December 2016

Drug Information Update

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NEW GENERIC APPROVALS

GENERIC DRUG NAME	STRENGTH & DOSAGE FORM	GENERIC MANUFACTURER	BRAND NAME
VENLAFAXINE HCL	225 mg ER 24H tablet	VERTICAL PHARM, TRIGEN LABORATO	VENLAFAXINE HCL ER
MYCOPHENOLATE MOFETIL HCL	**500 mg vial**	**PAR PHARM.**	**CELLCEPT**
ALLOPURINOL SODIUM	500 mg vial	WEST-WARD, INC.	ALOPRIM
METOPROLOL SUCCINATE/HCTZ	50 mg-12.5 mg ER 24H tablet 100 mg-12.5 mg ER 24H tablet	SOLUBIOMIX, LLC	DUTOPROL
BIMATOPROST	0.03% drop	SANDOZ	LATISSE
OSELTAMIVIR PHOSPHATE	30, 45, and 75mg capsules	ALVOGEN INC	TAMIFLU
TIGECYCLINE	50mg vial	FRESENIUS KABI	TYGACIL
NITROPRUSSIDE SODIUM	25 mg/mL vial	SAGENT PHARMACECUETICALS	NITROPRESS
EPINEPHRINE	0.3 mg/0.3 mL auto injector	MYLAN SPECIALTY	EPIPEN 2-PAK
EPINEPHRINE	0.15 mg/0.3 mL auto injector	MYLAN SPECIALTY	EPIPEN JR 2-PAK
EZETIMIBE	10 mg tablet	PAR PHARM.	ZETIA
DORIPENEM	250mg and 500mg vials	APOTEX CORP	DORIBAX

NEW DRUG ENTITIES/COMBINATIONS/STRENGTHS

DESCRIPTION	BRAND NAME	GENERIC NAME	STRENGTH	NOTES
PANCREATIC ENZYMES	PERTZYE	LIPASE/PROTEASE/AMYLASE	4,000 unit-14,375 unit-15,125 unit capsule,delayed release	New Strength
HEPATITIS B TREATMENT AGENTS	VEMLIDY	TENOFOVIR ALAFENAMIDE FUMARATE	25 mg oral tablet	New Entity
ANTIHYPERGLY,INSULIN,LONG ACT-GLP-1 RECEPT.AGONIST	XULTOPHY	INSULIN DEGLUDEC/LIRAGLUTIDE	100 unit-3.6 mg/mL (3 mL) subcutaneous insulin pen	New Entity
ANTIBACTERIAL MONOCLONAL ANTIBODIES	ZINPLAVA	BEZLOTOXUMAB	1,000 mg/40 mL (25 mg/mL) IV vial	New Entity, Approved labeler
ANTIHYPERGLY,INCRETIN MIMETIC(GLP-1 RECEP.AGONIST)	ADLYXIN	LIXISENATIDE	10 mcg/0.2 mL per dose (1)-20 mcg/0.2 mL per dose (1)	New Entity
ANTIHYPERGLY,INCRETIN MIMETIC(GLP-1 RECEP.AGONIST)	ADLYXIN	LIXISENATIDE	20 mcg/0.2 mL per dose	New Entity
ANTIHYPERGLY,INSULIN,LONG ACT-GLP-1 RECEPT.AGONIST	SOLIQUA	INSULIN GLARGINE/LIXISENATIDE	100 unit-33 mcg/mL (3 mL)	New Combination
NARCOTIC ANTAGONISTS	EVZIO	NALOXONE HCL	2 mg/0.4 mL	New Dosage Form

NEW INDICATIONS (EXISTING DRUGS)

DARZALEX®

November 21, 2016

Janssen Biotech, Inc. announced today the U.S. Food and Drug Administration (FDA) has approved DARZALEX® (daratumumab) in combination with lenalidomide and dexamethasone, or bortezomib and dexamethasone, for the treatment of patients with multiple myeloma who have received at least one prior therapy.1 Clinical studies have shown that DARZALEX, in combination with lenalidomide (an immunomodulatory agent) and dexamethasone, reduced the risk of disease progression or death by 63 percent, compared to lenalidomide and dexamethasone alone, in patients with multiple myeloma who received a median of one prior therapy (Hazard Ratio [HR]=0.37; 95 percent CI [0.27, 0.52], p<0.0001).1 In combination with bortezomib (a proteasome inhibitor [PI]) and dexamethasone, DARZALEX reduced the risk of disease progression or death by 61 percent, compared to bortezomib and dexamethasone alone, in patients with multiple myeloma who received a median of two prior lines of therapy (HR=0.39; 95 percent CI [0.28, 0.53], p<0.0001).1 Multiple myeloma is an incurable blood cancer that occurs when malignant plasma cells grow uncontrollably in the bone marrow.

Source: Janssen Biotech, Inc.

FluLaval® Quadrivalent

November 18, 2016

GSK [LSE/NYSE: GSK] announced today it has received approval from the US Food and Drug Administration's (FDA) Center for Biologics Evaluation and Research expanding the indication for FluLaval® Quadrivalent (Influenza Vaccine) to include use in children 6 months and older. Prior to this, the vaccine was only approved for active immunization against influenza A subtype viruses and type B viruses, in persons 3 years of age and older.

Source: GlaxoSmithKline

Jardiance®

December 5, 2016

The U.S. Food and Drug Administration (FDA) approved a new indication for Jardiance® (empagliflozin) tablets to reduce the risk of cardiovascular death in adults with type 2 diabetes and established cardiovascular disease. JARDIANCE is the first type 2 diabetes treatment approved with this additional indication and the only oral type 2 diabetes medicine shown in a clinical trial to provide a life-saving cardiovascular benefit. JARDIANCE is marketed by Boehringer Ingelheim and Eli Lilly and Company (NYSE: LLY).

Source: Boehringer Ingelheim and Eli Lilly and Company

Avastin®

December 6, 2016

Genentech, a member of the Roche Group (SIX: RO, ROG; OTCQX: RHHBY), today announced that the U.S. Food and Drug Administration (FDA) has approved Avastin® (bevacizumab), either in combination with carboplatin and paclitaxel or in combination with carboplatin and gemcitabine chemotherapy, followed by Avastin alone, for the treatment of patients with platinum-sensitive recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer. Women are said to have a 'platinum-sensitive' form of the disease if a relapse occurs six months or longer following the last treatment with a platinum-basedchemotherapy.
Source: Genentech

Synjardy® XR

December 12, 2016

The U.S. Food and Drug Administration (FDA) has approved Synjardy® XR (empagliflozin and metforminhydrochloride extended-release) tablets for adults with type 2 diabetes. When used alongwith diet and exercise, SYNJARDY XR is indicated to improve blood sugar in adults with type2 diabetes when both empagliflozin and metformin can be taken. It is marketed by Boehringer Ingelheim and Eli Lilly and Company (NYSE: LLY).

Source: Eli Lilly and Company

FDA NEWS/BULLETINS/ADVISORIES/SAFETY ALERTS

Sterile Drug Products by Cantrell Drug Company: Recall - Lack of Sterility Assurance

[Posted 11/21/2016]

ISSUE: Cantrell Drug Company is voluntarily recalling certain unexpired sterile drug products due to lack of sterility assurance. Administration of a drug product intended to be sterile that is not sterile could result in serious infections that may be life-threatening. See the press release for a listing of affected products and lot numbers.

BACKGROUND: The recalled products were distributed nationwide to health care facilities from May 25 to October 31, 2016.

RECOMMENDATION: Cantrell Drug Company will begin notifying its customers by email and phone and is arranging for the return of all recalled products. Consumers who have product subject to the recall should stop using it and contact the company.
To return medication or request assistance related to this recall, contact Cantrell Drug Company at 877-666-5222, Monday through Friday between 9 a.m. and 5 p.m. CST. Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report
- Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

Source: U.S. Food and Drug Administration (FDA)

Tri-Coast Pharmacy Sterile Products: Recall - Lack of Sterility Assurance

[Posted 11/21/2016]

ISSUE: Tri-Coast Pharmacy Inc. is voluntarily recalling all sterile products prepared between May 17, 2016 and November 17, 2016 and that remain within expiry due to FDA concerns over the lack of sterility assurance of the drugs named in this recall. Administration of a drug product intended to be sterile that has microbial contamination has the potential to result in serious infections which may be life-threatening. No portion of any lot of these medications has been found to be non-sterile, but the FDA is concerned that the conditions under which they were produced introduce a lack of sterility assurance for these products.
See the press release for a list of affected products.

BACKGROUND: The recalled drug products were used for a variety of indications. All recalled products have a Tri-Coast Pharmacy Inc. label that includes the name Tri-Coast Pharmacy Inc., the logo, the drug name, lot number and the expiration date.

RECOMMENDATION: All patients and providers that received any sterile compounded products from Tri-Coast Pharmacy Inc. prepared between May 17, 2016 and November 17, 2016 and that remain with expiry should take the following actions:

- Quarantine any unused product until further instruction are received to facilitate the product being returned to Tri-Coast Pharmacy Inc.
- Discontinue the use of any products contained in the recall
- Please contact Tri-Coast Pharmacy Inc at 1 (561) 776-7510 or toll free 1 (877) 823-3284, Monday through Friday, 10am to 6pm EST. or email at pharmacist@tricoastrx.com to discuss the returning of any unused product associated with this recall. Patients should contact their physician or healthcare provider if they have experienced any problems that may be associated with using these products. Providers who have

dispensed any sterile products prepared between May 17, 2016 and November 17, 2016 to a patient should contact the patient(s) to whom the product was dispensed and make the patient(s) aware of this recall. Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report
- Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

Source: U.S. Food and Drug Administration (FDA)

Products Containing Belladonna Extract by Raritan Pharmaceuticals: Recall - Possible Belladonna Alkaloids

[Posted 11/25/2016]

ISSUE: Raritan Pharmaceuticals, a contract manufacturer for Homeolab USA, is voluntarily recalling homeopathic products containing belladonna extract (see products below) due to the potential for variation in the content of belladonna extract in the products. The FDA has tested some products and recovered varying levels of belladonna extract content from what is declared on the label.

BACKGROUND: Raritan Pharmaceuticals is a contract manufacturer of these products for Homeolab USA that supplies the belladonna blends to Raritan Pharmaceuticals. These products were distributed Nationwide: 1) Product: CVS Homeopathic Infants' Teething Tablet 135 tablets, UPC: 050428424162, Lots: 41116 and 43436; 2) Product: Kids Relief Homeopathic Ear Relief Oral Liquid 0.85 fl. oz., UPC: 778159090639, Lot: 35254 3) Product: CVS Homeopathic Kids' Ear Relief Liquid 0.85 fl. oz., UPC: 050428441633, Lot: 33149.

RECOMMENDATION: Consumers with any product being recalled should stop using the product. Consumers with questions regarding this recall can contact Raritan Pharmaceuticals by phone at 1-866-467-2748 (Monday-Friday from 8am to 5:30pm EST). 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.
Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report
- Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

Source: U.S. Food and Drug Administration (FDA)

Pioglitazone-containing Medicines: Drug Safety Communication - Updated FDA Review, Increased Risk of Bladder Cancer

Includes Actos, Actoplus Met, Actoplus Met XR, Duetact, and Oseni
[Posted 12/12/2016]

ISSUE: As a result of an updated review, the FDA has concluded that use of the type 2 diabetes medicine pioglitazone (Actos, Actoplus Met, Actoplus Met XR, Duetact, Oseni) may be linked to an increased risk of bladder cancer. The labels of pioglitazone-containing medicines already contain warnings about this risk, and FDA has approved label updates to describe the additional studies reviewed. See the FDA Drug Safety Communication for more details, including a data summary.

BACKGROUND: FDA alerted the public about the possible risk of bladder cancer in September 2010 and June 2011 based on interim results from a 10-year epidemiologic study. FDA changed the labels of pioglitazone-containing

medicines in August 2011 to include warnings about this risk, and required the manufacturer to modify and continue the 10-year study. Pioglitazone is approved to improve blood sugar control, along with diet and exercise, in adults with type 2 diabetes. Pioglitazone works by increasing the body's sensitivity to insulin, a natural hormone that helps control blood sugar levels. Untreated, type 2 diabetes can lead to serious problems, including blindness, nerve and kidney damage, and heart disease.

RECOMMENDATION: Health care professionals should not use pioglitazone in patients with active bladder cancer, and should carefully consider the benefits and risks before using pioglitazone in patients with a history of bladder cancer. Patients should contact their health care professionals if they experience any of the following signs or symptoms after starting pioglitazone, as these may be due to bladder cancer:

- Blood or a red color in the urine
- New or worsening urge to urinate
- Pain when urinating

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report
- Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

Source: U.S. Food and Drug Administration (FDA)

STUDIES and RECENT TOPICS

Viagra Linked With Reduced Heart Attack Risk and Improved Heart Attack Survival

November 18, 2016

Men with type-2 diabetes taking treatments for erectile dysfunction could be reducing their risk of a heart attack and improving their chances of surviving a heart attack, according to a study funded by the British Heart Foundation (BHF) and the United Kingdom National Institute for Health Research.

Source: formkit.com

A pill may soon replace the costly EpiPen

November 19, 2016

As allergy sufferers reel from the soaring costs of the EpiPen — a handheld auto-injection device of epinephrine made by Mylan that prevents life-threatening anaphylactic shock — a new oral tablet alternative is being tested that could solve a host of issues.

Source: cnbc.com

FTC Steps In Where FDA Fears To Tread: On Homeopathy

November 21, 2016

The federal government is probably wincing right now from the after-effects of the election, but one agency deserves a robust round of applause: the Federal Trade Commission. This week, the FTC announced, in a strongly-worded report on homeopathic advertising, that homeopathic drugs should "be held to the same truth-in-advertising standards as other products claiming health benefits."

Source: forbes.com

Bonus From Your Blood Pressure Med: Fewer Fractures?

