January 2015*

Drug Information Update

*Includes drug information from December 2014

DRUG INFORMATION UPDATE

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NEW GENERICS TO MARKET

GENERIC DRUG NAME	STRENGTH & DOSAGE FORM	GENERIC MANUFACTURER	BRAND NAME	APPROVAL DATE
Clobetasol Propionate	0.05% spray	Perrigo Co.	Clobex	12/30/2014
Testosterone	25 mg (1%) packet	Perrigo Co.	Androgel	12/30/2014
Lamivudine	10 mg/ml solution	Silarx Pharm	Epivir	1/5/2015
Linezolid	600 mg/300 ml IV solution	Teva Parenteral	Zyvox	1/5/2015
Colchicine	0.6 mg tablet	Prasco Labs	Colcrys	1/12/2015
Colchicine	0.6 mg capsule	West-Ward, Inc.	Mitigare	1/12/2015

NEW DRUG ENTITIES

DESCRIPTION	BRAND NAME	GENERIC NAME	STRENGTH	NOTES
INFLUENZA VIRUS VACCINES	FLUZONE INTRADERM QUAD 2014-15	FLU VACC QS 2014 (18-64YRS)/PF	36MCG/.1ML	New Entity
NASAL ANTI-INFLAMMATORY STEROIDS	CHILDREN'S QNASL	BECLOMETHASONE DIPROPIONATE	40 MCG	New Dosage Form
TOPICAL LOCAL ANESTHETICS	LIDOVEX	LIDOCAINE	3.75 %	New Strength
VITAMIN D PREPARATIONS	REVESTA	VITAMIN D3/FOLIC ACID	5750 UNIT	New Strength
IRRITANTS/COUNTER-IRRITANTS	SOLAICE	CAPSAICIN/MENTHOL	0.05%-5%	New Strength
NARCOTIC ANTITUSSIVE-EXPECTORANT COMBINATION	OBREDON	GUAIFENESIN/HYDROCODONE	200-2.5/5	New Combination
DIETARY SUPPLEMENT, MISCELLANEOUS	CERENX	CITICOLINE SODIUM	500 MG	New Entity
ANALGESICS, NARCOTICS	OXYCONTIN	OXYCODONE HCL	10 MG	NDC Reclass-ification
ANALGESICS, NARCOTICS	OXYCONTIN	OXYCODONE HCL	20 MG	NDC Reclass-ification
ANALGESICS, NARCOTICS	OXYCONTIN	OXYCODONE HCL	15 MG	NDC Reclass-ification
ANALGESICS, NARCOTICS	OXYCONTIN	OXYCODONE HCL	30 MG	NDC Reclass-ification
ANALGESICS, NARCOTICS	OXYCONTIN	OXYCODONE HCL	40 MG	NDC Reclass-ification
ANALGESICS, NARCOTICS	OXYCONTIN	OXYCODONE HCL	60 MG	NDC Reclass-ification
ANALGESICS, NARCOTICS	OXYCONTIN	OXYCODONE HCL	80 MG	NDC Reclass-ification
ANALGESICS, NARCOTICS	EMBEDA	MORPHINE SULFATE/NALTREXONE	20MG-0.8MG	New Formulation
ANALGESICS, NARCOTICS	EMBEDA	MORPHINE SULFATE/NALTREXONE	30MG-1.2MG	New Formulation
ANALGESICS, NARCOTICS	EMBEDA	MORPHINE SULFATE/NALTREXONE	50 MG-2 MG	New Formulation
ANALGESICS, NARCOTICS	EMBEDA	MORPHINE SULFATE/NALTREXONE	60MG-2.4MG	New Formulation
ANALGESICS, NARCOTICS	EMBEDA	MORPHINE SULFATE/NALTREXONE	80MG-3.2MG	New Formulation

DESCRIPTION	BRAND NAME	GENERIC NAME	STRENGTH	NOTES
ANALGESICS, NARCOTICS	EMBEDA	MORPHINE SULFATE/NALTREXONE	100MG-4MG	New Formulation
ANTIPSYCHOTICS, ATYP, D2 PARTIAL AGONIST/5HT MIXED	ABILIFY MAINTENA	ARIPIPRAZOLE	300 MG	New Dosage Form
ANTIPSYCHOTICS, ATYP, D2 PARTIAL AGONIST/5HT MIXED	ABILIFY MAINTENA	ARIPIPRAZOLE	400 MG	New Dosage Form
ADRENERGICS, AROMATIC, NON-CATECHOLAMINE	VYVANSE	LISDEXAMFETAMINE DIMESYLATE	10 MG	New Strength
DIRECT FACTOR XA INHIBITORS	SAVAYSA	EDOXABAN TOSYLATE	15 MG	New Entity
DIRECT FACTOR XA INHIBITORS	SAVAYSA	EDOXABAN TOSYLATE	30 MG	New Entity
DIRECT FACTOR XA INHIBITORS	SAVAYSA	EDOXABAN TOSYLATE	60 MG	New Entity

NEW INDICATIONS (EXISTING DRUGS)

[None]

FDA NEWS/BULLETINS/ADVISORIES/SAFETY ALERTS

Highly Concentrated Potassium Chloride Injection, 10 mEq per 100 mL by Baxter: Recall - Mislabeled Overpouch

[Posted 11/21/2014]

ISSUE: Baxter International Inc. voluntarily recalled one lot of Highly Concentrated Potassium Chloride Injection, 10 mEq per 100 mL to the user level due to a complaint of mislabeling of the overpouch. Some containers of Product Code 2B0826, Highly Concentrated Potassium Chloride Injection, 10 mEq per 100 mL, Lot Number P319160, Exp. 06/30/2015, NDC 0338-0709-48 were incorrectly labeled on the overpouch as Highly Concentrated Potassium Chloride Injection, 20 mEq per 100 mL.
The inability to detect this overpouch mislabeling at the point of care may result in the administration of a dose lower than intended. In the high-risk patient population – patients prone to severe electrolyte imbalance – this hazardous situation may lead to serious, life-threatening adverse health consequences. There have been no reported adverse events associated with this issue to date.

BACKGROUND: Potassium Chloride is indicated for treatment of potassium deficiency and administered intravenously. Products were distributed to customers in the U.S. between June 23, 2014 and October 2, 2014.

RECOMMENDATION: Baxter has notified customers, who are being directed not to use product from the recalled lot. Recalled product should be returned to Baxter for credit by contacting Baxter Healthcare Center for Service at 1-888-229-0001, Monday through Friday, between the hours of 7:00 a.m. and 6:00 p.m., Central Time. Unaffected lot numbers can continue to be used according to the instructions for use. Unaffected lots of product are available for replacement. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to using this drug product.
Source: U.S. Food and Drug Administration (FDA)
Article link:
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm424276.htm

Gabapentin Capsules, USP 300 mg, by Aurobindo Pharma USA: Recall - Complaints of Empty Capsules

[Posted 11/24/2014]

ISSUE: Aurobindo Pharma USA is voluntarily recalling lot GESB14011-A of Gabapentin Capsules, USP 300 mg 100-count bottles to the consumer level. The product lot has been found to contain some empty capsules.

Empty capsules could result in missed dose(s) of gabapentin resulting in adverse health consequences that could range from no effect, short term reduction in efficacy, short term withdrawal effect, or status epilepticus (long period seizures) that could be life-threatening.

BACKGROUND: Gabapentin is used as in the treatment of epilepsy and for the management of post-herpetic neuralgia (pain after shingles). The affected Gabapentin lot is GESB14011-A, Expiration 12/2015 and is packaged in 100-count bottles, NDC 16714-662-01. Product was distributed through Northstar label to retail outlets nationwide.

RECOMMENDATION: Consumers, distributors, and retailers that have product which is being recalled should stop using, distributing, or dispensing the affected lot and return to place of purchase. Consumers with questions regarding this recall can contact Aurobindo Pharma USA Pharmacovigilance group at (732) 839-9400 Option 2. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.
Source: U.S. Food and Drug Administration (FDA)
Article link:
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm424519.htm

Tecfidera (dimethyl fumarate) by Biogen Idec: Drug Safety Communication - Case of Rare Brain Infection PML Reported

[Posted 11/25/2014]

ISSUE: FDA is warning that a patient with multiple sclerosis (MS) who was being treated with Tecfidera (dimethyl fumarate) developed a rare and serious brain infection called progressive multifocal leukoencephalopathy (PML), and later died. The patient who died was not taking any other drugs that affect the immune system or drugs that are thought to be associated with PML. As a result, information describing this case of PML is being added to the Tecfidera drug label.
PML is a rare and serious brain infection caused by the John Cunningham (JC) virus. The JC virus is a common virus that is harmless in most people but can cause PML in some patients who have weakened immune systems.
See the FDA Drug Safety Communication for additional clinical information about this case.

BACKGROUND: Tecfidera is a drug used to treat relapsing forms of multiple sclerosis (MS), a brain and spinal cord disease in which patients experience multiple episodes of weakness, numbness, and other nervous system signs and symptoms that partially or completely resolve overs weeks or months. Patients may develop persistent symptoms and disability over time.

RECOMMENDATION: Healthcare professionals should:

- Tell patients taking Tecfidera to contact you if they develop any symptoms that may be suggestive of progressive multifocal leukoencephalopathy (PML). Symptoms of PML are

diverse, progress over days to weeks, and include the following: progressive weakness on one side of the body or clumsiness of limbs; disturbance of vision; and changes in thinking, memory and orientation, leading to confusion and personality changes. The progression of deficits can lead to severe disability or death.

- Stop Tecfidera immediately at the first sign or symptom suggestive of PML and perform an appropriate diagnostic evaluation.
- Monitor lymphocyte counts in Tecfidera-treated patients according to approved labeling.

Source: U.S. Food and Drug Administration (FDA)
Article link:
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm424752.htm

Ziprasidone (Marketed as Geodon and Generics): Drug Safety Communication - Rare But Potentially Fatal Skin Reactions

[Posted 12/11/2014]

ISSUE: FDA is warning that the antipsychotic drug ziprasidone (marketed under the brand name, Geodon, and its generics) is associated with a rare but serious skin reaction that can progress to affect other parts of the body. A new warning has been added to the Geodon drug label to describe the serious condition known as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). See the FDA Drug Safety Communication for a Data Summary and additional information.
DRESS may start as a rash that can spread to all parts of the body. It can include fever, swollen lymph nodes, and inflammation of organs such as the liver, kidney, lungs, heart, or pancreas. DRESS also causes a higher-than-normal number of a particular type of white blood cell called eosinophils in the blood. DRESS can lead to death.

BACKGROUND: Ziprasidone is an atypical antipsychotic drug used to treat schizophrenia and bipolar I disorder.
FDA reviewed information from six patients in whom the signs and symptoms of DRESS appeared between 11 and 30 days after ziprasidone treatment was started. None of these patients died (see Data Summary in the Drug Safety Communication). Based on this information, FDA required the manufacturer of Geodon to add a new warning for DRESS to the Warnings and Precautions section of the drug labels for the capsule, oral suspension, and injection formulations.

RECOMMENDATION: Patients who have a fever with a rash and/or swollen lymph glands should seek urgent medical care. Health care professionals should immediately stop treatment with ziprasidone if DRESS is suspected.
Source: U.S. Food and Drug Administration (FDA)

Article link:
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm426624.htm

0.9 Percent Sodium Chloride Injection USP in 100 mL MINI-BAG PLUS Container by Baxter: Recall - Particulate Matter

[Posted 12/16/2014]

ISSUE: Baxter International Inc. initiated a recall in the United States of two lots of 0.9% Sodium Chloride Injection USP in 100 mL MINI-BAG PLUS Container to the hospital/user level. The recall is being initiated as a result of two complaints (one per lot) of particulate matter that was identified as a fragment of the frangible from the vial adapter. The issue was identified upon standard visual inspection prior to patient administration.
This recall affects lot numbers P317842 and P317891.
Intravenous administration of a solution containing sterile particulate matter may lead to adverse health consequences. The extent and severity of harm depends on the size, number, and composition of the foreign material, and the patient's underlying medical condition. In the absence of in-line filtration, particles may cause: local vein irritation, inflammatory reaction, aggravation of preexisting infections, allergic reactions, and systemic embolization (blockage of blood vessels, which can result in stroke, heart attack, or damage to other organs such as the kidney or liver).

BACKGROUND: 0.9% Sodium Chloride Injection USP in 100 mL MINI-BAG PLUS Container is a sterile, non-pyrogenic solution for intravenous administration after admixture with a single dose powdered drug.

RECOMMENDATION: According to the 0.9% Sodium Chloride Injection USP in 100 mL MINI-BAG PLUS Container product labeling, the product should be inspected visually for particulate matter and discoloration whenever solution and container permit.
Baxter has notified customers, who are being directed not to use product from the recalled lots. Recalled product should be returned to Baxter for credit by contacting Baxter Healthcare Center for Service at 1-888-229-0001, Monday through Friday, between the hours of 7:00 a.m. and 6:00 p.m., Central Time. Unaffected lots of product are available for replacement.
Source: U.S. Food and Drug Administration (FDA)
Article link:
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm426996.htm

Mitoxantrone by Hospira: Recall - Confirmed Subpotency and Out-Of-Specification
[Posted 12/23/2014]

ISSUE: Hospira, Inc. announced today it has initiated a worldwide voluntary recall to the user level of 10 lots of MitoXANTRONE (both human and veterinary), due to confirmed subpotency and elevated impurity levels. Risk factors associated with these types of out of specifications may include the potential for decreased potency which can lead to decreased effectiveness, additional dosing and the potential for cumulative impurity toxicity requiring medical intervention.

BACKGROUND: Affected lots were distributed to hospitals and veterinary clinics worldwide from February 2013 through November 2014. See Firm Press Release for affected product information. Hospira initiated an investigation to determine the root cause and corrective and preventive actions. The root cause was subsequently found and appropriate implementations of improvements have been initiated for batches manufactured from March 2014.

RECOMMENDATION: Anyone with an existing inventory of the recalled lot should stop use and distribution, and quarantine the product immediately. Customers should notify all users in their facility. Customers who have further distributed the recalled product should notify any accounts or additional locations which may have received the recalled product and instruct them if they have redistributed the product to notify their accounts, locations or facilities to the consumer level.
Hospira has notified its direct customers via a recall letter and is arranging for impacted product to be returned to Stericycle in the United States. For additional assistance in the U.S., call Stericycle at 1-844-265-7407 between the hours of 8a.m. to 5 p.m. ET, Monday through Friday.
Source: U.S. Food and Drug Administration (FDA)
Article link:
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm427967.htm

IV Solutions from Wallcur of San Diego: CDER Statement - FDA Warns Health Care Professionals Not to Inject Patients
[Posted 1/10/2015]

ISSUE: The U.S. Food and Drug Administration is alerting health care professionals not to use Wallcur, LLC, simulated intravenous (IV) products in human or animal patients. These products are for training purposes only. There have been reports of serious adverse events associated with the use of certain of these products – i.e., Practi IV Solution Bags.

BACKGROUND: FDA has become aware that some Wallcur training IV products have been distributed to health care facilities and administered to patients. FDA will continue to investigate and monitor this issue. The agency is also working with the Centers for Disease Control and Prevention to inform health care professionals and state health departments.

RECOMMENDATION: Before administering IV solutions to patients, health care providers should carefully check the labels to ensure that the products are not training products, such as Practi IV Solution Bags marketed by Wallcur. Wallcur's training products, which may bear the words "for clinical simulation," are not to be administered to patients.
Source: U.S. Food and Drug Administration (FDA)
Article link:
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm428496.htm

STUDIES and RECENT TOPICS

FDA drug approvals reached 18-year high in 2014

January 2, 2015

The Food and Drug Administration approved 41 first-of-a-kind drugs in 2014, including a record number of medicines for rare diseases, pushing the agency's annual tally of drug approvals to its highest level in 18 years.

Article Link:

http://www.bigstory.ap.org/article/e85c9213414f40f98fea7196a6a2dba5/fda-drug-approvals-reached-18-year-high-2014

Source: ap.org

E-prescribing of Controlled Substances Grows, Challenges Remain

January 2, 2015

Over the past couple of years, the healthcare industry has seen significant growth in the adoption and use of electronic prescribing (e-prescribing) for controlled substances. Accounting for 12 percent of all prescriptions annually, controlled substances such as opioid narcotics and stimulants have the potential for abuse. Yet, e-prescribing was unavailable until the Drug Enforcement Administration legalized it in 2010. Since then, electronic prescriptions have grown dramatically, according to 18 months of transactional data recently released in a study co-authored by the Office of the National Coordinator for Health IT's Office of Planning, Evaluation, and Analysis.

Article Link:

http://www.healthdatamanagement.com/news/E-prescribing-of-Controlled-Substances-Grows-Challenges-Remain-49562-1.html

Source: healthdatamanagement.com

Fauci: 2015 Will be 'Bad Year' for the Flu

January 4, 2015

Flu season has hit the U.S. particularly hard this year and the widespread outbreak has officially been declared an epidemic by the Centers for Disease Control and Prevention. High flu activity is reported in 22 states, with increased hospitalizations across the country. Dr. Anthony Fauci, director of the National Institute of Allergy and Infectious Diseases, said today that Americans are in for a rough flu season.

