



March 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
Clocortolone pivalate	0.1 % cream pump	Dr. Reddy's Lab	Cloderm	02-13-2014
Clocortolone pivalate	0.1 % cream	Dr. Reddy's Lab	Cloderm	02-13-2014
Doxercalciferol	0.5 mcg capsule	Roxane Labs Prasco Labs	Hectorol	02-19-2014, 02-26-2014
Doxercalciferol	1 mcg capsule	Roxane Labs Prasco Labs	Hectorol	02-19-2014, 02-26-2014
Doxercalciferol	2.5 mcg capsule	Roxane Labs Prasco Labs	Hectorol	02-19-2014, 02-26-2014
Doxorubicin HCl	50 mg vial	Mylan	Adriamycin	02-26-2014
Lidocaine-prilocaine	2.5%-2.5% kit	Sandoz	Lidocaine-prilocaine	06-27-2005
Telmisartan HCTZ	40-12.5 mg tablet	Roxane Labs Mylan Torrent Pharm	Micardis HCT	02-28-2014, 03-07-2014, 02-26-2014
Telmisartan HCTZ	80-12.5 mg tablet	Roxane Labs Mylan Torrent Pharm	Micardis HCT	02-28-2014, 03-07-2014, 02-26-2014
Telmisartan HCTZ	80-25 mg tablet	Roxane Labs Mylan Torrent Pharm	Micardis HCT	02-28-2014, 03-07-2014, 02-26-2014
Testosterone cypionate	100 mg/ml vial	Sandoz	Depo-testosterone	10-17-2006

NEW DRUG ENTITIES

DESCRIPTION	BRAND NAME	GENERIC NAME	STRENGTH	NOTES
Dietary supplement, Miscellaneous	Nicadan	B3/B6/C/FA/COPPR/ MG/ZN/ALIP AC	800-10-100	New Entity
Dietary supplement, Miscellaneous	Rheumate	ME-THFOLATE GLUC/B12/HERB #236	1-1-500mg	New Entity
PKU TX AGENTCOFACTOR OF PHENYLALANINE HYDROXYLASE	Kuvan	SAPROPTERIN DIHYDROCHLORIDE	100mg	New Dosage Form
BETAADRENERGIC AND ANTICHOLINERGIC COMBINATIONS	Anoro Ellipta	UMECLIDINIUM BRM/VILANTEROL TR	62.5- 25mcg	New Entity

NEW INDICATIONS (EXISTING DRUGS)

KALYDECO™

February 21, 2014

U.S. Food and Drug Administration Approves (ivacaftor) for Use in Eight Additional Mutations that Cause Cystic Fibrosis. KALYDECO is the first medicine to treat the underlying cause of CF for people with specific mutations in the CFTR gene--KALYDECO facilitates increased chloride transport by potentiating the channel-open probability (or gating) of the CFTR protein--
-The eight additional mutations are present in approximately 150 people ages six and older in the United States-

BOSTON--(BUSINESS WIRE) - Vertex Pharmaceuticals Incorporated (NASDAQ: VRTX) today announced the U.S. Food and Drug Administration (FDA) approved a supplemental New Drug Application (sNDA) for KALYDECOTM (ivacaftor) for people with cystic fibrosis (CF) ages 6 and older who have one of eight additional mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene. KALYDECO was first approved in January 2012 for people with CF ages 6 and older who have at least one copy of the G551D mutation. With the approval of the sNDA, KALYDECO is now approved for use in people with CF with the following nine mutations: G551D, G178R, S549N, S549R, G551S, G1244E, S1251N, S1255P and G1349D. In the United States, approximately 150 people ages 6 and older have one of the additional eight mutations for which KALYDECO is now approve

Article link:<http://investors.vrtx.com/releasedetail.cfm?ReleaseID=827435>

Source website: <https://www.vrtx.com/>

FDA NEWS/BULLETINS/ADVISORIES/SAFETY ALERTS

The FDA Enforcement Report

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

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

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

Doribax (doripenem): Drug Safety Communication - Risk When Used to Treat Pneumonia on Ventilated Patients

[Posted: 1/17/2014]

ISSUE: The FDA has concluded that Doribax (doripenem), an antibacterial drug used to treat patients who develop pneumonia while on ventilators, carries an increased risk of death and lower clinical cure rates compared to use of imipenem and cilastatin for injection (marketed in the U.S. under the name Primaxin). Based on an FDA analysis of data from a three-year clinical trial that was prematurely stopped in 2011 due to these safety concerns, FDA approved changes to the Doribax drug label that describe these risks. The revised label includes a new warning about this unapproved use. Doribax is not approved to treat any type of pneumonia.

BACKGROUND: In the clinical trial that was stopped early, patients with ventilator associated bacterial pneumonia received either 7-day Doribax treatment or 10-day treatment with imipenem and cilastatin. In the intent-to-treat population, the 28-day all-cause mortality was higher in the Doribax arm (23.0%; n=31/135) than in the imipenem and cilastatin arm (16.7%; n=22/132). Clinical cure rates were also lower in the Doribax arm.

RECOMMENDATION: Health care professionals should consider whether the benefits of Doribax treatment is likely to exceed its potential risks in patients who develop pneumonia while on ventilators. Doribax is still considered safe and effective for its FDA approved indications - treatment of adults with complicated intra-abdominal infections and complicated urinary tract infections, including kidney infections (pyelonephritis)

Article link: [link: http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm388328.htm](http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm388328.htm)

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

DIANEAL PD-2 Peritoneal Dialysis Solution with 1.5 Percent Dextrose 6000mL: Recall - Contamination With Mold

[Posted: 3/6/2014]

ISSUE: Baxter International notified health professionals and their care organizations of the recall in the United States of a single lot of DIANEAL PD-2 Peritoneal Dialysis Solution with 1.5% Dextrose 6000ml to the hospital/user level. The recall is being initiated as a result of complaints of particulate matter, identified as mold. The affected lot is C903799, expiration 05/15 (product code L5B9710), NDC 00941-0411-11. Product affected by this recall was packaged in flexible plastic containers and distributed to dialysis centers, facilities, distributors and patients in the United States between May 2013 and January 2014.

BACKGROUND: DIANEAL is a peritoneal dialysis (PD) solution for use in chronic renal failure patients being maintained on PD therapy.

RECOMMENDATION: Baxter notified customers by recall letter to instruct customers to locate and remove any affected product from their facility. All patients who received product from the affected lot also were contacted by recall letter and provided instructions to arrange for product return. Dialysis centers, facilities, distributors and patients should stop use and return to place of purchase. As per product labeling, the container should be inspected visually for signs of leakage prior to use. Solutions that are cloudy, discolored, contain visible particulate matter, or show evidence of leakage should not be used

Article link: <http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm388323.htm>

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

Effexor XR 150 Mg Extended-Release Capsules (Pfizer) and Venlafaxine HCl 150 Mg Extended-Release Capsules (Greenstone): Recall - Possible Presence of Tikosyn Capsules

[Posted: 3/7/2014]

ISSUE: Pfizer Inc. issued a voluntary recall of one lot of 30-count Effexor XR(venlafaxine HCl) 150 mg extended-release capsules, one lot of 90-count Effexor XR (venlafaxine HCl) 150 mg extended-release capsules, and one lot of 90-count Greenstone LLC-branded Venlafaxine HCl 150 mg extended-release capsules. This action is being taken because of a pharmacist report that one bottle of Pfizer's Effexor XR contained one capsule of Tikosyn (dofetilide) 0.25mg in addition to the Effexor XR capsules. The use of Tikosyn by an Effexor XR/Venlafaxine HCl patient, where the contraindications and drug-drug interactions with Tikosyn have not been considered by the prescribing physician, could cause serious adverse health consequences that could be fatal. This recall is to the patient level and involves Pfizer lot numbers V130142 and V130140, which both expire in October 2015, and Greenstone lot number V130014, which expires in August 2015.



BACKGROUND: These products were distributed nationally to wholesalers, distributors, certain government agencies, patient assistance programs and retailers, such as pharmacies and hospitals. These direct customers are being notified by UPS next day mail, and Pfizer is arranging for the return of all recalled products.

RECOMMENDATION: Pharmacists should immediately quarantine, discontinue distribution of and return all recalled lots of these products, as well as notify any of their customers to whom they distributed the products. Patients with affected product should notify their physicians and/or return product to their pharmacies. Patients with questions regarding the return of product should contact Stericycle at 1-888-345-0481 (Monday to Friday 8am to 5pm ET). Patients with questions regarding this recall can contact Pfizer Medical Information at 1-800-438-1985 (Monday to Thursday 9am to 8pm ET or Friday, 9am to 5pm ET)

Article link: <http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm388352.htm>

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

STUDIES and RECENT TOPICS

More Americans Getting High Blood Pressure Under Control: CDC

February 12, 2014

Almost two-thirds of those enrolled in health plans have been properly treated, but more must be done. Efforts to help millions of Americans battling high blood pressure may be succeeding, but much more work needs to be done, U.S. health officials report. According to the U.S. Centers for Disease Control and Prevention, about two-thirds (64 percent) of people with high blood pressure had the problem "under control" during 2012, the latest year for which figures are available. The agency defined "controlled" blood pressure as readings at or below 140 mm Hg/90 mm Hg. But that still falls short of the 70 percent goal that the U.S. Department of Health and Human Services "Million Hearts" campaign set for 2017.

Article link: <http://consumer.healthday.com/cardiovascular-health-information-20/highblood-pressure-health-news-358/progress-being-made-in-getting-americans-bloodpressure-under-control-cdc-says-684847.html>

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

FDA Rejects Wider Use of J&J Xarelto for 3rd Time

February 14, 2014

Johnson & Johnson said Friday that the Food and Drug Administration has rejected — for a third time — its application to expand use of the blood thinner Xarelto to reduce dangerous blood clots and related problems in patients with coronary artery disease.

Article link: <http://www.businessweek.com/ap/2014-02-14/fda-rejects-wider-use-of-jand-j-xarelto-for-3rd-time>

Source website: <http://www.businessweek.com/>

Generic drug makers fight rule on health risk warnings

February 16, 2014

The proposed FDA regulation would close a legal loophole and allow patients to sue. An industry group predicts costs will soar, but others say it's the right thing to do. Companies that make generic drugs, the medications most Americans buy, are fighting to kill a proposed federal regulation that would require them for the first time to warn patients of all the known health risks of each drug they sell.

Article link: <http://www.latimes.com/nation/la-na-generic-drugs-20140217,0,6322393.story#ixzz2uGuwEkdC>

Source website: <http://www.latimes.com/>

Antidepressant Celexa May Help Ease Alzheimer's-Linked Agitation

February 18, 2014

Study finds it might be safer alternative to standard antipsychotics -- The antidepressant Celexa shows promise in easing the agitation people with Alzheimer's disease often suffer, and may offer a safer alternative to antipsychotic drugs, a new study finds.

Article link: <http://consumer.healthday.com/cognitive-health-information-26/alzheimer-news-20/antidepressant-celexa-may-help-ease-agitation-linked-to-alzheimer-s-disease-684922.html>

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

Many U.S. Seniors Get Prescription Painkillers From Multiple Doctors

February 19, 2014

Overuse raises risk for hospitalization, study finds -- About one-third of Medicare patients who get prescriptions for powerful narcotic painkillers receive them from multiple doctors, which raises their risk for hospitalization, according to a new study. Narcotics (also called opioids) include painkillers such as hydrocodone (Vicodin), oxycodone (Oxycontin) and morphine. Prescriptions for these drugs have risen sharply in the United States in the past 20 years -- as have overdoses.

Article link: <http://consumer.healthday.com/senior-citizen-information-31/misc-agingnews-10/one-third-of-elderly-patients-get-potent-painkillers-from-multiple-doctors-685010.html>

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

Lilly Lung Cancer Drug Improves Survival in late-Stage Trial

February 19, 2014

An experimental cancer drug developed by Eli Lilly, touted by some to be the company's next blockbuster, significantly improved survival rates in lung cancer patients, sending the company's shares up 3 percent in early trading. Lilly needs new drugs to offset declining sales of its older drugs as they lose patent protection. Ramucirumab, designed to treat multiple cancers, has the potential to generate annual sales of \$1.5 billion by 2020, according to some analysts.

Article link: <http://www.reuters.com/article/2014/02/19/us-lilly-study-lungcanceridUSBREA1111L20140219>

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

Avastin Shows Mixed Results Against Different Cancers

February 19, 2014

Drug improved survival by 4 months with cervical cancer, but no such benefit seen with brain tumors -- Clinical trials investigating new uses for the anti-cancer drug Avastin have produced mixed results. When combined with standard chemotherapy, Avastin extended the survival of patients with advanced cervical cancer by nearly four months, doctors reported in one trial.

Article link: <http://consumer.healthday.com/cancer-information-5/avastin-news-806/avastin-drug-trials-685044.html>

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

High Potency Statins Linked to Better Outcome Following Heart Attack

February 20, 2014

A study looking at the data of thousands of patients who suffered heart attacks has suggested treatment with high-potency statins offers a significantly improved chance of survival compared to those taking normal statins. The study, led by the University of Dundee, also found a combination of statins and the drug ezetimibe showed no improved survival rate, although researchers caution this finding needs further testing.