November 21, 2016

High blood pressure and weakened bones are two big health issues for seniors. Now, new data suggests that one class of drugs might help protect against both. The study of thousands of Veterans Affairs (VA) and Medicare patients found that antihypertension meds called thiazide diuretics also seemed to lower odds of a patient suffering a hip or pelvic fracture, compared with people on other high blood pressure medications.

Source: healthday.com

Prescription drug reactions send more older Americans to the ER

November 22, 2016

We are a nation of prescription drug users. In any given month, half the population – an estimated 48% -- take at least one pharmaceutical medicine. One possible downside to what are often helpful medications is made clear in a study from the Centers for Disease Control and Prevention, published Tuesday in the Journal of the American Medical Association.

Source: cnn.com

8 Things to Know About Biosimilars

November 23, 2016

With the recent US Food and Drug Administration (FDA) approval of a fourth biosimilar medication, these compounds remain a hot topic in many areas of medicine, including nephrology, oncology, endocrinology, gastroenterology, and rheumatology, as attested by the several biosimilar trials presented at the recent American College of Rheumatology Annual Meeting.

Source: medscape.com

The FDA's Historic Caution On Abuse Deterrent Labeling

November 25, 2016

Before the market open on Friday, IntelliPharmaCeutics reported its NDA submission for its abuse-deterrent Rexista (oxycodone hydrochloride) extended release tablets designed in 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg and 80 mg strengths.

Source: yahoo.com

An AI Ophthalmologist Shows How Machine Learning May Transform Medicine

November 29, 2016

Google researchers got an eye-scanning algorithm to figure out on its own how to detect a common form of blindness, showing the potential for artificial intelligence to transform medicine remarkably soon. The algorithm can look at retinal images and detect diabetic retinopathy—which affects almost a third of diabetes patients—as well as a highly trained ophthalmologist can. It makes use of the same machine-learning technique that Google uses to label millions of Web images.

Source: technologyreview.com

F.D.A. Agrees to New Trials for Ecstasy as Relief for PTSD Patients

November 29, 2016

After three tours in Iraq and Afghanistan, C. J. Hardin wound up hiding from the world in a backwoods cabin in North Carolina. Divorced, alcoholic and at times suicidal, he had tried almost all the accepted treatments for post-traumatic stress disorder: psychotherapy, group therapy and nearly a dozen different medications.

Source: nytimes.com

After criticism from scientists, Congress eases its pursuit of faster stem cell therapies

November 30, 2016

Tapping the brakes on an effort to speed new stem cell treatments to patients by relaxing regulations, Congress this week is considering a modified proposal that is attracting cautious support from the research community. Stem cell experts say they are still trying to tease apart how exactly the regenerative medicine sections of the 21st Century Cures Act, a behemoth bill that would expedite drug approval and increase funding for medical research, would affect the field. But a number of vocal critics of the original measure, the so-called Regrow Act, said some of their worries had been assuaged.

Source: statnews.com

Wider Low-Dose Aspirin Use Would Save U.S. $692 Billion: Study

November 30, 2016

Taking low-dose aspirin daily can reduce older Americans' risk of heart disease and cancer, and lead to significant savings in health care spending, a new study contends. University of Southern California researchers used national data to assess the long-term benefits of daily aspirin usage. They calculated that taking low-dose aspirin every day would prevent 11 cases of heart disease and four cases of cancer for every 1,000 Americans ages 51 to 79.

Source: healthday.com

FDA gives Lannett more time to fight for generic ADHD drug

November 30, 2016

The Food and Drug Administration granted the Northeast Philadelphia generic drug developer Lannett a 90-day extension to submit documentation supporting a company product the federal agency wants to pull from the market.

Source: bizjournals.com

The true story of America's sky-high prescription drug prices

November 30, 2016

Let's say you're at the doctor. And the doctor hands you a prescription. The prescription is for Humira, an injectable medication used to treat a lot of common conditions like arthritis and psoriasis. Humira is an especially popular medication right now. In 2015, patients all around the world spent $14 billion on Humira prescriptions — that's roughly the size of Jamaica's entire economy.

Source: vox.com

Tighter Prescribing Rules: An Anti-Abuse Strategy That Could Hurt Patients In Pain

November 30, 2016

As rates of prescription painkiller abuse remain stubbornly high, a number of states are attempting to cut off the supply at its source by making it harder for doctors to prescribe the addictive pills to Medicaid patients. Recommendations on how to make these restrictions and requirements were detailed in a "best practices" guide from the federal Centers for Medicare and Medicaid Services.

Source: khn.org

Sandoz imports infant treatment from Canada after U.S. shortage arises

December 1, 2016

Sandoz and the FDA earlier this year struck a deal to let the generic unit of Novartis to import from a Canadian plant an infant parenteral nutrition product after a shortage arose in the U.S. Meanwhile, Sandoz is clearing the market of more than 50,000 vials of product that a contractor had produced for it after questions were raised about sterility at the facility where it was produced.

Source: fiercepharma.com

GSK recalls athlete's foot treatment wrongly labeled for use on jock itch

December 1, 2016

Labeling issues can sometimes lead to recalls because they pose serious health threats, and sometimes because a treatment for athlete's foot is labeled as a treatment for jockitch. GlaxoSmithKline's consumer unit is recalling 462,732 bottles of Zeasorb AF miconazole nitrate 2% that it manufactured for its North Carolina-based Stiefel Laboratories. According to the FDA Enforcement report, some of the labels have incorrect NDC codes while some back labels incorrectly state "use for the cure of most jock itch" rather than "use for the cure of most athlete's foot."

Source: fiercepharma.com

Immune System, Unleashed by Cancer Therapies, Can Attack Organs

December 3, 2016

As Chuck Peal lay in a Waterbury, Conn., emergency room one Sunday in early September, doctors furiously tried to make sense of his symptoms. Mr. Peal, 61, appeared to be dying, and they were not sure why. He slipped in and out of consciousness, his blood pressure plummeted, his potassium levels soared and his blood sugar spiked to 10

times the normal level. A doctor suspected a heart attack, but uncertainty left him urgently researching the situation on his phone.

Source: nytimes.com

Global prescription drug spend seen at $1.5 trillion in 2021: report

December 6, 2016

Global spending on prescription medicines will reach nearly $1.5 trillion by 2021, although the annual rate of growth will decrease from recent years, according to a forecast by Quintiles IMS Holding released on Tuesday. That figure, based on wholesale pricing, is up nearly $370 billion from estimated 2016 spending. The United States will account for up to $675 billion of the $1.5 trillion.

Source: reuters.com

Alerts remind people to stock up on medications before storms

December 5, 2016

Calls or texts from pharmacies before major storms help prompt people to stock up on their medications, according to a new study. People who received a call or text before a major blizzard struck the northeastern United States in January 2016 were 9 percent more likely than those who didn't receive a reminder to refill medications before travel became hazardous, researchers found.

Source: reuters.com

Doctors see regular misuse of antibiotics, narcotics

December 5, 2016

Antibiotics and narcotics are often prescribed when they aren’t the best option for patients and may do more harm than good, a survey of U.S. physicians suggests. The survey asked doctors to identify treatments that they see routinely used despiteguidelines recommending against the interventions and little or no value for patients.

Source:reuters.com

The Success Of HIV Treatment Is Increasing The Risk Of Drug-Resistance

December 6, 2016

Global health agencies are succeeding in getting more people with HIV on antiretroviral therapy, a combination of drugs that suppress the virus to undetectable levels in the blood and reduce the risk of transmission to another person. But scientists are beginning to detect a disturbing new trend: The rise of drug-resistant HIV strains, especially in countries such as Kenya, Zambia, Uganda, Nigeria, Tanzania and South Africa.

Source: huffingtonpost.com

Potentially Unsafe Med Scripts Up for Dual Users with Dementia

December 6, 2016

For veterans with dementia, Veterans Affairs (VA)-Medicare Part D (dual-system) users have increased rates of potentially unsafe medication (PUM) prescribing, according to a study published online Dec. 6 in the Annals of Internal Medicine. Joshua M. Thorpe, Ph.D., M.P.H., from the Veterans Affairs Pittsburgh Healthcare System, and colleagues conducted a retrospective cohort study in national VA outpatient care facilities in 2010 to examine the effect of dual health care system use on PUM prescribing. Data were included from 75,829 veterans with dementia: 80 percent were VA-only users and 20 percent were dual users.

Source: physiciansbriefing.com

U.S. Doctors Still Over-Prescribing Drugs: Survey

December 06, 2016

Despite evidence that certain drugs aren't always necessary, doctors are still prescribing these treatments, a new survey of doctors reveals. Antibiotics are by far the drugs most frequently used in situations where they'll provide no value for patients. The survey found that more than a quarter of doctors surveyed (27 percent) said that antibiotics are often administered to patients when the drugs will do no good.

Source:realclearhealth.com

7 ways to make the FDA great again, from a former agency official

December 6, 2016

When it comes to reviewing drugs, the FDA's job seems straightforward: make sure a drug is safe. Then make sure that it actually works and does what it is supposed to. It's an essential mission that this deeply dysfunctional organization appears to be having trouble fulfilling. The EpiPen pricing scandal and the controversial approvals of flibanserin (Addyi) to improve underactive sexual desire in women and eteplirsen (Exondys 51) for treating Duchenne muscular dystrophy illustrate that the FDA appears to be having trouble following its own guidelines.

Source: statnews.com

Trump's Vow to Control Drug Costs Alerts Another Industry

December 7, 2016

President-elect Donald Trump promised to drive down the cost of medicines, defying investors who saw a boon in his election last month and injecting himself again into a contentious economic debate. "I'm going to bring down drug prices," Trump said, according to a transcript of an interview posted on Time magazine's website as it named him its Man of the Year. "I don't like what's happened with drug prices."

Source: bloomberg.com

Painkillers Tied to Overuse Headache in Acute Migraine

December 07, 2016

Analgesics and opioids were linked to a higher risk of developing medication-overuse headache compared with other treatments in patients receiving acute migraine treatment, researchers reported.

Source: medpagetoday.com

Standing Up To The Test Of Time: Two Cancer Drugs That Could Survive A Hobbled FDA

December 7, 2016

If the Food and Drug Administration gets gutted, and pressured by politicians to lower its standards to allow more drugs on the market more quickly, how would that change the pharmaceutical business? That's a big question with many answers. Pharmaceutical companies and their investors, at least in the short term, would celebrate the quicker path to the market for new medicines. But in the long term, it would probably erode public confidence in the safety and effectiveness of the U.S. drug supply. Doctors and insurers might stake out a more cautious "buyer beware" position before prescribing, or paying for, any new drugs. In that world, where an FDA approval might not mean much, a premium would be placed on medicines that can prove their mettle in long-term follow up studies.

Source: forbes.com

Shoddy Medication? Search Engines May Already Know

December 6, 2016

"Google, should I be worried about the quality of my pills?" It's not a question anybody wants to ask, but if you regularly take medication and things don't feel quite right, it would be an obvious one to type into a search engine. That's certainly what Elad Yom-Tov from Microsoft Research thought when he set out to investigate whether search queries could be used to predict when a drug might be recalled.

Source: technologyreview.com

Why it's time to turn the page on the FDA drug approval process

December 9, 2016

As healthcare leaders and policy experts come together for the annual Food and Drug Administration (FDA) CMS Summit in Washington this month, much of the focus will be on how quickly both agencies are evolving to meet the needs of patients. By most accounts, 2017 is gearing up to be a year in which the voice of the individual patient will be front and center in historically bureaucratic and highly-technical environments.

Source: thehill.com

Study reveals how many U.S. adults are taking psychiatric drugs

December 12, 2016

New research estimates about one in six American adults takes at least one psychiatric drug over the course of a year. The report, published today in JAMA Internal Medicine, also found that over 80 percent of those taking these medications reported long-term use, which experts say is concerning since some of the drugs are recommended for shorter use and carry a number of serious risks.

Source: cbsnews.com

How Much Hope Is There For Alzheimer's Drugs?

December 9, 2016

Last night, Alzheimer's researchers held a celebration over their field's latest failure. A study of Eli Lilly's experimental Alzheimer's drug, solanezumab, failed to show a statistically significant benefit on its main goal, but every outcome seemed to go in the same direction. That yields some modicum of hope for other Alzheimer's drugs in development, particularly one from Biogen called aducanumab that is, in some ways, an amped up solanezumab. The results were webcast from the Clinical Trails in Alzheimer's Disease meeting in San Diego.

Source: forbes.com

Payers may see biosims as a no-brainer, but marketing them won't be

December 12, 2016

Spurring demand for biosimilars may become the new pharma marketing challenge in 2017, even as biosimilar launches accelerate in the U.S. Companies with entrenched biologic drugs—think Roche and its cancer stars, or AbbVie and Humira—have their advantages, said Will Suvari, principal at Pricewaterhouse Coopers' consultancy Strategy. They have longstanding relationships with pharmacy benefit managers for volume-based rebates, for one. And they boast customer-friendly infrastructure, including co-pay, reimbursement and nursing support programs. That's likely to make it difficult for biosimiliar drug companies to break in.

Source: fiercepharma.com

3 Drugs Heading to the FDA Soon

December 12, 2016

It's incredibly difficult to usher a drug successfully through scientifically controlled clinical trials to the FDA, but when drug developers pull it off, the payoff for investors can be huge. At least that's what investors in Flexion Therapeutics, Kite Pharma, and Agios Pharma hope. All three of these companies are about to deliver their respective drugs to the FDA for approval next year, and if the FDA gives them a go-ahead, then these stocks could become top performers in 2017.

Source: fool.com

Drugmakers Push Profitable, but Unproven, Opioid Solution

December 15, 2016

By matthew perrone, geoff mulvihill and liz essley whyte Pilloried for their role in the epidemic of prescription painkiller abuse, drugmakers are aggressively pushing their remedy to the problem: a new generation of harder-tomanipulate opioids that have racked up billions in sales, even though there's little proof they reduce rates of overdoses or deaths.