Article Link:

http://abcnews.go.com/blogs/politics/2015/01/fauci-2015-will-be-bad-year-for-the-flu/

Source: abcnews.go.com

Diclegis: Drug Makes 30-Year Comeback

January 4, 2015

Class A morning sickness medication gains FDA approval after decades of being misunderstood. Long out of favor, the combination of pyridoxine and doxylamine is now available as Diclegis as

a treatment for pregnancy-related gastric distress. The prescription version is very costly but a much cheaper over-the-counter alternative may serve for many patients.
Article Link:
http://www.medpagetoday.com/EmergencyMedicine/EmergencyMedicine/49368
Source: medpagetoday.com

First Biosimilar Gets FDA Staff Nod as Amgen Drug Draws Imitator

January 5, 2015
The first attempt in the U.S. to bring to market cheaper imitations of expensive biologic drugs gained support from U.S. regulators. Novartis' imitation, or biosimilar, is "highly similar" to Amgen's blockbuster cancer medicine Neupogen, Food and Drug Administration staff said today in a report. FDA advisers will consider the report when they meet Jan. 7 to make a recommendation on whether the biosimilar should be approved for all five conditions Neupogen is sold to treat, most which help increase the white cell blood count of cancer patients.
Article Link:
http://www.bloomberg.com/news/2015-01-05/first-biosimilar-gets-fda-staff-nod-as-amgen-drug-draws-imitator.html
Source: bloomberg.com

Methotrexate: A New Tx Option in Eosinophilic Fasciitis?

January 5, 2015
Methotrexate appeared to be an effective treatment for the rare disease, eosinophilic fasciitis (EF), according to a small study. In a retrospective review of 16 patients, treatment with methotrexate led to complete remission in about 60%, reported Florentina Berianu, MD, of the Mayo Clinic in Jacksonville, Fla., and colleagues.
Article Link:
http://www.medpagetoday.com/Rheumatology/GeneralRheumatology/49389
Source: medpagetoday.com

Shots Beat Pills for Knee Arthritis Relief

January 5, 2015
The most effective treatment for the pain of knee osteoarthritis may be an injection of hyaluronic acid or corticosteroids, and the least effective may be Tylenol or Celebrex pills, a review of studies concludes.
Article Link:
http://well.blogs.nytimes.com/2015/01/05/shots-beat-pills-for-knee-arthritis-relief/?ref=health&_r=1
Source: nytimes.com

'Miracle' weight loss? Stay away, warns FDA

January 5, 2015

It's the season to get fit, but the Food and Drug Administration is warning consumers to stay away from “miracle” weight loss products when meeting their New Year's resolutions. “Many so-called 'miracle' weight loss supplements and foods, including teas and coffees, don’t live up to their claims,” FDA regulators said in a statement. “Worse, they can cause serious harm.”

Article Link:

http://thehill.com/regulation/228490-with-wight-loss-resolutions-fda-warns-beware-of-miracle-drugs

Source: thehill.com

Many Insurers Do Not Cover Drugs Approved To Help People Lose Weight

January 6, 2015

In December, the Food and Drug Administration approved a new anti-obesity drug, Saxenda, the fourth prescription drug the agency has given the green light to fight obesity since 2012. But even though two-thirds of adults are overweight or obese — and many may need help sticking to New Year’s weight-loss resolutions — there’s a good chance their insurer won’t cover Saxenda or other anti-obesity drugs.

Article Link:

http://kaiserhealthnews.org/news/many-insurers-do-not-cover-drugs-approved-to-help-people-lose-weight/

Source: kaiserhealthnews.org

Court to Decide Next Month on Actavis Tactic for its Alzheimer’s Drug

January 7, 2015

In a few weeks, Actavis will know whether it can proceed with controversial plans to remove an older version of its Namenda medication for Alzheimer’s from pharmacy shelves. A federal appeals court yesterday agreed to expedite an appeal the drug maker filed last month after a lower-court judge issued an injunction that prevented the move. A decision is expected by Feb. 16.

Article Link:

http://blogs.wsj.com/pharmalot/2015/01/07/court-to-decide-next-month-on-actavis-tactic-for-its-alzheimers-drug/

Source: wsj.com

For First Time, F.D.A. Panel Approves Generic Copy of Costly Biologic Drug

January 7, 2015

SILVER SPRING, Md. — An expert panel unanimously recommended on Wednesday that the Food and Drug Administration approve a cheaper copy of a special drug used in cancer therapy, paving the way for alternatives to an entire class of complex and costly drugs to enter the United States market.

Article Link:

http://www.nytimes.com/2015/01/08/science/fda-panel-vote-biologics.html?_r=1

Source: nytimes.com

Herceptin May Benefit Some Women With Early Breast Cancer

January 7, 2015

For some women with early breast tumors, lower-dose chemotherapy and the drug Herceptin may help ward off a cancer recurrence, a new study suggests. Experts said the findings, published in the Jan. 8 New England Journal of Medicine, could offer the first standard treatment approach for women in the early stages of HER2-positive breast cancer.

Article Link:

http://consumer.healthday.com/cancer-information-5/breast-cancer-news-94/herceptin-may-benefit-some-women-with-early-breast-cancer-695287.html

Source: healthday.com

Overdose Deaths due to Prescription Painkillers May Peak Soon: Study.

January 7, 2015

Will the number of overdose deaths attributed to prescription drugs peak in a few years? A new analysis suggests this may be possible when viewing the problem as an epidemic. After applying a theory known as Farr's Law, a group of Columbia University professors calculate that the number of prescription drug overdoses each year in the U.S. will peak in 2017 at 16.1 deaths per 100,000 people, and by 2034 will fall back to much lower rates last seen in the early 1980's.

Article Link:

http://blogs.wsj.com/pharmalot/2015/01/07/overdose-deaths-due-to-prescription-painkillers-may-peak-soon-study/

Source: wsj.com

FDA Approvals 1996 vs. 2014: The Two Most Prolific Years, But Stark Differences

January 7, 2015

As highlighted in a number of recent stories, 2014 was a banner year for the biopharmaceutical industry with 41 new drugs approved by the FDA. These same stories point out that this is the largest total of New Medical Entities (NMEs) approved by the FDA since 1996, when 53 drugs were approved. Actually, looking at the FDA's own account, 2014 represents the second highest number of approvals since President Roosevelt signed the Food, Drug and Cosmetic Act which completely revamped the food and drug approval process in 1938.

Article Link:

http://www.forbes.com/sites/johnlamattina/2015/01/07/fda-approvals-1996-vs-2014-the-two-most-prolific-years-but-stark-differences/

Source: forbes.com

Antibiotic Pulled From Dirt Ends 25-Year Drug Drought

January 7, 2015

Scientists have discovered an antibiotic capable of fighting infections that kill hundreds of thousands of people each year, a breakthrough that could lead to the field's first major new drug in more than a quarter-century.

Article Link:
http://www.businessweek.com/news/2015-01-07/antibiotic-breakthrough-ends-25-year-discovery-drought
Source: businessweek.com

Should FDA Change Metformin's Black Box Warning?

January 8, 2015
Diabetes experts are building a case to lift restrictions on using metformin in patients with moderate chronic kidney disease. Two groups of researchers who have separately filed citizens petitions with the FDA have published studies in JAMA journals in the past few weeks showing a lack of evidence for metformin-associated lactic acidosis -- a severe complication that prompted the FDA to warn against the drug's use in CKD patients when it came on the market 20 years ago.
Article Link:
http://www.medpagetoday.com/Endocrinology/Diabetes/49431
Source: medpagetoday.com

This Contraceptive Is Linked to a Higher Risk of HIV

January 8, 2015
Depending on the contraceptive they're using, women may be at higher risk of getting HIV When it comes to the double duty of preventing both pregnancy and HIV, condoms are the best option, especially in the developing world where treatment for the infectious disease is harder to access. But the same isn't true of other contraceptive methods, according to the latest study in Lancet Infectious Diseases.
Article Link:
http://time.com/3660564/contraceptives-hiv-risk/#3660564/contraceptives-hiv-risk/
Source: time.com

Novel Anticoagulants Rapidly Adopted Into Clinical Practice

January 8, 2015
Novel anticoagulants have been rapidly adopted into clinical practice, and their use is associated with increased health care costs, according to a study published in the November issue of The American Journal of Medicine.
Article Link:
http://www.physiciansbriefing.com/Article.asp?AID=695193
Source: physiciansbriefing.com

U.S. official urges use of antivirals to fight 'bad' flu season

January 9, 2015
Influenza is widespread across the United States and this flu season is shaping up to be especially harsh, the director of the U.S. Centers for Disease Control and Prevention said on Friday. Antiviral drugs such as Roche's Tamiflu were underutilized, the CDC's Dr. Thomas

Frieden said, urging doctors to prescribe the drugs to patients with flu-like symptoms even before tests confirm influenza as the cause.
Article Link:
http://www.reuters.com/article/2015/01/09/us-usa-health-flu-idUSKBN0KI20820150109
Source: reuters.com

From Vertigo to Tinnitus, Ear Ailments Are New Focus for Drugs

January 9, 2015
Driving to a meeting in 2008, Jay Lichter, a venture capitalist, suddenly became so dizzy he had to pull over and call a friend to take him to the emergency room. The diagnosis: Ménière's disease, a disorder of the inner ear characterized by debilitating vertigo, hearing loss and tinnitus, or ringing in the ears.
Article Link:
http://www.nytimes.com/2015/01/10/business/ear-disorders-long-neglected-attract-drug-makers-attention-.html?_r=0
Source: nytimes.com

Treating chronic illness with cough syrup: Life in the coverage gap

January 9, 2015
Some 4 million Americans are left in the cracks of our health care system, and many turn to over-the-counter remedies just to get by. Genesis Matos Rodriguez wakes at 6:30 a.m. and shuffles to the kitchen, where garlic ropes hang on beige walls. Air cleansers, her grandmother calls them. Her mom lays out Robitussin cough syrup and a glass of Alka-Seltzer, substitutes for the prescription pills they can no longer afford.
Article Link:
http://www.washingtonpost.com/news/storyline/wp/2015/01/09/treating-chronic-illness-with-cough-syrup-life-in-the-coverage-gap/
Source: washingtonpost.com

The Coming Wave of New Cancer-Fighting Drugs

January 10, 2015
The hottest area in cancer drugs is going mainstream this year. If 2014 proved that the most promising new group of oncology drugs in generations could work, 2015 brings a crowded field that sees winners and losers in a market eventually worth $30 billion a year or more in the next decade.
Article Link:
http://www.bloomberg.com/news/2015-01-11/drugmakers-pile-into-newest-cancer-treatment-classes-health.html
Source: bloomberg.com

Extended-Release Drugs Get Extra Scrutiny in U.S. Quality Focus

January 12, 2015

Extended-release therapies, taken by many Americans to moderate a drug's effect over a stretch of time, face stricter scrutiny from U.S. regulators questioning whether the therapies work as intended. While such medicine from companies like Teva Pharmaceutical Industries Ltd. (TEVA) and Wockhardt Ltd. (WPL) has been withdrawn or recalled before, modified-release drugs are more difficult to test and may require different standards than regular pills. Typically, the drugs use time-release technology to slow the products' absorption by the body.

Article Link:

http://www.bloomberg.com/news/2015-01-13/extended-release-drugs-get-extra-scrutiny-in-u-s-quality-focus.html

Source: bloomberg.com

The Problem With Treating Pain in America

January 12, 2015

Chronic pain affects an estimated 100 million Americans, and between 5 to 8 million use opioids for long-term pain management. Data shows the number of prescriptions written for opioids as well opioid overdose deaths have skyrocketed in recent years, highlighting a growing addiction problem in the U.S. In response, the National Institutes of Health (NIH) released a report on Monday citing major gaps in the way American clinicians are treating pain.

Article Link:

http://time.com/3663907/treating-pain-opioids-painkillers/#3663907/treating-pain-opioids-painkillers/

Source: time.com

Too many people take aspirin to prevent heart attacks, stroke, study says

January 12, 2015

Aspirin is a popular drug for people who've never had a heart attack or stroke and would like to keep it that way. But for more than one in 10 people who do so, aspirin could do more harm than good, a new study suggests.

Article Link:

http://www.latimes.com/science/sciencenow/la-sci-sn-aspirin-use-inappropriate-risks-20150112-story.html

Source: latimes.com

Ramucirumab Improves Survival in Second-Line mCRC

January 12, 2015

Second-line treatment with the VEGFR2 inhibitor ramucirumab (Cyramza) combined with standard FOLFIRI extended survival by 1.6 months versus FOLFIRI alone in patients with metastatic colorectal cancer (mCRC), according to results from the phase III RAISE trial. The data were presented at a presscast held ahead of the 2015 Gastrointestinal Cancers Symposium.

Article Link:

http://www.onclive.com/conference-coverage/GI-2015/Ramucirumab-Improves-Survival-in-Second-Line-mCRC
Source: onclive.com

Should IL-6 be Targeted in Vasculitis?

January 13, 2015

Tocilizumab (Actemra) may offer a treatment option for refractory giant cell arteritis (GCA), providing symptomatic relief and reductions in markers of inflammation, a small, multicenter study suggested.

Among a group of 22 patients who had already received high-dose corticosteroids and other immunosuppressives, 19 had rapid and persistent clinical responses to this monoclonal antibody that targets the interleukin (IL)-6 receptor, according to Miguel A. Gonzalez-Gay, MD, of Hospital Universitario Marques de Valdecilla in Santander, Spain, and colleagues.

Article Link:
http://www.medpagetoday.com/Rheumatology/GeneralRheumatology/49505
Source: medpagetoday.com

ADHD Drug Might Help Treat Binge-Eating Disorder

January 14, 2015

A drug used to treat attention-deficit/hyperactivity disorder (ADHD) may also help treat binge-eating disorder, preliminary research suggests. At higher doses tested, the prescription drug Vyvanse curtailed the excessive food consumption that characterizes binge-eating disorder, researchers said.

Article Link:
http://www.webmd.com/mental-health/eating-disorders/binge-eating-disorder/news/20150114/adhd-drug-might-help-treat-binge-eating-disorder-study-suggests
Source: webmd.com

RECALLS*

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
Drugs	Calcium Chloride Preservative Free Sterile injection, 100 mg/ml, 10 ml vial	Lot #: 05152013@4 (also written as 051513-4), Exp 11/11/13	Class I	Non-Sterility: The firm's contract testing laboratory found sterility failures	Abrams Royal Pharmacy
Drugs	Lidocaine 18.18 mg/mL/ Bupivacaine 2.27 mg/mL/ Epinephrine 0.0022 mg/mL/ Hyaluronidase 13.64 u/mL, supplied in 11 mL Sterile Syringes	Lot# 041013-13 (also been written as "041013@13") Exp: 06/09/2013	Class I	Non-Sterility	Abrams Royal Pharmacy
Drugs	Trace Mineral-5 MDV, supplied in 10 mL vials, Each ML contains: 1 mg Zinc (as sulfate), 0.4 mg Copper (as sulfate), 0.1 mg Manganese (as sulfate), 4 mcg Chromium (as chloride), 20 mcg Selenium (as sodium), 0.9% Benzyl alcohol in water for injection	Lot number 04302013@21 (also written as 043013-21), exp 10/27/2013	Class I	Non-Sterility; contract laboratory identified Staphylococcus warneri in the product	Abrams Royal Pharmacy
Drugs	New Life Nutritional SUPER FAT BURNER, bottle contains 30 CAPSULES, product is packaged in a white plastic bottle with black, red and green font.	no identifying lot numbers present	Class I	Marketed without an approved NDA/ANDA - New Life Nutritional Center is recalling SUPER FAT BURNER, MAXI GOLD WEIGHT LOSS PILL and Esmeralda products marketed as Dietary Supplements due to the presence of undeclared and unapproved drugs.	New Life Nutritional Center
Drugs	MAXI GOLD WEIGHT LOSS PILL, bottle contains 30 CAPSULES, product is packaged in a clear plastic bottle with	no identifying lot numbers present	Class I	Marketed without an approved NDA/ANDA - New Life Nutritional Center is recalling	New Life Nutritional Center

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
	blue lid, gold and orange label with orange font.			SUPER FAT BURNER, MAXI GOLD WEIGHT LOSS PILL and Esmeralda products marketed as Dietary Supplements due to the presence of undeclared and unapproved drugs.	
Drugs	Esmeralda, bottle contains 30 Softgels, product is packaged in a white plastic bottle with green labeling and black font.	no identifying lot numbers present	Class I	Marketed without an approved NDA/ANDA - New Life Nutritional Center is recalling SUPER FAT BURNER, MAXI GOLD WEIGHT LOSS PILL and Esmeralda products marketed as Dietary Supplements due to the presence of undeclared and unapproved drugs.	New Life Nutritional Center
Drugs	Ascorbic Acid 500 mg/mL Sterile Injection, 50mL Multi-dose Vial	Lot #: 05082014@7, Exp 11/04/2014	Class I	Non-Sterility: Failing sterility results were obtained from the recalling firm's contract testing facility indicating that the products may not be sterile.	Pharmacy Creations
Drugs	Glutathione 100mg/mL Sterile Injection, 30 mL Multi Dose Vial	Lot #: 05122014@4, Exp 09/09/2014	Class I	Non-Sterility: Failing sterility results were obtained from the recalling firm's contract testing facility indicating that the products may not be sterile.	Pharmacy Creations
Drugs	Magnesium Chloride 20% (200mg/mL) Sterile Injection, 50mL	Lot #: 05202014@7, Exp	Class I	Non-Sterility: Failing sterility results were	Pharmacy Creations

