

May 16, 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/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=982
Source link:http://www.ashp.org

Etomidate Injection

May 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

Dobutamine Injection

May 19, 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 2014. Ben Venue supplies multiple sterile injectable products for Bedford Laboratories. Suppliers 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

Ezetimibe and Atorvastatin Tablets

May 19, 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

Fluorouracil Injection

May 19, 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

Levothyroxine Sodium Injection

May 19, 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

Lorazepam Injectable Presentations

May 19, 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=747
Source link:http://www.ashp.org

Mecasermin Injection

May 19, 2014

Reason for the Shortage

- Ipsen Pharmaceuticals states the shortage is due to a manufacturing delay and raw material shortage.
- Ipsen is working with FDA to allow the release of Increlex lot #341203F. This lot was produced at an alternate manufacturing site that has not been approved by FDA. Please see the Dear Health Care Provider letter for additional information.
- Additional information is available here and here.

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

Mitomycin Injection

May 19, 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. Suppliers 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

Morphine Injections

May 19, 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

Phenylephrine 2.5% and 10% Ophthalmic Solution

May 19, 2014

Reason for the Shortage

- Akorn stopped manufacturing their phenylephrine ophthalmic solution in April 2014 and the company will no longer distribute after June 30, 2014
- Alcon discontinued phenylephrine 2.5% ophthalmic solution with the Sandoz label in April 2014
- Alcon could not provide a reason for the shortage of Mydfrin 2.5% ophthalmic solution. Mydfrin is an unapproved product.
- Hub discontinued phenylepherine 2.5% and 10% ophthalmic solution in 2013
- Phenylephrine 2.5% and 10% from Paragon BioTeck is the only FDA-approved phenylephrine ophthalmic produc
- Paragon BioTeck supplied phenylephrine opthalmic solution 2.5% and 10% and this is distributed by Bausch & Lomb.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1105
Source link:http://www.ashp.org

Thiotepa for Injection

May 19, 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. Suppliers 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/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=589
Source link:http://www.ashp.org

Butorphanol Injection

May 20, 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/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=939
Source link:http://www.ashp.org

Furosemide Injection

May 20, 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 increased demand
- Wockhardt has discontinued all furosemide injection presentations

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

Glycopyrrolate Injection

May 20, 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

Rifampin for Injection

May 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.
- 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/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=350
Source link:http://www.ashp.org

Ampicillin Sulbactam

May 21, 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

Azithromycin Injection

May 21, 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 has 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

Calcitriol Injection

May 21, 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

Cisatracurium Injection

May 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

Dihydroergotamine Mesylate Injection

May 21, 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. Suppliers 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

Famotidine Injection

May 21, 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=810
Source link:http://www.ashp.org

Fluorescein Sodium Injection

May 21, 2014

Reason for the Shortage

- Altaire Pharmaceuticals temporarily discontinued fluorescein and fluorescein lite products. Altaire Pharmaceuticals could not provide a reason for the temporary discontinuation.
- Akorn and Alcon could not provide a reason for the shortage.

Article
link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1104
Source link:http://www.ashp.org

Granisetron Hydrochloride Injection

May 21, 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

Haloperidol Lactate Injection

May 21, 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. 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 could not provide a reason for the shortage
- Sagent has haloperidol lactate on shortage due to manufacturing delays
- 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

Indigo Carmine Injection

May 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.
- Akorn has indigo carmine on back order due to shortage of raw material. Akorn is looking for a new raw material supplier

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

Leucovorin Calcium Injection

May 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.
- 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.
- Sagent states the reason for the shortage is manufacturing delay