Article link: <http://www.sciencedaily.com/releases/2014/02/140220102923.htm>

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

FDA to Review Merck's New HPV Vaccine

February 20, 2014

Merck announced today that the Food and Drug Administration has accepted a marketing application for V503, its new vaccine against human papillomavirus, or HPV. The pharmaceutical giant currently sells Gardasil, which protects against four types of HPV. GlaxoSmithKline also sells an HPV vaccine, Cervarix, but it only guards against two types of HPV.

Article link: <http://www.fool.com/investing/general/2014/02/20/fda-to-review-mercksnew-hpv-vaccine.aspx>

Source website: <http://www.fool.com/?source=illsitima0000001>

> 14 Percent of Women Given an Opioid Rx During Pregnancy

February 20, 2014

Opioid dispensation split fairly evenly during all three trimesters, but highest in third Trimester. Opioids are fairly commonly dispensed during pregnancy, with 14.4 percent of women dispensed an opioid at some point during pregnancy, according to a study published online Feb. 12 in Anesthesiology.

Article link: <http://www.physiciansbriefing.com/Article.asp?AID=684964>

Source website: <http://www.physiciansbriefing.com/>

Use of Tylenol in Pregnancy Tied to Higher ADHD Risk in Child

February 24, 2014

Risk increases with longer use, researchers say; experts caution the finding needs verification. Expectant mothers suffering from fever or headache may face a new dilemma when they open the medicine cabinet. Pregnant women who take acetaminophen -- best known under the brand name Tylenol -- might be more likely to have a child with attention deficit-hyperactivity disorder (ADHD), a new long-term study suggests. Acetaminophen is the most commonly used over-the-counter medication for pregnant women who experience fever or pain.

Article link: <http://consumer.healthday.com/kids-health-information-23/attention-deficitdisorder-adhd-news-50/use-of-tylenol-in-pregnancy-tied-to-higher-adhd-risk-in-childstudy-685181.html>

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

Link Between BP Meds and Falls Affirmed for Some

February 24, 2014

Older adults with multiple chronic health conditions -- including hypertension -- appear to be at greater risk for sustaining serious fall injuries when treated for high blood pressure, an observational study showed.

Article link: <http://www.medpagetoday.com/Cardiology/Hypertension/44460>

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

FDA Unveils First U.S. Testing of Generic Drugs

February 24, 2014

The Food and Drug Administration has begun the nation's first widespread testing program for generic drugs that make up almost 80 percent of U.S. prescriptions. The \$20 million effort, coming as concerns grow about the quality of products from abroad, started in September

without any public notice. At least a dozen academic centers are involved in a testing program that will run through 2017, agency officials confirmed. The research this year will focus on heart drugs, ADHD treatments, immunosuppressants, anti-seizure medicines and antidepressants. Results aren't yet available.

Article link: http://www.washingtonpost.com/national/health-science/fda-unveils-first-ustesting-of-generic-drugs/2014/02/22/b5b12a70-9b28-11e3-ad71-e03637a299c0_story.html
Source website: <http://www.washingtonpost.com/>

FDA approves adding radiographic data to Xeljanz label

February 24, 2014

The FDA approved a supplemental new drug application to update the label of Pfizer's tofacitinib citrate 5 mg tablets with data from two phase 3 trials demonstrating a reduction in radiographic progression in patients with rheumatoid arthritis, the company announced.

Article link: <http://www.healio.com/rheumatology/rheumatoidarthritis/news/online/%7B87d9a4af-c3f5-4a04-90f5-1a79a4dfc51b%7D/fda-approvesadding-radiographic-data-to-xeljanz-label>
Source website: <http://www.healio.com/>

Prescriptions higher for women, long a target of tranquilizer ads

February 25, 2014

When it comes to benzodiazepines — tranquilizers that are often used in a deadly combination with opioids — women are prescribed the drugs more than twice as often as men. In 2013, 61 million benzodiazepine prescriptions were written for women, compared with 29 million for men, according to data provided to the Milwaukee Journal Sentinel and MedPage Today by IMS Health, a drug market research firm. That uneven usage may be a legacy of drug company advertising that from the beginning targeted women.

Article link: <http://www.jsonline.com/watchdog/watchdogreports/prescriptions-higher-forwomen-long-a-target-of-tranquilizer-ads-b99202401z1-247184351.html>
Source website: <http://www.jsonline.com/>

Lilly weekly diabetes drug as effective as market leader Victoza-study

February 25, 2014

An experimental once-weekly medicine for type 2 diabetes developed by Eli Lilly proved as effective in lowering blood sugar as Victoza from Danish drugmaker Novo Nordisk in an eagerly anticipated late stage study. The Lilly drug, dulaglutide, achieved the primary goal of the 599-patient study by demonstrating so-called non-inferiority to the highest approved dose of

Victoza after 26 weeks, according to initial results released by the company on Tuesday. Lilly shares rose more than 1 percent before retreating.

Article link: <http://in.reuters.com/article/2014/02/25/lilly-diabetesidINL1N0LU1DO20140225>

Source website: <http://in.reuters.com/>

Study Sees No Evidence Linking Diabetes Drugs With Pancreatic Cancer

February 26, 2014

But FDA assessment calls for further look at injectable type-2 treatments. There's no firm evidence that the type 2 diabetes medications known as incretin-based drugs cause pancreatitis or pancreatic cancer, U.S. and European health officials say. But it's too early to say there's definitely no link between the injectable drugs and pancreatitis or pancreatic cancer, according to the safety assessment by the FDA and its counterpart overseas, the European Medicines Agency (EMA).

Article link: <http://consumer.healthday.com/cancer-information-5/mis-cancer-news-102/no-evidence-linking-diabetes-drugs-with-pancreatic-cancer-study-685240.html>

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

Groups Push FDA to Revoke Approval of Highly Potent Painkiller

February 26, 2014

One dose of Zohydro could kill a child, say coalition of consumer advocates, addiction Specialists. Dozens of experts and health care agencies sent a letter this week urging that the FDA revoke its approval of the supercharged painkiller, Zohydro. In the petition sent to the FDA on Wednesday, more than 40 consumer watchdog groups, addiction treatment groups and others noted that the drug was approved despite significant resistance from the FDA's own advisory committee, which voted 11-2 against allowing Zohydro to be sold.

Article link: <http://consumer.healthday.com/mental-health-information-25/addictionnews-6/experts-push-fda-to-revoke-approval-of-highly-potent-painkiller-685259.html>

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

Not All Acute Coronary Syndrome Patients Get Appropriate Tx

February 26, 2014

About one in five not receiving angiotensin-converting enzyme inhibitors, receptor blockers per guidelines -- Nearly one in five eligible patients hospitalized for acute coronary syndrome do not receive American College of Cardiology/American Heart Association (ACC/AHA) class I guideline - recommended angiotensin-converting enzyme inhibitor (ACEI) or angiotensin receptor blocker (ARB) therapy, according to a study published online Feb. 25 in Circulation: Cardiovascular Quality and Outcomes.

Article link: <http://www.physiciansbriefing.com/Article.asp?AID=685175>

Source website: <http://www.physiciansbriefing.com/>

Eliquis earns best safety score in its class in analysis of FDA adverse event reports

February 26, 2014

What's the safest anticoagulant? According to AdverseEvents, which analyzes and distills data filed with the FDA, that would be Eliquis, the latest entrant into the warfarin alternative market. After running adverse event reports filed with the FDA through its filters and algorithms, AdverseEvents found Eliquis (apixaban) to be significantly safer than its rivals. Marketed by Bristol-Myers Squibb and Pfizer, the drug showed up with an "RxScore"--the data firm's scale of safety--of 39.45 on a 100-point scale, with 100 representing the highest risk.

Article link: <http://www.fiercepharma.com/story/eliquis-earns-best-safety-score-its-classanalysis-fda-adverse-event-report/2014-02-26>

Source website: <http://www.fiercepharma.com/>

FDA advisory committees turn down Primatene HFA application for OTC status

February 26, 2014

A pair of Food and Drug Administration advisory committees on Tuesday voted against the over-the-counter sale of Armstrong Pharmaceuticals' Primatene HFA, an epinephrine inhalation aerosol indicated for the temporary relief of mild symptoms of intermittent asthma for people ages 12 years or older.

Article link: <http://www.drugstorenews.com/article/fda-advisory-committees-turn-downprimatene-hfa-application-otc-status?ad=latest-news>

Source website: <http://www.drugstorenews.com/>

New pain pill's approval: 'Genuinely frightening'

February 26, 2014

A potent little painkiller is causing a big stir. A coalition of more than 40 health care, consumer and addiction treatment groups is urging the Food and Drug Administration to revoke approval of the prescription drug Zohydro. The hydrocodone-based drug is the latest in a long line of painkillers called opioid analgesics. The FDA approved the medication last fall to treat chronic pain, and it is set to become available to patients in March.

Article link: <http://www.cnn.com/2014/02/26/health/zohydro-approval>

Source website: <http://www.cnn.com/>

Newer diabetes drugs cost more, but may not work better

February 27, 2014

Two newer classes of drugs to treat adult-onset diabetes may be no more effective than the old standby, yet they cost significantly more over the course of a patient's disease. That's according to a National Science Foundation-funded study by researchers at the University of Michigan, Mayo Clinic and North Carolina State University.

Article link: <http://ns.umich.edu/new/releases/22014-newer-diabetes-drugs-cost-morebut-may-not-work-better>

Source website: <http://ns.umich.edu/>

The FDA Opens Its Vast Files on Drug Side Effects to the Public

February 27, 2014

Thousands of times each day, the U.S. Food and Drug Administration receives reports about unwanted side effects of the prescription and over-the-counter medications it oversees. They stream in from patients and doctors—and from drugmakers, which are required to relay accounts of problems. This data, cataloging reactions as mild as rashes and headaches and as serious as internal bleeding and death, help the agency monitor drug safety. With millions of records created since the system began in 1998, it's the world's most extensive record of how drugs interact with the human body.

Article link: <http://www.businessweek.com/articles/2014-02-27/fda-opens-its-files-ondrug-side-effects-to-public>

Source website: <http://www.businessweek.com/>

Actelion diarrhea treatment gets fast-track from U.S. FDA

February 27, 2014

Actelion, Europe's biggest biotech company, said on Thursday that the U.S. health regulator has granted fast-track status to its antibiotic treatment for diarrhea. A fast track designation by the FDA speeds up regulatory review of drugs that aim to treat serious diseases and fill unmet medical needs.

Article link: <http://www.reuters.com/article/2014/02/27/us-actelion-diarrhoea-fdaidUSBREA1Q1TZ20140227>

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

Groups urge FDA to halt launch of Zohydro pain drug

February 27, 2014

A coalition of addiction experts, physicians and others is urging U.S. health officials to reverse course and block the launch of a powerful painkiller called Zohydro, expected to hit the market next month. The opioid drug, manufactured by Zogenix Inc, contains a potent amount of an active ingredient that could be lethal to new patients and children and is not safer than other current pain drugs, the groups told the Food and Drug Administration.

Article link: <http://www.reuters.com/article/2014/02/27/us-usa-fda-zohydroidUSBREA1Q1VT20140227>

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

Chronically ill facing high drugs costs under U.S. health law

February 28, 2014

President Barack Obama's ban on discriminatory health insurance practices against the sick has not stopped insurers from increasing up-front charges for the expensive drugs needed to control chronic illnesses from leukemia to multiple sclerosis.

Article link: <http://www.reuters.com/article/2014/02/28/us-usa-healthcare-costsidUSBREA1R08420140228?feedType=RSS&feedName=healthNews>

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

Pradaxa, Xarelto makers dispute purported Eliquis safety edge

February 28, 2014

Is Pfizer and Bristol-Myers Squibb's Eliquis really safer than its competitors? A recent analysis of FDA adverse events reports suggested that it is. Clinical trials certainly found it safer than warfarin, the old anticoagulant these new generation clot-fighters seek to replace. And before Eliquis (apixaban) won FDA approval, analysts figured it would snap up market share precisely because clinical trials hinted that it might work better.

Article link: http://www.fiercepharma.com/story/pradaxa-xarelto-makers-disputepurported-eliquis-safety-edge/2014-02-28?utm_medium=nl&utm_source=internal

Source website: <http://www.fiercepharma.com/>

Generic drugmakers ramp up campaign against FDA label proposal

February 28, 2014

Generic drugmakers are furiously campaigning against a proposed U.S. rule that would require them to change the prescribing information on their products if they receive new safety information, which they say would open them to product liability lawsuits.

Article link: <http://www.cnbc.com/id/101457443>

Source website: <http://www.cnbc.com/>

Common Asthma Meds May Raise Sleep Apnea Risk, Study Says

February 28, 2014

Medicines commonly used to control asthma may increase the risk of a potentially serious sleep problem in some people, a small, early study suggests. "Inhaled corticosteroids may predispose to sleep apnea in some asthma patients," said study author Dr. Mihaela Teodorescu, an associate professor of medicine at the University of Wisconsin School of Medicine and Public Health, in Madison.

Article link: <http://consumer.healthday.com/respiratory-and-allergy-information-2/asthma-news-47/do-common-asthma-medicines-raise-sleep-apnea-risk-685108.html>

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

Steroids Often Prescribed for Psoriasis, Countering Guidelines

February 28, 2014

Although corticosteroid pills are not recommended for the management of psoriasis, new research reveals these drugs are commonly prescribed by dermatologists treating this chronic skin condition.