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
	Multi-Dose Vial	11/19/2014		obtained from the recalling firm's contract testing facility indicating that the products may not be sterile.	
Drugs	Tropi/Cyclo/Phenyl/Tobra/Flurb (1/1/10/0.3/0.03)% Sterile Ophthalmic Solution, 1 mL Dropper in a 3 mL bottle	Lot #: 05202014@3, Exp 11/16/2014	Class I	Non-Sterility: Failing sterility results were obtained from the recalling firm's contract testing facility indicating that the products may not be sterile.	Pharmacy Creations
Drugs	HEPARIN SODIUM, 1000 USP Heparin Units/500 mL (2 USP Heparin Units/mL), in 0.9% Sodium Chloride Injection, 500 mL flexible container unit, NDC 0409-7620-03	Lot #: 41-046-JT, Exp 11/01/2015	Class I	Presence of Particulate Matter: A particulate, confirmed as human hair, was found sealed between the tube and film at the round seal of the unused administrative port of the container.	Hospira Inc.
Drugs	Mercaptopurine Tablets, USP 50mg, a) 60-count bottle (NDC 49884-922-02), b) 250-count bottle (NDC 49884-922-04)	Lot #: a) 140B11, Exp Feb 2016; 14B012, Exp Feb 2016; 14B013, Exp Feb 2016 Lot #: b) 13F046, Exp Jun 2015; 13K073, Exp Oct 2015; 13L075, Exp Oct 2015; 14B010, Exp Feb 2016.	Class II	Failed Dissolution Specifications: Product found to be out of specification (OOS) during stability testing.	Prometheus Laboratories Inc.
Drugs	LOSARTAN POTASSIUM TABLETS USP, 25 mg, 1000 Tablet Bottles	Lot #LJAG003, Expiry: 05/2015	Class II	Failed Content Uniformity Specifications; Dry mix failed blend	Micro Labs Usa, Inc S

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
				uniformity.	
Drugs	Tetrahydrozoline Hydrochloride, USP, 1 KG Bottle	Lot #: 1BJ0479; Expiry: 06/2017	Class II	CGMP Deviations; Stored/dispensed in a non-GMP compliant warehouse at S.I.M.S., Italy.	Spectrum Laboratory Products
Drugs	Normosol-R pH 7.4 Multiple Electrolytes Injection Type 1, USP, 1000 mL container	Lot # 32-082-JT; Exp. 08/15	Class II	Lack of Assurance of Sterility: Potential of punctures through the overwrap and primary container which may result in IV bag leaks.	Hospira Inc.
Drugs	Potassium Chloride in 5% Dextrose and 0.45% Sodium Chloride Injection, USP, 1000 mL container	Lot # 34-017-JT; Exp. 10/15 Lot # 35-100-JT; Exp. 11/15	Class II	Lack of Assurance of Sterility: Potential of punctures through the overwrap and primary container which may result in IV bag leaks.	Hospira Inc.
Drugs	5% Dextrose Injection, USP, 1000 mL container	Lot # 33-094-JT; Exp. 09/15 Lot # 35-028-JT; Exp. 11/15	Class II	Lack of Assurance of Sterility: Potential of punctures through the overwrap and primary container which may result in IV bag leaks.	Hospira Inc.
Drugs	5% Dextrose and 0.45% Sodium Chloride Injection, USP, 1000 mL container	Lot # 33-095-JT; Exp. 09/15 Lot # 36-030-JT; Exp. 12/15	Class II	Lack of Assurance of Sterility: Potential of punctures through the overwrap and primary container which may result in IV bag leaks.	Hospira Inc.
Drugs	Lactated Ringer's and 5% Dextrose Injection, USP; 1000 mL container	Lot # 34-134-JT Exp. 10/15 Lot # 34-166-JT Exp. 10/15	Class II	Lack of Assurance of Sterility: Potential of punctures through the overwrap and primary container which may result in IV bag leaks.	Hospira Inc.
Drugs	5% Dextrose and 0.9% Sodium Chloride Injection, USP, 1000 mL container	Lot # 32-104-JT; Exp. 08/15 Lot # 34-136-JT; Exp. 10/15	Class II	Lack of Assurance of Sterility: Potential of punctures through the overwrap and	Hospira Inc.

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
		Lot # 36-092-JT; Exp. 12/15		primary container which may result in IV bag leaks.	
Drugs	Lactated Ringer's Injection, USP, 1000 mL container	Lot # 32-099-JT; Exp. 08/15 Lot # 32-103-JT; Exp. 08/15 Lot # 34-070-JT; Exp. 10/15 Lot # 34-086-JT; Exp. 10/15 Lot # 34-165-JT; Exp. 10/15 Lot # 35-085-JT; Exp. 11/15 Lot # 35-115-JT; Exp. 11/15 Lot # 35-121-JT; Exp. 11/15 Lot # 36-057-JT; Exp. 12/15	Class II	Lack of Assurance of Sterility: Potential of punctures through the overwrap and primary container which may result in IV bag leaks.	Hospira Inc.
Drugs	Normosol-R Multiple Electrolytes Injection Type 1, USP, 1000 mL container	Lot # 32-081-JT; Exp. 08/15 Lot # 34-115-JT; Exp. 10/15	Class II	Lack of Assurance of Sterility: Potential of punctures through the overwrap and primary container which may result in IV bag leaks.	Hospira Inc.
Drugs	0.9% Sodium Chloride Injection, USP, 1000 mL container	Lot # 32-044-JT; Exp. 08/15 Lot # 32-072-JT; Exp. 08/15 Lot # 32-102-JT; Exp. 08/15 Lot # 33-028-JT; Exp. 09/15 Lot # 33-046-JT; Exp. 09/15 Lot # 33-049-JT; Exp. 09/15 Lot # 33-061-JT; Exp. 09/15 Lot # 33-085-JT; Exp. 09/15 Lot # 33-096-JT; Exp. 09/15	Class II	Lack of Assurance of Sterility: Potential of punctures through the overwrap and primary container which may result in IV bag leaks.	Hospira Inc.

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
		Lot # 33-101-JT; Exp. 09/15 Lot # 33-102-JT; Exp. 09/15 Lot # 34-016-JT; Exp. 10/15 Lot # 34-085-JT; Exp. 10/15 Lot # 34-122-JT; Exp. 10/15 Lot # 34-123-JT; Exp. 10/15 Lot # 35-026-JT; Exp. 11/15 Lot # 35-030-JT; Exp. 11/15 Lot # 35-067-JT; Exp. 11/15 Lot # 36-002-JT ;Exp. 12/15 Lot # 36-029-JT; Exp. 12/15 Lot # 36-049-JT; Exp. 12/15 Lot # 36-058-JT; Exp. 12/15 Lot # 36-103-JT; Exp. 12/15 Lot # 37-013-JT; Exp. 01/16			
Drugs	0.45% Sodium Chloride Injection, USP, 1000 mL container	Lot # 33-027-JT; Exp.09/15 Lot # 33-045-JT; Exp.09/15 Lot # 33-097-JT; Exp.09/15 Lot # 35-068-JT; Exp.11/15 Lot # 36-112-JT; Exp.12/15 Lot # 37-012-JT; Exp.01/15	Class II	Lack of Assurance of Sterility: Potential of punctures through the overwrap and primary container which may result in IV bag leaks.	Hospira Inc.
Drugs	Sterile Water for Injection, USP, 1000 mL container	Lot# 36-084-JT; Exp.12/15	Class II	Lack of Assurance of Sterility: Potential of punctures through the overwrap and primary container	Hospira Inc.

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
				which may result in IV bag leaks.	
Drugs	Diclofenac Sodium and Misoprostol Delayed-Release Tablets, 75 mg/0.2 mg, 60-count bottle	Lot # 694320A, Expiry: 02/28/2015.	Class II	Failed Tablet/Capsule Specifications: Presence of split or broken tablets.	Actavis Laboratories, FL, Inc.
Drugs	Potassium Chloride Injection, 10mEq per 100mL, 100 mL Sterile single dose container bags	Lot #: P319160, Exp 06/30/15	Class II	Labeling: Label Error On Declared Strength: Bags of Potassium Chloride 10 mEq per 100 mL were incorrectly overpouched with wraps labeled as Potassium Chloride Injection, 20 mEq per 100 mL.	Baxter Healthcare Corp.
Drugs	Heparin Sodium in 0.9% Sodium Chloride Injection, 1000 USP Heparin Units, 500 mL in a VIAFLEX Plus Container	Lot #: N003061; N003079; and N003087.	Class II	Subpotent Drug: Heparin raw material was found to have low potency	Baxter Healthcare Corporation
Drugs	Testosterone CYP-250/PROP-20 mg, 10 Ml Syringe, NDC 88888-0326-44	141006HH, 11/6/14	Class II	Lack of sterility assurance; All lots of sterile products compounded by the pharmacy that are within expiry were recalled due to concerns associated with quality control procedures that present a potential risk to sterility assurance that were observed during a recent FDA inspection.	Perry Drug Inc.
Drugs	Methyl B12 25 mg/mL Inj., 10 Syringes, NDC 88888-2014-37	141006GG, 11/6/14; 141009FF, 11/9/14; 141014BB, 11/9/14;	Class II	Lack of sterility assurance; All lots of sterile products compounded by the pharmacy that are within expiry were	Perry Drug Inc.

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
		141014BB, 11/14/14; 1410164, 11/16/14; 141021GG, 11/21/14; 141030DD, 11/30/14		recalled 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	Tri-Mix (PGE-10MCG/PAP-30MG/PT 5Ml vials, NDC 88888-5123-09	141008BB, 11/8/14; 141008CC, 11/8/14; 141010G, 11/10/14; 141010J, 11/10/14; 141010K, 11/10/14; 141013GG, 11/13/14; 141015DD, 11/15/14; 141015BB, 11/15/14; 141020GG, 11/20/14; 141024HH, 11/24/14; 141024II, 11/24/14; 141024JJ, 11/24/14; 141028BB, 11/28/14; 141028CC, 11/28/14; 141031GG, 12/1/14;	Class II	Lack of sterility assurance; All lots of sterile products compounded by the pharmacy that are within expiry were recalled due to concerns associated with quality control procedures that present a potential risk to sterility assurance that were observed during a recent FDA inspection.	Perry Drug Inc.
Drugs	Leuprolide 50 mcg/0.1 mL Micro Lupron Kit, 5Ml, NDC 88888-1124-57	141007DD, 11/7/14; 141015GG, 11/15/14; 141031II, 12/1/2014; 141031AA,	Class II	Lack of sterility assurance; All lots of sterile products compounded by the pharmacy that are within expiry were recalled due to	Perry Drug Inc.

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
		11/31/14; 141031JJ, 12/1/14;		concerns associated with quality control procedures that present a potential risk to sterility assurance that were observed during a recent FDA inspection.	
Drugs	Phenylephrine HCl (100 mcg/mL syr) in 0.9% NaCl 1 mg / 10 mL, 3Ml Syringes, NDC 88888-5230-12	141008AA, 11/8/14; 141017E, 11/17/14; 141030EE, 11/30/14	Class II	Lack of sterility assurance; All lots of sterile products compounded by the pharmacy that are within expiry were recalled due to concerns associated with quality control procedures that present a potential risk to sterility assurance that were observed during a recent FDA inspection.	Perry Drug Inc.
Drugs	Testosterone Cyp 200 mg/mL Sesame Inj., 4Ml Syringes, NDC 88888-7906-71	141013DD, 11/13/14	Class II	Lack of sterility assurance; All lots of sterile products compounded by the pharmacy that are within expiry were recalled due to concerns associated with quality control procedures that present a potential risk to sterility assurance that were observed during a recent FDA inspection.	Perry Drug Inc.
Drugs	HCG Low Dose 30 IU/0.1 mL, 5 Ml vial, NDC 88888-0231-54	141009DD, 11/9/14	Class II	Lack of sterility assurance; All lots of sterile products compounded by the pharmacy that are	Perry Drug Inc.

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
				within expiry were recalled 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	Tri-mix Antidote 10 each Syringes, NDC 88888-0205-17	141010K, 11/10/14	Class II	Lack of sterility assurance; All lots of sterile products compounded by the pharmacy that are within expiry were recalled due to concerns associated with quality control procedures that present a potential risk to sterility assurance that were observed during a recent FDA inspection.	Perry Drug Inc.
Drugs	HCG Low Dose 10 IU / 0.1 mL, 5 Ml vials, NDC 88888-2596-17	141010I, 11/10/14; 141017F, 11/17/14;	Class II	Lack of sterility assurance; All lots of sterile products compounded by the pharmacy that are within expiry were recalled due to concerns associated with quality control procedures that present a potential risk to sterility assurance that were observed during a recent FDA inspection.	Perry Drug Inc.
Drugs	HCG 200 IU/mL Injection, 30Ml, 10 mL vials, NDC 88888-7745-	141015DD, 11/15/14	Class II	Lack of sterility assurance; All lots of sterile products	Perry Drug Inc.

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
	68			compounded by the pharmacy that are within expiry were recalled 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	HCG 10,000 U/ 10 mL PF Inj, 8Ml vials, NDC 88888-5012-34	141015FF, 11/15/14; 141024KK, 11/24/14; 141031CC, 12/1/14	Class II	Lack of sterility assurance; All lots of sterile products compounded by the pharmacy that are within expiry were recalled due to concerns associated with quality control procedures that present a potential risk to sterility assurance that were observed during a recent FDA inspection.	Perry Drug Inc.
Drugs	2Ml HCG 10,000 U/ MB12 - 12,000 MCG/10 Ml Inj, 0.25ML (250IU), NDC 88888-7945-17	141016A, 11/16/14	Class II	Lack of sterility assurance; All lots of sterile products compounded by the pharmacy that are within expiry were recalled due to concerns associated with quality control procedures that present a potential risk to sterility assurance that were observed during a recent FDA inspection.	Perry Drug Inc.
Drugs	Cyclosporine 0.045 %	141013CC,	Class II	Lack of sterility	Perry Drug

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
	Sol PF, 12 mL bottle, NDC 88888-5120-67	11/13/14		assurance; All lots of sterile products compounded by the pharmacy that are within expiry were recalled due to concerns associated with quality control procedures that present a potential risk to sterility assurance that were observed during a recent FDA inspection.	Inc.
Drugs	HCG-20,000 U/2 mL Vial, NDC 88888-2195-47	141021DD, 11/21/14;	Class II	Lack of sterility assurance; All lots of sterile products compounded by the pharmacy that are within expiry were recalled due to concerns associated with quality control procedures that present a potential risk to sterility assurance that were observed during a recent FDA inspection.	Perry Drug Inc.
Drugs	Tri Mix PF SYR 0.5 mL Inj., Compounded Rx, 10 each, NDC 88888-5036-49	141021FF, 11/21/14; 141028CC, 11/28/14	Class II	Lack of sterility assurance; All lots of sterile products compounded by the pharmacy that are within expiry were recalled due to concerns associated with quality control procedures that present a potential risk to sterility assurance that were observed during a recent FDA inspection.	Perry Drug Inc.

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
Drugs	HCG - 10,000 Unit PF Inject, 1mL Syringe, NDC 88888-0216-49	141021CC, 11/21/14	Class II	Lack of sterility assurance; All lots of sterile products compounded by the pharmacy that are within expiry were recalled due to concerns associated with quality control procedures that present a potential risk to sterility assurance that were observed during a recent FDA inspection.	Perry Drug Inc.
Drugs	Sodium Tetradecyl SO4 0.3% Inj., 30 Ml vials, NDC 88888-6427-90	141030FF, 11/30/14	Class II	Lack of sterility assurance; All lots of sterile products compounded by the pharmacy that are within expiry were recalled due to concerns associated with quality control procedures that present a potential risk to sterility assurance that were observed during a recent FDA inspection.	Perry Drug Inc.
Biologics	Meningococcal Polysaccharide Vaccine, Groups A, C, Y, W135 Combined	M12115	Class II	Lot of MENVEO Meningococcal (Groups A, C, Y and W-135) Oligosaccharide Diphtheria CRM-197 Conjugate Vaccine, with higher than specified levels of residual moisture, was distributed.	NOVARTIS VACCINES AND DIAGNOSTICS S.r.l
Drugs	MIDAZOLAM HYDROCHLORIDE INJECTION, 5 mg/1 mL,	Lot 6003827, Exp. Date 04/2015	Class II	Lack of Assurance of Sterility: Glass vials may have finish	Fresenius Kabi USA, LLC

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
	C-IV, For IM or IV Use, 2 mL Vials, NDC: 63323-412-25.			fractures and glass particles.	
Drugs	ONDANSETRON INJECTION, USP, 4 mg/ 2 mL (2 mg/mL), For IM or IV Use, Single Dose 2 mL Vials, NDC: 63323-373-02	Lot 6003930, exp. date 04/2014	Class II	Lack of Assurance of Sterility: Glass vials may have finish fractures and glass particles.	Fresenius Kabi USA, LLC
Drugs	CYANOCOBALAMIN INJECTION, USP, 1000 mcg/mL, For IM or IV Use, Multiple Dose 2 mL Vials, NDC: 63323-044-01.	Lot 6003853, exp. date 04/2014	Class II	Lack of Assurance of Sterility: Glass vials may have finish fractures and glass particles.	Fresenius Kabi USA, LLC
Drugs	Famotidine Injection 20 mg, Rx Only, GALAXY Single Dose Container, Code 2G3424, Sterile Nonpyrogenic, 50 mL Iso-osmotic, NDC 0338-5197-41.	Lot #: NC082768, Exp 12/23/2014	Class II	Presence of Particulate Matter: Baxter Healthcare Corporation has received a complaint reporting the presence of particulate matter identified as plastic/rubber in famotidine Injection premixed containers.	Baxter Healthcare Corp.
Drugs	Tikosyn (dofetilide) 125 mcg (0.125 mg), a) 14-count bottle (NDC 0069-5800-61), b) 60-count bottle (NDC 0069-5800-60)	Lot # a) H79652, Exp. 10/15; b) H79653, Exp. 10/15	Class II	Failed Tablet/Capsule Specifications: Product being recalled due to the potential presence of cracked or broken capsules.	Pfizer Inc.
Drugs	GENTAMICIN INJECTION, USP, equivalent to 40 mg/mL, Rx only, 20 mL Multiple Dose Vial, NDC 63323-010-20	Product Code: 1020; NDC: 63323-010-20; Lot Number: 6107992; Expiration Date: 09/2015	Class II	Defective Container: Vials may be missing stoppers.	Fresenius Kabi USA, LLC
Drugs	Fentanyl Citrate Injection, USP, 2500 mcg Fentanyl/50 mL, 50	Lot 41-099-DK, exp 01MAY2016,	Class II	Lack of Assurance of Sterility; improperly crimped fliptop vials	Hospira Inc.