Source: abcnews.go.com

Actuaries are bringing Netflix-like predictive modeling to health care

December 13, 2016

I'm an actuary. That means I use numbers to try to understand human behavior, managerisk, and evaluatethe likelihood that a particular thing will happen in the future. Most people associate my work with green eyeshades and the morbid business of predicting how long someone is likely to live. But actuaries are on the ground floor of precision medicine, which will rely in part on number-fueled predictive modeling.

Source: statnews.com

RECALLS

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drugs	Testosterone 200 mg/Anastrazole 20mg Pellet, Compounded by: Wells Pharmacy Network	Class II	Lot Number 08162016@5, BUD: 02/12/2017	Superpotent and Subpotent drugs	Wells Pharmacy Network, LLC 450 US Hwy 51 Byp N Dyersburg, TN 38024-3655
Drugs	L-Cysteine Hydrochloride Injection, USP, 0.5 g/10 mL (50 mg/mL), 10 mL Single Dose Vial (NDC 66758-004-01), packaged in 10 x 10mL Vials per carton (NDC 66758-004-02), Rx only, Manufactured for: Sandoz Inc., Princeton, NJ 08540.	Class II	Lot #: 2081915, 2082015, 2082115, 2082815, 2083115, Exp 08/17; 2090115, Exp 09/17	Lack of Assurance of Sterility: a recent FDA inspection at the manufacturing firm raised concerns that the product sterility may be compromised.	Sandoz Inc 100 College Rd W Princeton, NJ 08540-6604
Drugs	L-Cysteine Hydrochloride Injection, USP, 50 mg/mL, 50 mL Pharmacy Bulk Package Vials (NDC 66758-005-01), packaged in 5 x 50 mL Vials per carton(NDC 66758-005-02), Rx only, Manufactured for: Sandoz, Inc., Princeton, NJ.	Class II	Lot #: 2070915, 2071015, 2071415, 2071515, 2071615, 2071715, 2072115, 2072215, Exp 07/17; 2092315, 2093015, Exp 09/17; 2100115, Exp 10/17; 2120115, 2120215, Exp 12/17	Lack of Assurance of Sterility: a recent FDA inspection at the manufacturing firm raised concerns that the product sterility may be compromised.	Sandoz Inc 100 College Rd W Princeton, NJ 08540-6604
Drugs	Phenobarbital Tablets, USP 60mg 100=count bottles, Rx Only, Mfd. by: West-Ward Pharmaceutical Corp. Eatontown, NJ 07724, NDC 0143-1455-01	Class II	Lot #: 71294A, Exp. 5/2017	Failed Dissolution Specifications: Phenobarbital Tablets have an out of specification for dissolution at the 12 month stability time point	West-Ward Pharmaceuticals Corp. 401 Industrial Way West Eatontown, NJ 07724-2209
Drugs	Fentanyl Citrate Injection, USP, 100 mcg Fentanyl/ 2mL, Single Dose, 50 mcg/mL, Rx only, Hospira, Inc., Lake Forest IL 60045, NDC 0409-4093-32	Class II	Lot #5 9277EV, 60028EV, 6008EV, Exp 11/1/17	Lack of Assurance of Sterility: Complaints of broken tips on the ampules.	Hospira Inc. 600 N Field Dr Lake Forest, IL 60045-4835
Drugs	LEVOXYL(R) (levothyroxine sodium tablets, USP), 200 mcg, 100 count bottles, Rx only, Manufactured and Distributed by: King Pharmaceuticals, Inc., Bristol, TN 37620, NDC 60793-860-01	Class II	16H21, Exp. 08/2017	Superpotent	Pfizer Inc. 235 East 42nd Street New York, NY 10017-5703
Drugs	Lactulose Solution, USP, 10 g/15 mL, 15 mL unit dose cups (NDC 66689-039-01), packaged in 15 mL x 50 unit dose cups per case (NDC 66689-039-50), Rx only, Manufactured by VistaPharm, Inc., Largo, FL 33771.	Class II	Lot No. 378300, Exp 11/16	Microbial Contamination of Non-Sterile Products: bulk solution tested positive for the presence of the bacteria, Burkholderia cepacia.	VistaPharm, Inc. 7265 Ulmerton Rd Largo, FL 33771-4809
Drugs	Ondansetron HCl API, Bulk, Manufacturer: Cadila Pharmaceuticals, Ltd., Ankleshwar, Gujarat, India 393002	Class II	Supplied Batch, 150N004; Exp. 08/20 Supplied Batch, 150N006; Exp. 09/20	Microbial Contamination of Non-Sterile Product	Cadila Pharmaceuticals Limited 294, G.I.D.C. Industrial Estate Ankleshwar
Drugs	Travoprost Ophthalmic Solution USP, 0.004%, a) 2.5 mL and b) 5 mL bottles, Rx only, FOR USE IN THE EYES ONLY, Made in India, Distributed by: Par Pharmaceutical Cos., Inc, Spring Valley, NY 10977	Class II	G40814 - Exp. Date 09/2016, GA50089 - Exp. Date 12/2016, GA50259 - Exp. Date 01/2017, GA50657 - Exp. Date 03/2017, GA51073 - Exp. Date	Lack of Assurance of Sterility; damage to the internal portion of the dropper tip portion of the container	Par Pharmaceutical, Inc. 1 Ram Ridge Rd Chestnut Ridge, NY 10977-6714

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
			06/2017, GA51651 - Exp. Date 09/2017, GA51652 - Exp. Date 09/2017, GA51722 - Exp. Date 09/2017, GA51723 - Exp. Date 09/2017, GA51760 - Exp. Date 10/2017, and GA51761 - Exp. Date 10/2017 b) GA45033 - Exp. Date 10/2016, GA50258 - Exp. Date 01/2017, GA50944 - Exp. Date 05/2017, GA50174 - Exp. Date 06/2017, GA51340 - Exp. Date 07/2017, GA51479 - Exp. Date 08/2017, and GA51762 - Exp. Date 10/2017		
Drugs	Hyolev MB URINARY ANTISEPTIC Tablets, Each tablet for oral administration contains: Hyoscyamine Sulfate 0.12 mg, Methenamine 81 mg, Methylene Blue 10.8 mg, Phenyl Salicylate 32.4 mg, Sodium Phosphate Monobasic 40.8 mg, 90 count bottles, Rx only, Manufactured for: BUREL PHARMACEUTICALS, Richland, MS --- NDC 35573-301-90	Class II	LOT # 29001501, EXP 07/17	CGMP Deviations; deficiencies at the manufacturer may result in assay or content uniformity failures	Burel Pharmaceuticals Inc 199 Interstate Dr Ste N Richland, MS 39218-9433
Drugs	UROLET MB URINARY ANTISEPTIC, ANTISPASMODIC Tablets, Each tablet contains: Methenamine 81.6 mg, Monobasic Sodium Phosphate 40.8 mg, Phenyl Salicylate 36 mg, Methylene Blue, 10.8 mg; Hyoscyamine Sulfate, 0.12 mg, (a) 30 count (NDC 35573-302-30) and (b) 100 count bottles (NDC 35573-302-10), Rx only, Manufactured for: BUREL PHARMACEUTICALS, Richland, MS	Class II	(a) LOT # 28981501, EXP 8/17, NDC 35573-302-30; (b) LOT # 28981501, EXP 8/17, LOT # 28981601, EXP 4/18, NDC 35573-302-10	CGMP Deviations; deficiencies at the manufacturer may result in assay or content uniformity failures	Burel Pharmaceuticals Inc 199 Interstate Dr Ste N Richland, MS 39218-9433
Drugs	URAMIT MB URINARY ANTISEPTIC Capsules, Each capsule contains: Methenamine 118 mg, Monobasic Sodium Phosphate 40.8 mg, Phenyl Salicylate 36 mg, Methylene Blue 10 mg, Hyoscyamine Sulfate, 0.12 mg, 100 count bottles, Rx only, Manufactured for: BUREL PHARMACEUTICALS, Richland, MS --- NDC 35573-300-10	Class II	LOT # 28751601, exp 8/18	CGMP Deviations; deficiencies at the manufacturer may result in assay or content uniformity failures	Burel Pharmaceuticals Inc 199 Interstate Dr Ste N Richland, MS 39218-9433
Drugs	UROPHEN MB URINARY ANTISEPTIC Tablets, Each tablet contains: Methenamine 81.6 mg, Benzoic Acid 9.0 mg, Phenyl Salicylate 36 mg, Methylene Blue 10.8 mg, Hyoscyamine Sulfate 0.12 mg, 100 count bottles, Rx only, Manufactured for: BUREL PHARMACEUTICALS, Richland, MS --- NDC 35573-307-10	Class II	LOT # 29131501, EXP 9/17	CGMP Deviations; deficiencies at the manufacturer may result in assay or content uniformity failures	Burel Pharmaceuticals Inc 199 Interstate Dr Ste N Richland, MS 39218-9433
Drugs	AZUPHEN MB URINARY ANTISEPTIC Capsules, Each capsule contains: Methenamine 120 mg, Monobasic Sodium Phosphate 40.8 mg, Phenyl Salicylate 36 mg, Methylene Blue 10 mg,	Class II	LOT # 29421501, EXP 10/17	CGMP Deviations; deficiencies at the manufacturer may result in assay or content uniformity	Burel Pharmaceuticals Inc 199 Interstate Dr Ste N Richland, MS 39218-9433

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
	Hyoscyamine Sulfate, 0.12 mg, 100 count bottles, Rx only, Manufactured for: BUREL PHARMACEUTICALS, Richland, MS --- NDC 35573-314-10			failures	
Drugs	Indiomin MB URINARY ANTISEPTIC, ANTISPASMODIC Capsules, Each capsule contains: Methenamine 120 mg, Monobasic Sodium Phosphate 40.8 mg, Methylene Blue, 10 mg; Hyoscyamine Sulfate, 0.12 mg, 100 count, Rx only, Manufactured for: BUREL PHARMACEUTICALS, NDC 35573-315-10	Class II	LOT # 29401501, EXP 10/17	CGMP Deviations; deficiencies at the manufacturer may result in assay or content uniformity failures	Burel Pharmaceuticals Inc 199 Interstate Dr Ste N Richland, MS 39218-9433
Drugs	Phenazopyridine Hydrochloride Tablets, USP, 100 mg, 100 count bottles, Rx only, Manufactured for: Burel Pharmaceuticals, Inc., Richland, MS --- NDC 35573-304-10	Class II	Lot #: 28161601, EXP 1/18; 28161603, EXP 5/18; and 28161604, EXP 6/18	CGMP Deviations; deficiencies at the manufacturer may result in assay or content uniformity failures	Burel Pharmaceuticals Inc 199 Interstate Dr Ste N Richland, MS 39218-9433
Drugs	Salsalate Tablets, USP, 500 mg, packaged in a) 500 count bottles (NDC 42937-703-18); b) 100 count bottles (NDC 42937-703-10); and c) 1000 count bottles (NDC 42937-703-20); Rx only, Manufactured for: Nationwide Laboratories LLC, Iselin, New Jersey 08830.	Class II	Lot #: a) 28121501, 28121502, 28121503, 28121504, Exp 03/17; 28121505, Exp 06/17; 28121506, 28121507, Exp 09/17; b) 28121503, 28121504, Exp 03/17; 28121505, Exp 06/17; 28121506, 28121507, Exp 09/17; c) 28121505, Exp 06/17; 28121506, 28121507, Exp 09/17	CGMP Deviations: manufactured under practices which may result in assay or content uniformity failures.	Nationwide Laboratories, LLC 33 Wood Ave S Ste 600 Iselin, NJ 08830-2717
Drugs	Salsalate Tablets, USP, 750 mg, packaged in a) 100 count bottles (NDC 42937-704-10); b) 500 count bottles (NDC 42937-704-18); and c) 1000 count bottles (NDC 42937-704-20); Rx only, Manufactured for: Nationwide Laboratories LLC, Iselin, New Jersey 08830.	Class II	Lot #: a) 28141502, 28141503, 28141504, 28141505, 28141506, Exp 03/17; 28141507, Exp 09/17; 28141508, 28141510, 28141511, Exp 10/17; b) 28141502, 28141504, 28141506, Exp 03/17; 28141507, Exp 09/17; 28141508, 28141510, 28141511, Exp 10/17; c) 28141501, 28141502, 28141504, 28141506, Exp 03/17; 28141507, Exp 09/17; 28141508, 28141510,	CGMP Deviations: manufactured under practices which may result in assay or content uniformity failures.	Nationwide Laboratories, LLC 33 Wood Ave S Ste 600 Iselin, NJ 08830-2717