Article link: <http://consumer.healthday.com/general-health-information-16/doctor-news-206/countering-guidelines-steroid-pills-often-prescribed-for-psoriasis-685155.html>

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

Lipitor: Pfizer Aims to Sell Over-the-Counter Version

March 2, 2014

Pfizer is forging ahead in its quest to sell an over-the-counter version of blockbuster cholesterol pill Lipitor, hoping to overcome skepticism that consumers can take the drug appropriately without doctor guidance.

Article link: http://online.wsj.com/news/articles/SB10001424052702304071004579410930136742414?mod=ITP_marketplace_0&mg=reno64-wsj&url=http%3A%2F%2Fonline.wsj.com

wsj.com%2Farticle%2FSB10001424052702304071004579410930136742414.html%3Fmod%3DTP_marketplace_0

Source website: <http://online.wsj.com/>

Teva Braces for Tussle With Insurers Over Copaxone's Heir

March 2, 2014

Teva is using records from its 24-hour support hotline in the U.S. to persuade thousands of multiple sclerosis patients to switch from its biggest-selling drug, Copaxone, to a new version that has patent protection until 2030.

Article link: <http://www.bloomberg.com/news/2014-03-02/teva-braces-for-tussle-withinsurers-over-copaxone-s-heir.html?cmpid=yhoo>

Source website: <http://www.bloomberg.com/>

Rare Mutation Kills Off Gene Responsible for Diabetes

March 2, 2014

A new study based on genetic testing of 150,000 people has found a rare mutation that protects even fat people from getting Type 2 diabetes. The effect is so pronounced — the mutation reduces risk by two-thirds — that it provides a promising new target for developing a drug to mimic the mutation's effect.

Article link: <http://www.nytimes.com/2014/03/03/health/rare-gene-protects-againsttype-2-diabetes-even-in-obese-people.html?action=click&module=Search®ion=searchResults%230&version=&url=http%3A%2F%2Fquery.nytimes.com%2Fsearch%2Fsitesearch%2F%23%2Fdrug%2Fsince1851%2Fa>

Source website: <http://www.nytimes.com/>

AbbVie Hepatitis C Combo Cures Almost All in Late Study

March 3, 2014

AbbVie's combination hepatitis C therapy cured almost all patients in a late stage study, moving the company closer to marketing a treatment that will compete with Gilead Sciences and Bristol-Myers Squibb. In a trial in 419 patients, AbbVie's as-yet-unnamed drug cocktail cured 99 percent of those given it after 12 weeks, regardless of whether they added the older booster medicine ribavirin, the North Chicago-based company said today at the Conference on Retroviruses and Opportunistic Infections in Boston. AbbVie said it will seek U.S. approval this quarter.

Article link: <http://www.bloomberg.com/news/2014-03-03/abbvie-hepatitis-c-combocures-almost-all-in-late-study.html>

Source website: <http://www.bloomberg.com/>

South African scientists map HIV antibodies in vaccine hunt

March 3, 2014

Scientists in South Africa have mapped the evolution of an antibody that kills different strains of the HIV virus, which might yield a vaccine for the incurable disease, the National Institute of Communicable Diseases said on Monday.

The scientists have been studying one woman's response to HIV infection from stored samples of her blood and isolated the antibodies that she developed, said Lynn Morris, head of the virology unit at the NICD.

Article link: <http://www.reuters.com/article/2014/03/03/us-safrica-hividUSBREA221IJ20140303>

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

Durable melanoma remission seen with Bristol immunotherapy drug

March 4, 2014

A drug that uses the body's own immune system to kill cancer cells has produced lasting remissions - some as long as two years - in patients with melanoma that had spread to other parts of the body, according to data published on Monday.

Article link: <http://in.reuters.com/article/2014/03/03/cancer-melanoma-bristolidINL1N0LX1R720140303>

Source website: <http://in.reuters.com/>

U.S. Hospitals Overuse, Misuse Antibiotics, CDC Says

March 4, 2014

Many hospitals across the United States overuse or misuse antibiotics, which fuels the growth of drug-resistant bacteria, federal health officials warned Tuesday. Doctors in some hospitals prescribe three times more antibiotics than doctors in the same departments at other medical centers, according to a new report from the U.S. Centers for Disease Control and Prevention.

Article link: <http://consumer.healthday.com/infectious-disease-information-21/antibioticsnews-30/hospitals-overuse-misuse-antibiotics-cdc-685478.html>

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

FDA launches orphan drug web resources

March 4, 2014

The U.S. Food and Drug Administration's Office of Orphan Products Development has launched a web-based resource of rare disease topics for patients and industry. The agency created the educational resource on FDA-related rare disease topics, with the FDA Center for Drug Evaluation and Research, according to FDA Consumer Health Information.

Article link: <http://www.delawareonline.com/story/delawareinc/2014/03/04/fda-healthorphan-drugs/6023573/>

Source website: <http://www.delawareonline.com/>

Insurers, Medicaid fear multibillion-dollar hepatitis C drug tab

March 4, 2014

U.S. health insurers are seeking help from state health officials to foot the bill for a new generation of hepatitis C treatments that could cost the nation \$200 billion or more in the next five years. Several insurers, including Molina Healthcare, which administer health plans for California's Medicaid program for the poor are asking states to step in and pay for Gilead Sciences's Sovaldi, a drug that costs \$84,000 per patient. The wrangling has reopened a national debate on how much the United States can afford to spend on the newest, costliest medications.

Article link: <http://www.reuters.com/article/2014/03/04/us-health-hepatitisidUSL1N0M10Z720140304>

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

FDA spurns Lilly, Boehringer diabetes drug, cites factory problems

March 5, 2014

Eli Lilly and partner Boehringer Ingelheim said U.S. regulators have declined to approve their experimental diabetes drug empagliflozin, citing previously observed problems at a facility where it would be made.

Article link: <http://www.reuters.com/article/2014/03/05/us-lilly-diabetesidUSBREA241DZ20140305>

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

Study Gives Hope of Altering Genes to Repel H.I.V.

March 5, 2014

The idea of genetically altering people's cells to make them resist the virus that causes AIDS may seem like a pipe dream, but a new report suggests it can be done. The research involves

the first use in humans of “gene editing,” a treatment that zeros in on a particular gene and disables it.

Article link: http://www.nytimes.com/2014/03/06/health/study-gives-hope-of-alteringgenes-to-repel-hiv.html?_r=0

Source website: <http://www.nytimes.com/>

DEA pushes forward on rescheduling hydrocodone combination products

In what could turn into a significant change of how retail pharmacy supplies hydrocodone combination products, the Drug Enforcement Administration last week published in the Federal Register a Notice of Proposed Rulemaking to move HCPs from Schedule III to Schedule II, as recommended by the assistant secretary for Health of the department of Health and Human Services and as supported by the DEA’s evaluation of relevant data.

Article link: <http://www.drugstorenews.com/article/dea-pushes-forwardreschedulinghydr-ocodone-combination-products>

Source website: <http://www.drugstorenews.com/>

Bristol-Myers’ AIDS Medicine Controls Virus in Study

March 5, 2014

Bristol-Myers Squibb’s experimental HIV drug controlled the virus as well as the company’s older treatment Reyataz in a study that suggests the medicine may help difficult-to-treat patients.

Article link: <http://www.bloomberg.com/news/2014-03-05/bristol-myers-aids-medicinecontrols-virus-in-study.html>

Source website: <http://www.bloomberg.com/>

Value-Based Insurance Plans Can Up Rx Adherence

March 5, 2014

Value-based insurance design (VBID) plans with certain features aside from solely lowering cost sharing can increase medication adherence, according to a study published in the March issue of Health Affairs. Niteesh K. Choudhry, M.D., Ph.D., from Harvard University in Boston, and colleagues evaluated 76 VBID plans introduced by a large pharmacy benefit manager from 2007 to 2010.

Article link: <http://www.physiciansbriefing.com/Article.asp?AID=684969>

Source website: <http://www.physiciansbriefing.com/>

Teens Likely to Get Opioid Rx for Headaches

March 6, 2014

Nearly half of teens who visit a doctor complaining of headache pain walk away with a prescription for a narcotic painkiller, researchers found. And teens who sought headache treatment at an emergency department were twice as likely to get an opioid for their headache as those who saw a doctor in a different setting.

Article link: <http://www.medpagetoday.com/Pediatrics/GeneralPediatrics/44647>

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

Chemo drug helps HIV patients respond to Sangamo gene therapy

March 6, 2014

Treating HIV patients first with a chemotherapy drug improved their response to an experimental gene-modifying technique for controlling the virus, according to Sangamo BioSciences. The company presented new data from a small early-stage trial of its treatment, SB-728-T, on Thursday at the Conference on Retroviruses and Opportunistic Infections in Boston.

Article link: <http://www.reuters.com/article/2014/03/06/us-hiv-sangamoidUSBREA242EA20140306>

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

Prescriptions for benzodiazepines rising and risky when combined with opioids, researchers warn

March 6, 2014

Prescriptions for benzodiazepines are rising in primary care, and their frequent combined use with opioid analgesics may be contributing to medication-related deaths, a finding that goes largely unreported, according to Stanford researchers.

Article link: <http://www.sciencedaily.com/releases/2014/03/140306211040.htm>

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

Pfizer recalls 104,000 bottles of antidepressant Effexor XR

March 7, 2014

The largest drugstore chains have been in a legal battle with Pfizer, accusing it of conspiring to keep generics of its antidepressant Effexor XR out of their stores for years. Now they will have to deal with losing some of the real thing. Pfizer is recalling three lots of the drug after a pharmacist discovered a capsule of one of Pfizer's heart pills in an Effexor XR bottle, a potentially fatal combo.

Article link: <http://www.fiercepharma.com/story/pfizer-recalls-104000-bottlesantidepressant-effexor-xr/2014-03-07>

Source website: <http://www.fiercepharma.com/>
Antibiotics May Be Linked to Serious Infections in Children

Missouri Legislature passes bill to lower cost of anti-cancer pills for patients

After a debate filled with personal stories of dealing with the ravages of cancer, the Missouri House passed on Thursday and sent to the governor a compromise bill aimed at making oral anti-cancer drugs more affordable. Currently, the pills can cost thousands of dollars a month, forcing patients to choose cheaper intravenous treatment instead.

Article link: http://www.stltoday.com/news/local/govt-and-politics/virginiayoung/missouri-legislature-passes-bill-to-lower-cost-of-anti-cancer/article_db1f480d-340a-52e9-8a58-db0a76636824.html

Source website: <http://www.stltoday.com/>

Antibiotics May Be Linked to Serious Infections in Children

March 7, 2014

Antibiotics prescribed in doctors' offices are linked with many cases of serious bacterial infections that can cause severe diarrhea in children, according to a new study. Researchers found that 71 percent of cases of Clostridium difficile infection among American children aged 1 to 17 occurred shortly after they took antibiotics that were prescribed in doctors' offices to treat other conditions.

Article link: <http://consumer.healthday.com/infectious-disease-information-21/antibioticsnews-30/antibiotics-linked-to-serious-infections-in-children-685593.html>

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

FDA probes cognitive impact of new cholesterol drugs

March 7, 2014

The Food and Drug Administration has asked Regeneron and Sanofi to assess potential neurocognitive side effects of their experimental cholesterol drug, Sanofi said in its annual report on Friday. Amgen, which is developing a similar drug, said it has also been in communication with the agency.

Article link: <http://www.reuters.com/article/2014/03/07/us-regeneron-cholesterolidUSBREA261KU20140307>

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

Ranbaxy recalls some batches of generic Lipitor in latest quality blow

March 8, 2014

Indian drugmaker Ranbaxy, reeling under a flurry of regulatory rebukes due to manufacturing quality concerns, has recalled more than 64,000 bottles of the generic version of a cholesterol-lowering drug in the United States after dosage mix-up was detected.

Article link: <http://www.reuters.com/article/2014/03/08/us-ranbaxylab-lipitor-usa-recallidUSBREA2703420140308>

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

Half of Veterans Prescribed Medical Opioids Continue to Use them Chronically

March 8, 2014

Of nearly 1 million veterans who receive opioids to treat painful conditions, more than half continue to consume opioids chronically or beyond 90 days, new research says. Results presented at the 30th Annual Meeting of the American Academy of Pain Medicine reported on a number of factors associated with opioid discontinuation with the goal of understanding how abuse problems take hold in returning veterans.

Article link: <http://www.sciencedaily.com/releases/2014/03/140308094821.htm>

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

3 Regimens Hold HIV in Check Without Efavirenz

March 8, 2014

Three different regimens for treating patients with HIV infection -- one using the twice daily integrase inhibitor raltegravir (Isentress) and two based with the ritonavir-boosted protease inhibitors atazanavir (Reyataz) and darunavir (Prezista) -- effectively suppressed the virus, researchers said here.

Article link: <http://www.medpagetoday.com/MeetingCoverage/CIBD/44675>

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

Prices of New Hepatitis C Drugs are Tough to Swallow for Insurers

March 9, 2014

Hepatitis C drugs Sovaldi and Olysio offer much better cure rates than other therapies, but they can cost up to \$1,000 a pill, a potentially staggering cost to taxpayers and health plans. A pair of new drugs to treat hepatitis C offer a cure for millions of Americans afflicted with the disease -- but at a potentially staggering cost to taxpayers and health plans.