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
	mL Single-dose Flip top Vial (C-II), Rx only, 25 units per box/50 units per case, NDC 0409-9094-61	NDC 0409-9094-61			
Drugs	Meropenem I.V. 1 g is supplied in 30 mL injection vials, NDC 0409-3506-01	Lot #: 609E014, Exp 1/2016; 609E015, Exp 1J/2016; 609E016, Exp 1/2016; 609E017, Exp 1/2016; 609E018, Exp 1/2016; 609E019, Exp 1/2016; 601E025, Exp 1/2016; 601E027, Exp 1/2016; 601E028A, Exp 1/2016; 601E028B, Exp 1/2016; 601E028C, Exp 1/2016	Class II	Defective Container: Glass vials may crack due to low (thin) out of specification vial wall thickness which may lead to contamination and lack of assurance of sterility.	Hospira Inc.
Drugs	Clinimix E 4.25/10 sulfite-free (4.25% Amino Acid with Electrolytes in 10% Dextrose with Calcium) Injections, in CLARITY Dual Chamber Container, NDC 0338-1115-04	Product Code 2B7717 Lot # P311357, exp 12/31/2015	Class II	Lack of Assurance of Sterility; leaks were observed from the bag seam and port seal	Baxter Healthcare Corp.
Drugs	Benzonatate Capsules, USP, 200 mg, 100-count bottles, NDC 68382-248-01	Lot #: MP2137, MP2138, MP2139, Exp 01/16; MP3614, Exp 03/16; MP5611, MP5613, Exp 05/16	Class II	Failed Tablet/Capsule Specifications: Recall due to wet and/or leaking capsules.	Zydus Pharmaceuticals USA Inc

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
Drugs	Mercaptopurine Tablets, USP, 50 mg, 30 Tablets (3 x 10) unit dose blisters per carton, NDC 68084-325-21	Lot #: 142450 Exp 05/2015; 140862 Exp 02/2015; 141596 Exp 03/2015; 134770 Exp 01/2015	Class II	Failed USP Dissolution Test Requirements: This sub-recall is in response to Prometheus Laboratories Inc. recall for Mercaptopurine USP 50mg because the lot does not meet the specification for dissolution.	American Health Packaging
Drugs	Walgreens ASPIRIN FREE TENSION HEADACHE, Pain Reliever/Pain Reliever Aid, Acetaminophen & Caffeine, 100 Coated Caplets, Item # 427594, NDC 0363-0428-12, UPC Code 311917134925	Lot Number P78221, expiration date 05/14; Lot Number P78222, expiration date 05/14	Class II	Incorrect/Undeclared Excipients: The firm recalled specific lots of Walgreens brand Aspirin Free Tension Headache Caplets due to the presence of sucralose, which was not declared on the label.	LNK International, Inc.
Drugs	Hydroxyprogesterone Caproate, 250 mg per mL, 5 mL vial	Lot #: 071714A	Class II	Lack of Assurance of Sterility: A recent FDA inspection of Vann Healthcare Services facility revealed deficiencies that raise concerns about the pharmacy's ability to consistently assure sterility of their products.	Vann Healthcare Services Inc
Drugs	Epinephrine 1:1000, 0.15 mL packaged in 0.3 mL syringes	Lot #s: 06094A, 06254A, 07164A, 08114A, and 08284C.	Class II	Lack of Assurance of Sterility: A recent FDA inspection of Vann Healthcare Services facility revealed deficiencies that	Vann Healthcare Services Inc

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
				raise concerns about the pharmacy's ability to consistently assure sterility of their products.	
Drugs	Lidocaine 4% Syr (PF) Rx, 1 mL packaged in 3 mL syringes	Lot #s: 06174A, 07214B, and 08154A.	Class II	Lack of Assurance of Sterility: A recent FDA inspection of Vann Healthcare Services facility revealed deficiencies that raise concerns about the pharmacy's ability to consistently assure sterility of their products.	Vann Healthcare Services
Drugs	Tri-mix #4 (Papaverine 30 mg, Phentolamine 1 mg, Prostaglandin-1 10 mcg/mL), packaged in 10 mL sterile glass vials	Lot #s: 04302014@1; 5 mL vial 05072014@4; 10 mL vial 05212014@2; 10 mL vial 06192014@2; 10 mL vial 08072014@4; 5 mL vial 10022014@4; 10 mL split into 2 - 5 mL vials for two different patients	Class II	Lack of Assurance of Sterility: A recent FDA inspection of Vann Healthcare Services facility revealed deficiencies that raise concerns about the pharmacy's ability to consistently assure sterility of their products.	Vann Healthcare Services
Drugs	MAYHEM capsules, Proprietary Blend 525 mg, Dietary Supplement, 60-count bottles, UPC 6 28586 67805 7.	Lot#: CLM061114, Exp 06/16	Class II	Marketed Without An Approved NDA/ANDA: FDA analysis found this product to contain undeclared dexamethasone and cyproheptadine which are FDA approved drugs	Chaotic Labz

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
				making this product an unapproved drug.	
Drugs	Alprazolam tablets, USP, CIV, 0.25 mg, Rx Only, a) 500 count bottle, b) 1000 count bottle, a) NDC 59762-3719-3, b) NDC 59762-3719-4.	Lot #: a) C100429, Exp 03/15, b) C120293, Exp 01/17	Class II	Failed Stability Specifications: Two lots of Alprazolam 0.25 mg tablets, were found to be below specification for assay (potency).	Neolpharma, Inc.
Drugs	Benzonatate Capsules, USP, 100 mg; 100-bottle capsules - NDC 68382-247-01, 500-bottle capsules - NDC 68382-247-05	Lot #: MP2625, MP2626, MP2627 Exp 2/16; MP4875, MP4876, MP4877, MP4878 Exp 4/16; MP6482, MP6483, MP6484, MP6493, MP6494 Exp 6/16	Class II	Failed Tablet/Capsule Specifications: Recall due to wet and/or leaking capsules.	Zydus Pharmaceuticals USA Inc
Drugs	GINSENG KIANPI PIL, 60 capsules, PRODUCT OF KWEILIN DRUG MANUFACTORY	All lots	Class II	Marketed Without An Approved NDA/ANDA: FDA analysis found this product to contain undeclared dexamethasone and cyproheptadine which are FDA approved drugs making this product an unapproved drug.	One and Zen
Drugs	Entertainer's Secret Throat Relief, 2.0 FL oz (59.2 mL), Honey Apple Flavor	Lot No. 141010, Best By Date: 10/2016; UPC Code: 728409847025	Class II	Microbial Contamination of Non Sterile Product; microbial assay reported unacceptable high plate counts and positive for E. Coli	Tropichem Research Labs, Inc.
Drugs	J-TAN D PD Drops (brompheniramine	Lot #: 7770, Expiry: 02/16	Class II	Labeling: Not Elsewhere	Jaymac Pharmaceutica

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
	maleate 1 mg and pseudoephedrine hcl 7.5 mg/ teaspoon), 1 fl oz (30 mL) Bottle, NDC: 64661-032-30.			Classified: Product is labeled "Dye Free" on front panel but contains Red Dye 40.	ls L.L.C.
Drugs	Gabapentin Capsules, USP 300 mg, 100-count bottles, NDC 16714-662-01	Lot #: GESB14011-A, Exp 12/15	Class II	Failed Tablet/Capsule Specifications: Complaints of empty capsules received.	Aurobindo Pharma USA Inc
Drugs	HydrALAZINE Hydrochloride Tablets, USP 25 mg, 100 count bottle	Lot 26708501, Exp. 01/17	Class II	Presence of Foreign Substance: Par Pharmaceutical, Inc. is recalling one lot of HydrALAZINE Hydrochloride tablets due to the presence of small aluminum particles.	Par Pharmaceutical Inc.
Drugs	Gabapentin Capsules, USP, 400 mg, Rx Only, a) 100 capsules per bottle, NDC 14550-513-02, b) 500 Capsules per bottle, NDC 45963-557-50	Lot #s: a) G01889A2 Exp 06/2015, b) G01942A1 Exp 08/2015	Class II	Failed Capsule/Tablet Specifications: Actavis has received several complaint for clumping and breaking of capsules with some bottles showing popped out bottle bottom (round bottom) and creased labels from one distribution center.	Actavis Elizabeth LLC
Drugs	Gabapentin Capsules, USP, 300 mg, Rx Only, 100 capsules per bottle, NDC 45963-556-11	Lot #s: G01960A1, Exp 09/2015, G01967A1, Exp 10/2015	Class II	Failed Capsule/Tablet Specifications: Actavis has received several complaint for clumping and breaking of capsules with some bottles showing popped out bottle bottom (round bottom) and creased labels from	Actavis Elizabeth LLC

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
				one distribution center.	
Drugs	Gabapentin Capsules, USP, 100 mg, Rx Only, a) 100 capsules per bottle, NDC 45963-555-11, b) 500 Capsules per bottle, NDC 45963-555-50	Lot #s: a) G01966A1, Exp 10/2015, b) G02004A1, Exp 03/2016	Class II	Failed Capsule/Tablet Specifications: Actavis has received several complaint for clumping and breaking of capsules with some bottles showing popped out bottle bottom (round bottom) and creased labels from one distribution center.	Actavis Elizabeth LLC
Drugs	Glutathione 200 mg/mL Injectable, packaged in a) 5 mL MDV (multiple dose vials), b) 30 mL MDV (multiple dose vials), and c) 100 mL MDV (multiple dose vials)	Lot #: 11142014@5, 10142014@17, 11032014@13, 08262014@6, 09162014@6, 06272014@12, 08052014@5, 07222014@18, 07222014@3, 06262014@11, 06182014@3	Class II	Incorrect Product Formulation: An incorrect gas was used to remove the oxygen from the vial.	Right Value Drug Stores, Inc.
Drugs	0.9% Sodium Chloride Injection, USP, 100mL, VisIV Container, NDC 0409-7984-11	Lot #: 42-306-C6	Class II	Lack of Assurance of Sterility: The product has the potential for solution to leak at the administrative port.	Hospira Inc.
Drugs	Sterile powder Vancomycin Hydrochloride for Injection, USP, Equivalent to 1 g in 25 ml fliptop vial, 10-count tray	Lot# 43-240-DD; Exp. 07/16 Lot# 44-205-DD,44-455-DD,44-460-DD,44-465-DD; Exp. 08/16	Class III	Correct Labeled Product Mispack: Product tray containing vials was mislabeled to contain another product.	Hospira Inc.
Drugs	Amlodipine Besylate Tablets, USP 10 mg, Rx Only, 90 Tablets per bottle, NDC 68382-123-	Lot #: MP4344, Exp 04/2016	Class III	Discoloration: Brown spots were noted embedded in Amlodipine Besylate	Zydus Pharmaceuticals USA Inc

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
	16			Tablets, 10 mg, Lot # MP4344.	
Drugs	BENZONATATE Capsules, USP, 200 mg, 100 Capsule Bottles, NDC: 68382-248-01	Lot #: MM8555, Expiry: 09/14; Lot #: MM6604, Expiry: 09/14; Lot #: MM8551, Expiry: 09/14; Lot #: MM8552, Expiry: 09/14; Lot #: MM8553, Expiry: 09/14; Lot #: MM8554, Expiry: 09/14.	Class III	Presence of Foreign Capsules/Tablets: Benzonatate 100 mg co-mingled with benzonatate 200 mg capsules.	Zydus Pharmaceuticals USA Inc
Drugs	candesartan cilexetil, tablets, 16 mg, 90-count bottles, NDC 0781-5938-92	Lot #: 3007330, Exp 11/2014	Class III	Failed Impurities/Degradation Specifications: An Out of Specification (OOS) result was generated for the 18 month stability time point for ketone cilexetil impurity and total impurities.	Sandoz, Inc
Drugs	Scrub Care Chlorhexidine Gluconate Solution, 4% Surgical Hand Scrub, OTC, NDC 57613-007-25	All Lots	Class III	Does Not Meet Monograph: Chlorhexidine Gluconate Surgical Scrub Brush is being recalled due to higher concentrations of available chlorhexidine gluconate.	CareFusion 213, LLC
Drugs	Fluoxetine Capsules USP, 20 mg, 100 count bottle, NDC 0781-2822-01	Lot ET5122, Exp. 10/17	Class III	Labeling: Illegible Label: Sandoz Inc. is recalling of one lot of Fluoxetine Capsules due to an illegible logo on the capsule.	Sandoz Incorporated
Drugs	Wockhardt Metoprolol Succinate, Extended-Release Tablets USP, 50	a) Lot # LN10392; Exp. 12/14 b) Lot #	Class III	Failed Dissolution Specifications: Product was out of	Wockhardt Usa Inc.

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
	mg, a)100-count HDPE bottle (NDC 64679-735-02), b) 4000-count pack (64679-735-08)	LN10360; Exp. 12/14		specification (OOS) at the 12 month long term stability testing point.	
Drugs	BELVIQ® (Lorcaserin HCl) Tablets, 10 mg, 60-count bottle, NDC 62856-52960.	Lot #13297008, Exp. 11/15; 13307008, Exp. 11/15; 13367008, Exp.12/15.	Class III	Labeling: Missing Label: Bottles may not have a product label, or have a label with missing or illegible lot number and/or expiry date.	Eisai Inc
Biologics	1 Single-Dose 0.7 mL Vial STERILE DILUENT For Merck Sharp & Dohme Corp., Live Virus Vaccines (Sterile Water) Rx Only, Contains No Preservative, NDC 0006-4309-01 - 10 Single-Dose vials per carton.	K009280	Class III	A single lot of Sterile Diluent, with the potential for the lot number and expiry to be missing from the primary label, was distributed.	Merck & Co Inc
Drugs	Dacarbazine, Injection, USP, 200mg, vials packaged in individual cartons, NDC 61703-327-22.	Lot #: B032223AA; Exp: July 2016	Class III	Discoloration: Reconstituted solution may appear pink instead of colorless to pale yellow when stored per the labeled conditions.	Hospira Inc.
Drugs	Eye Drops (Tetrahydrozoline HCl 0.05%), 0.5 FL OZ (15 mL) Bottles, OTC. Labeled: a) Best Choice, UPC 0 70038 47011 3; b) CVP, UPC: 7 61706 16500 3; c) Equaline, UPC: 0 41163 25110 6; d) exact, UPC: 0 60383 73613 2; e) FAMILY wellness, UPC: 0 32251 00459 9; f) Good Neighbor Pharmacy, UPC: 0 87701 14975 7, NDC: 24385-075-05; g) GOODSENSE, UPC: 1	Lot #: 3A001, Expiry: 01/16; Lot #: 3A002, Expiry: 01/16; Lot #: 3B004, Expiry: 02/16; Lot #: 3B003, Expiry: 02/16; Lot #: 3C005, Expiry: 03/16; Lot #: 3C006, Expiry: 03/16; Lot #: 3D007, Expiry: 04/16; Lot #: 3D008, Expiry: 04/16.	Class III	CGMP Deviations: Active Pharmaceutical Ingredient (API) used for manufacture was stored in a non-GMP compliant warehouse at S.I.M.S., Italy.	K C Pharmaceuticals Inc

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
	80410 00015 6, NDC: 48879-009-07; h) H-E-B, UPC: 0 41220 94731 7; i) Health Mart PHARMACY, UPC: 0 52569 13472 6, NDC: 62011-0102-1; j) healthy accents, UPC: 7 25439 93380 3; k) HyVee, UPC: 0 75450 29604 4; l) Kroger, UPC: 0 11110 38597 0; m) life BRAND, UPC: 057800-19616-7; n) life BRAND, UPC: 0 57800 19616 7; o) LiveBetter, UPC: 0 41310 62042 7; p) meijer, UPC: 0 41250 82916 4; q) Our Family, UPC: 0 70253 96684 2; r) Publix, UPC: 0 41415 01076 5; s) Redness Relief, UPC: 3 21130 70060 9; t) Rexall, UPC: 7 71058 10160 4; u) Rexall, UPC: 7 71058 10160 4; v) select brand, UPC: 0 15127 00066 6; w) Smart sense, UPC: 7 20007 78036 0; x) sunmark, UPC: 0 10939 16733 0, NDC: 49348-037-29; y) SWIFT, UPC: 6 69635 24061 0; z) TopCare, UPC: 0 36800 03639 0; aa) Western Family Foods, UPC:0 15400 03420 3;bb) ZEE, UPC: 6 90689 00614 3.				
Drugs	Eye Drops A.C. (Tetrahydrozoline HCl 0.05%, Zinc sulfate 0.25%), 0.5 FL OZ (15 mL) Bottles, OTC. Labeled: a) Astringent Redness Reliever, UPC:	Lot #: 3B251, Expiry: 02/16; Lot #: 3B250, Expiry: 02/16; Lot #: 3B251, Expiry: 02/16; Lot #: 3C252,	Class III	CGMP Deviations: Active Pharmaceutical Ingredient (API) used for manufacture was stored in a non-GMP	K C Pharmaceuticals Inc