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
			28141511, Exp 10/17		
Drugs	Metformin Hydrochloride Tablets, USP 500 mg, 1000 tablets, Rx Only Manufactured by: Alkem Laboratories Ltd., Mumbai - 400 013, India, Distributed by: Ascend Laboratories, LLC, Montvale, NJ NDC 67877-217-10	Class II	Lot 6121056, exp 5/2019	Presence of Foreign Tablets/Capsules; report of Amlodipine Tablets found in 1000 count bottles of Metformin Hydrochloride Tablets USP	Ascend Laboratories LLC 180 Summit Ave Ste 200 Montvale, NJ 07645-1722
Drugs	Phenazopyridine Hydrochloride Tablets, USP, 100 mg, 100 count bottles, Rx only, Manufactured for: Nationwide Laboratories LLC, Iselin, New Jersey 08830, NDC 42937-701-10.	Class II	Lot #: 28161501, Exp 03/17; 28161502, 28161503, Exp 08/17; 28161601, 28161602, Exp 01/18	CGMP Deviations: manufactured under practices which may result in assay or content uniformity failures.	Nationwide Laboratories, LLC 33 Wood Ave S Ste 600 Iselin, NJ 08830-2717
Drugs	Phenazopyridine Hydrochloride Tablets, USP, 200 mg, 100 count bottles, Rx only, Manufactured for: Nationwide Laboratories LLC, Iselin, New Jersey 08830, NDC 42937-702-10.	Class II	Lot #: 28181501, 28181502, Exp 03/17; 28181503, 28181504, Exp 08/17; 28181505, 28181506, Exp 09/17; 28181601, Exp 01/18	CGMP Deviations: manufactured under practices which may result in assay or content uniformity failures.	Nationwide Laboratories, LLC 33 Wood Ave S Ste 600 Iselin, NJ 08830-2717
Drugs	Range Trauma Kit Hardcase - Product Code 85-0889, North American Rescue	Class II	Kit Part # 85-0889 - Kit Lot # 85-0889082416, 85-0889071816, 85-0889071916, 85-0889071416, 85-0889052316, 85-0889050416, 85-0889042016, 85-0889041416, 85-0889090616, 85-0889090716, 85-0889060216, 85-0889062216, 85-0889080116, 85-0889080816	Lack of Assurance of Sterility: Concerns with product sterility by the manufacturer of the eye wash irrigating solution.	North American Rescue LLC. 35 Tedwall Ct Greer, SC 29650-4791
Drugs	PAPA/PHEN/PROST (papverine/phentolamine/prostaglandin) 18 mg/0.6 mg/0.006 mg/mL Injection, 1 mL vials, Fallon Wellness Pharmacy LLC, 1057 Troy-Schenectady Rd, Latham, NY 12110.	Class II	Lot #: 09192016@41,09192016@69, Exp 11/04/2016	Lack of Assurance of Sterility: product produced on a day there was an excursion in environmental monitoring data.	Fallon Wellness Pharmacy, L.L.C. 1057 Troy Schenectady Rd Latham, NY 12110-1002
Drugs	PAPA/PHEN/PROST (papverine/phentolamine/prostaglandin) 30 mg/4 mg/0.04 mg/mL Injection, 1 mL vials, Fallon Wellness Pharmacy LLC, 1057 Troy-Schenectady Rd, Latham, NY 12110.	Class II	Lot #: 09202016@8, Exp 11/04/2016	Lack of Assurance of Sterility: product produced on a day there was an excursion in environmental monitoring data.	Fallon Wellness Pharmacy, L.L.C. 1057 Troy Schenectady Rd Latham, NY 12110-1002
Drugs	Range Trauma Kit ORG - Product Code 80-0213, 80-0299, 80-0298, North American Rescue	Class II	Kit Part # 80-0213 - Kit Lot # 80-0213080816W, 80-0213071316W, 80-0213041816W, 80-0213051716W, 80-0213050516W, 80-0213050916W, 80-0213081116W, 80-0213081716W, 80-0213082516W, 80-0213090216	Lack of Assurance of Sterility: Concerns with product sterility by the manufacturer of the eye wash irrigating solution.	North American Rescue LLC. 35 Tedwall Ct Greer, SC 29650-4791

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
			W, 80-0213090916 W, 80-0213070716 W, 80-0213080316 W, 80-0213080116 W, 80-0213072716 W, 80-0213090916 W; Kit Part # 80-0299 - Kit Lot # 80-0299080916W, 80-0299071116W, 80-0299060116W, 80-0299051916W, 80-0299081716W, 80-0299050316W, 80-0299051016W, 80-0299082216W; 80-0299082416W, 80-0299090616W, 80-0299090716W, 80-0299090716W, 80-0299080416W; Kit Part # 80-0298 -Kit Lot # 80-0298081116W, 80-0298060116W, 80-0298062316W, 80-0298090716W		
Drugs	Range Trauma Kit - Product Code 85-1274, North American Rescue	Class II	Kit Part # 85-1274 - Kit Lot # 85-1274072516W	Lack of Assurance of Sterility: Concerns with product sterility by the manufacturer of the eye wash irrigating solution.	North American Rescue LLC. 35 Tedwall Ct Greer, SC 29650-4791
Drugs	Advance Trauma Kit - Product Code 85-0742, 85-0746, 85-0745, 85-0639, 85-0744, 85-0744, 85-0741, North American Rescue	Class II	Kit Part # 85-0742 Kit Lot # 85-0742071816; Kit Part # 85-0748 Kit Lot # 85-0746061016; Kit Part # 85-0745 - Kit Lot # 85-0745042516; Kit Part # 85-0639 - Kit Lot # 85-0639080516, 85-0639060116, 85-0639061016, 85-0639071416, 85-0639072116, 85-0639050316, 85-0639050416, 85-0639051316, 85-0639082216, 85-0639090116, 85-0639090716, 85-0639080116, 85-0639091316; Kit Part# 85-0744 - Kit Lot # 85-0744072516, 85-0744060916, 85-0744052516; Kit Part # 85-0741- Kit Lot # 85-0741071416	Lack of Assurance of Sterility: Concerns with product sterility by the manufacturer of the eye wash irrigating solution.	North American Rescue LLC. 35 Tedwall Ct Greer, SC 29650-4791
Drugs	K-9 Trauma Field Kit - Product Code 80-0211, 80-0304, 80-0209, 80-0210, 80-0300, 80-0301, North American Rescue	Class II	Kit Part # 80-0211 - Kit Lot # 80-0211070616, 80-0211051316, 80-0211041816, 80-0211030216, 80-0211072216, 80-02100	Lack of Assurance of Sterility: Concerns with product sterility by the manufacturer of the eye wash irrigating solution.	North American Rescue LLC. 35 Tedwall Ct Greer, SC 29650-4791

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
			70716, 80-0210050416W, 80-0210072216; Kit Part # 80-0304 - Kit Lot # 80-0304041916; Kit Part # 80-0209 - Kit Lot # 80-0209082216, 80-0209051816, 80-0209051616, 80-029050316, 80-0209041916, 80-0209060316; Kit Part # 80-210 Kit Lot # 80-021007076, 80-0210050416W, 80-0210072216;Kit Part # 80-0300 - Kit Lot # 80-0300081216, 80-0300050916, 80-0300050316, 80-0300041916, 80-0300082416; Kit Part #80-0301 - Kit Lot # 80-0301042916, 80-0301050316		
Drugs	Amphibious Trauma Kit - Product Code 85-0639, North American Rescue	Class II	Kit Part # 85-0639 - Kit Lot # 85-0639080516, 85-0639060116, 85-0639061016, 85-0639071416, 85-0639072116, 85-0639050316, 85-0639050416, 85-0639051316, 85-0639082216, 85-0639090116, 85-0639091316	Lack of Assurance of Sterility: Concerns with product sterility by the manufacturer of the eye wash irrigating solution.	North American Rescue LLC. 35 Tedwall Ct Greer, SC 29650-4791
Drugs	Mini Resupply Trauma Kit - Product Code 85-0835, North American Rescue	Class II	Kit Part # 85-0835 - Kit Lot # 85-0835061016, 85-0835052416, 85-0835051116, 85-0835050216, 85-0835042916, 85-0835072616, 85-0835072016	Lack of Assurance of Sterility: Concerns with product sterility by the manufacturer of the eye wash irrigating solution.	North American Rescue LLC. 35 Tedwall Ct Greer, SC 29650-4791
Drugs	Aid Backpack Kit - Product Code 85-0917, North American Rescue	Class II	Kit Part # 85-0917 - Kit Lot # 85-0917041916	Lack of Assurance of Sterility: Concerns with product sterility by the manufacturer of the eye wash irrigating solution.	North American Rescue LLC. 35 Tedwall Ct Greer, SC 29650-4791
Drugs	USCG Boat Response Kit - Product Code 80-0353, North American Rescue	Class II	Kit Part # 80-0353 - Kit Lot # 80-0353051916	Lack of Assurance of Sterility: Concerns with product sterility by the manufacturer of the eye wash irrigating solution.	North American Rescue LLC. 35 Tedwall Ct Greer, SC 29650-4791
Drugs	Calcium Chloride 1 g/50 mL* Added to 5% Dextrose (20 mg/mL)*, Single-Dose Bag, Rx Only, Hospital/Office Use Only, Cantrell Drug Co. 7321 Cantrell Road Little Rock, AR 72207, NDC 52533-175-37	Class II	Lot: 169170	Lack of Assurance of Sterility - the firm is recalling select sterile drug products.	Cantrell Drug Company 7321 Cantrell Rd Little Rock, AR 72207-4144
Drugs	Phenylephrine HCl 1 mg/10 mL (100 mcg/mL) in 0.9% Sodium Chloride, 10 mL Single-Dose Syringe, Rx Only Cantrell	Class II	Lot: 8502 BUD: 11/21/2016, Lot: 8962 BUD: 02/21/2017	Lack of Assurance of Sterility - the firm is recalling select sterile	Cantrell Drug Company 7321 Cantrell Rd

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
	Drug Company 7321 Cantrell Rd Little Rock, AR 72207, NDC 52533-171-12			drug products.	Little Rock, AR 72207-4144
Drugs	Calcium Chloride (20 mg/mL) in 0.9% Sodium Chloride 500 mL Bag, Rx Only, Single-Dose Bag Cantrell Drug Company 7321 Cantrell Road Little Rock, AR 72207, NDC 52533-102-09	Class II	Lot: 168032	Lack of Assurance of Sterility - the firm is recalling select sterile drug products.	Cantrell Drug Company 7321 Cantrell Rd Little Rock, AR 72207-4144
Drugs	Calcium Chloride, (1 g/10 mL) Injection Solution 10 mL, 10% Single-Dose Vial, Rx Only, Cantrell Drug Co. 7321 Cantrell Road Little Rock, AR 72207	Class II	Lot: 169924	Lack of Assurance of Sterility - the firm is recalling select sterile drug products.	Cantrell Drug Company 7321 Cantrell Rd Little Rock, AR 72207-4144
Drugs	Fentanyl Citrate 1,500 mcg in 0.9% Sodium Chloride (10 mcg/mL) 150 mL Bag, Single-Dose Bag, Rx Only, Cantrell Drug Company 7321 Cantrell Road Little Road, AR 72207, NDC 52533-024-35	Class II	Lot: 9002	Lack of Assurance of Sterility - the firm is recalling select sterile drug products.	Cantrell Drug Company 7321 Cantrell Rd Little Rock, AR 72207-4144
Drugs	Fentanyl Citrate 2,500 mcg in 0.9% Sodium Chloride (10 mcg/mL) 250 mL* Bag, Single-Dose Bag, Rx Only, Cantrell Drug Company 7321 Cantrell Road Little Road, AR 72207, NDC 52533-024-61	Class II	Lot: 8990	Lack of Assurance of Sterility - the firm is recalling select sterile drug products.	Cantrell Drug Company 7321 Cantrell Rd Little Rock, AR 72207-4144
Drugs	Fentanyl Citrate 2 mcg/mL & Bupivacaine HCl 0.125% in 0.9% Sodium Chloride, 100 mL* Bag, Epidural Use Only, Single-Dose Bag, Hospital/Office Use Only, Rx Only, Cantrell Drug Company 7321 Cantrell Road Little Road, AR 72207, NDC 52533-080-75	Class II	Lot: 8942 BUD: 2/19/2017, Lot: 9207 BUD: 4/17/2017	Lack of Assurance of Sterility - the firm is recalling select sterile drug products.	Cantrell Drug Company 7321 Cantrell Rd Little Rock, AR 72207-4144
Drugs	Glycopyrrolate 1 mg/5 mL (0.2 mg/mL) Injection Solution, 5 mL Single-Dose Syringe, For IV Use, Hospital/Office Use Only, Rx Only, Cantrell Drug Co. 7321 Cantrell Rd. Little Rock, AR 72207, NDC 52533-028-15	Class II	Lot: 9006 BUD: 1/20/2017, Lot: 8757 BUD: 11/30/2016, Lot: 8954 BUD: 1/6/2017, Lot: 9174 BUD: 2/20/2017	Lack of Assurance of Sterility - the firm is recalling select sterile drug products.	Cantrell Drug Company 7321 Cantrell Rd Little Rock, AR 72207-4144
Drugs	Heparin Sodium, 1 USP Unit/2 mL (0.5 USP Units/mL) in 0.45% Sodium Chloride, Single-Dose Syringe, Hospital/Office Use Only, Rx Only, Cantrell Drug Co. 7321 Cantrell Rd. Little Rock, AR 72207, NDC 52533-148-16	Class II	Lot: 9220	Lack of Assurance of Sterility - the firm is recalling select sterile drug products.	Cantrell Drug Company 7321 Cantrell Rd Little Rock, AR 72207-4144
Drugs	Heparin Sodium 5,000 USP Units Added to 0.9% Sodium Chloride 1,000 mL* Bag (5 USP units/mL), Single-Dose Bag.,Hospital/Office Use Only, Injection Solution For IV Use, Rx Only, Cantrell Drug Company 7321 Cantrell Road Little Rock, AR 72207, NDC 52533-097-24	Class II	Lot: 167081	Lack of Assurance of Sterility - the firm is recalling select sterile drug products.	Cantrell Drug Company 7321 Cantrell Rd Little Rock, AR 72207-4144
Drugs	HYDROmorphone HCl 6 mg/30 mL in 0.9% Sodium Chloride (0.2 mg/mL) Single-Dose Syringe, Rx Only, Cantrell Drug Co. 7321 Cantrell Road Little Rock, AR 72207, NDC 52533-002-03	Class II	Lot: 8742	Lack of Assurance of Sterility - the firm is recalling select sterile drug products.	Cantrell Drug Company 7321 Cantrell Rd Little Rock, AR 72207-4144
Drugs	HYDROmorphone HCl 50 mg/50 mL in 0.9% Sodium Chloride (1 mg/mL) Single-Dose Syringe, Rx Only, Cantrell Drug Co. 7321 Cantrell Road Little Rock, AR 72207, NDC 52533-006-04	Class II	Lot: 9016 BUD: 3/7/2017	Lack of Assurance of Sterility - the firm is recalling select sterile drug products.	Cantrell Drug Company 7321 Cantrell Rd Little Rock, AR 72207-4144
Drugs	Hydromorphone HCl 1 mg/mL in 0.9% Sodium Chloride 30 mL PCA Vial (1 mg/mL), Single-Dose Injection Solution For Slow IV Use, Rx Only, Cantrell Drug Co. 7321 Cantrell Road Little Rock, AR	Class II	Lot: 163941	Lack of Assurance of Sterility - the firm is recalling select sterile drug products.	Cantrell Drug Company 7321 Cantrell Rd Little Rock, AR 72207-4144