Article link: <http://www.latimes.com/business/la-fi-hepatitis-c-drug-costs-20140310,0,53084>

61.story#axzz2vbF4hW24

Source website: <http://www.latimes.com/>

Teva Copaxone Appeal Action Delayed by U.S. Supreme Court

March 10, 2014

The U.S. Supreme Court deferred a decision on whether to hear an appeal by Teva that aims to delay generic competition to its top selling Copaxone multiple-sclerosis drug. The justices took no action today on Teva's bid for a hearing and are now scheduled to consider the case at their March 21 private conference, according to the court's public docket.

Article link: <http://www.bloomberg.com/news/2014-03-10/teva-copaxone-appeal-actiondelayed-by-u-s-supreme-court.html>

Source website: <http://www.bloomberg.com/>

Sun Pharma, Ranbaxy Recall Some Generic Drug Batches in U.S.

March 10, 2014

Indian generic-drug makers Sun Pharma and Ranbaxy recalled some batches of drugs in the U.S. after separate complaints of bottling mix-ups. Sun Pharma is recalling a batch of generic diabetes tablets after a customer complained of finding pills of an epilepsy medication mixed in. Separately, rival Ranbaxy pulled two batches of its version of Pfizer's Lipitor cholesterol-lowering drug from the U.S. market. Both recalls were listed in the Food and Drug Administration's enforcement report for the week of March 5.

Article link: <http://www.bloomberg.com/news/2014-03-10/sun-pharma-ranbaxy-recallsome-generic-drug-batches-in-u-s-.html>

Source website: <http://www.bloomberg.com/>

Indian Supplier for Drugmakers Warned By U.S. FDA

March 11, 2014

An Indian company that says it supplies ingredients for major drugmakers was warned by U.S. regulators for forging test results and failing to properly clean equipment. The Food and Drug Administration is stepping up enforcement in India where growing quality concerns have led the agency to ban U.S. sales from some factories. Canton Laboratories was warned in a letter dated Feb. 27 for a variety of manufacturing practices, including reporting results for tests it never performed to measure microorganisms in active ingredients and failing to ensure equipment was cleaned to prevent contamination.

Article link: <http://www.bloomberg.com/news/2014-03-11/indian-supplier-fordrugmakers-warned-by-u-s-fda.html>

Source website: <http://www.bloomberg.com/>

Statins May Lower Blood Clot Risk Following joint Replacement Surgery

March 11, 2014

Statins have long been known to lower cholesterol and, more recently, to decrease the risk of deep vein thrombosis (blood clots) in healthy, non-surgical patients. New, first-of-its-kind research presented today at the 2014 Annual Meeting of the American Academy of Orthopaedic Surgeons (AAOS), found that statins, when used in conjunction with conventional blood clot prevention therapies, significantly reduced the risk for venous thromboembolic (VTE) events following total joint replacement (TJR) surgery.

Article link: http://www.sciencedaily.com/releases/2014/03/140311101305.htm?utm_source=feedburner&utm_medium=feed&utm_campaign=Feed%3A+sciencedaily+%28Latest+Science+News+--+ScienceDaily%29

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

Report Says Medication Use is Rising for Adults with Attention Disorder

March 12, 2014

The number of young American adults taking medications for attention deficit hyperactivity disorder nearly doubled from 2008 to 2012, according to a report to be released Wednesday by the nation's largest prescription drug manager.

Article link: http://www.nytimes.com/2014/03/12/us/report-says-medication-use-is-rising-for-adults-with-attention-disorder.html?partner=rss&emc=rss&_r=1

Source website: <http://www.nytimes.com/>

Purdue Pill May Force Zogenix's Rival Drug Off Market

March 12, 2014

Purdue Pharma plans to apply for regulatory approval of a tamper-resistant competitor to Zogenix's powerful pain pill, a move that could get its rival's drug pulled from the market by U.S. regulators. Purdue's experimental drug hydrocodone bitartrate met the goal of reducing chronic low-back pain in a final-stage trial, the closely held company said today in a statement. Purdue's pill is hard to crush and snort or inject, while Zogenix's Zohydro ER doesn't have abuse-deterrent features.

Article link: <http://www.bloomberg.com/news/2014-03-12/purdue-pill-may-forcezogenix-s-rival-drug-off-market.html>

Source website: <http://www.bloomberg.com/>

RECALLS

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
Drugs	B-50 capsules	Lot numbers: C02R and F03Q	Class I	Marketed without an Approved NDA/ANDA; product found to contain methasterone and dimethazine which are steroid and/or steroid-like drug ingredients, making it an unapproved new drug	Mira Health Products Ltd.
Drugs	BEST Slim, Dietary Supplement, 100%	All lots (lot 109400, Exp 12/31/2016)	Class I	Marketed without an Approved NDA/ANDA: Product contains an undeclared drug, sibutramine, making it an unapproved new drug.	CTV Best Group
Drugs	Dextrose* Vial In Sterile Water, 50%, 50 mL Single Dose Vial	All unexpired lots, manufactured and distributed between 07/01/2013 and 10/19/2013; including Lot #s: 07222013@19, 07222013@22, 07222013@23, 07222013@24, Exp 10/20/13; 07232013@1, 07232013@2, 07232013@3, 07232013@5, Exp 10/21/13; 07252013@1, 07252013@3, 07252013@4, 07252013@5, Exp 10/23/13; 07302013@24,	Class I	Non-Sterility: 50% dextrose is being recalled after particulate matter, later identified as mold, was found floating in the product.	Specialty Medicine Compounding Pharmacy, P.C.

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
		07302013@28, 07302013@30, 07302013@31, 07302013@32, Exp 10/28/13; 08052013@4, 08052013@6, 08052013@7, 08052013@8, 08052013@9, 08052013@10, Exp 11/03/13; 08092013@1, 08092013@8, 08092013@3, 08092013@4, 08092013@5, 08092013@6, Exp 11/07/13; 08122013@1, 08122013@3, 08122013@4, 08122013@5, 08122013@6, 08122013@7, Exp 11/10/13; 08162013@1, 08162013@3, 08162013@4, Exp 11/14/13; 08192013@2, 08192013@4, Exp 11/17/13			
Drugs	METHA-DROL Extreme capsules	lot number: L54Q	Class I	Marketed without an Approved NDA/ANDA; product found to contain dimethazine which is a steroid and/or steroid-like drug ingredient, making it an unapproved new drug	Mira Health Products Ltd
Drugs	Super-DMZ Rx 2.0 Capsules	lot numbers: 1) M55Q (A) Exp	Class I	Marketed without an Approved	Mira Health Products Ltd.

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
		04/2016, 2) M55Q (2) Exp 05/16, 3)E07Q Exp unknown		NDA/ANDA; product contains the steroid ingredient 2, 17a-dimethyl-17b-hydroxy-5a-androst-1-en-3-one, making it an unapproved new drug	
Drugs	0.9% Sodium Chloride Injection, USP 1000 mL Flexible Container	Lot 34-609-FW; Exp 10/15	Class II	Lack of Assurance of Sterility:Solution leaking through the port cover of the primary container, which was identified during a retain sample visual inspection.	Hospira Inc.
Drugs	5-Fluorouracil pf in methocel 1% ophth	All lot numbers within expiry.	Class II	Lack of Sterility Assurance: All lots of sterile products compounded by the pharmacy that are not expired due to concerns associated with quality control procedures that present a potential risk to sterility assurance that were observed during a recent FDA inspection.	Natures Pharmacy & Compounding Center
Drugs	Acetylcysteine 10% ophthalmic	All lot numbers within expiry.	Class II	Lack of Sterility Assurance: All lots of sterile products compounded by the pharmacy that are not expired due to concerns associated with quality control procedures that present a potential risk to sterility assurance that were observed during a	Natures Pharmacy & Compounding Center

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
				recent FDA inspection.	
Drugs	Alprazolam 1 mg Tablets	Lot # 1826E131, Exp 04/2015	Class II	Failed Tablet/Capsule Specifications: Complaints were received for significant tablet erosion for Alprazolam 1 mg.	Actavis Elizabeth LLC
Drugs	Alprazolam Extended-Release Tablets, USP, 3 mg	Lot #: 57617531, Exp 03/14	Class II	Failed Dissolution Specifications: Product did not meet specification requirements for dissolution.	Actavis Elizabeth LLC
Drugs	AMP/M-B12/Pyridox/Methionine Inositol	All lot numbers within expiry.	Class II	Lack of Sterility Assurance: All lots of sterile products compounded by the pharmacy that are not expired due to concerns associated with quality control procedures that present a potential risk to sterility assurance that were observed during a recent FDA inspection.	Natures Pharmacy & Compounding Center
Drugs	Atorvastatin Calcium Tablets, 10 mg	2407255, 2407256 Exp. 05/14	Class II	Presence of Foreign Tablets: A product complaint was received by a pharmacist who discovered an Atorvastatin 20 mg tablet inside a sealed bottle of 90-count Atorvastatin 10 mg.	Ranbaxy Inc.
Drugs	Bleomycin Sulfate 1unit/ml	All lot numbers within expiry.	Class II	Lack of Sterility Assurance: All lots of sterile products compounded by the pharmacy that are	Natures Pharmacy & Compounding Center

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
				not expired due to concerns associated with quality control procedures that present a potential risk to sterility assurance that were observed during a recent FDA inspection.	
Drugs	Bupivacaine HCl Inj. USP, 0.5% (5 mg/mL)	Lot 25-097-DK; Exp 01/01/2015	Class II	Presence of Particulate Matter: Confirmed customer report of visible particulate embedded in the glass vial.	Hospira Inc.
Drugs	Clonazepam Tablets, USP 2 mg tablets	lot 58468552 Exp. 05/15	Class II	Subpotent Drug: During routine stability testing one tablet was found with tablet weight below specification.	Actavis Elizabeth LLC
Drugs	Cyano B-12 (Cmpd) 1000mcg/ml	All lot numbers within expiry.	Class II	Lack of Sterility Assurance: All lots of sterile products compounded by the pharmacy that are not expired due to concerns associated with quality control procedures that present a potential risk to sterility assurance that were observed during a recent FDA inspection.	Natures Pharmacy & Compounding Center
Drugs	Cyano B-12 p-f 1000mcg/ml	All lot numbers within expiry.	Class II	Lack of Sterility Assurance: All lots of sterile products compounded by the pharmacy that are not expired due to concerns associated	Natures Pharmacy & Compounding Center

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
				with quality control procedures that present a potential risk to sterility assurance that were observed during a recent FDA inspection.	
Drugs	Cyanocobalamin 100mcg/ml injection	All lot numbers within expiry.	Class II	Lack of Sterility Assurance: All lots of sterile products compounded by the pharmacy that are not expired due to concerns associated with quality control procedures that present a potential risk to sterility assurance that were observed during a recent FDA inspection.	Natures Pharmacy & Compounding Center
Drugs	Dexamethasone (pf) 0.05 % opth	All lot numbers within expiry.	Class II	Lack of Sterility Assurance: All lots of sterile products compounded by the pharmacy that are not expired due to concerns associated with quality control procedures that present a potential risk to sterility assurance that were observed during a recent FDA inspection.	Natures Pharmacy & Compounding Center
Drugs	Dexamethasone phosphate 24mg/ml inj	All lot numbers within expiry.	Class II	Lack of Sterility Assurance: All lots of sterile products compounded by the pharmacy that are not expired due to concerns associated	Natures Pharmacy & Compounding Center

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
				with quality control procedures that present a potential risk to sterility assurance that were observed during a recent FDA inspection.	
Drugs	Dexamethosone/Tobramycin pf 0.1%/0.3% ophthalmic	All lot numbers within expiry.	Class II	Lack of Sterility Assurance: All lots of sterile products compounded by the pharmacy that are not expired due to concerns associated with quality control procedures that present a potential risk to sterility assurance that were observed during a recent FDA inspection.	Natures Pharmacy & Compounding Center
Drugs	Dextroamphetamine Saccharate, Amphetamine Asparate, Dextroamphetamine Sulfate and Amphetamine Sulfate Tablets, CII, 10 mg (mixed salts)	Lot # 34017575A, Exp. 10/16.	Class II	CGMP Deviations: Dextroamphetamine Saccharate, Amphetamine Asparate, Dextroamphetamine Sulfate and Amphetamine Sulfate Tablets, CII, 10 mg were manufactured using unapproved material: the finished product was not properly quarantined as rejected due to inadequate cleaning of equipment.	Teva Pharmaceuticals USA
Drugs	EDTA 3% ophthalmic	All lot numbers within expiry.	Class II	Lack of Sterility Assurance: All lots of sterile products compounded by the pharmacy that are	Natures Pharmacy & Compounding Center

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
				not expired due to concerns associated with quality control procedures that present a potential risk to sterility assurance that were observed during a recent FDA inspection.	
Drugs	Estradiol Cypionate 2mg/cc testosterone cypionate 50mg	All lot numbers within expiry.	Class II	Lack of Sterility Assurance: All lots of sterile products compounded by the pharmacy that are not expired due to concerns associated with quality control procedures that present a potential risk to sterility assurance that were observed during a recent FDA inspection.	Natures Pharmacy & Compounding Center
Drugs	Ethambutol Hydrochloride Tablets, USP, 400 mg	Lot # 34013698A, Exp. 01/16. Lot # 34013699A, Exp. 01/16. Lot # 34013700A, Exp. 01/16. Lot # 34013756A, Exp. 01/16.	Class II	CGMP Deviations: Ethambutol Hydrochloride Tablets, USP, 400 mg were manufactured using unapproved material: the incorrect gelatin excipient than specified in the product formulation.	Teva Pharmaceuticals USA
Drugs	Ethanol 20% ophth	All lot numbers within expiry.	Class II	Lack of Sterility Assurance: All lots of sterile products compounded by the pharmacy that are not expired due to concerns associated with quality control procedures that	Natures Pharmacy & Compounding Center