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
	3 21130 70067 8; b) Best Choice, UPC: 0 70038 47010 6; c) EQUALINE, UPC: 0 41163 25114 4; d) GOODSENSE, UPC: 1 80410 00018 7, NDC: 48879-010-07; e) H-E-B, UPC: 0 41220 86936 7; f) healthy accents, UPC: 7 25439 93382 7; g) HyVee, UPC: 0 75450 29777 5; h) Kroger, UPC: 0 11110 38599 4; i) life, UPC: 0 57800 19617 4; j) LiveBetter, UPC: 0 41310 62041 0; k) meijer, UPC: 0 41250 82918 8; l) Publix, UPC: 0 41415 01176 2; m) QUALITY CHOICE, UPC: 6 35515 99505 5; n) REDNESS RELIEF ASTRINGENT, UPC: 0 50428 79686 3; o)Rexall, UPC: 7 71058 10159 8; p) Rexall, UPC: 7 71058 10159 8; q) select brand, UPC: 0 15127 00363 6; r) Smart sense, UPC: 7 20007 96092 2; s) TopCare, UPC: 0 36800 03640 6; t)WESTERN FAMILY, UPC: 0 15400 04552 0.	Expiry: 03/16; Lot #: 3C253, Expiry: 03/16.		compliant warehouse at S.I.M.S., Italy.	
Drugs	Eye Drops Industrial Strength (Polyethylene glycol 400 1%, Tetrahydrozoline HCl 0.05%), 0.5 FL OZ (15 mL) Bottles, OTC. Labeled: a) Manufactured for Petragon, Inc.; b) SWIFT, UPC: 6 69635 24082 5; c) Xpect First	Lot #: 3A450, Expiry: 01/06.	Class III	CGMP Deviations: Active Pharmaceutical Ingredient (API) used for manufacture was stored in a non-GMP compliant warehouse at S.I.M.S., Italy.	K C Pharmaceuticals Inc

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
	aid; d) ZEE, UPC: 6 90689 00609 9.				
Drugs	Eye Drops Advanced Relief (Dextran 70 0.1%, Polyethylene glycol 400 1%, Povidone 1%, Tetrahydrozoline HCl 0.05%), 0.5 FL OZ (15 mL) Bottles, OTC. Labeled: a) Advanced Relief, UPC: 3 21130 70064 7; b) Best Choice, UPC: 0 70038 47009 0; c) EQUALINE, UPC: 0 41163 25392 6; d) equate, UPC: 1 83164 00022 9; e) exchange select, UPC: 6 14299 39625 8; f) GOOD NEIGHBOR PHARMACY, UPC: 0 87701 10663 7, NDC: 24385-077-05; g) GOODSENSE, UPC: 1 80410 00019 4, NDC: 48879-007-07; h) H-E-B, UPC: 0 41220 89137 5; i) Health Mart, UPC: 0 52569 13474 0, NDC: 62011-0104-1; j) healthy accents, NDC: 7 25439 93383 4; k) HyVee, UPC: 0 75450 29778 2; l) Kroger, UPC: 0 11110 38598 7; m) life, UPC: 0 57800 15640 6; n) LiveBetter, UPC: 0 41310 62043 4; o) Medic's Choice, UPC: 0 95072 01251 8, NDC: 055654-025; p) meijer, UPC: 0 41250 82917 1; q) Our Family, UPC: 0 70253 96683 5; r) Publix, UPC: 0 41415 06776 9; s) Rexall, UPC: 7 71058 10462 8; t) Rexall, UPC: 7 71058	Lot #: 3A350, Expiry: 01/16; Lot #: 3B351, Expiry: 02/16; Lot #: 3C352, Expiry: 03/16; Lot #: 3C353, Expiry: 03/16; Lot #: 3C354, Expiry: 03/16.	Class III	CGMP Deviations: Active Pharmaceutical Ingredient (API) used for manufacture was stored in a non-GMP compliant warehouse at S.I.M.S., Italy.	K C Pharmaceuticals Inc

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
	10462 8; u) select brand, UPC 0 15127 00364 3; v) sunmark, UPC: 0 10939 16833 7, NDC: 49348-697-29; w) TopCare, UPC: 0 36800 03641 3; x) WESTERN FAMILY, UPC: 0 15400 03281 0.				
Drugs	sulfur8(R) medicated anti-dandruff conditioner, dandruff treatment for Braids, spray, Active Ingredient: Salicylic Acid, 2%, 12 FL OZ (356ml) spray bottle, UPC: 0 7561044510 7	Lot number: 13TG	Class III	Failed pH specification: Product pH test value of 5.72 failed to meet its product specification of 6.0 to 7.5.	J. Strickland and Co
Drugs	Triamcinolone Acetonide Lotion USP, 0.025% is supplied in the following size: 60 mL (NDC 61748-219-60).	Lots 1413900, 1417200, 1417300, Exp. 02/15	Class III	Failed Impurities/Degradation Specifications: The known impurity went out of specification at 12 months stability point.	Akorn, Inc.
Drugs	ACETAMINOPHEN and CODEINE PHOSPHATE ORAL SOLUTION USP, 120 mg/12 mg per 5 mL, packaged in a) 4 oz. (120 mL) bottles, NDC 0603-9013-54, UPC 3 0603-9013-54 8 and b) ONE PINT (473 mL) bottles, NDC 0603-9013-58, UPC 3 0603-9013-58 6	Lot #: a) L140H13B, Exp. 03/15; L001D14A. Exp. 08/15; b) L140H13A, Exp. 03/15; L205K13A, Exp. 05/15; L019L13A, L020L13A, Exp. 06/15; L001D14B, 08/15; L091D14A, Exp. 10/15	Class III	Failed Impurities/Degradation Specifications: High out of specification results for the known impurity p-Aminophenol.	Qualitest Pharmaceuticals

*Please refer to FDA website for further information; http://www.fda.gov/Safety/Recalls/EnforcementReports/default.htm

CURRENT DRUG SHORTAGES‡

Labetalol Injection

November 21, 2014

Reason for the Shortage

- Hospira had 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.
- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired several products from Bedford Laboratories in July 2014 including labetalol injection. West-Ward is not actively marketing labetalol injection.

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

Trypan Blue 0.15% Ophthalmic Solution

November 21, 2014

Reason for the Shortage

- Dutch Ophthalmic has MembraneBlue on shortage due to difficulty in obtaining raw materials.
- There are no other manufacturers of trypan blue.
- Dutch Ophthalmic has VisionBlue 0.06% ophthalmic solution available (NDC 68803-0612-10). VisionBlue is used as an adjunct in cataract surgery.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1145
Source link: http://www.ashp.org

Vasopressin Injection

November 21, 2014

Reason for the Shortage

- American Regent has vasopressin injection on shortage due to manufacturing delays.
- Par Sterile Products (formerly JHP) discontinued Pitressin injection in November 2014.
- Par Sterile Products introduced Vasostrict injection in November 2014. This is the only FDA-approved vasopressin injection.
- Fresenius Kabi has vasopressin on shortage due to increased demand for the product.

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

Methyldopate Injection

November 25, 2014

Reason for the Shortage

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

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

Pancuronium Injection

November 25, 2014

Reason for the Shortage

- Teva discontinued their pancuronium presentations in May, 2010.
- Hospira's product is on back order due to manufacturing delays and retesting of raw material. Hospira is the only manufacturer of pancuronium.

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

Propranolol Injection

November 25, 2014

Reason for the Shortage

- Ben Venue closed its plant in Bedford, Ohio in July 2014.
- Fresenius Kabi has propranolol injection on back order due to shortage of raw materials.
- Sandoz cannot provide a reason for the shortage.
- West-Ward had propranolol injection on shortage due to manufacturing delays.

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

Synthetic Conjugated Estrogen

November 25, 2014

Reason for the Shortage

- Teva discontinued Cenestin in late-August 2014.
- Premarin is not affected by this shortage.

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

Mercaptopurine Tablets

November 26, 2014

Reason for the Shortage

- Par discontinued mercaptopurine tablets in October 2014.
- Teva could not provide a reason for the shortage.

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

Naproxen Oral Suspension

November 26, 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.

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

Nicardipine Hydrochloride Injection

December 1, 2014

Reason for the Shortage

- Cornerstone Therapeutics discontinued Cardene ampules in March 2014. The company could not provide a reason for the discontinuation.
- Teva recalled 4 lots nicardipine injection because the product did not meet purity specifications. The recalled lots are 31302508B, 31302510B, 31302957B, 31303195B.
- Teva discontinued nicardipine injection in September, 2010.
- American Regent had temporarily suspended distribution of all drug products in April, 2011.
- American Regent resumed manufacturing in Shirely, New York in early-May, 2011.
- Mylan Institutional could not provide a reason for the shortage.
- Wockhardt has nicardipine on shortage due to an FDA import alert.

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

Norepinephrine Injection

December 1, 2014

Reason for the Shortage

- Ben Venue closed its plant in Bedford, Ohio in July 2014.
- Teva temporarily discontinued norepinephrine in June 2010.
- Hospira had Levophed on shortage due manufacturing delays.

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

Amphetamine Mixed Salts, Immediate-Release Tablets

December 2, 2014

Reason for the Shortage

- Teva has product on allocation is due to DEA quotas that are projected annually.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=836
Source link: http://www.ashp.org

Sodium Chloride 0.9% Irrigation

December 2, 2014

Reason for the Shortage

- Baxter has 0.9% sodium chloride irrigation on shortage due manufacturing delays.
- BBraun has 0.9% sodium chloride irrigation on shortage due to increased demand and only has product available for existing customers.
- Hospira has 0.9% sodium chloride irrigation on shortage due manufacturing delays and only has product available for existing customers.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1118
Source link: http://www.ashp.org

Sterile Water Irrigation

December 2, 2014

Reason for the Shortage

- Baxter has sterile water for irrigation on shortage due manufacturing delays.
- BBraun only has product available for existing customers.
- Hospira only has product available for existing customers.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1120
Source link: http://www.ashp.org

Amikacin Injection

December 3, 2014

Reason for the Shortage

- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired amikacin injection from Bedford in July 2014. West-Ward is not actively marketing amikacin 250 mg/mL 4 mL vials at this time.
- Hospira discontinued amikacin in May, 2010 due to a raw material shortage.
- Teva's product was unavailable due to manufacturing delays.
- Sandoz discontinued Amikin injection in 2006.
- Heritage launched amikacin injection in March 2014.

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

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

Calcium Acetate Capsules

December 3, 2014

Reason for the Shortage

- Fresenius Medical cannot provide a reason for the shortage.
- Hawthorne states the reason for the shortage was manufacturing delay.
- Paddock discontinued calcium acetate tablets in February 2012.

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

Choline Magnesium Trisalicylate

December 3, 2014

Reason for the Shortage

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

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

Atenolol Tablets

December 5, 2014

Reason for the Shortage

- Avkare and Mylan Pharmaceuticals could not provide a reason for the shortage.
- Pack Pharmaceuticals discontinued atenolol tablets in October 2014.
- Ranbaxy has atenolol tablets on shortage due to manufacturing delays.
- Zydus has atenolol tablets on allocation due to increased demand.
- Aurobindo and Caraco have discontinued atenolol tablets.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1127
Source link: http://www.ashp.org

Cefpodoxime

December 10, 2014

Reason for the Shortage

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

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

Phenazopyridine Hydrochloride

December 10, 2014

Reason for the Shortage

- Amneal Pharmaceuticals and SDA Laboratories discontinued phenazopyridine tablets.
- Avkare and Marlex could not provide a reason for the shortage.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1144
Source link: http://www.ashp.org

Sincalide Injection

December 10, 2014

Reason for the Shortage

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

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

Tipronin Tablets

December 10, 2014

Reason for the Shortage

- Mission Pharmacal had Thiola on shortage due to raw materials being discontinued.
- Thiola tablets are supplied by Mission Pharmacal and distributed by Retrophin.

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

Black Widow Antivenin (Latrodectus Mactans)

December 12, 2014

Reason for the Shortage

- Merck has low inventory of Antivenin Latrodectus Mactans.
- Merck, working in combination with FDA, announced on July 3, 2014 that the expiration date for Antivenin lot H019984 was extended to January 3, 2015. The packaged Antivenin lot H019984 contains one vial of Antivenin lot 0672105, one vial of sterile diluent lot 0671078, and a 1 mL vial of horse serum for sensitivity testing. The expiration dating for the sterile diluent has not been extended. Discard the sterile diluent and reconstitute the Antivenin vial with 2.5 mL of sterile water for injection.

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

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

Dextran Low Molecular Weight (Dextran 40), 10% Injection

December 12, 2014

Reason for the Shortage

- Hospira states the reason for the shortage is manufacturing delay.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1108
Source link: http://www.ashp.org

Disopyramide Phosphate Controlled-release Capsules

December 12, 2014

Reason for the Shortage

- Pfizer had their Norpace CR on shortage due to manufacturing delays.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1139
Source link: http://www.ashp.org

Doxycycline Capsules and Tablets

December 12, 2014

Reason for the Shortage

- Actavis states the reason for the shortage is supply and demand.
- Akorn acquired VersaPharm in August 2014.
- Aqua could not provide a reason for the shortage.
- Teva discontinued their doxycycline presentations in May 2013.
- Major discontinued most doxycycline presentations in February 2013. The company could not provide a reason for the discontinuation.

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

Magnesium Sulfate Injection

December 12, 2014

Reason for the Shortage

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

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

Phytonadione (Vitamin K) Injection

December 12, 2014

Reason for the Shortage

- Amphastar has vitamin K injection on shortage due to increased demand for the product.
- Hospira had vitamin K injection on shortage due to increased demand for the product.
- Oral vitamin K is not affected by this shortage.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=852
Source link: http://www.ashp.org

Triamcinolone Injection

December 12, 2014

Reason for the Shortage

- Sandoz could not provide a reason for the shortage.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1134
Source link: http://www.ashp.org

Vitamin E Aqueous Oral Solution

December 12, 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/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=965
Source link: http://www.ashp.org

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

December 15, 2014

Reason for the Shortage

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

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

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

December 15, 2014

Reason for the Shortage

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

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

Epinephrine Injection

December 15, 2014

Reason for the Shortage

- American Regent has epinephrine on shortage due to manufacturing delays.
- Amphastar states the shortage is due to increased demand.
- BPI Labs received FDA approval for epinephrine injection in 2014 and the company plans to launch product in January 2015.
- Hospira has epinephrine syringes on shortage due to manufacturing delays.

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

Haemophilus B Conjugate Vaccine

December 15, 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.
- Merck announced in March 2014 plans to discontinue Comvax vaccine. Product will no longer be available directly from Merck after December 31, 2014.

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

Ephedrine Injection

December 16, 2014

Reason for the Shortage

- Hospira discontinued ephedrine in March, 2011.

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

Zinc Injection

December 16, 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 states the shortage of zinc sulfate injection is due to manufacturing delays.
- FDA is allowing temporary importation of zinc gluconate trihydrate 1 mg/mL 10 mL vials from Aguettant Laboratories in France. This product is being distributed through Baxter Healthcare. The labeling will come in the original container which is in French. Information translated into English along with a table comparing the US and French products can be found in the Dear Healthcare Professional Letter.

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

Bleomycin Injection

December 17, 2014

Reason for the Shortage

- Fresenius Kabi states bleomycin was on shortage due to increased demand.
- Hospira states bleomycin was in short supply due to manufacturing delays.
- Teva states bleomycin was on shortage due to increased demand.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=276
Source link: http://www.ashp.org

Bupropion Hydrochloride 24 hour ER Tablets

December 17, 2014

Reason for the Shortage

- Par states the reason for the shortage is increased demand of product.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1106
Source link: http://www.ashp.org

Ciprofloxacin Immediate-Release Tablets

December 17, 2014

Reason for the Shortage

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

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

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

Denileukin Diftitox Injection

December 17, 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/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1009
Source link: http://www.ashp.org

Lactated Ringer's Injection Bags

December 17, 2014

Reason for the Shortage

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

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

Calcitriol Injection

December 18, 2014

Reason for the Shortage

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

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

Famotidine Injection

December 18, 2014

Reason for the Shortage

- Ben Venue stopped production in its plant in Bedford, Ohio and closed in July 2014.
- West-Ward states the shortage was due to manufacturing delays.
- Oral famotidine products are not affected by this shortage.
- Pfizer launched famotidine injections in March, 2012.

- Mylan Institutional acquired famotidine injections from Pfizer on December 6, 2013.