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

NEW DRUGS COMING TO MARKET

PRODUCT	MFR	ROUTE	INDICATION	PHARMACOLOGY	MARKET RELEASE
Esomeprazole (Nexium 24HR)	Pfizer	PO	GERD	PPI suppressing gastric acid secretion by specific inhibition of the H+/K+-ATPase in the gastric parietal cell	Pfizer acquired exclusive global rights from AstaZeneca in 2012. FDA approved 3/28/14. Launch as **OTC** 5/27/14.
Inhaled Technosphere ® Insulin (Afrezza)	MannKind	Inhaled Insulin	Type I & II diabetes	Palm-sized inhaler with single use cartridges	NDA re-filed 10/14/13. FDA action extended to 7/15/14.
Dulaglutide	Lilly	Inj (SC)	Type II diabetes	GLP-1 receptor agonist (once weekly)	NDA filed 9/18/13.
Empagliflozin and linagliptin	Boehringer Ingelheim/ Eli Lilly	PO	Type II diabetes	Sodium-glucose cotransporter-2 (SGLT2) inhibitor and DPP-4 inhibitor	NDA filed 4/14.
Dalbavancin (Dalvance)	Durata	Inj (IV)	Treat methicillin-resistant Staphylococcus	Second-generation lipoglycopeptide agent that belongs to the same class as vancomycin, once-weekly IV	NDA 12/04. Second approvable letter issued 12/07. NDA withdrawn 9/08. NDA re-filed 9/26/13. FDA action date 5/26/14.
Tedizolid	Trius Therapeutics	PO, IV	Skin and soft tissue infections	Second-generation oxazolidinone antibacterial	NDA filed 10/22/13. Qualified Infectious

PRODUCT	MFR	ROUTE	INDICATION	PHARMACOLOGY	MARKET RELEASE
				agent with activity against drug-resistant Gram-positive infections	Disease Product (QIDP) designation 1/13. FDA priority review with FDA action date 6/20/14.
Abacavir/ Dolutegravir/l amivudine	ViiV Healthcare	PO	HIV	Single tab combining integrase inhibitor, replication inhibitor, nucleoside reverse transcriptase inhibitor	NDA filed 10/22/13. FDA action date 10/14.
Ledipasvir/ sofosbuvir	Gliead	PO	Hepatitis C	Fixed dose combination of NS5A protein inhibitor, nucleotide NS5B inhibitor	NDA filed 2/14. Break-through therapy designation granted 8/13. Priority review: FDA action date 10/10/14.
Daclatasvir	Bristol-Myers Squibb	PO	Hepatitis C	NS5A protein inhibitor	NDA filed 4/14. Triple therapy break-through therapy designation (with asunaprevir &BMS 791325) for chronic

PRODUCT	MFR	ROUTE	INDICATION	PHARMACOLOGY	MARKET RELEASE
					Hepatitis C.
Asunaprevir	Bristol-Myers Squibb	PO	Hepatitis C	NS3 protease inihibitor	NDA filed 4/14. Triple therapy break-through therapy desingnation (with daclatasvir & BMS 791325) for chronic Hepatitis C.
Cobicistat (Tybost)	Gilead	PO	HIV	"boosting" agent that increases blood levels of certain HIV medicines	NDA filed 6/12. FDA complete response letter 4/27/13. NDA re-submitted 4/14.
Elvitegravir	Gilead	PO	HIV	Integrase inhibitor	NDA filed 6/12. FDA complete response letter 4/27/13. NDA re-submitted 4/14. FDA action date 10/4/14.
ABT-450 (plus ritonavir)	AbbVie	PO	Hepatitis C	Hepatitis C virus (HCV) NS3/4A protease inhibitor (given with ritonavir as booster)	All oral triple therapy (with ABT-267 and ABT-333) receives FDA break-through therapy

PRODUCT	MFR	ROUTE	INDICATION	PHARMACOLOGY	MARKET RELEASE
					designation 5/13. NDA filed 4/22/14.
Ombitasvir (ABT-267)	AbbVie	PO	Hepatitis C	Hepatitis C virus (HCV) NS5A inhibitor	All oral triple therapy (with ABT-450 and ABT-333) receives FDA break-through therapy designation 5/13. NDA filed 4/22/14.
Dasabuvir (ABT-333)	AbbVie	PO	Hepatitis C	Hepatitis C virus (HCV) non-nucleoside polymerase inhibitor	All oral triple therapy (with ABT-267 and ABT-450) receives FDA breakthroug h therapy designation 5/13. NDA filed 4/22/14.
Darunavir and cobicistat	Gilead	PO	HIV	Protease inhibitor and pharmacokinetic enhancer	NDA filed 4/14.
Ceftolozane/ Tazobactam	Cubist	Inj (IV)	Complicated Urinary Tract Infections (cUTI) and Complicated Intra-Abdominal Infections (cIAI)	Cephalosporin/be ta-lactase inhibitor combination	NDA filed 4/23/14. FDA fast-track and QIDP designation, priority review.
Oritavancin	The Medicines Company	Inj (IV)	Gram positive infections	Lipoglycopeptide that inhibits cell wall synthesis	QIDP designation 11/13. NDA