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
				present a potential risk to sterility assurance that were observed during a recent FDA inspection.	
Drugs	Folic acid (pf) 10mg/cc inj	All lot numbers within expiry.	Class II	Lack of Sterility Assurance: All lots of sterile products compounded by the pharmacy that are not expired due to concerns associated with quality control procedures that present a potential risk to sterility assurance that were observed during a recent FDA inspection.	Natures Pharmacy & Compounding Center
Drugs	Gentamycin 80mg/1000cc 0.9% NS	All lot numbers within expiry.	Class II	Lack of Sterility Assurance: All lots of sterile products compounded by the pharmacy that are not expired due to concerns associated with quality control procedures that present a potential risk to sterility assurance that were observed during a recent FDA inspection.	Natures Pharmacy & Compounding Center
Drugs	Glutathione 1.25%/Ascorbic 1.25%/DMSO 6.25%	All lot numbers within expiry.	Class II	Lack of Sterility Assurance: All lots of sterile products compounded by the pharmacy that are not expired due to concerns associated with quality control procedures that	Natures Pharmacy & Compounding Center

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
				present a potential risk to sterility assurance that were observed during a recent FDA inspection.	
Drugs	Glutathione 6%/ascorbic 1%/DMSO 6.25%	All lot numbers within expiry.	Class II	Lack of Sterility Assurance: All lots of sterile products compounded by the pharmacy that are not expired due to concerns associated with quality control procedures that present a potential risk to sterility assurance that were observed during a recent FDA inspection.	Natures Pharmacy & Compounding Center
Drugs	Glutathione Inhalation 200mg/5ml	All lot numbers within expiry.	Class II	Lack of Sterility Assurance: All lots of sterile products compounded by the pharmacy that are not expired due to concerns associated with quality control procedures that present a potential risk to sterility assurance that were observed during a recent FDA inspection.	Natures Pharmacy & Compounding Center
Drugs	Heparin Sodium Injection, USP 10,000 USP units per 10 mL	Lot Number: 6004137, Expiration date: 06/2014	Class II	Subpotent; 18 month time point	Fresenius Kabi USA, LLC
Drugs	Hydroxocobalamin inj.	All lot numbers within expiry.	Class II	Lack of Sterility Assurance: All lots of sterile products compounded by the pharmacy that are	Natures Pharmacy & Compounding Center

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
				not expired due to concerns associated with quality control procedures that present a potential risk to sterility assurance that were observed during a recent FDA inspection.	
Drugs	Hydroxyprogesterone Caproate	All lot numbers within expiry.	Class II	Lack of Sterility Assurance: All lots of sterile products compounded by the pharmacy that are not expired due to concerns associated with quality control procedures that present a potential risk to sterility assurance that were observed during a recent FDA inspection.	Natures Pharmacy & Compounding Center
Drugs	Hydroxyzine Pamoate Capsules, USP, 100 mg	Lot # 34017426A, Exp. 10/16.	Class II	CGMP Deviations: Hydroxyzine Pamoate Capsules, USP, 100 mg were manufactured using an unapproved material: API was incorrectly released for use in manufacturing.	Teva Pharmaceuticals USA
Drugs	Hydroxyzine Pamoate Capsules, USP, 25 mg	Lot # 34016752A, Exp. 09/16. Lot # 34016753A, Exp. 09/16.	Class II	CGMP Deviations: Hydroxyzine Pamoate Capsules, USP, 25 mg were manufactured using an unapproved material: API was incorrectly released for use in manufacturing.	Teva Pharmaceuticals USA
Drugs	Idoxuridine 0.1%	All lot numbers	Class II	Lack of Sterility	Natures

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
	Ophthalmic	within expiry.		Assurance: All lots of sterile products compounded by the pharmacy that are not expired due to concerns associated with quality control procedures that present a potential risk to sterility assurance that were observed during a recent FDA inspection.	Pharmacy & Compounding Center
Drugs	L-Glutathione inhalation	All lot numbers within expiry.	Class II	Lack of Sterility Assurance: All lots of sterile products compounded by the pharmacy that are not expired due to concerns associated with quality control procedures that present a potential risk to sterility assurance that were observed during a recent FDA inspection.	Natures Pharmacy & Compounding Center
Drugs	Lidocaine 4% Urethral Gel	Lot# 101213, Exp. 04/14 Lot# 09202013, Exp. 03/14 Lot# 08272013, Exp. 02/14 Lot# 08022013, Exp. 01/14	Class II	Lack of Sterility Assurance: All lots of sterile products compounded by the pharmacy that are not expired due to concerns associated with quality control procedures that present a potential risk to sterility assurance that were observed during a recent FDA inspection.	Natures Pharmacy & Compounding Center
Drugs	Metformin HCl	Batch	Class II	Presence of Foreign	Caraco

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
	Extended-Release Tablets, USP, 500 mg	JKM2433A, Mfg Date 04/2013; Exp 03/2016		Tablet; customer complaint of some tablets of Gabapentin found in a bottle of Metformin HCl ER	Pharmaceutical Laboratories, Ltd.
Drugs	Methotrexate Intraocular 400mcg 0.1cc	All lot numbers within expiry.	Class II	Lack of Sterility Assurance: All lots of sterile products compounded by the pharmacy that are not expired due to concerns associated with quality control procedures that present a potential risk to sterility assurance that were observed during a recent FDA inspection.	Natures Pharmacy & Compounding Center
Drugs	Methylcobalamin	All lot numbers within expiry.	Class II	Lack of Sterility Assurance: All lots of sterile products compounded by the pharmacy that are not expired due to concerns associated with quality control procedures that present a potential risk to sterility assurance that were observed during a recent FDA inspection.	Natures Pharmacy & Compounding Center
Drugs	Novarel (IM)	All lot numbers within expiry.	Class II	Lack of Sterility Assurance: All lots of sterile products compounded by the pharmacy that are not expired due to concerns associated with quality control procedures that present a potential	Natures Pharmacy & Compounding Center

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
				risk to sterility assurance that were observed during a recent FDA inspection.	
Drugs	Papaverine 12mg/phent 1mg/Pros 9mcq/ml	All lot numbers within expiry.	Class II	Lack of Sterility Assurance: All lots of sterile products compounded by the pharmacy that are not expired due to concerns associated with quality control procedures that present a potential risk to sterility assurance that were observed during a recent FDA inspection.	Natures Pharmacy & Compounding Center
Drugs	Papaverine 1nj 30mg/ml	All lot numbers within expiry.	Class II	Lack of Sterility Assurance: All lots of sterile products compounded by the pharmacy that are not expired due to concerns associated with quality control procedures that present a potential risk to sterility assurance that were observed during a recent FDA inspection.	Natures Pharmacy & Compounding Center
Drugs	Prostaglandin all combinations	All lot numbers within expiry.	Class II	Lack of Sterility Assurance: All lots of sterile products compounded by the pharmacy that are not expired due to concerns associated with quality control procedures that present a potential	Natures Pharmacy & Compounding Center

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
				risk to sterility assurance that were observed during a recent FDA inspection.	
Drugs	Pyridoxine (p-f) 100mg/ml	All lot numbers within expiry.	Class II	Lack of Sterility Assurance: All lots of sterile products compounded by the pharmacy that are not expired due to concerns associated with quality control procedures that present a potential risk to sterility assurance that were observed during a recent FDA inspection.	Natures Pharmacy & Compounding Center
Drugs	Renacidin Irrigation	All lot numbers within expiry.	Class II	Lack of Sterility Assurance: All lots of sterile products compounded by the pharmacy that are not expired due to concerns associated with quality control procedures that present a potential risk to sterility assurance that were observed during a recent FDA inspection.	Natures Pharmacy & Compounding Center
Drugs	Scopolamine 0.25 oph	All lot numbers within expiry.	Class II	Lack of Sterility Assurance: All lots of sterile products compounded by the pharmacy that are not expired due to concerns associated with quality control procedures that present a potential	Natures Pharmacy & Compounding Center

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
				risk to sterility assurance that were observed during a recent FDA inspection.	
Drugs	Sodium Bicarbonate 8.4% inj	All lot numbers within expiry.	Class II	Lack of Sterility Assurance: All lots of sterile products compounded by the pharmacy that are not expired due to concerns associated with quality control procedures that present a potential risk to sterility assurance that were observed during a recent FDA inspection.	Natures Pharmacy & Compounding Center
Drugs	Tacrolimus (H2O-based) 0.03% ophth	All lot numbers within expiry.	Class II	Lack of Sterility Assurance: All lots of sterile products compounded by the pharmacy that are not expired due to concerns associated with quality control procedures that present a potential risk to sterility assurance that were observed during a recent FDA inspection.	Natures Pharmacy & Compounding Center
Drugs	Tacrolimus 0.02% ophth. (H2O-based)	All lot numbers within expiry.	Class II	Lack of Sterility Assurance: All lots of sterile products compounded by the pharmacy that are not expired due to concerns associated with quality control procedures that present a potential	Natures Pharmacy & Compounding Center

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
				risk to sterility assurance that were observed during a recent FDA inspection.	
Drugs	Terbutaline/Ipratropium 0.5mg/2.5ml	All lot numbers within expiry.	Class II	Lack of Sterility Assurance: All lots of sterile products compounded by the pharmacy that are not expired due to concerns associated with quality control procedures that present a potential risk to sterility assurance that were observed during a recent FDA inspection.	Natures Pharmacy & Compounding Center
Drugs	Testosterone Cypionate 100mg/ml	All lot numbers within expiry.	Class II	Lack of Sterility Assurance: All lots of sterile products compounded by the pharmacy that are not expired due to concerns associated with quality control procedures that present a potential risk to sterility assurance that were observed during a recent FDA inspection.	Natures Pharmacy & Compounding Center
Drugs	Testosterone Cypionate 200mg/ml	All lot numbers within expiry.	Class II	Lack of Sterility Assurance: All lots of sterile products compounded by the pharmacy that are not expired due to concerns associated with quality control procedures that present a potential	Natures Pharmacy & Compounding Center

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
				risk to sterility assurance that were observed during a recent FDA inspection.	
Drugs	Tetracaine 0.5% ophth	All lot numbers within expiry.	Class II	Lack of Sterility Assurance: All lots of sterile products compounded by the pharmacy that are not expired due to concerns associated with quality control procedures that present a potential risk to sterility assurance that were observed during a recent FDA inspection.	Natures Pharmacy & Compounding Center
Drugs	Triamcinolone Acetonide 3mg/ml	All lot numbers within expiry.	Class II	Lack of Sterility Assurance: All lots of sterile products compounded by the pharmacy that are not expired due to concerns associated with quality control procedures that present a potential risk to sterility assurance that were observed during a recent FDA inspection.	Natures Pharmacy & Compounding Center
Drugs	Vancomycin (fortified) 25mg/ml ophth	All lot numbers within expiry.	Class II	Lack of Sterility Assurance: All lots of sterile products compounded by the pharmacy that are not expired due to concerns associated with quality control procedures that present a potential	Natures Pharmacy & Compounding Center

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
				risk to sterility assurance that were observed during a recent FDA inspection.	
Drugs	Vit A (olive oil) 0.1% oph	All lot numbers within expiry.	Class II	Lack of Sterility Assurance: All lots of sterile products compounded by the pharmacy that are not expired due to concerns associated with quality control procedures that present a potential risk to sterility assurance that were observed during a recent FDA inspection.	Natures Pharmacy & Compounding Center
Drugs	Vitamin D (Ergocalciferol) 800 u/ml	All lot numbers within expiry.	Class II	Lack of Sterility Assurance: All lots of sterile products compounded by the pharmacy that are not expired due to concerns associated with quality control procedures that present a potential risk to sterility assurance that were observed during a recent FDA inspection.	Natures Pharmacy & Compounding Center
Drugs	Voriconazole 0.5mg/ml	All lot numbers within expiry.	Class II	Lack of Sterility Assurance: All lots of sterile products compounded by the pharmacy that are not expired due to concerns associated with quality control procedures that present a potential	Natures Pharmacy & Compounding Center

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
				risk to sterility assurance that were observed during a recent FDA inspection.	
Drugs	Voriconazole 0.5mg/ml	All lot numbers within expiry.	Class II	Lack of Sterility Assurance: All lots of sterile products compounded by the pharmacy that are not expired due to concerns associated with quality control procedures that present a potential risk to sterility assurance that were observed during a recent FDA inspection.	Natures Pharmacy & Compounding Center
Drugs	Voriconazole 1% ophth	All lot numbers within expiry.	Class II	Lack of Sterility Assurance: All lots of sterile products compounded by the pharmacy that are not expired due to concerns associated with quality control procedures that present a potential risk to sterility assurance that were observed during a recent FDA inspection.	Natures Pharmacy & Compounding Center
Drugs	Walgreens Lansoprazole Delayed Release Capsules, USP 15 mg/Acid Reducer	Lot #: a) 79305114A, b) 79305114B, c) 79305114C, d) 79305114D, e) 79305114E, f) 79305114F, Exp 05/2015	Class II	Microbial Contamination of Non-Sterile Products: Out-of-specification results for microbial count were observed at the initial stability interval for Lansoprazole Delayed Release Capsules.	Dr. Reddy's Laboratories, Inc.