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

Lidocaine Injection

December 18, 2014

Reason for the Shortage

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

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

Methylene Blue Injection

December 18, 2014

Reason for the Shortage

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

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

Bupivacaine Injection

December 19, 2014

Reason for the Shortage

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

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

Sodium Acetate Injection

December 19, 2014

Reason for the Shortage

- American Regent has sodium acetate on shortage due to manufacturing delays.
- American Regent has discontinued sodium acetate 2 mEq/mL 100 mL vials.
- Fresenius Kabi had sodium acetate on shortage due to increased demand.
- Hospira had sodium acetate on shortage due to increased demand.
- Baxter discontinued sodium acetate in June, 2008.

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

Testosterone Cypionate Intramuscular Injection

December 19, 2014

Reason for the Shortage

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

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

Etomidate Injection

December 22, 2014

Reason for the Shortage

- American Regent has etomidate injection on shortage due to manufacturing delays.
- Ben Venue stopped production in its plant in Bedford, Ohio and closed in July 2014.
- Hospira has Amidate injection on shortage due to manufacturing delays.
- Mylan Institutional acquired etomidate injection from Pfizer on December 6, 2013. Mylan Institutional divested some presentations of etomidate injection to JHP Pharmaceuticals in April 2014.
- Mylan recalled 10 lots of etomidate injection with the Pfizer label in February 2014. The recall was due to the presence of particulate matter and missing lot numbers and expiration dates on the vials.
- Par Pharmaceuticals acquired JHP Pharmaceuticals in early 2014. Par Sterile Products will discontinue etomidate once supply is depleted.

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

Methotrexate Injection

December 22, 2014

Reason for the Shortage

- Hospira states the reason for the shortage is a manufacturing delay.
- Sandoz recalled two lots of methotrexate 40 mL preservative-free vials in May 2013 due to discover of particulate matter during routine quality control inspection.
- Mylan Institutional acquired methotrexate injection from Pfizer on December 6, 2013.
- Mylan Institutional divested three presentations of methotrexate injection to Intas (Accord Healthcare) in April 2014.
- Bioniche was acquired by Mylan Institutional in September, 2011.
- Teva discontinued methotrexate 4 mL vials in October 2013 due to business reasons.
- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired several products from Bedford Laboratories in July 2014 including methotrexate injection. West-Ward is not actively marketing methotrexate injection.

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

Morphine Injection

December 22, 2014

Reason for the Shortage

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

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

Posaconazole Oral Suspension

December 22, 2014

Reason for the Shortage

- Merck states the shortage is due to manufacturing delays.
- Noxafil delayed-release tablets and intravenous injections are not affected by this shortage.
- Merck is the only supplier of posaconazole oral suspension.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=695

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

Potassium Phosphate Injection

December 22, 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 had potassium phosphate 15 mL vials on shortage due to increased demand.
- In cooperation with FDA, Fresenius Kabi USA is providing Glycophos (sodium glycerophosphate) injection to the US market to help alleviate the shortage. Glycophos is manufactured in an FDA-approved facility in Norway by Fresenius Kabi AG.
- Fresenius Kabi, USA (formerly APP) launched potassium phosphate injection in November 2013.

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

Rocuronium Injection

December 22, 2014

Reason for the Shortage

- Merck discontinued Zemuron 10 mL multidose vials in the 3rd Quarter of 2013. Merck discontinued Zemuron 5 mL vials in June 2014.
- 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.
- Fresenius Kabi and Sagent cited increased demand as the reason for this shortage.
- The Medicines Company launched rocuronium in early 2014.

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

Alcohol Dehydrated Injection (Ethanol)

December 23, 2014

Reason for the Shortage

- American Regent has alcohol dehydrated on back order due to manufacturing delays.
- Hospira and Consolidated Midland discontinued all injectable alcohol dehydrated products.

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

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

Cefotaxime Injection

December 23, 2014

Reason for the Shortage

- Fresenius Kabi discontinued all cefotaxime presentations in April 2011.
- Hospira has discontinued Claforan. Sanofi-Aventis manufactured Claforan for Hospira and is no longer making the product.

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

Sodium Phosphate Injection

December 23, 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 had 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.
- Fresenius Kabi launched sodium phosphate injection in mid-January 2014.

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

Daunorubicin Hydrochloride Injection

December 30, 2014

Reason for the Shortage

- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired daunorubicin injection and Cerubidine injection from Bedford in July 2014. West-Ward is not actively marketing daunorubicin injection or Cerubidine injection at this time.
- Teva's daunorubicin injection has a 12 month shelf-life after manufacturing.
- Teva states daunorubicin was on back order due to manufacturing delays.

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

Dextrose 5% Injection Large Volume Bags

December 31, 2014

Reason for the Shortage

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

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

Gentamicin Injection

December 31, 2014
Reason for the Shortage

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

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

L-Cysteine Hydrochloride Injection

December 31, 2014
Reason for the Shortage

- American Regent has L-cysteine hydrochloride injection on back order due to manufacturing delays.
- Sandoz cannot provide a reason for the shortage.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=632
Source link: http://www.ashp.org

Ranitidine Injection

December 31, 2014
Reason for the Shortage

- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired ranitidine injection from Bedford in July 2014. West-Ward is not actively marketing ranitidine injection.
- Covis has Zantac on shortage due to capacity issues at the manufacturer.
- Oral ranitidine products are not affected by this shortage.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=820
Source link: http://www.ashp.org

Sodium Chloride 0.45% Injection Bags

December 31, 2014

Reason for the Shortage

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

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

Carboplatin Solution for Injection

January 2, 2015

Reason for the Shortage

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

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

Amifostine Injection

January 5, 2015

Reason for the Shortage

- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired amifostine injection from Bedford in July 2014. West-Ward is actively marketing amifostine injection.
- Caraco discontinued their amifostine injection.
- Medimmune discontinued brand name Ethyol 500 mg injection in August, 2009.

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

Bupivacaine with Epinephrine Injection

January 6, 2015

Reason for the Shortage

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

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

Dimercaprol Injection

January 6, 2015

Reason for the Shortage

- Akorn states BAL in Oil is on shortage due to manufacturing delays.

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

Memantine Hydrochloride

January 6, 2015

Reason for the Shortage

- Forest states the reason for the shortage of Namenda XR capsules is manufacturing delay.

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

Nalbuphine Injection

January 6, 2015

Reason for the Shortage

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

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

Acetaminophen and Codeine Phosphate 300 mg/30 mg Tablets

January 7, 2015

Reason for the Shortage

- Mallinckrodt states the shortage is due to production delays and increased demand.
- Aurobindo, Qualitest, and Teva could not provide a reason for the shortage.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1152
Source link: http://www.ashp.org

Acyclovir Injection

January 7, 2015

Reason for the Shortage

- Fresenius Kabi (formerly APP) is not manufacturing acyclovir lyophilized powder to concentrate on supplying the solution for injection.
- Ben Venue stopped production in its plant in Bedford, Ohio and closed in July 2014.
- AuroMedics introduced acyclovir injection in February 2014.

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

Benztropine Injection

January 7, 2015

Reason for the Shortage

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

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

Ceftazidime Injection

January 7, 2015

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 has ceftazidime on shortage due to manufacturing delays.
- Covis purchased all rights to Fortaz from GlaxoSmithKline. Covis began changing NDC numbers in December 2012.
- Sagent has ceftazidime injection on shortage due to increased demand for the product.
- WG Critical Care launched ceftazidime 1 gram vials in July 2013 and product is available at wholesalers. Ceftazidime 2 gram and 6 gram presentations were launched in August 2013.

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

Doxorubicin Injection

January 7, 2015

Reason for the Shortage

- West-Ward Pharmacetuicals' parent company, Hikma Pharmaceuticals, acquired Adriamycin injection from Bedford in July 2014. West-Ward is not actively marketing Adriamycin injection at this time.
- Pfizer had doxorubicin solution for injection 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.
- Teva could not provide a reason for the shortage.

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

Indocyanine Green

January 7, 2015

Reason for the Shortage

- Akorn states the reason for the shortage was increased demand.
- Hub Pharmaceuticals states the reason for the shortage is increased demand.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1107
Source link: http://www.ashp.org

Lidocaine 4% Solution

January 7, 2015

Reason for the Shortage

- Hospira discontinued LTA Syringes kits on August 5, 2014 due to a business decision.
- Amphastar IMS has Laryng-O-Jets on shortage due to increased demand.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1128
Source link: http://www.ashp.org

Lorazepam injectable presentations

January 7, 2015

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 had 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 increased production to help meet demand.
- Amphastar had lorazepam 2 mg/mL vials on shortage due to increased demand.

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

Moxifloxacin Injection

January 7, 2015
Reason for the Shortage

- Merck cannot provide a reason for the shortage.
- Merck is the sole supplier of moxifloxacin intravenous presentations. Moxifloxacin tablets are not affected by this shortage.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1151
Source link: http://www.ashp.org

Nimodipine Capsules

January 7, 2015
Reason for the Shortage

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

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

Physostigmine Salicylate Injection

January 7, 2015
Reason for the Shortage

- Akorn states the shortage is due to increased demand.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1143
Source link: http://www.ashp.org

Reteplase Injection

January 7, 2015
Reason for the Shortage

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

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

Tamoxifen Tablets

January 7, 2015

Reason for the Shortage

- Teva could not provide a reason for the shortage.
- Mylan discontinued tamoxifen 10 mg 500 count and 20 mg 100 count presentations.
- Actavis could not provide a reason for the shortage.

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

Tamsulosin Hydrochloride Capsules

January 7, 2015

Reason for the Shortage

- Boehringer Ingelheim could not provide a reason for the shortage.
- Actavis and Zydus state the reason for the shortage is increased demand.
- Aurobindo is not marketing the 100 count size.
- Caraco cannot provide a reason for the shortage.
- Teva discontinued tamsulosin 0.4 mg capsules in April 2014.
- Par discontinued tamsulosin 0.4 mg capsules.
- Sandoz has tamsulosin on shortage due to increased demand for the product.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1112
Source link: http://www.ashp.org

Diltiazem Injection

January 8, 2015

Reason for the Shortage

- Ben Venue stopped production in its plant in Bedford, Ohio and closed in July 2014.
- Hospira states the reasons for the shortage are manufacturing delays and increases in demand.
- West-Ward had diltiazem injection on shortage due to manufacturing delays caused by increased demand due to current market conditions.
- Akorn states the reason for the shortage is increased demand due to market conditions.
- Teva discontinued all diltiazem presentations in March, 2011.
- Biovail discontinued Cardizem Lyo-Ject in 2007 due to business reasons.

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

Dopamine Injection

January 8, 2015

Reason for the Shortage

- BBraun 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 had dopamine on allocation due to increased demand.

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

Fluorescein sodium Injection

January 8, 2015

Reason for the Shortage

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

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

Sufentanil Injection

January 8, 2015

Reason for the Shortage

- West-Ward had sufentanil on shortage due to manufacturing delays.
- Hospira has sufentanil on shortage due to manufacturing delays.
- Akorn could not provide a reason for the shortage.

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

Adenosine Injection

January 9, 2015

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 closed in July 2014.
- Sagent has adenosine vials on shortage due to manufacturing delay.

- Teva has discontinued their adenosine injection.
- West-Ward could not provide a reason for the shortage.
- Wockhardt discontinued their adenosine 3 mg/mL 2 mL and 4 mL syringes.

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

Atropine Sulfate Injection

January 9, 2015
Reason for the Shortage

- American Regent states the shortage is due to manufacturing delays.
- Hospira states the shortage is due to manufacturing delays.
- Amphastar has atropine on shortage due to increased demand.

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

Azathioprine Tablets

January 9, 2015
Reason for the Shortage

- Roxane, Salix, and Zydus cannot provide a reason for the shortage.
- Prometheus Laboratories states the reason for the shortage was increased demand.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1123
Source link: http://www.ashp.org

Azithromycin Injection

January 9, 2015
Reason for the Shortage

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

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

Ceftriaxone Sodium Injection

January 9, 2015
Reason for the Shortage

- Ben Venue stopped production in its plant in Bedford, Ohio and closed in July 2014.
- Fresenius Kabi states the reason for the shortage is increased demand.

- Hospira states the reason for the shortage is manufacturing delay.
- Sagent states the reason for the shortage is increased demand.
- Sandoz could not provide a reason for the shortage.
- WG Critical Care states the reason for the shortage is increased demand.

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

Chloroprocaine Injection

January 9, 2015

Reason for the Shortage

- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired several products from Bedford Laboratories in July 2014 including chloroprocaine injection. West-Ward is not actively marketing chloroprocaine injection.
- Hospira discontinued chloroprocaine injection in January, 2012 due to inability to obtain raw materials. All supply was depleted in January.
- Fresenius Kabi (formerly APP) has transitioned from 1 count presentations to 25 count sizes. All 1 count presentations were depleted in early 2012.
- Fresenius Kabi (formerly APP) had Nesacaine on shortage from depletion of raw materials due increased demand for the product.

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

Citric acid and Potassium Citrate Oral

January 9, 2015

Reason for the Shortage

- Cypress Pharmaceuticals has Cytra-K crystals and solution on back order because the product is being relabeled.

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

Cyanocobalamin Injection

January 9, 2015

Reason for the Shortage

- American Regent has cyanocobalamin injection on shortage due to manufacturing delays.
- Fresenius Kabi had cyanocobalamin injection on shortage due to increased demand for the product.

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

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

Fluconazole Injection

January 9, 2015

Reason for the Shortage

- Teva has fluconazole injection on shortage due to manufacturing delays.
- Pfizer had fluconazole injection on shortage due to manufacturing delays related to labeling changes.
- West-Ward had fluconazole injection on shortage due to manufacturing delays.
- Ben Venue has stopped production in its plant in Bedford, Ohio and closed in July 2014.

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

Lactated Ringer's Irrigation

January 9, 2015

Reason for the Shortage

- Baxter has lactated ringer's on shortage due manufacturing delays.
- BBraun has lactated ringer's irrigation on shortage due to increased demand.
- Hospira had lactated ringer's irrigation on shortage due to manufacturing delays.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1119
Source link: http://www.ashp.org

Methylprednisolone Acetate Injection

January 9, 2015

Reason for the Shortage

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

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

Oxacillin Sodium Injection

January 9, 2015

Reason for the Shortage

- Auromedics states the reason for the shortage is increased demand.
- Sagent states the reason for the shortage is manufacturing delay.
- Sandoz states the reason for the shortage is difficulty obtaining the active pharmaceutical ingredient.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1121

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

Paclitaxel Injection

January 9, 2015

Reason for the Shortage

- Fresenius Kabi (formerly APP) had paclitaxel on shortage due to increase demand for the product.
- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired paclitaxel injection from Bedford in July 2014. West-Ward is not actively marketing paclitaxel.
- Teva has paclitaxel on shortage due to manufacturing delays.
- Sandoz has paclitaxel on back order due to a raw material shortage.
- Hospira had paclitaxel on shortage due to increased demand.
- Sagent has paclitaxel on shortage due to increased demand.
- Sagent discontinued paclitaxel 30 mg/5 mL and 100 mg/16.7 mL presentations in October 2014.
- 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.
- WG Critical Care launched paclitaxel injection in September 2014.

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

Pantoprazole Tablets

January 9, 2015

Reason for the Shortage

- Actavis, Aurobindo, Mylan, Teva, and Torrent could not provide a reason for the shortage.
- Actavis discontinued pantoprazole 20 mg tablets in October 2014.
- Kremers Urban state the shortage is due to increased demand.
- FDA imposed an import ban in mid-2013 on several Wockhardt products including pantoprazole.

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

Piperacillin Tazobactam Injection

January 9, 2015

Reason for the Shortage

- Apotex has piperacillin/tazobactam on shortage due to regulatory delays.
- AuroMedics and Sandoz could not provide a reason for the shortage.

- Baxter has Zosyn frozen premixes on allocation due to increased demand.
- Fresenius Kabi has piperacillin/tazobactam on shortage due to increased demand.
- Sagent has piperacillin/tazobactam on shortage due to increased demand.
- Pfizer has Zosyn on shortage due to manufacturing delays. Pfizer estimates there will be supply shortages through 2nd quarter 2015.
- WG Critical Care states the reason for the shortage is increased demand.

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

Proparacaine Hydrochloride Ophthalmic Solution

January 9, 2015

Reason for the Shortage

- Alcon and Valeant cannot provide a reason for the shortage.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1147
Source link: http://www.ashp.org

Succinylcholine chloride Injection

January 9, 2015

Reason for the Shortage

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

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

Vancomycin Hydrochloride Injection

January 9, 2015

Reason for the Shortage

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

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

Aminohippurate Sodium

January 12, 2015

Reason for the Shortage

- Merck cannot provide a reason for the shortage.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1135
Source link: http://www.ashp.org

Amoxicillin 875 mg Tablets

January 12, 2015

Reason for the Shortage

- Aurobindo had amoxicillin on shortage due to manufacturing delays.
- Dr Reddy's discontinued amoxicillin 875 mg tablets in June 2014.
- Ranbaxy has an FDA import ban on amoxicillin tablets.
- Sandoz cannot provide a reason for the shortage.
- West-Ward has amoxicillin on allocation due to increased demand.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1141
Source link: http://www.ashp.org

Bacitracin Topical Ointment

January 12, 2015

Reason for the Shortage

- Altaire, Sandoz, and Qualitest cannot provide a reason for the shortage.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=677
Source link: http://www.ashp.org

Barium Sulfate Oral Suspension

January 12, 2015

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. Bracco has provided an updated product portfolio detailing the product changes and the recommended alternate products.