PRODUCT	MFR	ROUTE	INDICATION	PHARMACOLOGY	MARKET RELEASE
					filed 2/14. FDA action date 8/6/14 with priority review.
Faldaprevir	Boehringer Ingelheim	PO	Hepatitis C	Inhibitor of the NS3/4A serine protease	NDA filed 3/6/14. FDA fast track status.
Peramivir	BioCryst	Inj (IV)	Influenza	Cyclosporine compound that selectively inhibits the influenza A and B neuraminidase enzyme	NDA filed 12/13. FDA action date 12/23/14.
Idelalisib (GS-1101)	Gilead	PO	Non-Hodgkin's lymphoma (NHL), chronic lymphocytic leukemia (CLL)	Phosphoinositide-3-kinase (PI3K) inhibitor	NDA for NHL filed 9/11/13 and CLL on 12/6/13. FDA action date 6/8/14 for CLL and 9/11/14 for NHL. FDA break-through therapy designation for relapsed CLL.
Lambrolizumab (MK-3475)	Merck	Inj (IV)	Melanoma, NSCLC	Specifically targets the "programmed death" 1 (PD-1) receptor	FDA break-through therapy designation 4/13. Rolling BLA submitted 1/14. FDA action date 10/28/14.

PRODUCT	MFR	ROUTE	INDICATION	PHARMACOLOGY	MARKET RELEASE
Belinostat	Spectrum	Inj (IV)	Peripheral T-cell lymphoma	Inhibitor of class I and class II histone deacetylase (HDAC) enzymes, which promote growth of tumor cells	NDA submitted 12/13. FDA priority review. FDA action date 8/9/14.
Olaparib	Astra Zeneca	PO	Breast cancer, ovarian cancer	Poly-ADP-ribose polymerase (PARP) enzyme inhibitor	NDA filed 4/14. FDA priority review. FDA advisory cmte to review 6/14.
Edoxaban (Savaysa)	Daiichi Sankyo	PO	Stroke prevention in A-Fib, embolism prevention, venous thromboembolism prevention	Reversible, direct inhibitor of coagulation factor Xa	NDA submitted 1/14. FDA action date 1/8/14.
Bupropion SR and naltrexone SR (Contrave)	Orexigen Thera-peutics	PO	Obesity	Sustained release combination of atypical antidepressant & opioid receptor antagonist	NDA filed 3/10. FDA complete response 1/11 requires more CV safety study. NDA re-submitted 12/13. FDA action date 6/10/14.
Levadex	Astra Zeneca/ MAP	Nasal	Migraine	Nasal form of DHE	NDA filed 5/11. NDA resubmitted 10/16/12. FDA second complete response issued 4/15/13.

PRODUCT	MFR	ROUTE	INDICATION	PHARMACOLOGY	MARKET RELEASE
					NDA resubmitted 12/31/13.
Donepezil HCl/memantide ER (Arimenda)	Adamas	PO	Alzheimer's Disease	Fixed dose combination of NMDA receptor antagonist and an acetylcholinesterase inhibitor	NDA filed 3/4/14.
Vedolizumab (Entyvio)	Takeda	Inj (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 for Crohn's 6/18/14.
Naloxegol	Nectar/ Astra Zeneca	PO	Opioid-induced constipation	PEGylated tablet formulation of naloxol (an analogue of naloxone)	NDA filed 9/13. FDA action date 9/14/14.
Secukinumab (AIN-457)	Novartis	Inj (SC, IV)	Psoriatic arthritis, plaque psoriasis	Fully human monoclonal antibody targeting interleukin-17 (IL-17)	BLA submitted 10/13 (plaque psoriasis).
Reconest	Saliz	Inj (IV)	Hereditary angioedema	Complement C1r inhibitor-the major inhibitor of activated Hageman factor, plasmin and kallikrein of the coagulation pathway	BLA filed 4/13. FDA action date delayed until 7/16/14.
Ferric citrate (Zerenex)	Keryx	PO	Hyperphosphatemia	Small-molecule phosphate binder	NDA filed 8/13. FDA action date 6/7/14.
Interferon beta with PEG (Plegridy)	Biogen Idec	Inj (SC)	Multiple Sclerosis	Pegylated version of Avonex that allows every other	BLA filed 5/22/13. FDA action date

PRODUCT	MFR	ROUTE	INDICATION	PHARMACOLOGY	MARKET RELEASE
				week subcutaneous dosing	extended three months.