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
Drugs	Atripla (efavirenz 600 mg/ emtricitabine 200 mg/ tenofovir disoproxil fumarate 300 mg) Tablets	Lot #'s: 002390, 002400, Exp 02/17.	Class III	Presence of Particulate Matter: Red Silicone Rubber Particulates are Present in Drug.	Gilead Sciences, Inc
Drugs	Carisoprodol Tablets, USP, 350 mg	Lots and Expiration Dates: 3037463, Expires 2/2014; 3039466, Expires 3/2014; 3040644, Expires 4/2014; 3043463, Expires 6/2014; 3049568, Expires 3/2015	Class III	Failed Impurity/degradation Specification	Mylan Institutional, Inc. (d.b.a. UDL Laboratories)
Drugs	Gelnique (oxybutynin chloride) Gel 10%, 100 mg in 1 g sachet	Lot #: 514656; Expiry: 03/14	Class III	Subpotent Drug: Drug potency was compromised during shipment.	Actavis
Drugs	Photofrin (porfimer sodium) for Injection, 75 mg Single Use Flip-Top Vial	Lot Number: 0M396; Expiry: Nov 2014	Class III	Stability Data Does Not Support Expiry: Printed expiration date should be Nov 2013 rather than Nov 2014.	Pinnacle Biologics Inc
Drugs	Triamcinolone Acetonide Cream USP, 0.1%	Lot #: 485P, 486P, 487P, 488P, Exp 06/15; 638P, 639P, 640P, Exp 07/15; 753P, 754P, 755P, Exp 08/15; 898P, 756P, 757P, 758P, 899P, 900P, 901P, 902P, Exp 09/15	Class III	Labeling: Label Error on Declared Strength: There is a misprint on the end flap which read 01% rather than 0.1%.	Fougera Pharmaceuticals Inc.
Drugs	Tussin CF Adult Maximum Strength Multi-Symptom Cold liquid (dextromethorphan HBr 10 mg,	Lot #: 151631, Exp 10/15 and 152767, Exp 11/15	Class III	Presence of Precipitate: Recall is due to complaints of a white substance, confirmed as Guaifenesin, an active	Aaron Industries Inc

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
	guaifenesin 200 mg, phenylephrine HCl 5 mg) per 5 mL			ingredient in the product which is precipitating out.	

CURRENT DRUG SHORTAGES

Promethazine Injection

January 24, 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/DrugShortages/Current/Bulletin.aspx?id=654>

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

Mesna Injection

January 24, 2014

Reason for the Shortage

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

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=642>

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

Sterile Empty Vials

January 27, 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/DrugShortages/Current/Bulletin.aspx?id=890>

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

Methylene Blue Injection

January 27, 2014

Reason for the Shortage

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

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

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

Indigo Carmine Injection

January 27, 2014

Reason for the Shortage

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

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

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

Caffeine and Sodium Benzoate Injection

January 27, 2014

Reason for the Shortage

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

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=817>

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

Haemophilus B Conjugate Vaccine

January 29, 2014

Reason for the Shortage

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

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=1052>

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

Choline Magnesium Trisalicylate

January 29, 2014

Reason for the Shortage

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

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=556>

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

Aspirin Tablets (Buffered)

January 29, 2014

Reason for the Shortage

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

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=950>

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

Testosterone Enanthate Injection

January 30, 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/DrugShortages/Current/Bulletin.aspx?id=1045>

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

Morrhuate Sodium Injection

February 3, 2014

Reason for the Shortage

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

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

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

Caffeine and Ergotamine Tartrate

February 3, 2014

Reason for the Shortage

- Sandoz states the shortage is due to a change in the raw material plant location.
- Sandoz is the only manufacturer of caffeine and ergotamine tablets.
- Cypress discontinued their caffeine and ergotamine tablets in February, 2011 and West-Ward discontinued their product in April, 2010.

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

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

BCG Vaccine Live Intravesical

February 3, 2014

Reason for the Shortage

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

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=915>

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

Azathioprine Injection

February 3, 2014

Reason for the Shortage

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

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

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

Fludarabine Injection

February 5, 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 increased demand for product.
- 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/DrugShortages/Current/Bulletin.aspx?id=648>

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

Esmolol Injection

February 5, 2014

Reason for the Shortage

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

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

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

Sodium Thiosulfate Injection

February 6, 2014

Reason for the Shortage

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

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=766>

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

Propofol Injection

February 6, 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).^{5,6} Fresenius Kabi has a Dear Healthcare professional letter at ^{5,6} Report any offers to sell Propoven by an entity other than Fresenius Kabi to drugshortages@fda.hhs.gov.

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=573>

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

Methylergonovine Maleate

February 6, 2014

Reason for the Shortage

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

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=906>

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

Magnesium Sulfate Injection

February 7, 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/DrugShortages/Current/Bulletin.aspx?id=757>

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

Ketamine Injection

February 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.
- JHP and Mylan Institutional could not provide a reason for the shortage.

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=592>

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

Vitamin A Injection

February 10, 2014

Reason for the Shortage

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

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

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

Vecuronium Bromide Injection

February 10, 2014

Reason for the Shortage

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

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=490>

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

Sodium Acetate Injection

February 10, 2014

Reason for the Shortage

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

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

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

Methyldopate Injection

February 10, 2014

Reason for the Shortage

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

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

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

Hydroxyzine Injection

February 10, 2014

Reason for the Shortage

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

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

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

Electrolyte Concentrate

February 10, 2014

Reason for the Shortage

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

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=1054>

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

Droperidol Injection

February 10, 2014

Reason for the Shortage

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

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

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

Copper Injection

February 10, 2014

Reason for the Shortage

- American Regent had temporarily suspended manufacture of most drug products in April, 2011.
- American Regent resumed manufacturing in Shirley, New York in early-May, 2011.
- Hospira has cupric chloride on shortage due to manufacturing delays.

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=946>

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

Chromium (Chromic Chloride) Injection

February 10, 2014

Reason for the Shortage

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

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

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

Prochlorperazine Edisylate Injection

February 11, 2014

Reason for the Shortage

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

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=1063>

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

Chlorprocaine Injection

February 11, 2014

Reason for the Shortage

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

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

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=849>

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

Atropine Sulfate Injection

February 11, 2014

Reason for the Shortage

- American Regent had temporarily suspended manufacture of most drug products in April, 2011.
- American Regent resumed manufacturing in Shirley, New York in early-May, 2011.
- Hospira states the shortage is due to manufacturing delays.
- West-Ward acquired Baxter's atropine injection products in May, 2011. NDC codes began changing for these products in early, 2012. West-Ward is not manufacturing the 0.4 mg/mL or 1 mg/mL 1 mL vials.
- Amphastar had atropine on shortage due to increased demand.

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=814>

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

Amino Acid Products

February 11, 2014

Reason for the Shortage

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

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

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

Vincristine Injection

February 14, 2014

Reason for the Shortage

- Hospira states the shortage is due to manufacturing delays.

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=42>

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

Tranexamic Acid Injection

February 14, 2014

Reason for the Shortage

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

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=1049>

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

Leuprolide Acetate 14-Day Kit

February 14, 2014

Reason for the Shortage

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

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=737>

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

Indomethacin Injection

February 14, 2014

Reason for the Shortage

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

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

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

Cyclosporine Injection

February 14, 2014

Reason for the Shortage

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

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

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

Alprostadil Products

February 14, 2014

Reason for the Shortage

- Bedford discontinued alprostadil in May, 2011 to concentrate on the manufacturing of other products.
- Teva's product is on long-term back order due to manufacturing difficulties.
- Pfizer's Caverject Impulse is on back order while the product is reformulated. The company has discontinued Caverject injection 10 mcg lyophilized powder and 20 mcg/mL solution for injection. Prostin VR Pediatric was on back order for unknown reasons.
- Actient has acquired several products from Schwarz (UCB) including Edex cartridges in 2010.
- Auxilium acquired Actient's urology products including Edex cartridges in April 2013.
- Meda Pharmaceuticals has acquired Muse from Vivus.

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=474>

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

Furosemide Injection

February 18, 2014

Reason for the Shortage

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

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

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

Memantine Hydrochloride

February 19, 2014

Reason for the Shortage

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

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=1082>

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

Sodium Chloride 0.45% Injection Bags

February 20, 2014

Reason for the Shortage

- Baxter has sodium chloride 0.9% on shortage due to increased demand.
- BBraun had sodium chloride 0.9% on allocation due to increased demand.
- Hospira cites increased demand as the reason for the shortage.

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

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

Iron Dextran Injection

February 20, 2014

Reason for the Shortage

- American Regent cannot provide a reason for the shortage.

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=1069>

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

Dactinomycin Injection

February 20, 2014

Reason for the Shortage

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

manufactured elsewhere that are not affected by this closure, but dactinomycin is not one of these products.

- Recordati acquired several products from Lundbeck in January 2013 including Cosmegen.
- Cosmegen can be ordered through wholesalers or ASD Healthcare at 1-800-746-6273

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

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

Methocarbamol Injection

February 21, 2014

Reason for the Shortage

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

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=920>

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

Empty Evacuated Containers

February 21, 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/DrugShortages/Current/Bulletin.aspx?id=983>

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

Acyclovir Injection

February 21, 2014

Reason for the Shortage

- Fresenius Kabi (formerly APP) is not manufacturing acyclovir lyophilized powder to concentrate on supplying the solution for injection.
- Ben Venue has stopped production in its plant in Bedford, Ohio and will close in early 2014. Ben Venue supplies multiple sterile injectable products for Bedford Laboratories.

Supplies of product that has already been manufactured will continue to be released until inventory is depleted. Bedford Laboratories has a small number of products manufactured elsewhere that are not affected by this closure.

- AuroMedics introduced acyclovir injection in February 2014.

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

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

Haloperidol Decanoate Injection

February 24, 2014

Reason for the Shortage

- Teva products are on shortage due to manufacturing delays.

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

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

Lomustine Capsules

February 24, 2014

Reason for the Shortage

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

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

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

Iron Sucrose Injection

February 24, 2014

Reason for the Shortage

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

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

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

Gentamicin injection

February 24, 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/DrugShortages/Current/Bulletin.aspx?id=728>

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

Doxorubicin Liposomal Injection

February 24, 2014

Reason for the Shortage

- Janssen Products, LP states the shortage is due to manufacturing issues. Janssen Products, LP has updates with information about the shortage on the Doxil website that is updated regularly.
- Janssen is working to transition Doxil manufacturing to additional suppliers. The recent solution 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 several lots of 2 mg/mL 10 mL (20 mg) vials but no more lots using this process will be released.
- 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/DrugShortages/Current/Bulletin.aspx?id=806>

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

Zinc Injection

February 26, 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 Aguetant 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/DrugShortages/Current/Bulletin.aspx?id=777>

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

Potassium Acetate Injection

February 26, 2014

Reason for the Shortage

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

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

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

Levocarnitine Injection

February 26, 2014

Reason for the Shortage

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

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

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

Calcium Chloride Injection

February 26, 2014

Reason for the Shortage

- American Regent had temporarily suspended distribution of most drug products including calcium chloride in April, 2011.
- American Regent resumed manufacturing in Shirley, New York in early-May, 2011.
- American Regent has issued a statement that one lot (Lot #2476) of calcium chloride has a potential for particulate formation due to interaction with the rubber from the stoppers. Do not use if any particles are present. The product was inspected and no particulates were seen prior to the release. A filter is required for withdrawal from the vial and administration as a precautionary measure.
- Hospira has calcium chloride on shortage due to manufacturing delays.
- Amphastar had product on shortage due to increased demand for the product.
- FDA, in cooperation with Amneal-Agila LLC, is allowing temporary importation of calcium chloride 100 mg/mL 10 mL syringes. These are the same concentration and size as the Hospira Ansyf syringes. These can be ordered by calling Amneal-Agila customer service at 1-866-525-7270. Further information can be found online. A comparison chart between the Hospira calcium chloride Ansyf syringes and the calcium chloride syringes from Amneal-Agila can be found online.

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

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

Ascorbic Acid Injection

February 26, 2014

Reason for the Shortage

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

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

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

Ammonium Molybdate Injection

February 26, 2014

Reason for the Shortage

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

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

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

Tobramycin Injection

February 27, 2014

Reason for the Shortage

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

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=701>

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

Ticarcillin Clavulanate

February 27, 2014

Reason for the Shortage

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

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=802>

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

Sumatriptan Succinate Injection

February 27, 2014

Reason for the Shortage

- Sagent states the reason for the shortage is increased demand.
- JHP could not provide a reason for the shortage.

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

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=1085>

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

Pantoprazole Tablets

February 27, 2014

Reason for the Shortage

- Kremers Urban states the reason for the shortage was increased demand.
- Actavis, Mylan, and Torrent could not provide a reason for the shortage.
- Watson and Actavis have merged and pantoprazole tablets are now being distributed by Watson.
- FDA imposed an import ban in mid-2013 on several Wockhardt products including pantoprazole.