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

Chorionic Gonadotropin (Human) Injection

January 12, 2015

Reason for the Shortage

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

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

Dexpanthenol Injection

January 12, 2015

Reason for the Shortage

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

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

Ezetimibe and Atorvastatin Tablets

January 12, 2015

Reason for the Shortage

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

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

Levocarnitine Injection

January 12, 2015

Reason for the Shortage

- American Regent has levocarnitine injection on back order due to manufacturing delays.
- Teva has discontinued levocarnitine injection in late 2014.
- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired several products from Bedford Laboratories in July 2014 including levocarnitine injection. West-Ward is not actively marketing levocarnitine injection.

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

Midazolam Injections

January 12, 2015

Reason for the Shortage

- West-Ward acquired Baxter's midazolam injection products in May, 2011.
- Ben Venue stopped production in its plant in Bedford, Ohio and closed in 2014.
- 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.
- Sagent has midazolam on shortage due to manufacturing delay.
- Caraco discontinued two midazolam presentations in 2014.
- FDA imposed an import ban in mid-2013 on several Wockhardt products including midazolam injection.
- Medicines Company has midazolam on shortage due to short-dated product.
- BD RX introduced midazolam injection in 2014.

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

Oxycodone/Acetaminophen Oral Solution

January 12, 2015

Reason for the Shortage

- Roxane states that the reason for the shortage is that they are validating a new source for raw materials.
- Roxane discontinued oxycodone/acetaminophen 5 mL unit-dose cups in July 2014.
- Oxycodone/acetaminophen oral solution is not available from other manufacturers or in other concentrations.
- This shortage does not affect single-ingredient oxycodone solutions or oxycodone/acetaminophen solid oral dosage forms.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1117
Source link: http://www.ashp.org

Phenylephrine 2.5% and 10% Ophthalmic Solution

January 12, 2015

Reason for the Shortage

- Akorn stopped manufacturing phenylephrine ophthalmic solution in April 2014 and stopped distributing product on June 30, 2014.
- Alcon discontinued phenylephrine 2.5% ophthalmic solution with the Sandoz label in April 2014.

- Alcon discontinued Mydfrin 2.5% ophthalmic solution in 2014.
- Hub discontinued phenylephrine 2.5% and 10% ophthalmic solution in 2013.
- Phenylephrine 2.5% and 10% from Paragon BioTeck is the only FDA-approved phenylephrine ophthalmic product. Paragon BioTeck supplies phenylephrine ophthalmic solution 2.5% and 10% and this is distributed by Bausch & Lomb (a division of Valeant).

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

Promethazine Injection

January 12, 2015

Reason for the Shortage

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

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

Secretin Injection

January 12, 2015

Reason for the Shortage

- ChiRhoClin is qualifying a manufacturing site.
- ChiRhoClin has been working with FDA to release ChiRhoStim lot # 0636149. This lot was produced at a new manufacturing site that has not been approved by FDA. Please see the Dear Health Care Provider letter for additional information. ChiRhoClin anticipates the release of a new ChiRhoStim lot in 2015.

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

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

January 12, 2015

Reason for the Shortage

- Sanofi-Pasteur had 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.
- Sanofi-Pasteur updated the NDC numbers on the individual vials and syringes (unit of use). The NDC numbers on the outside cartons (unit of sale) remain the same.
- GlaxoSmithKline has available Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine (Boostrix). The 1 count Boostrix syringe is no longer made.

- GlaxoSmithKline has Boostrix on shortage due to increased demand.
- Adult Tetanus and Diphtheria Toxoids Adsorbed (Td) (Tenivac, Sanofi-Pasteur) is not affected by this shortage.

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

Albuterol Sulfate 0.5% Inhalation Solution

January 14, 2015

Reason for the Shortage

- Enterovirus D68 can cause mild to severe respiratory illness. In 2014, hospitals are seeing more children than usual with severe respiratory illness from enterovirus D68. This is leading to an increased demand for albuterol solution.
- Akorn acquired Hi-Tech Pharmacal in 2014. Hi-Tech had albuterol 0.5% solution on back order due to increased demand.
- Albuterol sulfate 0.083% solution and albuterol HFA inhalers supplies remain available.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1130
Source link: http://www.ashp.org

Cefuroxime Sodium Injection

January 14, 2015

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.
- Fresenius Kabi discontinued manufacturing cefuroxime in 2013.

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

Cidofovir Injection

January 14, 2015

Reason for the Shortage

- Gilead recalled one lot of Vistide on February 4, 2013, due to particulate matter in some vials.
- Gilead discontinued Vistide injection in July 2014.
- Mylan Institutional launched cidofovir injection in mid-March 2013.

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

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

Ciprofloxacin Injection

January 14, 2015

Reason for the Shortage

- Claris, Sagent, and Sandoz could not provide a reason for the shortage.
- Hospira has ciprofloxacin injection on back order due to manufacturing delays.

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

Cisatracurium Injection

January 14, 2015

Reason for the Shortage

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

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

Clindamycin Injection

January 14, 2015

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 had clindamycin injection on shortage due to increased demand.
- Sagent has clindamycin injection on shortage due to manufacturing delays.

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

Deferoxamine Mesylate Injection

January 14, 2015

Reason for the Shortage

- Fresenius Kabi states the shortage is due to increased demand.
- Hospira has deferoxamine on shortage due to manufacturing delays.
- Teva discontinued all deferoxamine presentations in 2013.
- Watson discontinued all deferoxamine presentations.
- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired deferoxamine injection from Bedford in July 2014. West-Ward is not actively marketing deferoxamine injection at this time.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1008
Source link: http://www.ashp.org

Dihydroergotamine Mesylate Injection

January 14, 2015

Reason for the Shortage

- Ben Venue has stopped production in its plant in Bedford, Ohio and closed in 2014.
- Valeant cannot provide a reason for the shortage of dihydroergotamine mesylate injection.

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

Dipyridamole Injection

January 14, 2015

Reason for the Shortage

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

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

Divalproex Sodium Delayed Release Tablets

January 14, 2015

Reason for the Shortage

- Caraco, Mylan, Teva and Unichem Laboratories cannot provide a reason for the shortage.
- Aurobindo, Dr. Reddy's Laboratories, Lupin, and Qualitest discontinued divalproex sodium delayed release tablets.
- Upsher-Smith had divalproex sodium on long-term back order due to manufacturing delay. Upsher-Smith has transitioned to new NDC numbers.
- Zydus has divalproex sodium delayed-release tablets on allocation due to increased demand.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1124
Source link: http://www.ashp.org

Droperidol Injection

January 14, 2015

Reason for the Shortage

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

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

Haloperidol Decanoate Injection

January 14, 2015

Reason for the Shortage

- Teva products are on shortage due to manufacturing delays.
- Fresenius Kabi could not provide a reason for the shortage.
- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired haloperidol decanoate injection from Bedford in July 2014. West-Ward is not actively marketing haloperidol decanoate injection at this time.

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

Haloperidol Lactate Injection

January 14, 2015

Reason for the Shortage

- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired several products from Bedford Laboratories in July 2014 including haloperidol lactate injection. West-Ward is not actively marketing haloperidol lactate at this time.
- Mylan Institutional could not provide a reason for the shortage.
- Sagent had haloperidol lactate on shortage due to manufacturing delays.
- Teva has haloperidol lactate on shortage due to manufacturing delays.
- Mylan Institutional acquired haloperidol lactate injection from Pfizer on December 6, 2013.
- Patriot Pharmaceuticals states the reason for the shortage was increased demand.

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

Hydromorphone Hydrochloride Injection

January 14, 2015

Reason for the Shortage

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

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

Hydroxychloroquine Sulfate Tablets

January 14, 2015

Reason for the Shortage

- Ranbaxy has hydroxychloroquine on shortage due to a regulatory issue.
- Sandoz states the hydroxychloroquine shortage is due to increased demand.
- Zydus could not provide a reason for hydroxychloroquine shortage.
- West-Ward discontinued hydroxychloroquine tablets in September 2014.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1126
Source link: http://www.ashp.org

Nebivolol Tablets

January 14, 2015

Reason for the Shortage

- Actavis could not provide a reason for the shortage.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1137
Source link: http://www.ashp.org

Pantoprazole Injection

January 14, 2015

Reason for the Shortage

- Pfizer has Protonix on shortage due to increased demand.
- Pfizer is the sole supplier of pantoprazole injection.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1153
Source link: http://www.ashp.org

Potassium Chloride Injection

January 14, 2015

Reason for the Shortage

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

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

Pramipexole Dihydrochloride Tablets

January 14, 2015

Reason for the Shortage

- Avkare, Aurobindo, Mylan, Sandoz, and Torrent cannot provide a reason for the shortage.

- Zydus has pramipexole on allocation due to increased demand.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1131
Source link: http://www.ashp.org

Prednisone Tablets

January 14, 2015

Reason for the Shortage

- Cadista states the shortage was due to a raw materials shortage.
- Perrigo discontinued prednisone tablets in 2013.
- Qualitest discontinued prednisone 20 mg tablets in August 2013.
- West-Ward states the reason for the shortage is manufacturing delays.

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

Sterile Water for Injection Large Volume Bags

January 14, 2015

Reason for the Shortage

- Baxter has sterile water for injection on shortage due manufacturing delays.
- BBraun has sterile water for injection on shortage due to increased demand and only has product available for existing customers.
- Hospira has sterile water for injection on shortage due to increased demand and only has product available for existing customers.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1132
Source link: http://www.ashp.org

Trace Elements Injection

January 14, 2015

Reason for the Shortage

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

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

Vecuronium Bromide Injection

January 14, 2015

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 closed in 2014.
- Sagent temporarily suspended the manufacture of vecuronium 10 mg and 20 mg vials.

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

Leuprolide Acetate 14-Day Kit

January 15, 2015

Reason for the Shortage

- Caraco could not provide a reason for the shortage.
- Teva states the shortage is due to manufacturing delays.

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

Octreotide Injection

January 15, 2015

Reason for the Shortage

- Caraco cannot provide a reason for the shortage.
- Fresenius Kabi (formerly APP) reports that the shortage was due to increased demand for the product.
- Sandoz discontinued octreotide injection in 2nd quarter 2013.
- Sagent has octreotide on shortage due to increased demand for the product.
- Teva has octreotide on shortage due to manufacturing delays.
- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired octreotide injection from Bedford in July 2014. West-Ward is not actively marketing octreotide injection except available 1000 mcg/mL, 5 mL vial.
- Wockhardt has octreotide on back order due to an import ban.
- Sandostatin LAR presentations from Novartis are not affected by this shortage.

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

Sterile Empty Vials

January 15, 2015

Reason for the Shortage

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

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

70% Dextrose Injection Large Volume Bags

January 16, 2015

Reason for the Shortage

- Baxter discontinued 70% dextrose 500 mL in 1000 mL partial-fill bags in late-2014.
- Baxter, BBraun, and Hospira state the reason for the shortage is increased demand for product.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1133
Source link: http://www.ashp.org

Acetazolamide Injection

January 16, 2015

Reason for the Shortage

- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired acetazolamide injection from Bedford in July 2014. West-Ward is not actively marketing acetazolamide injection at this time.
- Sagent has acetazolamide injection on shortage due to manufacturing delay.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=463
Source link: http://www.ashp.org

Acetylcysteine Inhalation Solution

January 16, 2015

Reason for the Shortage

- American Regent has acetylcysteine inhalation on shortage due to manufacturing delays.
- Roxane Labs discontinued acetylcysteine inhalation solution in April 2014. The product had previously been on shortage due to manufacturing delays.
- Hospira has acetylcysteine inhalation solution on shortage due to manufacturing delay.
- Fresenius Kabi (formerly APP) states the reason for the shortage is increased demand.

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

Acyclovir Suspension

January 16, 2015

Reason for the Shortage

- Akorn could not provide a reason for the shortage.

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

Atorvastatin Tablets

January 16, 2015

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 discontinued atorvastatin in late-2014.
- Apotex states the shortage is due to increased demand.
- Dr Reddy's, Greenstone, Major, and Sandoz could not provide a reason for the shortage.

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

Atracurium Injection

January 16, 2015

Reason for the Shortage

- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired several products from Bedford Laboratories in July 2014 including atracurium injection. West-Ward is not actively marketing atracurium.
- Hospira has atracurium on shortage due to manufacturing delays.
- Sagent has atracurium on shortage due to manufacturing delays.

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

Azathioprine Injection

January 16, 2015

Reason for the Shortage

- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired azathioprine injection from Bedford in July 2014.West-Ward is not actively marketing azathioprine injection.
- There are no other manufacturers of azathioprine injection.
- The oral presentations are not affected by this shortage.

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

Butorphanol Injection

January 16, 2015

Reason for the Shortage

- Apotex discontinued butorphanol injection in 2008.
- Ben Venue closed its plant in Bedford, Ohio in July 2014.
- Hospira states the shortage was due to manufacturing delays.
- West-Ward discontinued butorphanol injection in early 2012.
- Sandoz discontinued Stadol injection in 2010.

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

Caffeine Citrate Injection and Oral Solution

January 16, 2015

Reason for the Shortage

- American Regent has caffeine citrate on shortage due to manufacturing delays.
- Caraco cannot provide a reason for the shortage.
- Paddock discontinued caffeine citrate injection and oral solution in May 2014.
- Sagent states the reason for the shortage is manufacturing delays.
- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired Cafcit from Bedford in July 2014. West-Ward is actively marketing Cafcit injection.

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

Calcium Chloride Injection

January 16, 2015

Reason for the Shortage

- American Regent has calcium chloride on shortage due to manufacturing delays.
- Amphastar has calcium chloride on shortage due to increased demand.

- Hospira has calcium chloride on shortage due to manufacturing delays.
- Mylan Institutional acquired calcium chloride injection from Amneal in March 2014. FDA had previously given Amneal permission for temporary importation of calcium chloride 100 mg/mL 10 mL syringes from the United Kingdom. Mylan Institutional has FDA permission to sell the remaining imported calcium chloride product.

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

Calcium Gluconate Injection

January 16, 2015

Reason for the Shortage

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

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

Cisplatin Injection

January 16, 2015

Reason for the Shortage

- Fresenius states the shortage was due to increased demand and manufacturing delays.
- Teva was allocating cisplatin to prevent stockpiling.
- WG Critical Care was allocating product due to increased demand.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=57
Source link: http://www.ashp.org

Dacarbazine Injection

January 16, 2015

Reason for the Shortage

- Fresenius states the reason for the shortage is increased demand.
- Teva and Hospira have dacarbazine on back order due to manufacturing delays.
- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired dacarbazine injection from Bedford in July 2014. West-Ward is not actively marketing dacarbazine injection at this time.

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

Dexamethasone Sodium Phosphate

January 16, 2015

Reason for the Shortage

- American Regent has dexamethasone sodium phosphate on shortage due to manufacturing delays.
- Fresenius Kabi 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.
- Mylan Insitutional states the shortage is due to increased demand.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=751
Source link: http://www.ashp.org

Esmolol Injection

January 16, 2015

Reason for the Shortage

- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired esmolol injection from Bedford in July 2014. West-Ward is not actively marketing esmolol injection at this time.

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

Ethambutol Tablets

January 16, 2015

Reason for the Shortage

- Akorn acquired VersaPharm, Inc. in 2014.
- Akorn could not provide a reason for the shortage.
- X-Gen could not provide a reason for the shortage.
- G&W Laboratories discontinued ethambutol tablets in mid-April 2013.

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

Fenoldopam Mesylate Injection

January 16, 2015

Reason for the Shortage

- Hospira has Corlopam vials on shortage due to manufacturing delays.

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

Glycopyrrolate Injection

January 16, 2015

Reason for the Shortage

- American Regent has glycopyrrolate on shortage due to manufacturing delays.
- West-Ward has glycopyrrolate on shortage due to manufacturing delays.

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

Heparin Sodium Injection

January 16, 2015

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

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

Hydralazine Injection

January 16, 2015

Reason for the Shortage

- American Regent has hydralazine injection on shortage due to manufacturing delays.
- Fresenius Kabi has hydralazine injection on shortage due to manufacturing delays.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1129
Source link: http://www.ashp.org

Hydroxyzine Injection

January 16, 2015

Reason for the Shortage

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

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

Indigo Carmine Injection

January 16, 2015

Reason for the Shortage

- American Regent has indigo carmine on back order due to manufacturing delays.
- Akorn has discontinued production of indigo carmine due to shortage of raw material. Akorn is looking for a new raw material supplier.

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

Ketorolac Tromethamine Injection

January 16, 2015

Reason for the Shortage

- American Regent discontinued all ketorolac injection presentations in 2010.
- Fresenius Kabi states the shortage was due to manufacturing delays.
- 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 closed its plant in Bedford, Ohio in July 2014.
- 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.
- Sagent states the reason for the shortage is demand exceeding supply.

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

Mesna Injection

January 16, 2015

Reason for the Shortage

- Fresenius Kabi has mesna on shortage due to increased demand.
- Mylan cannot give a reason for the shortage of mesna.

- Sagent has mesna on shortage due to increased demand.
- Teva has a shortage of mesna injection due to manufacturing delays and does not expect product until late 2015.
- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired mesna injection from Bedford in July 2014. West-Ward is not actively marketing mesna injection at this time.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1148
Source link: http://www.ashp.org

Milrinone Injection

January 16, 2015

Reason for the Shortage

- Fresenius Kabi states the reason for the shortage is increased demand for the product.
- West-Ward states the shortage is due to manufacturing delays.
- Ben Venue stopped production in its plant in Bedford, Ohio and closed in July 2014.
- Apotex, Bioniche, and Teva discontinued milrinone 1 mg/mL vials.
- Sanofi-Aventis discontinued Primacor injection.