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
	72207, NDC 52533-006-10				
Drugs	Lidocaine HCl 1%, 10 mL Syringe, Hospital/Office Use Only, Rx Only, Cantrell Drug Co. 7321 Cantrell Rd. Little Rock, AR 72207	Class II	Lot: 165538	Lack of Assurance of Sterility - the firm is recalling select sterile drug products.	Cantrell Drug Company 7321 Cantrell Rd Little Rock, AR 72207-4144
Drugs	Midazolam HCl 50 mg/50 mL in 0.9% Sodium Chloride (1 mg/mL), Single-Dose Syringe, Hospital/Office Use Only, Rx Only, Cantrell Drug Co. 7321 Cantrell Road Little Rock, AR 72207, NDC 52533-001-04	Class II	Lot: 169619	Lack of Assurance of Sterility - the firm is recalling select sterile drug products.	Cantrell Drug Company 7321 Cantrell Rd Little Rock, AR 72207-4144
Drugs	Morphine Sulfate 1 mg/mL in 0.9% Sodium Chloride, 100 mL Bag, Single-Dose Bag, Rx Only, Cantrell Drug Co. 7321 Cantrell Road Little Rock, AR 72207, NDC 52533-160-75	Class II	Lot: 8625	Lack of Assurance of Sterility - the firm is recalling select sterile drug products.	Cantrell Drug Company 7321 Cantrell Rd Little Rock, AR 72207-4144
Drugs	Neostigmine Methylsulfate 5 mg/5 mL Injection Solution, 5 mL (1 mg/mL) Single-Dose Syringe, For Slow IV Use, Rx Only, Cantrell Drug Co. 7321 Cantrell Rd. Little Rock, AR 72207, NDC 52533-046-15	Class II	Lot: 8997 BUD: 12/1/2016, Lot: 9246 BUD: 1/23/2017	Lack of Assurance of Sterility - the firm is recalling select sterile drug products.	Cantrell Drug Company 7321 Cantrell Rd Little Rock, AR 72207-4144
Drugs	Oxytocin 30 USP Units Added to 0.9% Sodium Chloride, 500 mL Bag, Single-Dose Bag, Injection Solution for IV Use Only, Rx Only, Cantrell Drug Company 7321 Cantrell Road Little Rock, AR 72207, NDC 52533-056-30	Class II	Lot: 9210	Lack of Assurance of Sterility - the firm is recalling select sterile drug products.	Cantrell Drug Company 7321 Cantrell Rd Little Rock, AR 72207-4144
Drugs	Rocuronium Bromide 50 mg/5 mL Injection Solution, 5 mL (10 mg/mL) Single-Dose Syringe, Injection Solution For Slow IV Use, Rx Only, Cantrell Drug Co. 7321 Cantrell Rd. Little Rock, AR 72207, NDC 52533-064-15	Class II	Lot: 8995	Lack of Assurance of Sterility - the firm is recalling select sterile drug products.	Cantrell Drug Company 7321 Cantrell Rd Little Rock, AR 72207-4144
Drugs	Ropivacaine HCl 0.25% in 0.9% Sodium Chloride, 100 mL Bag, Epidural Use Only, Rx Only, Cantrell Drug Co. 7321 Cantrell Road Little Rock, AR 72207, NDC 52533-185-75	Class II	Lot: 169064	Lack of Assurance of Sterility - the firm is recalling select sterile drug products.	Cantrell Drug Company 7321 Cantrell Rd Little Rock, AR 72207-4144
Drugs	Succinylcholine Chloride 200 mg/10 mL Injection Solution 10 mL (20 mg/mL) ,Single-Dose Syringe Injection Solution, For Slow IV Use Only ,Rx Only, Cantrell Drug Company 7321 Cantrell Rd Little Rock, AR 72207, NDC 52533-067-12	Class II	Lot: 169262 BUD: 1/8/2017, Lot: 169812 BUD: 1/19/2017	Lack of Assurance of Sterility - the firm is recalling select sterile drug products.	Cantrell Drug Company 7321 Cantrell Rd Little Rock, AR 72207-4144
Drugs	Estradiol 12.5 mg Pellet, Compounded by: Wells Pharmacy Network	Class III	Lot Number 08172016@9, BUD: 02/13/2017	Superpotent and Subpotent drugs	Wells Pharmacy Network, LLC 450 US Hwy 51 Byp N Dyersburg, TN 38024-3655
Drugs	Clonazepam Tablets, USP, 0.5 mg, packaged in a)100- count unit dose box of 10 x 10 blister cards (NDC 51079-881-20) and b) 300-count unit dose box of 10 x 30 punch cards (NDC 51079-881-56), Rx only, Manufactured by Mylan Pharmaceuticals Inc, Morgantown, WV, 26505	Class III	Lot#: a) 3061779, Exp 11/16; 3071447, Exp 04/17; b)3071789, Exp 04/17	Failed Impurities/Degradation Specifications: out of specification result for Clonazepam Related Compound (RC) A (a known impurity) at 15 month timepoint.	Mylan Institutional, Inc. (d.b.a. UDL Laboratories) 1718 Northrock Ct Rockford, IL 61103-1201
Drugs	Clonazepam Tablets, USP, 1.0 mg, packaged in a 100- count unit dose box of 10 x 10 blister cards, Rx only, Manufactured by Mylan	Class III	Lot#: 3061784, Exp 11/16; 3067656, Exp 12/16; 3074902, Exp 08/17	Failed Impurities/Degradation Specifications: out of specification result for	Mylan Institutional, Inc. (d.b.a. UDL Laboratories)

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
	Pharmaceuticals Inc, Morgantown, WV, 26505, NDC 51079-882-20			Clonazepam Related Compound (RC) A (a known impurity) at 16 month timepoint.	1718 Northrock Ct Rockford, IL 61103-1201
Drugs	Zeasorb AF (miconazole nitrate), 2%, cures most athlete's foot, Net wt. 2.5 OZ (71 g), Manufactured for: Steifel Laboratories, Inc., Research Triangle Park, NC 27709, UPC 0 73462 15065 1; NDC 0145-1506-01	Class III	Lot #: 5M02ST*, 5M03ST*, 5M04ST*, Exp 10/17; 5P01ST, 5P01STA, 5P02ST, 5P03ST, 5P04ST, 5P05ST, Exp 11/17; 6C03ST, 6C04ST, 6C05ST, 6C06ST, 6C07ST, Exp 02/18 *Lots 5M02ST, 5M03ST, and 5M04ST contain the NDC code error only on front label, back label is correct.	Labeling Not Elsewhere Classified: front labels have the incorrect NDC or 0145-1506-01 instead of the correct NDC of 0145-1506-05 and some back labels have the incorrect indication stating "use for the cure of most jock itch" rather than "use for the cure of most athlete's foot".	GSK Consumer Healthcare 184 Liberty Corner Rd Ste 200 Warren, NJ 07059-6868
Drugs	FIRST Omeprazole 2mg/mL in FIRST PPI Suspension Compounding Kit , 5 oz., Rx only, Manufactured for CutisPharma Wilmington, MA, NDC# 65628-070-05	Class III	Lot #: E1396, Exp. 08/2018	Labeling: Label error on declared strength. Package Insert -Error in the Description section of the package insert refers to the strength as 3mg per mL; however it should state 2mg per mL	CutisPharma, Inc. 841 Woburn St Wilmington, MA 01887-3414
Drugs	Bupropion Hydrochloride Extended-Release Tablets, USP (XL), 300 mg, a) 90-count bottle (NDC 68001-264-05), b) 500-count bottle (NDC 68001-264-03) , Rx only, Manufactured by: Cadila Healthcare Limited, Ahmedabad, India For BluePoint Laboratories	Class III	Lot #: a) M601509, Exp 3/31/2018; M606506, Exp 4/30/2018; b) M601510, Exp 3/31/2018; M604444, Exp 4/30/2018; M606515, Exp 4/30/2018.	Failed Dissolution Specifications: The firm was notified that there was a dissolution out of specification result on the 6 month stability samples.	Amerisource Health Services 2550 John Glenn Ave Ste A Columbus, OH 43217-1188
Drugs	FIRST Omeprazole 2mg/mL in FIRST PPI Suspension Compounding Kit , 3 OZ, Rx only, Manufactured for CutisPharma Wilmington, MA, NDC# 65628-070-03	Class III	Lot #: E1414, Exp. 08/2018	Labeling: Label error on declared strength. Package Insert -Error in the Description section of the package insert refers to the strength as 3mg per mL; however it should state 2mg per mL	CutisPharma, Inc. 841 Woburn St Wilmington, MA 01887-3414
Drugs	NIFEdipine Capsules USP, 10 mg, Rx only, 100 count bottle, Manufactured and distributed by: Actavis Elizabeth LLC, 200 Elmora Avenue, Elizabeth, NJ 07207, NDC 0228-2407-10	Class III	Lot # 0598B151; Exp 03/18	Presence of Foreign Tablets/Capsules	Actavis Elizabeth LLC 200 Elmora Ave Elizabeth, NJ 07202-1106
Drugs	AHP NIFEdipine Capsules, 10mg USP, 100 count carton (NDC: 68084-022-01); Individual Blister (NDC: 68084-022-11), Rx Only, Manufactured by: Actavis Elizabeth, LLC, Packaged and Distributed by: American Health Packaging, Columbus, Ohio 43217	Class III	Lot #155404 ; Exp 01/18 Lot #161139,163060,164054, 164809; Exp 03/18	Presence of Foreign Tablets/Capsules	Amerisource Health Services 2550 John Glenn Ave Ste A Columbus, OH 43217-1188
Drugs	Ceftriaxone for Injection, USP, 1 gram, 10 Single use Vials, Rx only, For IM or I.V. Use, Manufactured by: Sandoz GMbH for Hospira Worldwide, Inc., Lake Forest,	Class III	Sandoz - Lot GJ7151(Pfizer- Lot 670028M); Exp. 07/19	Labeling: Missing Label	Sandoz Inc 100 College Rd W Princeton, NJ 08540-6604

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
	Il 60045, USA, Made in Austria, NDC 0409-7332-01				
Drugs	Amoxicillin for Oral suspension, USP 400 mg/5 mL, 100 mL (when reconstituted), Rx only, Manufactured by: Hikma Pharmaceuticals, P.O. Box 183400, Amman 11118 - Jordan, NDC 0143-9887-01	Class III	Lot #: AS1466A, Exp. Jan 2019	Labeling: Label Error on Declared Strength: Some bottles miss a color coded panel where the strength of the product is typically displayed.	West-Ward Pharmaceuticals Corp. 401 Industrial Way West Eatontown, NJ 07724-2209
Drugs	Diltiazem HCl Extended-release Capsules, USP 120 mg, 100-count bottle (NDC 0378-5220-01), 500-count bottle (NDC 0378-5220-05), Rx Only, Manufactured by: Mylan Pharmaceuticals Inc., Morgantown, WV, 26505 USA	Class III	0378-5220-01 Lot# 3065133; Exp. 03/17 0378-5220-01 Lot# 3066564; Exp. 05/17 0378-5220-05 Lot# 3066564; Exp. 05/17 0378-5220-01 Lot# 3069645; Exp. 08/17 0378-5220-05 Lot# 3069645; Exp. 08/17	Failed Impurities/Degradation Specifications: OOS results for known compound.	Mylan Pharmaceuticals Inc. 781 Chestnut Ridge Rd Morgantown, WV 26505-2730
Drugs	BuPROPion Hydrochloride Extended-Release Tablets, USP (XL) 300 mg, Rx Only, 500-count bottles, Manufactured by Cadila Healthcare Ltd. Ahmedabad, India Distributed by: Zydus Pharmaceuticals USA inc. Pennington, NJ 08534, NDC 68382-354-05	Class III	Lot #: MR3365, Exp. Feb 17	Failed Dissolution Specifications: Product did not meet dissolution specification at an intermediate time point.	Zydus Pharmaceuticals USA Inc 73 Route 31 N Pennington, NJ 08534-3601
Drugs	KENALOG (Triamcinolone Acetonide) Spray with Spray Tube Topical Aerosol, USP, (0.147 mg/g), 15 g bottle, Physician Sample: Not For Sale, Rx only, RANBAXY, Jacksonville, FL 32257, UPC 3 10631 09335 8.	Class III	Lot: GHEN, GLGL, GLGL-1, Exp 10/31/2016; HACS, HACS-1, HAFK, HAFK-1, Exp 1/31/2017; HDBB, HDBB-1, HDFS, HDFS-1, Exp 4/30/2017; HFDP, HFDP-1, Exp 6/30/2017	Failed Stability Specifications: Low Out of Specification results for alcohol content.	Sun Pharmaceutical Industries, Inc. 270 Prospect Plains Rd Cranbury, NJ 08512-3605
Drugs	5% Lidocaine HCL and 7.5% Dextrose Injection, USP, 2 mL Single-dose ampule, 5 count box, Rx Only, For Spinal Anesthesia Only, Manufactured by Hospira, Inc., Lake Forest, IL 60045, NDC 0409-4712-01	Class III	Lot # 34-547-DK, 34 -548-DK, Exp. 10/16 , Lot # 39-372-DK, E xp. 03/17 Lot Numb er may be followed by numbers from 0 1 to 99	Failed Stability Specifications: The recalled lots did not meet the specification for color and pH throughout shelf life.	Hospira Inc. 275 N Field Dr Lake Forest, IL 60045-2579
Drugs	Qnasl (beclomethasone dipropionate) Nasal Aerosol 40 Mcg, 60 Metered Sprays, Rx only, Manufactured for Teva Respiratory, LLC, Horsham, PA 19044, By: 3M Drug Delivery Systems, Northridge, CA 91324, NDC 59310-206-06 and 59310-206-08 (Physician Samples).	Class III	Lot #: 150096, Exp. 3/2017; Lot #: 1503 27, Exp. 10/2017	Failed Content Uniformity: Product was out of specification for spray content uniformity obtained during stability testing.	Teva Pharmaceuticals USA 1090 Horsham Rd North Wales, PA 19454-1505
Drugs	Qnasl (beclomethasone dipropionate) Nasal Aerosol 80 Mcg, 50 Metered Sprays, Rx only, Manufactured for Teva Respiratory, LLC, Horsham, PA 19044, By: 3M Drug Delivery Systems, Northridge, CA 91324, NDC 59310-210-13.	Class III	Lot #: 150335, 1503 36, Exp. 4/2017	Failed Content Uniformity: Product was out of specification for spray content uniformity obtained during stability testing.	Teva Pharmaceuticals USA 1090 Horsham Rd North Wales, PA 19454-1505
Drugs	SODIUM FERRIC GLUCONATE COMPLEX IN SUCROSE INJECTION, 62.5mg elemental iron/5mL, 10 (5mL vials) per shelf pack, Rx only, Mfd: Hikma	Class III	Lot #: 152032.1, Exp . Date. 2/2017	Subpotent Drug: Product has an out of specification in iron assay analysis found	West-Ward Pharmaceuticals Corp. 401 Industrial