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=979>

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

Nimodipine Capsules

February 27, 2014

Reason for the Shortage

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

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

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

Mirtazapine Tablets

February 27, 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/DrugShortages/Current/Bulletin.aspx?id=970>

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

Methylphenidate Hydrochloride

February 27, 2014

Reason for the Shortage

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

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=752>

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

Methotrexate Tablets

February 27, 2014

Reason for the Shortage

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

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

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

Doxazosin Tablets

February 27, 2014

Reason for the Shortage

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

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

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

Caffeine Citrate Injection and Oral Solution

February 27, 2014

Reason for the Shortage

- American Regent had temporarily suspended manufacture of most drug products in April, 2011.
- American Regent resumed manufacturing in Shirley, New York in early-May, 2011.
- 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 launched caffeine citrate in the latter half of 2012.

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=862>

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

Vitamin E Aqueous Oral Solution

March 3, 2014

Reason for the Shortage

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

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

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

Vinblastine Injection

March 3, 2014

Reason for the Shortage

- Ben Venue has stopped production in its plant in Bedford, Ohio and will close in early 2014. Ben Venue supplies multiple sterile injectable products for Bedford Laboratories. Supplies of product that has already been manufactured will continue to be released until inventory is depleted. Bedford Laboratories has a small number of products manufactured elsewhere that are not affected by this closure.¹
- Fresenius Kabi (formerly APP) had their product in short supply due to increased demand for the product and a manufacturing delay.

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

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

Testosterone Cypionate Intramuscular Injection

March 3, 2014

Reason for the Shortage

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

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=638>

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

Phenytoin Injection

March 3, 2014

Reason for the Shortage

- West-Ward discontinued their phenytoin in early-June, 2011 for business reasons since the company took over several Baxter products including phenytoin.
- 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 did not provide a reason for the shortage.

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=740>

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

Paclitaxel Injection

March 3, 2014

Reason for the Shortage

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

- Sagent had paclitaxel on shortage due to increased demand for the product.
- Pfizer launched paclitaxel 100 mg and 300 mg vials in March, 2012 and launched the 30 mg vials in April, 2012.
- Mylan Institutional acquired paclitaxel injection from Pfizer on December 7, 2013.

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=790>

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

Ondansetron Injection

March 3, 2014

Reason for the Shortage

Ondansetron 2 mg/mL vials

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

Ondansetron 32 mg/50 mL premixed bags

- All presentations of ondansetron 32 mg/50 mL premixed bags have been discontinued.
- Single-dose IV ondansetron 32 mg is no longer recommended due to an increased potential for QT prolongation and has been removed from the Zofran product labeling. The maximum dose for chemotherapy-induced nausea should not exceed 16 mg. FDA is working with manufacturers to voluntarily recall all ondansetron 32 mg premixed bags from the market by early 2013. Oral ondansetron dosing is not affected by the new recommendations, including the 24 mg oral dose for chemotherapy-induced nausea and vomiting.
- Baxter has discontinued and recalled their ondansetron premixed bags.
- Bedford discontinued their ondansetron premixed bags in December, 2012.

- Hospira discontinued their ondansetron premixed bags in December, 2012. Product has not been available on the market for several years.
- Claris recalled all lots of their ondansetron premixed bags in mid-2010.
- Claris discontinued their ondansetron premixed bags in June 2013.
- Pfizer discontinued their ondansetron premixed bags in January, 2012.
- Teva discontinued their ondansetron premixed bags in late-November, 2012. Product has not shipped since early 2010.
- West-Ward has discontinued their ondansetron premixed bags.

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=1040>

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

Nicardipine Hydrochloride Injection

March 3, 2014

Reason for the Shortage

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

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

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

Mecasermin Injection

March 3, 2014

Reason for the Shortage

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

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

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

Liotrix Tablets

March 3, 2014

Reason for the Shortage

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

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

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

Levothyroxine Sodium Injection

March 3, 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/DrugShortages/Current/Bulletin.aspx?id=24>

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

Haloperidol Lactate Injection

March 3, 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/DrugShortages/Current/Bulletin.aspx?id=24>

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

Fosphenytoin Injection

March 3, 2014

Reason for the Shortage

- Akorn discontinued fosphenytoin injection in 2011.
- American Regent discontinued fosphenytoin injection in late-2010.
- Fresenius Kabi (formerly APP) states the shortage was due to increased demand.
- Bedford discontinued fosphenytoin in May, 2011 to concentrate on the manufacturing of other products.
- Hospira states the shortage is due to manufacturing delays.

- Pfizer discontinued the Cerebyx 500 mg presentation in September, 2009 and the 1 gram presentation in early-February, 2010.
- Pfizer launched Cerebyx 2 mL and 10 mL vials in October 2013.
- Teva, Apotex, Baxter, GeneraMedix, and Wockhardt have discontinued their fosphenytoin presentations.
- West-Ward had fosphenytoin on shortage due to manufacturing delays.

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=127>

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

Doxapram Injection

March 3, 2014

Reason for the Shortage

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

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

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

Diltiazem Injection

March 3, 2014

Reason for the Shortage

- Ben Venue has stopped production in its plant in Bedford, Ohio and will close in early 2014. Ben Venue supplies multiple sterile injectable products for Bedford Laboratories. Supplies of product that has already been manufactured will continue to be released until inventory is depleted. Bedford Laboratories has a small number of products manufactured elsewhere that are not affected by this closure.
- 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/DrugShortages/Current/Bulletin.aspx?id=217>

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

Ciprofloxacin Immediate-Release Tablets

March 3, 2014

Reason for the Shortage

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

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=572>

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

Chloramphenicol Sodium Succinate Injection

March 3, 2014

Reason for the Shortage

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

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

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

Ceftazidime Injection

March 3, 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/DrugShortages/Current/Bulletin.aspx?id=869>

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

Calcium Gluconate Injection

March 3, 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/DrugShortages/Current/Bulletin.aspx?id=48>

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

Calcitriol Injection

March 3, 2014

Reason for the Shortage

- Akorn had calcitriol injection 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/DrugShortages/Current/Bulletin.aspx?id=940>

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

Butorphanol Injection

March 3, 2014

Reason for the Shortage

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

- Sandoz discontinued Stadol injection in 2010.

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

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

Buprenorphine Injection

March 3, 2014

Reason for the Shortage

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

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

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

Levothyroxine Oral Tablets

March 4, 2014

Reason for the Shortage

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

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

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

Benztropine Injection

March 4, 2014

Reason for the Shortage

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

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

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

Allopurinol Injection

March 4, 2014

Reason for the Shortage

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

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

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

Alcohol Dehydrated Injection (Ethanol)

March 4, 2014

Reason for the Shortage

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

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

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

Sufentanil Injection

March 5, 2014

Reason for the Shortage

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

Hospira has sufentanil on shortage due to manufacturing delays.

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

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

Rocuronium Injection

March 5, 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.⁶
- The Medicines Company launched rocuronium in early 2014.
-

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=434>

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

Reserpine Oral Tablets

March 5, 2014

Reason for the Shortage

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

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

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

Phenylephrine Hydrochloride Injection

March 5, 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.
- West-Ward could not provide a reason for the shortage of phenylephrine injection.

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=184>

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

Morphine Injections

March 5, 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/DrugShortages/Current/Bulletin.aspx?id=664>

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

Midazolam Injections

March 5, 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/DrugShortages/Current/Bulletin.aspx?id=858>

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

Labetalol Injections

March 5, 2014

Reason for the Shortage

- Ben Venue has stopped production in its plant in Bedford, Ohio and will close in early 2014. Ben Venue supplies multiple sterile injectable products for Bedford Laboratories. Supplies of product that has already been manufactured will continue to be released until inventory is depleted. Bedford Laboratories has a small number of products manufactured elsewhere that are not affected by this closure.
- 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/DrugShortages/Current/Bulletin.aspx?id=397>

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

Denileukin Diftitox Injection

March 5, 2014

Reason for the Shortage

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

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

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

Clarithromycin Immediate Release Tablets

March 5, 2014

Reason for the Shortage

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

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

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

Buprenorphine Sublingual Tablets

March 5, 2014

Reason for the Shortage

- Teva could not provide a reason for the shortage.

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

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

Bumetanide Tablets

March 5, 2014

Reason for the Shortage

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

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

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

Vasopressin Injection

March 6, 2014

Reason for the Shortage

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

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=795>

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

Tchnetium Tc99m Albumin Aggregated Injection

March 6, 2014

Reason for the Shortage

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

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=1053>

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

Tamoxifen Tablets

March 6, 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/DrugShortages/Current/Bulletin.aspx?id=1071>

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

Synthetic Conjugated Estrogen

March 6, 2014

Reason for the Shortage

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

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=1087>

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

Sulfacetamide and Prednisolone Ophthalmic Ointment

March 6, 2014

Reason for the Shortage

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

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=1033>

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

Oxytocin Injection

March 6, 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/DrugShortages/Current/Bulletin.aspx?id=876>

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

Octreotide Injection

March 6, 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/DrugShortages/Current/Bulletin.aspx?id=803>

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

Neostigmine Bromide Tablets

March 6, 2014

Reason for the Shortage

- Valeant could not provide a reason for the shortage.

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

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

Naproxen Oral Suspension

March 6, 2014

Reason for the Shortage

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

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

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

Doxycycline Capsules and Tablets

March 6, 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/DrugShortages/Current/Bulletin.aspx?id=977>

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

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

March 6, 2014

Reason for the Shortage

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

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=922>

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

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

March 6, 2014

Reason for the Shortage

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

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=921>

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

Dimercaprol Injection

March 6, 2014

Reason for the Shortage

- Akorn cannot provide a reason for the shortage.

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=1086>

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

Lidocaine with Epinephrine Injection

March 7, 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/DrugShortages/Current/Bulletin.aspx?id=860>

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

Lidocaine Injection

March 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 had lidocaine and dextrose premixed bags on shortage due to increased demand for the product.
- Baxter discontinued two lidocaine and dextrose premixed bag presentations in March, 2012.
- AuroMedics introduced lidocaine injection in February 2014.

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=859>

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

Famotidine Injection

March 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.
- West-Ward states the shortage is due to manufacturing delays.
- Oral famotidine products are not affected by this shortage.
- Pfizer launched famotidine injections in March, 2012.
- Mylan Institutional acquired famotidine injections from Pfizer on December 6, 2013.

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=810>

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

Epinephrine Injection

March 7, 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/DrugShortages/Current/Bulletin.aspx?id=685>

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

Dopamine Injection

March 7, 2014

Reason for the Shortage

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

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=88>

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

Cisatracurium Injection

March 7, 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/DrugShortages/Current/Bulletin.aspx?id=1072>

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

Terbutaline Sulfate Injection

March 10, 2014

Reason for the Shortage

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

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

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

Sodium Phosphate Injection

March 10, 2014

Reason for the Shortage

- American Regent has sodium phosphate injection on back order due to manufacturing delays.
- American Regent has issued a statement that all lots of sodium phosphate have potential for crystallization. Do not use if any particles are present.
- Hospira has sodium phosphate injection on shortage due to manufacturing delays.
- In cooperation with FDA, Fresenius Kabi USA is providing Glycophos (sodium glycerophosphate) injection to the US market to help alleviate the shortage. Glycophos is manufactured in an FDA-approved facility in Norway by Fresenius Kabi AG, the parent company of Fresenius Kabi USA.⁶
- Fresenius Kabi launched sodium phosphate injection in mid-January 2014.

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=770>

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

Sodium Chloride Concentrated Solution for Injection

March 10, 2014

Reason for the Shortage

- American Regent discontinued sodium chloride 23.4% 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 sodium chloride 14.6% 20 mL vials in February 2013.
- Hospira has sodium chloride 14.6% and 23.4% 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/DrugShortages/Current/Bulletin.aspx?id=724>

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

Erythromycin Lactobionate Injection

March 10, 2014

Reason for the Shortage

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

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

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

Chlorothiazide Oral Suspension

March 10, 2014

Reason for the Shortage

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

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=1076>

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

Acetylcysteine Inhalation Solution

March 10, 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 has acetylcysteine inhalation solution on shortage due to manufacturing delays.
- Hospira has acetylcysteine inhalation solution on shortage due to increased demand for the product.
- Fresenius Kabi (formerly APP) could not provide a reason for the shortage.

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=932>

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

Sulfamethoxazole/Trimethoprim Injection

March 11, 2014

Reason for the Shortage

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

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

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

Rifampin for Injection

March 11, 2014

Reason for the Shortage

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

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

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

Milrinone Injection

March 11, 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/DrugShortages/Current/Bulletin.aspx?id=741>

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

Hydromorphone Hydrochloride Injection

March 11, 2014

Reason for the Shortage

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

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=856>

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

Granisetron Hydrochloride Injection

March 11, 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/DrugShortages/Current/Bulletin.aspx?id=633>

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

Dexamethasone Sodium Phosphate

March 11, 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/DrugShortages/Current/Bulletin.aspx?id=751>

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

Clindamycin Injection

March 11, 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/DrugShortages/Current/Bulletin.aspx?id=1029>

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

Azithromycin Injection

March 11, 2014

Reason for the Shortage

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

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=936>

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

Tiopronin Tablets

March 12, 2014

Reason for the Shortage

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

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

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

Potassium Phosphate Injection

March 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 (formerly APP) is providing Glycophos (sodium glycerophosphate) injection to the US market to help alleviate the shortage. Glycophos is manufactured in an FDA-approved facility in Norway by Fresenius Kabi AG.
- Fresenius Kabi, USA (formerly APP) launched potassium phosphate injection in November 2013.

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=709>

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

Piperacillin Tazobactam Injection

March 12, 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/DrugShortages/Current/Bulletin.aspx?id=1075>

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

Neostigmine Methylsulfate Injection

March 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 is increased demand for the product.