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

Morrhuate Sodium Injection

January 16, 2015

Reason for the Shortage

- American Regent has morrhuate sodium injection on shortage due to manufacturing delays.

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

Oxytocin Injection

January 16, 2015

Reason for the Shortage

- Fresenius Kabi, USA (formerly APP) states the shortage is due to increased demand.
- Par Sterile Products (formerly JHP) discontinued generic oxytocin injection in July 2014.
- West-Ward states the shortage is due to stock becoming short-dated.

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

Sumatriptan Succinate Injection

January 16, 2015

Reason for the Shortage

- Sagent states the reason for the shortage is increased demand.
- GlaxoSmithKline could not provide a reason for the shortage.
- Pfizer has had Alsuma on shortage since September 2013 due to manufacturing issues.
- Zogenix sold Sumavel DosePro to Endo in 2014.
- Teva has temporarily suspended the production of sumatriptan injection.

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

Torsemide Injection

January 16, 2015

Reason for the Shortage

- Roche discontinued Demadex injection for business reasons. Demadex tablets are not affected by this shortage.
- American Regent has torsemide on shortage due to manufacturing delays.

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

Ampicillin Sulbactam

January 20, 2015

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 has ampicillin sulbactam vials on allocation due to increased demand for the product.
- WG Critical Care states the shortage is due to increased demand.
- Pfizer and Sandoz cannot provide a reason for the shortage.
- WG Critical Care launched ampicillin sulbactam 1.5 gram vials in March 2014.
- West-Ward acquired several Baxter products in early 2011.

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

Boceprevir Capsules

January 20, 2015

Reason for the Shortage

- Merck Sharp & Dohme has made a business decision to discontinue Victrelis capsules in the US by December 2015.
- Merck Sharp & Dohme is the sole supplier of boceprevir capsules.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1154
Source link: http://www.ashp.org

Cefazolin Injection

January 20, 2015

Reason for the Shortage

- Fresenius Kabi, BBraun, West-Ward, and WG Critical Care have cefazolin on shortage due to increased demand.
- Apotex and Sandoz have cefazolin on shortage due to manufacturing delays.
- Hospira has cefazolin on shortage due to manufacturing delays.
- Sagent has cefazolin on shortage due to manufacturing delays.

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

Digoxin Injection

January 20, 2015

Reason for the Shortage

- West-Ward states the shortage was due to manufacturing delays.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=748
Source link: http://www.ashp.org

Nafcillin Sodium

January 20, 2015

Reason for the Shortage

- AuroMedicss and Fresenius Kabi state the reason for the shortage is increased demand.
- Sagent states the reason for the shortage is manufacturing delay.
- Sandoz states the reason for the shortage is internal issues.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1136
Source link: http://www.ashp.org

Atropine Sulfate Ophthalmic Solution

January 21, 2015

Reason for the Shortage

- Akorn received FDA approval for atropine sulfate 1% ophthalmic solution in July 2014; this new product launched in January 2015. All other atropine sulfate ophthalmic solution products are unapproved products.
- Sandoz and Valeant could not provide a reason for the shortage.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1146
Source link: http://www.ashp.org

BCG Vaccine Live Intravesical

January 21, 2015

Reason for the Shortage

- Sanofi Pasteur states the reason for the shortage is manufacturing delay.
- Merck states the reason for the shortage is manufacturing delay.
- Merck states Tice BCG vaccine percutaneous for tuberculosis (Merck, NDC 00052-0603-02) is also affected because this product is manufactured at the same facility.

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

Benzonatate Capsules

January 21, 2015

Reason for the Shortage

- Amneal and Ascend Laboratories cannot provide a reason for the shortage.
- Caraco will discontinue benzonatate capsules when current supplies are depleted.
- Zydus states the reason for the shortage is manufacturing delay.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1155
Source link: http://www.ashp.org

Bumetanide Tablets

January 21, 2015

Reason for the Shortage

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

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

Dexrazoxane Tablets

January 21, 2015

Reason for the Shortage

- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired dexrazoxane injection from Bedford in July 2014. West-Ward is not actively marketing dexrazoxane injection at this time.
- Biocodex USA acquired Totect from Apricus Pharmaceuticals in April 2013.
- Apricus Pharmaceuticals acquired Topotarget USA in late 2011.
- Topotarget worked with FDA to extend the expiration date of specific batch numbers of Totect to 36 months. Information regarding this extension and the batch numbers can be found in four Dear Healthcare Customer letters available online.

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

Doxorubicin Liposomal Injection

January 21, 2015

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

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

Mannitol Injection

January 21, 2015

Reason for the Shortage

- Hospira had mannitol injection on shortage due to manufacturing delays.
- Fresenius Kabi had mannitol injection on shortage due to increased demand for the product.
- American Regent has mannitol injection on shortage due to manufacturing delays.
- Baxter could not provide a reason for the shortage.

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

Leucovorin Calcium Injection

January 22, 2015

Reason for the Shortage

- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired leucovorin calcium injection from Bedford in July 2014. West-Ward is not actively marketing leucovorin calcium injection at this time.
- Teva had leucovorin on shortage due to manufacturing delays. Teva imported leucovorin calcium (calcium folinate solution) 30 mL vials; however, all product expired in July 2014. Teva will not be importing any additional calcium folinate solution.
- Fresenius Kabi (formerly APP) has leucovorin on shortage due to increase demand.
- Fusilev (levoleucovorin) and leucovorin oral tablets are not affected by the shortage.

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

Neostigmine Methylsulfate Injection

January 22, 2015

Reason for the Shortage

- Bloxiverz is the only FDA-approved neostigmine injection product and this product is manufactured by Éclat Pharmaceuticals.
- All other neostigmine products are unapproved products and no longer marketed.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1150
Source link: http://www.ashp.org

Oseltamivir Phosphate

January 22, 2015

Reason for the Shortage

- Genentech has all Tamiflu presentations available at wholesalers. Emergency drop shipments are available through wholesalers when there is an increased demand for the medication.
- Genentech provides instructions for compounding an extemporaneous 6 mg/mL oral suspension from 75 mg capsules if required.
- Genentech also provides instructions for opening capsules and administering with chocolate syrup, corn syrup, caramel syrup, or dissolved light brown sugar in the product labeling.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1070
Source link: http://www.ashp.org

Reserpine Oral Tablets

January 22, 2015

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

Tacrolimus Capsules

January 22, 2015

Reason for the Shortage

- Accord, Mylan Pharmaceuticals, and Novartis cannot provide a reason for the shortage.
- Sandoz states the reason for the shortage is manufacturing delay.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1149
Source link: http://www.ashp.org

Tobramycin Injection

January 22, 2015

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.

- Mylan Institutional could not provide a reason for the shortage.
- Mylan Institutional has changed the NDC numbers of their tobramycin presentations.

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

Anagrelide Capsules

January 23, 2015
Reason for the Shortage

- Mylan and Teva cannot provide a reason for the shortage.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1156
Source link: http://www.ashp.org

Buphenorphine Sublingual Tablets

January 23, 2015
Reason for the Shortage

- Teva could not provide a reason for the shortage.
- Akorn acquired Hi-Tech Pharmacal in 2014.

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

Chlorothiazide Oral Suspension

January 23, 2015
Reason for the Shortage

- Salix cannot provide a reason for the shortage.
- Salix is the sole supplier of chlorothiazide oral suspension.

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

Desmopressin Injection

January 23, 2015
Reason for the Shortage

- Teva and Hospira have desmopressin injection on shortage due to manufacturing delays.
- Ferring acquired marketing rights of DDAVP from Sanofi in October 2014.

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

Dibucaine Ointment

January 23, 2015

Reason for the Shortage

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

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

Electrolyte Concentrate

January 23, 2015

Reason for the Shortage

- American Regent has Nutrilyte and Nutrilyte II on back order due to manufacturing delays.

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

Furosemide Injection

January 23, 2015

Reason for the Shortage

- Fresenius Kabi (formerly APP) has furosemide injection on shortage due to increased demand for the product.
- American Regent has furosemide injection on shortage due to manufacturing delays.
- Hospira states the shortage was due to manufacturing delays.
- Wockhardt has discontinued all furosemide injection presentations.
- Claris could not provide a reason for the shortage.

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

Lidocaine with Epinephrine Injection

January 23, 2015

Reason for the Shortage

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

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

Multiple Vitamins for Infusion

January 23, 2015

Reason for the Shortage

- Hospira states the shortage is due to manufacturing delays.
- Baxter states the reason for the shortage was manufacturing delays.

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

Nitroglycerin Injection

December 16, 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 had nitroglycerin premixes on shortage due to a raw material supply issue.
- In cooperation with FDA, Arbor Pharmaceuticals is importing glyceryl trinitrate (Nitronal) injection to the US market to help alleviate the national shortage. This glyceryl trinitrate is manufactured in an FDA-approved facility in Germany by Pohl Boskamp. Glyceryl trinitrate is another name for nitroglycerin.

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

Ondansetron Injection

December 22, 2014

Reason for the Shortage

- AuroMedics did not provide a reason for the shortage.
- Caraco temporarily discontinued ondansetron injection.
- Ben Venue stopped production in its plant in Bedford, Ohio and closed in July, 2014.
- Hospira had ondansetron on shortage due to manufacturing delays.
- Mylan Institutional has new NDC numbers for ondansetron 2 mg/mL injectable products.
- Teva plans to re-launch ondansetron 20 mL injection in January 2015.
- West-Ward had ondansetron on back order due to increased demand.
- Wockhardt has ondansetron injection on shortage due to an FDA import alert.

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

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

* Please refer to ASHP website for more information

NEW DRUGS COMING TO MARKET

PRODUCT	MFR	ROUTE	INDICATION	PHARMACOLOGY	MARKET RELEASE
Empagliflozin and linagliptin	Boehringer Ingelheim/ Eli Lilly	PO	Type II diabetes	Sodium-glucose cotransporter-2 (SGLT2) inhibitor and DPP-4 inhibitor	NDA filed 4/2014
Toujeo	Sanofi	INJ (SC)	Type I and II diabetes	Long acting U300 basal insulin	NDA filed 7/2014
LY2963016	Boehringer Ingelheim/ Eli Lilly	INJ (SC)	Type I and II diabetes	Novel version of insulin glargine (biosimilar to Lantus)	NDA was filed 12-2013 under 505(b)(2) application; received tentative approval 8/2014; patent infringement lawsuit may delay launch beyond 2/2015
Veruprevir (ABT-450)/ Ombitasvir (ABT-267)/ Dasabuvir (ABT-333)	AbbVie	PO	Hepatitis C	Hepatitis C virus NS3/4A protease inhibitor (given with ritonavir as booster)/NS5A inhibitor combination given with NS5B polymerase inhibitor dasabuvir	All oral triple therapy receives FDA breakthrough therapy designation 5/2013; NDA filed 4/22/2014; FDA action expected 12/2014
Darunavir and cobicistat	Gilead	PO	HIV	Protease inhibitor and pharmaco-kinetic enhancer	NDA filed 4/2014
Isavuconazole	Basilea	PO,IV	Treatment of systemic and invasive Candida and Aspergillus infections	Binds and inhibits ergosterol synthesis by inhibiting CYP450-dependent 14-alpha sterol demethylase	Orphan drug status; QIDP designation for Aspergillosis 12/2013; NDA filed 7/2014; FDA action expected

PRODUCT	MFR	ROUTE	INDICATION	PHARMACOLOGY	MARKET RELEASE
					3/2015
Avibactam/ ceftazidime	Astra/Zen	IV	Gram negative infections	Combination of novel β-lactamase inhibitor and broad-spectrum cephalosporin	QIDP designation 9/2013; NDA filed; FDA action expected 1Q2015
Panobinostat (Faridak; LBH-589)	Novartis	PO	Cutaneous T-cell lymphoma, CML, MDS	Novel and highly potent histone deacetylase (HDAC) inhibitor that induces cell death of tumor cell lines but not normal cells	NDA filed 3-2014; FDA priority review with action date 11-2014, FDA advisory committee voted 5-2 against approval 11/2014; FDA action expected 2/2015
Palbociclib	Pfizer	PO	Breast cancer	Blocks cyclin dependent kinases (CDK) 4 and 6	FDA Breakthrough Designation 10/2014; FDA action date 4/2015
Lenvatinib	Eisai	PO	Thyroid cancer	Multi-receptor tyrosine kinase inhibitor that inhibits RET kinase and vascular endothelial growth factor receptor (VEGFR)	NDA filed 10-2014; FDA orphan drug status; FDA priority review; FDA action date 4/2015
Sonidegib (LDE-225)	Novartis	PO	Basal cell carcinoma	Smoothend (Smo) antagonist; Hedgehog (Hh) signaling pathway inhibitor	NDA filed 10/2014
Ivabradine	Amgen/ Servier	PO	Chronic heart failure	Bradycardic agent with action on the sino-atrial node	NDA filed 6/2014; FDA fast-track and

PRODUCT	MFR	ROUTE	INDICATION	PHARMACOLOGY	MARKET RELEASE
				controlled by the If current	priority review with action day of 2/2015
Evolocumab (AMG-145)	Amgen	INJ (SC)	Hyper-cholesterolemia	Fully human antibody that targets PCSK9; dosed every 2 or every 4 weeks in studies	NDA filed 8/2014; FDA action date 8/2015
Donepezil HCl/ memantine Er (Arimenda)	Adamas	PO	Alzheimer's disease	Fixed dose combination of NMDA receptor antagonist and an acetylcholine-esterase inhibitor	NDA filed 3/2014
Brexpiprazole	Otsuka	PO	Depression, ADHD, schizophrenia	D2 dopamine partial agonist	NDA filed 7/2014; FDA action date 7/2015
Aripiprazole lauroxil	Alkermes	INJ	Schizophrenia	Long-acting atypical antipsychotic dosed every 2 months	NDA filed 8/2014; FDA action date 8/2015
Naloxegol (Movantik)	Nektar/ AstraZen	PO	Opioid-induced constipation	PEGylated tablet formulation of naloxol (an analogue of naloxone)	FDA approved 9/2014; Launch planned for 1Q2015
Eluxadoline (JNJ-27018966)	Janssen/ Furiex	PO	Irritable bowel syndrome	Opioid delta receptor antagonists; opioid mu receptor agonists	NDA filed 9/2014; FDA priority review
Rolapitant	TESARO/ OPKO Health	PO	Chemotherapy induced nausea and vomiting (prevention)	Neurokinin 1 receptor antagonists	NDA filed 9/2014
Secukinumab (AIN-457)	Novartis	INJ (SC and IV)	Psoriatic arthritis, plaque psoriasis)	Fully human monoclonal antibody targeting interleukin-17 (IL-17)	BLA filed 10/2013; FDA approved 1/2015
Drisapersen	Prosensa	INJ (SC)	Duchenne Muscular	Antisense nucleotide that	Phase III; FDA breakthrough

PRODUCT	MFR	ROUTE	INDICATION	PHARMACOLOGY	MARKET RELEASE
			Dystrophy	induced specific skipping of exon 51 during splicing	therapy designation granted 6/2013; Rolling NDA initiated 10/2014
Albuterol multi-dose dry powder inhaler (Spiromax)	Teva	INH	Reversible obstructive airway disease	Albuterol multi-dose dry powder inhaler (MDPI)	NDA filed 7/2014
Olodaterol/tio-tropium	Boehringer Ingelheim	INH	COPD	Fixed-dose LABA/LAMA combination with Respimat inhaler	NDA filed 8/2014
Mepolizumab (Bosatria)	GSK	INJ (IV,SC)	Asthma, nasal polyposis	Humanized monoclonal antibody against human interleukin-5 (IL-5)	BLA filed 11/2014 for treatment of asthma
Ivacaftor/lu-macaftor	Vertex	PO	Cystic fibrosis	Fixed-dose combination of lumacaftor and ivacaftor (transmembrane conductance regulator stimulants)	FDA Breakthrough Therapy Designation 1/2013; NDA filed 11/2014
Zarzio (Filgrastim biosimilar)	Sandoz	INJ (SC)	Neutropenia	Neupogen biosimilar	BLA submitted 7-2014 (biosimilar pathway); FDA action as early as 3/2015
Asfotase	Enobia Pharma	INJ (SC)	Hypophosphatas ia	Recombinant fusion protein that includes the catalytic domain of human tissue non-specific alkaline phosphate (TNSALP)	FDA breakthrough therapy designation 5/2013; rolling BLA initiated 4/2014
Patiromer	Relypsa	PO	Hyperkalemia	Non-absorbed oral polymeric	NDA filed 10/2014

PRODUCT	MFR	ROUTE	INDICATION	PHARMACOLOGY	MARKET RELEASE
				compound known as patiromer, a potassium binder	
CEP-33237	Teva	PO	Moderate to severe pain	Hydrocodone extended release with abuse deterrent properties; dosed once daily	Phase III; Rolling NDA initiated 10/2014
MNK-155	Mallinkrodt	PO	Moderate to moderately severe acute pain	Hydrocodone and acetaminophen extended release	NDA submitted 5/2014
Multicomponent meningococcal serogroup B vaccine (4CMenB or Bexsero)	Novartis	INJ (IM)	Prevention of meningitis B	Produced using reverse vaccinology, which decodes genetic makeup of MenB & selects proteins that are most likely to be protective vaccine candidates	FDA breakthrough therapy designation; NDA filed 6/2014; FDA approved 1/2015