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
	Farmaceutica (Portugal,) SA Distributed by: Westward Eatowntown NJ 07724 USA, Shelf pack NDC 0143-9570-10, Unit dose NDC 0143-9570-01			during 18 month stability testing.	Way West Eatontown, NJ 07724-2209
Drugs	Methylprednisolone Tablets, USP, 16 mg, 50-count bottles, Rx only, Manufactured by Jubilant Cadista Pharmaceuticals Inc., Salisbury, MD 21801, NDC 59746-003-14.	Class III	Lot #: 16P0176, Exp 02/2018 but labeled incorrectly as 02/0218.	Labeling: Incorrect or Missing Lot and/or Exp Date: incorrect expiration date of 02/0218 is printed on the container label instead of the correct expiration date of 02/2018.	Jubilant Cadista Pharmaceuticals, Inc. 207 Kiley Dr Salisbury, MD 21801-2249

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

CURRENT DRUG SHORTAGES

Erythromycin Lactobionate Injection

November 21, 2016

Reason for the Shortage

- Pfizer (Hospira) has Erythrocin on shortage due to manufacturing delays.

Estimated Resupply Dates

- Pfizer (Hospira) has Erythrocin 500 mg ADD-Vantage vials on back order and the company estimates a release date in late-January 2017.

http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=546

Diltiazem Extended-Release Capsules (Twice-Daily Dosing)

November 21, 2016

Reason for the Shortage

- Mylan Institutional did not provide a reason for the shortage.

Estimated Resupply Dates

- Mylan Institutional has diltiazem 90 mg extended-release capsules in 100 count blister packs on back order and the company estimates a release date of mid-December 2016.

http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1250

Ceftriaxone Sodium Injection

November 21, 2016

Reason for the Shortage

- Fresenius Kabi states the reason for the shortage is increased demand.
- Hospira states the reason for the shortage was manufacturing delay.
- Sagent states the reason for the shortage is manufacturing delay.
- Sandoz cannot provide a reason for the shortage.
- WG Critical Care states the reason for the shortage is increased demand.

Estimated Resupply Dates

- Apotex has ceftriaxone 500 mg vials available in limited supply.
- Fresenius Kabi has ceftriaxone 2 gram vials on back order and the company estimates a released date of 1st quarter 2017.
- Hospira has ceftriaxone 1 gram vials, 2 gram vials, and 10 gram vials available in limited supply.
- Lupin has all ceftriaxone presentations on allocation.
- Sagent has ceftriaxone 2 gram vials on allocation.
- Sandoz has ceftriaxone 2 gram vials on back order and the company estimates a release date of mid-December 2016.
- WG Critical Care has ceftriaxone 1 gram and 2 gram vials on back order and the company estimates a release date of January 2017.
- West-Ward has ceftriaxone 1 gram and 2 gram vials on allocation. The 250 mg vials are on back order and the company cannot estimate a release date.
- Wockhardt has ceftriaxone 250 mg, 500 mg, 1 gram, and 2 gram vials on back order and the company estimates a release date of January 2017 for the 1 gram and 2 gram vials and cannot estimate a release date for the 250 mg and 500 mg vials.

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

Tigecycline Injection

November 22, 2016

Reason for the Shortage

- Pfizer has Tygacil on shortage due to manufacturing delays. The company is supplying 50 mg/5 mL vials during the shortage of the 10 mL vials.

Estimated Resupply Dates

- Pfizer has Tygacil 50 mg/10 mL vials on back order and the company estimates a release date of February 2017.

http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1218

Procainamide Hydrochloride Injection

November 22, 2016

Reason for the Shortage

- Hospira (Pfizer) has procainamide hydrochloride injection on shortage due to manufacturing delays.

Estimated Resupply Dates

- Hospira has procainamide 100 mg/mL 10 mL vials and 500 mg/mL 2 mL vials on back order and the company estimates a release date of 1st quarter 2017.

http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=868

Mitoxantrone Hydrochloride Injection

November 22, 2016

Reason for the Shortage

- Fresenius Kabi has mitoxantrone available for direct order.
- Hospira has mitoxantrone injection on shortage due to manufacturing delay.
- Teva has mitoxantrone injection on allocation due to current market conditions.
- Estimated Resupply Dates
- Fresenius Kabi has mitoxantrone 10 mL vials on allocation.
- Hospira has all mitoxantrone injection on long-term back order and the company estimates a release date of February 2017.
- Teva has mitoxantrone 10 mL vials on back order and the company cannot estimate a release date.

http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1212

Cefotetan Disodium Injection

November 22, 2016

Reason for the Shortage

- BBraun had cefotetan on allocation due to current market conditions.
- Fresenius Kabi states the reason for the shortage is manufacturing delay.
- Teligent received FDA approval for Cefotan in 2015.Teligent launched Cefotan in March 2016.

Estimated Resupply Dates

- Fresenius Kabi has cefotetan 10 gram vials on back order and the company estimates a release date of late-January 2017.

http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1097

Calcium Gluconate Injection

November 22, 2016

Reason for the Shortage

- American Regent has calcium gluconate on shortage due to manufacturing delays.
- Fresenius Kabi has calcium gluconate available.
- 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.

Estimated Resupply Dates

- American Regent has calcium gluconate 100 mg/mL 50 mL and 100 mL vials on back order and the company cannot estimate a release date.
- Fresenius Kabi has calcium gluconate 100 mg/mL 50 mL and 100 mL vials available with expiration dates of <7 months.

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

Bleomycin Sulfate Injection

November 22, 2016

Reason for the Shortage

- Fresenius Kabi has bleomycin on back order due to shortage of active pharmaceutical ingredient.
- Hospira had bleomycin on shortage due to increase demand for the product.
- Teva had temporarily discontinued bleomycin but are releasing product again.
- FDA is allowing temporary importation of bleomycin sulfate powder for injection 15,000 IU (15 units bleomycin sulfate USP). These vials were manufactured for Amneal Australia. The labeling and bar coding for the imported product is different from the US version. The imported product should be used in the same way as the US product. FDA Dear Healthcare Professional letter. The product should be available to order through major wholesalers.

Estimated Resupply Dates

- Fresenius Kabi has bleomycin 15 unit vials on allocation. The 30 unit vials are on back order and the company estimates a release date of 2nd quarter 2017.
- Teva has bleomycin 15 unit and 30 unit vials on allocation and the company is releasing product regularly.

http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1233

Yellow Fever Vaccine Injection

November 29, 2016

Reason for the Shortage

- Sanofi Pasteur could not provide a reason for the shortage of YF-Vax.
- There are no other suppliers of yellow fever vaccine.
- Additional information is available

Estimated Resupply Dates

- Sanofi Pasteur has YF-Vax multi-dose vials and single dose vials available in limited supply. Customers can call Sanofi Pasteur to order product for patients traveling in the next 30 days.

http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=383

Potassium Chloride Injection

November 29, 2016

Reason for the Shortage

- Baxter has a consistent supply of potassium chloride injection.
- Fresenius Kabi has some potassium chloride injection available.
- Hospira has potassium chloride injection on shortage due to increase demand and manufacturing delays.

Estimated Resupply Dates

- Hospira has potassium chloride 2 mEq/mL 250 mL vials and 10 mEq/500 mL in 5% dextrose and 0.225% sodium chloride on back order and the company cannot estimate a release date.

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

Orphenadrine Citrate Injection

November 29, 2016

Reason for the Shortage

- Akorn had orphenadrine citrate injection on shortage due to manufacturing delays.
- Actavis and Sagent did not provide a reason for the orphenadrine citrate shortage.

Estimated Resupply Dates

- Actavis has orphenadrine injection on back order and the company cannot estimate a release date.
- Sagent has orphenadrine injection on back order and the company cannot estimate a release date.

http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=884

Dolasetron Mesylate Injection

November 29, 2016

Reason for the Shortage

- Validus Pharmaceuticals acquired Anzemet injection from Sanofi US in December 2015. Validus Pharmaceuticals has temporarily discontinued all Anzemet injection presentations and cannot estimate a resupply date.

Estimated Resupply Dates

- Validus Pharmaceuticals has temporarily discontinued all Anzemet injection presentations and the company cannot estimate a resupply date. The company does not expect product before the second half of 2017.

http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1230

Diltiazem Injection

November 29, 2016

Reason for the Shortage

- Akorn states the reason for the shortage is increased demand due to market conditions.

- 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.

Estimated Resupply Dates

- Akorn has diltiazem 5 mg/mL 5 mL vials, 10 mL vials, and 25 mL vials in 1 count and 10 count available but with short-expiration dating of 3rd quarter 2017.
- Hospira has diltiazem 5 mg/mL 5 mL vials on back order and the company estimates a release date of 1st quarter 2017. The 5 mg/mL 10 mL vials are available in limited supply.

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

Atropine Sulfate Injection

November 29, 2016

Reason for the Shortage

- Hospira states the shortage was due to manufacturing delays.

Estimated Resupply Dates

- Hospira has atropine 0.05 mg/mL 5 mL Ansyr syringes on back order and the company cannot estimate a release date.

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

Alcohol Dehydrated Injection (Ethanol)

November 29, 2016

Reason for the Shortage

- Akorn states the back order is due to manufacturing delays.

Estimated Resupply Dates

- Akorn has dehydrated alcohol vials on back order and the company estimates a release date of mid-December 2016.
- American Regent has dehydrated alcohol 1 mL and 5 mL ampules on back order and the company cannot estimate a release date.

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

Acetylcysteine Oral and Inhalation Solution

November 29, 2016

Reason for the Shortage

- American Regent has a consistent supply of acetylcysteine oral and inhalation solution.
- Roxane Labs discontinued acetylcysteine oral and inhalation solution in April 2014.
- Hospira states the reason for the shortage was manufacturing delays.
- Fresenius Kabi states the reason for the shortage was manufacturing delays.

Estimated Resupply Dates

- American Regent has acetylcysteine solution 100 mg/mL 10 mL vials and 200 mg/mL 10 mL vials on back order and the company cannot estimate a release date. Acetylcysteine 200 mg/mL 30 mL vials are available in limited quantities with a short expiration date (December 2016).

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

Leuprolide Acetate 14-Day Kit

November 30, 2016

Reason for the Shortage

- Caraco will not provide availability information.
- Sandoz states the reason for the shortage was increased demand.
- Teva states the shortage is due to manufacturing delays.

Estimated Resupply Dates

- Teva has leuprolide acetate injection on back order and the company estimates a release date in first quarter of 2018.

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

Flumazenil Injection

December 01, 2016

Reason for the Shortage

- Fresenius Kabi had flumazenil on shortage due to short-term manufacturing delays.
- Mylan Institutional could not provide a reason for the shortage.
- Sandoz discontinued flumazenil injection in 2015.
- West-Ward states the reason for the shortage is increased demand.

Estimated Resupply Dates

- All marketed presentations are available.

http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1184

Cefuroxime Sodium Injection

December 01, 2016

Reason for the Shortage

- Teligent has Zinacef on shortage due to increased demand.
- West-Ward did not provide a reason for the cefuroxime injection shortage.

Estimated Resupply Dates

- West-Ward has cefuroxime 1.5 gram vials on allocation.
- Sagent has cefuroxime 750 mg and 1.5 gram vials on allocation. The 7.5 gram vials are on back order and the company cannot estimate a release date.
- Teligent has Zinacef 1.5 gram vials on back order and the company estimates a release date of 1st quarter 2017.

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

Oxytocin Injection

December 02, 2016

Reason for the Shortage

- Fresenius Kabi states the shortage was due to increased demand.

- Par Sterile Products (formerly JHP) discontinued generic oxytocin injection in July 2014. Par Sterile Products discontinued Pitocin 10 unit/mL 50 mL vials in September 2015.
- West-Ward is not actively marketing oxytocin.

Estimated Resupply Dates

- Fresenius Kabi has oxytocin 10 units/mL 1 mL and 30 mL vials on back order and the company estimates a release date of late-December 2016 for the 1 mL vials and mid-December 2016 for the 30 mL vials.