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=311>

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

Intravenous Fat Emulsion

March 12, 2014

Reason for the Shortage

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

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

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

Ethambutol Tablets

March 12, 2014

Reason for the Shortage

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

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

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

Doxorubicin Injection

March 12, 2014

Reason for the Shortage

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

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

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

Dexmethylphenidate Hydrochloride

March 12, 2014

Reason for the Shortage

- Teva cannot provide a reason for the shortage.

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

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

Cephalexin Oral Suspension

March 12, 2014

Reason for the Shortage

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

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

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

Carboplatin Solution for Injection

March 12, 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/DrugShortages/Current/Bulletin.aspx?id=1005>

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

Black Widow Antivenin (*Latrodectus Mactans*)

March 12, 2014

Reason for the Shortage

- Merck has low inventory of Antivenin *Latrodectus Mactans*.

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

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

Amikacin Injection

March 12, 2014

Reason for the Shortage

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

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=501>

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

Procainamide Hydrochloride Injection

March 13, 2014

Reason for the Shortage

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

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

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

Nalbuphine Injection

March 13, 2014

Reason for the Shortage

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

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

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

Cyanocobalamin Injection

March 13, 2014

Reason for the Shortage

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

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=947>

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

Trace Elements Injection

March 14, 2014

Reason for the Shortage

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

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

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

Prednisone Tablets

March 14, 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 has temporarily suspended manufacturing of oral solid pharmaceutical products.

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=930>

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

Potassium Chloride Injection

March 14, 2014

Reason for the Shortage

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

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=696>

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

Methylprednisolone Sodium Succinate Injection

March 14, 2014

Reason for the Shortage

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

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=1077>

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

Hydrocortisone Sodium Succinate Injection

March 14, 2014

Reason for the Shortage

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

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=925>

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

Fluconazole Injection

March 14, 2014

Reason for the Shortage

- Teva has fluconazole injection on shortage due to manufacturing delays.
- West-Ward has fluconazole injection on shortage due to manufacturing delays.

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

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

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

Dobutamine Injection

March 14, 2014

Reason for the Shortage

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

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=929>

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

Cidofovir Injection

March 14, 2014

Reason for the Shortage

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

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

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

Cefuroxime Sodium Injection

March 14, 2014

Reason for the Shortage

- Sagent states manufacture of cefuroxime 1.5 gram was suspended in March, 2013. No further production is planned.

- Hospira discontinued cefuroxime 1.5 gram and 7.5 gram vials in January, 2013.
- Covis launched the new NDC numbers in August 2013.
- BBraun discontinued their cefuroxime solution in December 2013.

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=990>

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

Bupivacaine with epinephrine Injection

March 14, 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/DrugShortages/Current/Bulletin.aspx?id=937>

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

Aminophylline Injection

March 14, 2014

Reason for the Shortage

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

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

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

Aminocaproic Acid Injection

March 14, 2014

Reason for the Shortage

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

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

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

Tesamorelin Injection

March 17, 2014

Reason for the Shortage

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

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=1065>

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

Rabies Immune Globulin

March 17, 2014

Reason for the Shortage

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

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

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

Phenobarbital Tablets

March 17, 2014

Reason for the Shortage

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

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=1061>

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

Metoprolol Injection

March 17, 2014

Reason for the Shortage

- American Regent had temporarily suspended manufacture of most drug products including metoprolol in April, 2011.¹ The company Regent resumed manufacturing in Shirley, New York in early-May, 2011.
- Fresenius Kabi (formerly APP) and Hospira state the shortage was due to increased demand for the product.
- Ben Venue has stopped production in its plant in Bedford, Ohio and will close in early 2014. Ben Venue supplies multiple sterile injectable products for Bedford Laboratories. Supplies of product that has already been manufactured will continue to be released

until inventory is depleted. Bedford Laboratories has a small number of products manufactured elsewhere that are not affected by this closure; metoprolol is not one of these medications.

- Sagent had metoprolol injection on shortage due to increased demand for the product.

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=813>

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

Methylprednisolone Acetate Injection

March 17, 2014

Reason for the Shortage

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

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

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

Glycopyrrolate Injection

March 17, 2014

Reason for the Shortage

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

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=385>

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

Fluorouracil Injection

March 17, 2014

Reason for the Shortage

- Fresenius Kabi (formerly APP) states fluorouracil is on allocation to prevent excessive purchases.
- Teva stated their fluorouracil shortage was due to manufacturing delays.
- 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/DrugShortages/Current/Bulletin.aspx?id=798>

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

Fluorometholone Ophthalmic Ointment

March 17, 2014

Reason for the Shortage

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

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=1034>

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

Ezetimibe and Atorvastatin Tablets

March 17, 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/DrugShortages/Current/Bulletin.aspx?id=1084>

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

Dihydroergotamine Mesylate Injection

March 17, 2014

Reason for the Shortage

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

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=1050>

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

Dibucaine Ointment

March 17, 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/DrugShortages/Current/Bulletin.aspx?id=1074>

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

Citric acid and Potassium Citrate Oral

March 17, 2014

Reason for the Shortage

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

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

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

Chorionic Gonadotropin (Human) Injection

March 17, 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/DrugShortages/Current/Bulletin.aspx?id=382>

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

Calcium Acetate Capsules

March 17, 2014

Reason for the Shortage

- Fresenius cannot provide a reason for the shortage.
- Hawthorne states the reason for the shortage is manufacturing delay.
- Roxane cannot provide a reason for the shortage.

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=1002>

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

Bupivacaine Injection

March 17, 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/DrugShortages/Current/Bulletin.aspx?id=864>

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

Barium Sulfate Oral Suspension

March 17, 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/DrugShortages/Current/Bulletin.aspx?id=963>

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

Adenosine Injection

March 17, 2014

Reason for the Shortage

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

- Sagent has adenosine syringes on shortage because the company is transferring suppliers of raw materials. The current supplier has exited the market.
- Teva has discontinued their adenosine injection.
- Wockhardt discontinued their adenosine 3 mg/mL 2 mL and 4 mL syringes.

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=976>

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

Thiothixene Capsules

March 18, 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/DrugShortages/Current/Bulletin.aspx?id=835>

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

Sodium Chloride 0.9% Injection Bags

March 18, 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.

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=993>

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

Sodium Chloride 0.45% Injection Bags

March 18, 2014

Reason for the Shortage

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

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

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

Lactated Ringer's Injection Bags

March 18, 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/DrugShortages/Current/Bulletin.aspx?id=1078>

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

Heparin Sodium Injection

March 18, 2014

Reason for the Shortage

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

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

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

Ephedrine Injection

March 18, 2014

Reason for the Shortage

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

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

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

Dextrose 5% Injection Large Volume Bags

March 18, 2014

Reason for the Shortage

- Baxter could not provide a reason for the shortage.
- BBraun had 5% dextrose on allocation due to increased demand.
- Hospira states the shortage is due to increased demand and manufacturing delays.

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=1081>

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

Cefazolin Injection

March 18, 2014

Reason for the Shortage

- Apotex could not provide a reason for the shortage.
- BBraun has cefazolin on shortage due to increased demand.
- Hospira has cefazolin on shortage due to manufacturing delays.
- Sagent has cefazolin on shortage due to increased demand.
- Sandoz has cefazolin on shortage due to manufacturing delays.

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=987>

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

Water-Miscible Oral Multiple Vitamins

March 20, 2014

Reason for the Shortage

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

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

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

Vancomycin Hydrochloride Injection

March 20, 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/DrugShortages/Current/Bulletin.aspx?id=132>

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

Topiramate Sprinkle Capsules

March 20, 2014

Reason for the Shortage

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

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

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

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

March 20, 2014

Reason for the Shortage

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

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

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

Succinylcholine chloride Injection

March 20, 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/DrugShortages/Current/Bulletin.aspx?id=582>

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

Papaverine Injection

March 20, 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/DrugShortages/Current/Bulletin.aspx?id=781>

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

Nitroglycerin Injection

March 20, 2014

Reason for the Shortage

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

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=786>

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

Multiple Vitamins for Infusion

March 20, 2014

Reason for the Shortage

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

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

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

Methotrexate Injection

March 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.
- Sandoz recalled two lots of methotrexate 40 mL preservative-free vials in May 2013 due to discover of particulate matter during routine quality control inspection.
- Mylan Institutional acquired methotrexate injection from Pfizer on December 6, 2013.
- Bioniche was acquired by Mylan Institutional in September, 2011.
- Teva discontinued methotrexate 4 mL vials in October 2013 due to business reasons.

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=26>

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

Methazolamide Tablets

March 20, 2014

Reason for the Shortage

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

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=901>

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

Mercaptopurine Tablets

March 20, 2014

Reason for the Shortage

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

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

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

Loteprednol Etabonate 0.5% Ophthalmic Suspension

March 20, 2014

Reason for the Shortage

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

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

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

Ketorolac Tromethamine Injection

March 20, 2014

Reason for the Shortage

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

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

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

Fentanyl Injection

March 20, 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/DrugShortages/Current/Bulletin.aspx?id=647>

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

Etomidate Injection

March 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.¹
- 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 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/DrugShortages/Current/Bulletin.aspx?id=419>

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

Cytarabine Injection

March 20, 2014

Reason for the Shortage

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

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

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

Ciprofloxacin Injection

March 20, 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/DrugShortages/Current/Bulletin.aspx?id=944>

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

Cefpodoxime

March 20, 2014

Reason for the Shortage

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

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

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

Atorvastatin Tablets

March 20, 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/DrugShortages/Current/Bulletin.aspx?id=989>

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

Sincalide Injection

March 21, 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/DrugShortages/Current/Bulletin.aspx?id=1032>

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

Secretin Injection

March 21, 2014

Reason for the Shortage

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

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

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

Lorazepam injectable presentations

March 21, 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 has lorazepam 2 mg/mL vials on shortage due to increased demand.

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=747>

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

Bumetanide Injection

March 21, 2014

Reason for the Shortage

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

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

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

Atracurium Injection

March 21, 2014

Reason for the Shortage

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

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

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

Ampicillin Sulbactam

March 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/DrugShortages/Current/Bulletin.aspx?id=805>

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

Tuberculin Purified Protein Derivate for Intradermal Injection

March 24, 2014

Reason for the Shortage

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

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

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

Thiotepa for Injection

March 24, 2014

Reason for the Shortage

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

concentration of 10 mg/mL and therefore use caution in choosing vial size and volume of diluent.

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

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

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

Norepinephrine Injection

March 24, 2014

Reason for the Shortage

- Ben Venue has stopped production in its plant in Bedford, Ohio and will close in early 2014. Ben Venue supplies multiple sterile injectable products for Bedford Laboratories. Supplies of product that has already been manufactured will continue to be released until inventory is depleted. Bedford Laboratories has a small number of products manufactured elsewhere that are not affected by this closure.
- 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/DrugShortages/Current/Bulletin.aspx?id=712>

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

Leucovorin Calcium Injection

March 24, 2014

Reason for the Shortage

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

Article link: <http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=488>

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

Isosorbide Dinitrate Immediate Release Tablets

March 24, 2014

Reason for the Shortage

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

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

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

NEW DRUGS COMING TO MARKET

PRODUCT	MFR	ROUTE	INDICATION	PHARMACOLOGY	MARKET RELEASE
Albiglutide (Syncria)	Human Genome Science/ GSK	SC	Type 2 Diabetes Mellitus	Biological generated from the genetic fusion of human albumin and modified GLP-1 peptide	BLA filed 1/13; FDA action by 4/15/2014
Inhaled Technosphere Insulin (Afrezza)	MannKind	Inhaled insulin	Type I & II Diabetes	Palm-sized inhaler with single use cartridges	NDA re-filed 10/14/2013; FDA action expected 4/15/2014
Tedizolid	Trius Therapeutics	PO,IV	Skin and soft tissue infections	Second-generation oxazolidinone antibacterial agent with activity against drug-resistant Gram-positive infections	NDA filed 10/22/2013; QIDP designation by the FDA 1/2013; FDA priority review with FDA action date of 6/20/2014
Dalbavancin (Dalvance)	Durata	IV	Treat methicillin-resistant Staphylococcus	Second-generation lipoglycopeptide agent that belongs to the same class as vancomycin, once-weekly IV	NDA re-filed 9/26/2013; FDA action date 5/26/14
Epanova	Omthera	PO	Hypertriglyceridemia	Omega-3 fatty acid	NDA filed 7/13; FDA action date 5/5/14
Bupropion SR and naltrexone SR (Contrave)	Orexigen Therapeutics	PO	Obesity	Sustained release combination of atypical antidepressant & opioid receptor antagonist	NDA re-submitted 12/2013; FDA action date 6/10/2014
Ruconest	Salix	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 4/16/14
Vedolizumab (Entyvio)	Takeda	SC, IV	Crohn's disease, ulcerative colitis	Humanized monoclonal antibody that acts as an $\alpha 4\beta 7$ integrin inhibitor	BLA filed 6/13; Priority review; FDA action date 2/18/14 (ulcerative colitis) and 6/18/14 (Crohn's

PRODUCT	MFR	ROUTE	INDICATION	PHARMACOLOGY	MARKET RELEASE
					disease)
Ferric citrate (Zerenex)	Keryx	PO	Hyperphosphatemia	Small-molecule phosphate binder	NDA filed 8/2013; FDA action date 6/7/2014