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

Lidocaine Injection

December 02, 2016

Reason for the Shortage

- Amphastar had lidocaine 2% emergency syringes on shortage due to increase demand for the product.
- AuroMedics introduced lidocaine injection in February 2014.
- Fresenius Kabi has generic lidocaine presentations on shortage due to a supply interruption of API. Xylocaine products are not affected.
- Hospira has lidocaine presentations on shortage due to manufacturing delays and increased demand

Estimated Resupply Dates

- AuroMedics has 1% lidocaine 2 mL ampules, 5 mL ampules, 2 mL vials, 5 mL vials, and 30 mL vials on intermittent back order and the company is releasing product as it becomes available. AuroMedics has 2% lidocaine 2 mL and 5 mL vials on intermittent back order and the company is releasing product as it becomes available. Fresenius Kabi has 0.5% Xylocaine-MPF 50 mL vials on back order and the company estimates a release date of late-December 2016. The 1% Xylocaine 20 mL vials are on intermittent back order and the company is releasing product as it becomes available. The 1% Xylocaine 50 mL vials are on back order and the company estimates a release date of mid-December 2016. The 1% Xylocaine-MPF 30 mL vials and 10 mL sterile-pack vials are on back order and the company estimates a release date of mid-December 2016. The 2% Xylocaine 20 mL vials are on intermittent back order and the company is releasing product as it becomes available. The 2% Xylocaine-MPF 5 mL vials are on back order and the company estimates a release date of early-December 2016. Hospira has 1% lidocaine 30 mL vials, preservative free, in sterile pack on back order and the company cannot estimate a release date. The 2% lidocaine 5 mL vials are available in limited supply.

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

Tetracaine Hydrochloride Ophthalmic Drops

December 05, 2016

Reason for the Shortage

- Alcon and OCuSOFT did not provide a reason for the shortage.

Estimated Resupply Dates

- Alcon has tetracaine 0.5% ophthalmic drops in 2 mL bottles on allocation.
- OCuSOFT has Tetravisc 0.5% 5 mL bottles and 0.6 mL unit-dose containers in 12 count on intermittent back order and the company is releasing product as it becomes available.
- OCuSOFT has Tetravisc Forte 0.5% 5 mL bottles and 0.6 mL unit-dose containers in 12 count on intermittent back order and the company is releasing product as it becomes available.

http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1242

Sterile Empty Vials

December 05, 2016

Reason for the Shortage

- Hospira states the shortage was due to increased demand.
- Fresenius Kabi 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.

Estimated Resupply Dates

- All presentations are available.

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

Sincalide Injection

December 05, 2016

Reason for the Shortage

- Bracco Diagnostics has Kinevac injection on shortage due to a supply disruption. There are no approved alternatives to Kinevac for the labeled indications.

Estimated Resupply Dates

- Bracco has Kinevac on back order and the company cannot estimate a release date.

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

Poliovirus Vaccine Inactivated

December 05, 2016

Reason for the Shortage

- Sanofi Pasteur had IPOL vaccine on allocation due to the shortage of other combination vaccines (e.g., Pentacel).

Estimated Resupply Dates

- Sanofi Pasteur has IPOL vaccine available.

http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1228

Methylphenidate Transdermal

December 05, 2016

Reason for the Shortage

- Noven has Daytrana patches on shortage due to shipping delays.

Estimated Resupply Dates

- Noven has all Daytrana presentations on intermittent back order and the company is releasing supplies as they become available.

http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1216

Mannitol Injection

December 05, 2016

Reason for the Shortage

- American Regent has mannitol injection on shortage due to manufacturing delays.
- Hospira had mannitol injection on shortage due to manufacturing delays.

Estimated Resupply Dates

- American Regent has mannitol 250 mg/mL 50 mL vials on back order and the company cannot estimate a release date.
- Fresenius Kabi has mannitol 250 mg/mL 50 mL vials on back order and the company estimates a release date of early-December 2016.

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

Intranasal Mucosal Atomization Device

December 05, 2016

Reason for the Shortage

- Teleflex Medical has recalled multiple lots of MAD nasal devices due to potential for inaccurate delivery of atomized medications. There have been several reports of the lots producing streams of medication instead of atomized sprays.

Estimated Resupply Dates

- Teleflex Medical has LMA MAD Nasal Intranasal Mucosal Atomization Devices on intermittent back order and the company is releasing product as it becomes available.

http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1255

Gadoteridol Injection

December 05, 2016

Reason for the Shortage

- Bracco diagnostics could not provide a reason for the shortage.

Estimated Resupply Dates

- Bracco diagnostics has ProHance 15 mL vials on allocation.

http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1237

Avibactam/Ceftazidime Injection

December 05, 2016

Reason for the Shortage

- Allergan had Avycaz on shortage due to manufacturing issues.

Estimated Resupply Dates

- Allergan has Avycaz 0.5 gram/2 gram vials available.

http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1244

Chloroquine Phosphate Tablets

December 08, 2016

Reason for the Shortage

- Rising has chloroquine phosphate tablets on shortage due to manufacturing delays related to obtaining raw materials.

Estimated Resupply Dates

- Rising has chloroquine phosphate 250 mg and 500 mg tablets on back order and the company estimates a release date of early-January 2017.

http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1258salsa

Thrombin Topical Solution (Bovine)

December 09, 2016

Reason for the Shortage

- Pfizer states the reason for the shortage is manufacturing delay.
- Recombinant thrombin topical solution products (Recothrom) are available and not affected by this shortage.

Estimated Resupply Dates

- Pfizer has Thrombin JMI 5,000 unit epistaxis kits on back order and the company estimates a release date of mid-to-late-December 2016. Pfizer has Thrombin JMI 5,000 unit syringe spray kits on back order and the company estimates a release date of late-December 2016.

http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1199

Promethazine Injection

December 09, 2016

Reason for the Shortage

- Teva states the shortage is due to manufacturing delays.
- West-Ward states the shortage was due to manufacturing delays.
- Hospira discontinued promethazine in 2016.
- X-Gen has promethazine available.

Estimated Resupply Dates

- Teva has all promethazine injection presentations on back order and the company estimates a release date of January 2017.
- West-Ward has promethazine 25 mg/mL 1 mL vials and 1 mL ampules on a weekly allocation. Phenergan 25 mg/mL 1 mL vials are on back order and the company estimates a release date of December 2016.

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

Octreotide Injection

December 09, 2016

Reason for the Shortage

- Fresenius Kabi did not provide a reason for the shortage.
- Sagent has octreotide on shortage due to manufacturing delays.
- Teva is relaunching several presentations this year.
- Sun Pharma will not provide availability information at this time.

Estimated Resupply Dates

- Fresenius Kabi has octreotide 50 mcg/mL 1 mL vials on back order and the company estimates a release date of 1st quarter 2017.
- Sagent has octreotide 50 mcg/mL 1 mL vials and 200 mcg/mL 5 mL vials on back order and the company estimates a release date of December 2016. The 500 mcg/mL 1 mL vials are on allocation.

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

Nalbuphine Injection

December 09, 2016

Reason for the Shortage

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

Estimated Resupply Dates

- Hospira has nalbuphine injection available.

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

Lidocaine with Epinephrine Injection

December 09, 2016

Reason for the Shortage

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

Estimated Resupply Dates

- Hospira has 1% lidocaine with epinephrine (1:100,000) 30 mL and 50 mL vials on back order and the company estimates a release date of early-January 2017 for the 30 mL vials and mid-December 2016 for the 50 mL vials.
- Hospira has 0.5% lidocaine with epinephrine (1:200,000) 50 mL vials on back order and the company estimates a release date of mid-December 2016.
- Fresenius Kabi has 1% Xylocaine with epinephrine (1:200,000) 10 mL, 20 mL, and 50 mL vials on back order and the company estimates a release date of mid-April 2017 for the 10 mL vials and mid- to late-December 2016 for the 20 mL vials, and mid-December 2016 for the 50 mL vials. The 1% Xylocaine-MPF with epinephrine (1:200,000) 10 mL and 30 mL vials are on back order and the company estimates a release date of mid-April 2017 for the 10 mL vials and mid-December 2016 for the 30 mL vials. The 1.5% Xylocaine-MPF with epinephrine (1:200,000) 10 mL vials are on back order and the company estimates a release date of mid-April 2017. The 2% Xylocaine-MPF with epinephrine (1:200,000) 10 mL vials are on back order and the company estimates a release date of mid-April 2017 for the 10 mL vials

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

Hydralazine Injection

December 09, 2016

Reason for the Shortage

- Akorn did not provide a reason for the hydralazine injection on shortage.
- American Regent has hydralazine injection on shortage due to manufacturing delays.
- Fresenius Kabi has hydralazine injection available.
- X-Gen launched hydralazine injection in September 2015.

Estimated Resupply Dates

- Akorn has hydralazine 20 mg/mL 1 mL vials in 25 count available with expiration dates of July or August 2017.
- American Regent has hydralazine 20 mg/mL 1 mL vials on back order and the company cannot estimate a release date.

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

Famotidine Injection

December 09, 2016

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.
- Baxter has famotidine premixed bags available.
- Fresenius Kabi did not provide a reason for the shortage.

Estimated Resupply Dates

- Mylan Institutional has temporarily discontinued famotidine 10 mg/mL 2 mL vials. Famotidine 10 mg/mL 4 mL and 20 mL vials are on back order and the company cannot estimate a release date.
- West-Ward has famotidine 10 mg/mL 20 mL vials on allocation.

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

Dextrose (25%) Injection

December 09, 2016

Reason for the Shortage

- Hospira had 25% dextrose syringes on shortage due to increased demand.

Estimated Resupply Dates

- Hospira has 25% dextrose 10 mL Ansyr syringes available.

http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1011

Chlorothiazide Oral Suspension

December 09, 2016

Reason for the Shortage

- Valeant could not provide a reason for the shortage.

Estimated Resupply Dates

- Valeant has chlorothiazide oral suspension (Diuril) on back order, and the company estimates a resupply date of late-December 2016.

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

Ceftazidime Injection

December 09, 2016

Reason for the Shortage

- IGI Laboratories changed its name to Teligent in late-October 2015.
- Covis divested Fortaz injection to IGI Laboratories in October 2015.
- Hospira had Tazicef on shortage due to manufacturing delays.
- Sagent has ceftazidime injection on shortage due to manufacturing delays.
- Sandoz discontinued ceftazidime 1 gram and 2 gram vials in 2015.
- BBraun has ceftazidime on allocation due to increased demand.

Estimated Resupply Dates

- BBraun has ceftazidime 1 gram/50 mL and 2 gram/50 mL premixed bags on allocation.
- Teligent has Fortaz 1 gram and 6 gram vials on back order and the company estimates a release date of December 2016. The 1 gram/50 mL premixed bags are on back order and the company estimates a release date of February 2017.
- Sagent has ceftazidime 1 gram, 2 gram, and 6 gram vials on back order and the company estimates a release date of December 2016.
- Hospira has Tazicef 1 gram vials and 1 gram ADD-Vantage vials on back order and the company estimates a release date of mid-December 2016. Tazicef 2 gram vials are on back order and the company estimates a release date of early-February 2017. Tazicef 6 gram vials are on back order and the company estimates a release date of late-January 2017.
- WG Critical Care has ceftazidime 2 gram vials on back order and the company estimates a release date of February 2017.

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

Cefoxitin Sodium Injection

December 09, 2016

Reason for the Shortage

- Fresenius Kabi and West-Ward did not provide a reason for the shortage.
- Sagent has cefoxitin on shortage due to manufacturing delays.
- BBraun has cefoxitin on allocation due to increased demand.

Estimated Resupply Dates

- Apotex has cefoxitin 10 gram vials available with an expiration date of October 2017.
- BBraun has cefoxitin 1 gram and 2 gram premixes on allocation.
- Fresenius Kabi has cefoxitin 2 gram vials on back order and the company estimates a release date in mid-December 2016.
- Sagent has cefoxitin 2 gram and 10 gram vials on back order and the company estimates a release date of December 2016.
- West-Ward has cefoxitin 2 gram and 10 gram vials on back order and the company cannot estimate a release date

http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1256

Cefepime Injection

December 09, 2016

Reason for the Shortage

- Fresenius Kabi and West-Ward did not provide a reason for the shortage.
- Sagent has cefoxitin on shortage due to manufacturing delays.

- BBraun has cefoxitin on allocation due to increased demand.

Estimated Resupply Dates

- Braun has cefepime 1 and 2 gram premixed bags on allocation to contracted customers. Baxter has cefepime 1 gram/50 mL and 2 gram/100 mL premixed bags on allocation.
- Fresenius Kabi has cefepime 1 gram and 2 gram vials on back order and the company estimates a release date of mid-January 2017.
- Hospira has Maxipime 1 gram ADD-Vantage vials, 2 gram ADD-Vantage vials, and 2 gram vials on allocation. The 1 gram vials are on back order and the company estimates a release date of March 2017.
- Sagent has cefepime 1 gram and 2 gram vials on back order and the company estimates a release date of December 2016.
- WG Critical Care has cefepime 1 gram and 2 gram vials on intermittent back order and is releasing product as it becomes available to contracted customers.

http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1176

Calcium Chloride Injection

December 09, 2016

Reason for the Shortage

- American Regent has calcium chloride on shortage due to manufacturing delays.
- Amphastar has calcium chloride available.
- Hospira has calcium chloride on shortage due to manufacturing delays.
- Mylan Institutional has withdrawn calcium chloride syringes from the market. The company recalled the syringes in April 2015 due to incompatibility of the syringes and some needless adaptors.

Estimated Resupply Dates

- American Regent has calcium chloride 100 mg/mL 10 mL vials on back order and the company cannot estimate a release date. Hospira has calcium chloride 100 mg/mL 10 mL Ansyr syringes available in limited supply.
- Hospira has calcium chloride 100 mg/mL 10 mL LifeShield syringes on back order and the company estimates a release date of mid-December 2016.

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

Ofloxacin Ophthalmic Solution

December 12, 2016

Reason for the Shortage

- Allergan has Ocuflox ophthalmic solution available.
- Akorn did not provide a reason for the shortage.
- Rising did not provide a reason for the shortage.
- Valeant did not provide a reason for the shortage.

Estimated Resupply Dates

- Akorn has ofloxacin ophthalmic solution in 5 mL and 10 mL bottles on back order and the company estimates a release date of early-January 2017.
- Valeant has temporarily discontinued ofloxacin ophthalmic solution in 5 mL and 10 mL bottles and the company cannot estimate a release date.
- Rising has ofloxacin ophthalmic solution in 5 mL bottles on allocation.

http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1235

Multiple Vitamins for Infusion

December 12, 2016

Reason for the Shortage

- Hospira states the shortage is due to manufacturing delays.
- Baxter has all presentations fully available at this time.

Estimated Resupply Dates

- Hospira has MVI Adult 10 mL two-chambered vials and MVI-12 without vitamin K 50 mL Dual vials on back order and the company cannot estimate a release date. The MVI Adult 5 mL Dual vials and MVI Adult 50 mL Dual vials are on back order and the company estimates a release date of 1st quarter 2017.

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

Magnesium Sulfate Injection

December 12, 2016

Reason for the Shortage

- American Regent has had magnesium sulfate unavailable since late 2012.
- Fresenius Kabi has magnesium sulfate injection on shortage due to increased demand for the product. The company has launched 2 new NDC codes for magnesium sulfate 20 mL and 50 mL vials (these replace the older codes of the 20 mL (NDC 63323-0064-20) and 50 mL (NDC 63323-0064-50) vials).
- Hospira has magnesium sulfate injection on shortage due to manufacturing delays.
- X-Gen had magnesium sulfate injection on shortage due to increased demand.

Estimated Resupply Dates

- Fresenius Kabi has magnesium sulfate 500 mg/mL 10 mL, 20 mL, and 50 mL vials on intermittent back order and the company is releasing product as it becomes available.
- Hospira has magnesium sulfate 500 mg/mL 20 mL vials on back order and the company estimates a release date of 1st quarter 2018.

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

Levocarnitine Oral Tablets and Solution

December 12, 2016

Reason for the Shortage

- Akorn has levocarnitine tablets available.
- Sigma-Tau has Carnitor presentations on shortage due to increased demand.

Estimated Resupply Dates

- Akorn has levocarnitine 330 mg tablets are on back order and the company estimates a release date in late-December 2016.
- Akorn has levocarnitine oral solution on back order and the company estimates a release date in late-December 2016.
- Sigma-Tau has Carnitor tablets on allocation.
- Sigma-Tau has Carnitor 100 mg/mL oral solution and Carnitor SF 100 mg/mL Sugar-Free oral solution on allocation.

http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1254

Leucovorin Calcium Injection

December 12, 2016

Reason for the Shortage

- Fresenius Kabi has leucovorin on shortage due to increase demand.
- Teva has leucovorin on allocation due to increased demand.
- West-Ward has leucovorin available.
- Sagent has leucovorin on shortage due to manufacturing delay.

Estimated Resupply Dates

- Fresenius Kabi has leucovorin 200 mg and 500 mg vials on back order and the company estimates a release date of mid-December 2016.
- Sagent has leucovorin 200 mg and 350 mg vials on back order and the company estimates a release date of December 2016. The 100 mg vials are available with an expiration date of January 2017.
- Teva has leucovorin 100 mg and 350 mg vials on allocation.
- West-Ward has leucovorin 350 mg vials on a weekly allocation.

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

Ioversol Injection

December 12, 2016

Reason for the Shortage

- Guerbet could not provide a reason for the Optiray shortage.

Estimated Resupply Dates

- Guerbet has most Optiray products on allocation.

http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1253

Indocyanine Green

December 12, 2016

Reason for the Shortage

- Akorn could not provide a reason for the shortage.
- Hub Pharmaceuticals states the reason for the shortage was increased demand.

Estimated Resupply Dates

- Akorn has IC-Green on back order and the company estimates a release date in late-December 2016.

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

Ethiodized Oil

December 12, 2016

Reason for the Shortage

- Guerbet states their Lipiodol product is in short supply due to manufacturing problems at Jubliant HollisterStier, the manufacturing site in Canada that supplies Lipiodol for Guerbet. The company estimates the shortage will last at least one year.

Estimated Resupply Dates

- Guerbet is shipping supplies of Lipiodol Ultra-Fluide.2 Lipiodol Ultra-Fluide is not FDA approved. In order to prevent a drug shortage, FDA is allowing Guerbet to import Lipiodol Ultra-Fluide, a product manufactured for Guerbet in France by Delpharm Tours.
- Customers must order Lipiodol Ultra-Fluide directly from Guerbet by calling 1-877-729-6679. Lipiodol Ultra-Fluide is non-refundable and may not be resold.

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

Clindamycin Injection

December 12, 2016

Reason for the Shortage

- Akorn cannot provide a reason for the shortage.
- Pfizer has Cleocin available.
- Alvogen has clindamycin injection available.
- Sandoz has clindamycin injection available.
- Sagent has clindamycin injection available.

Estimated Resupply Dates

- Akorn has clindamycin 600 mg/50 mL and 900 mg/50 mL premixed bottles available in limited supply.
- Fresenius Kabi has clindamycin 150 mg/mL 2 mL and 4 mL vials available with short expiration dating of < 7 months for the 2 mL vials and <9 months for the 4 mL vials.

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

Benztropine Injection

December 12, 2016

Reason for the Shortage

- American Regent discontinued benztropine injection in May 2015.
- Fresenius Kabi launched benztropine in September 2016.

Estimated Resupply Dates

- West-Ward has benztropine 1 mg/mL 2 mL ampules on back order and the company estimates a release date of mid-December 2016.

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

Atropine Sulfate Ophthalmic Solution

December 12, 2016

Reason for the Shortage

- Alcon has discontinued Isopto Atropine.
- Akorn received FDA approval for atropine sulfate 1% ophthalmic solution in July 2014; this new product launched in January 2015.
- Sandoz has discontinued atropine sulfate ophthalmic solution.
- Valeant discontinued their atropine sulfate 1% ophthalmic solution products in 2015.

Estimated Resupply Dates

- Akorn has atropine sulfate ophthalmic solution in 2 mL, 5 mL, and 15 mL bottles on allocation.

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

Asparaginase Erwinia chrysanthemi

December 12, 2016

Reason for the Shortage

- Jazz Pharmaceuticals has Erwinaze on shortage due to manufacturing issues.

Estimated Resupply Dates

- Jazz Pharmaceuticals has asparaginase Erwinia chrysanthemi on back order, and the company estimates a release date of late-December 2016.

http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1252

Amoxicillin and Clavulanate 1000 mg/62.5 mg Extended-Release Tablets

December 12, 2016

Reason for the Shortage

- Dr. Reddy's states they are having raw ingredient issues.
- Sandoz did not provide a reason for the shortage.

Estimated Resupply Dates

- Dr. Reddy's has Augmentin XR and generic amoxicillin/clavulanate 1000 mg / 62.5 mg tablets on back order and the company cannot estimate a release date.
- Sandoz has amoxicillin/clavulanate 1000 mg / 62.5 mg tablets on back order and the company cannot estimate a release date.

http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1259

Scopolamine Transdermal Patch

December 13, 2016

Reason for the Shortage

- Baxter had Transderm Scop on shortage due to a manufacturing hold. Baxter changed their NDC numbers in late 2016.
- Sandoz had Transderm Scop on shortage due to increased demand. Sandoz changed their NDC number in late 2016.

Estimated Resupply Dates

- Baxter has Transderm Scop in 10 count and 24 count available.
- Sandoz has Transderm Scop in 4 count available.

http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=837

Hepatitis A Virus Vaccine Inactivated

December 13, 2016

Reason for the Shortage

- Merck did not provide a reason for the Vaqta shortage.
- GlaxoSmithKline has Havrix available.

Estimated Resupply Dates

- Merck has Vaqta pediatric/adolescent formulation 25U/0.5 mL prefilled syringes in 10 count on back order and the company estimates a release date in 2nd quarter 2017.

- Merck has Vaqta adult formulation 50U/1 mL vials in 1 count and 10 count on back order and the company estimates a release date in 2nd quarter 2017.

http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=180

Amoxicillin and Clavulanate 1000 mg/62.5 mg Extended-Release Tablets

December 12, 2016

Reason for the Shortage

- Dr. Reddy's states they are having raw ingredient issues.
- Sandoz did not provide a reason for the shortage.

Estimated Resupply Dates

- Dr. Reddy's has Augmentin XR and generic amoxicillin/clavulanate 1000 mg / 62.5 mg tablets on back order and the company cannot estimate a release date.
- Sandoz has amoxicillin/clavulanate 1000 mg / 62.5 mg tablets on back order and the company cannot estimate a release date.

http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1259

Estradiol Valerate Injection

December 13, 2016

Reason for the Shortage

- Par states the reason for the shortage is manufacturing delay.
- Perrigo states the reason for the shortage is manufacturing issues.

Estimated Resupply Dates

- Par Sterile Products has Delestrogen 10 mg/mL 5 ml vials, 20 mg/mL 5 mL vials, and 40 mg/mL 5 mL vials on back order and the company estimates a release date of 1st quarter 2017.
- Perrigo has estradiol valerate 40 mg/mL 5 mL vials on intermittent back order and the company is releasing product as it becomes available.

http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1186

Amikacin Injection

December 14, 2016

Reason for the Shortage

- West-Ward launched amikacin injection in 2 mL and 4 mL vials in December 2015.
- Teva has amikacin on shortage due to manufacturing delays. Teva recalled 7 lots in August 2016.2 The recall details are available on the FDA website.
- Heritage had amikacin injection on shortage due to manufacturing delays.
- Fresenius Kabi launched amikacin in early 2016. Both 2 mL and 4 mL vials are available

Estimated Resupply Dates

- Teva has amikacin 250 mg/mL 2 mL and 4 mL vials on back order and the company estimates a release date of late-December 2016.
- West-Ward has amikacin 250 mg/mL 2 mL and 4 mL vials on back order and the company cannot estimate a release date.

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

Sodium Chloride 0.9% Injection Bags

December 15, 2016

Reason for the Shortage

- Baxter discontinued 0.9% sodium chloride 250 mL and 500 mL AVIVA bags. The other presentations are available or on allocation.
- BBraun has 0.9% sodium chloride available for current customers.
- Hospira cites increased demand as the reason for the shortage.
- Fresenius Kabi is no longer importing product.
- Baxter has received FDA approval for 0.9% sodium chloride in Viaflo containers manufactured in an FDA-approved facility in Spain.

Estimated Resupply Dates

- Baxter has 0.9% sodium chloride in 1000 mL PVC/DEHP-free bags available in limited supply. The 1000 mL Viaflex bags are on allocation.
- BBraun has 0.9% sodium chloride in 250 mL, 500 mL, and 1000 mL PVC/DEHP-free bags on allocation.

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

Alcohol Dehydrated Injection (Ethanol)

December 15, 2016

Reason for the Shortage

- Akorn states the back order is due to manufacturing delays.

Estimated Resupply Dates

- Akorn has dehydrated alcohol vials on back order and the company estimates a release date of late-December 2016.
- American Regent has dehydrated alcohol 1 mL ampules on back order and the company cannot estimate a release date.

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

Tobramycin Injection

December 16, 2016

Reason for the Shortage

- Akorn has recently launched tobramycin solution for injection.
- Fresenius Kabi has tobramycin solution for injection on shortage due to increased demand.
- Mylan Institutional could not provide a reason for the shortage.
- Teva has tobramycin solution for injection on shortage due to manufacturing delays.

Estimated Resupply Dates

- Akorn has tobramycin 40 mg/mL 30 mL vials on back order and the company estimates a release date of mid-December 2016. The 40 mg/mL 2 mL vials are on back order and the company cannot estimate a release date.

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

Sodium Nitroprusside Injection

December 16, 2016

Reason for the Shortage

- Valeant only has short-dated Nitropress available.
- Sagent launched sodium nitroprusside in late 2016. They have product available.

Estimated Resupply Dates

- Valeant has Nitropress 25 mg/mL 2 mL vials available but with an expiration date of August 2017.

http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1223

Penicillin G Benzathine/Penicillin G Procaine

December 16, 2016

Reason for the Shortage

- Pfizer has Bicillin C-R and Bicillin C-R 900/300 on shortage due to manufacturing delays.

Estimated Resupply Dates

- Pfizer has Bicillin C-R 1,200,000 units/2 mL prefilled syringes on back order and 1,200,000 units/2 mL pediatric prefilled syringes on back order and the company estimates a release date of first quarter 2017.
- Pfizer has Bicillin C-R 900/300 2 mL pediatric prefilled syringes on allocation. These syringes have an expiration date of February 2017.

http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1249

Methylprednisolone Acetate Injection

December 16, 2016

Reason for the Shortage

- Sandoz could not provide a reason for the shortage.
- Pfizer had Depo-Medrol injection on a short-term shortage due to increased demand of Solu-Medrol.
- Teva has methylprednisolone acetate on shortage due to manufacturing delays.

Estimated Resupply Dates

- Sandoz has methylprednisolone acetate injection temporarily unavailable and the company cannot estimate a release date.
- Teva has all methylprednisolone acetate presentations on back order and the company estimates a release date of late 2017.

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

Methotrexate Injection

December 16, 2016

Reason for the Shortage

- Accord did not provide a reason for the shortage.
- Fresenius Kabi has methotrexate injection available.
- Mylan did not provide a reason for the shortage.
- Teva has methotrexate on shortage due to manufacturing delays.
- Pfizer (Hospira) has methotrexate injection available.

Estimated Resupply Dates

- Accord has methotrexate 25 mg/mL 2 mL, 10 mL, and 40 mL vials on back order and the company estimates a release date of late-January 2017.
- Mylan Institutional has methotrexate injection temporarily unavailable and the company cannot estimate a release date.
- Teva has methotrexate 25 mg/mL 2 mL and 10 mL vials on intermittent back order and the company is releasing product as it becomes available.

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

Doxorubicin Injection

December 16, 2016

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.
- Teva had doxorubicin solution for injection on allocation due to current market conditions.
- Fresenius Kabi has doxorubicin solution for injection available.
- Caraco has discontinued doxorubicin solution for injection 25 mL and 100 mL vials.
- Pfizer had doxorubicin solution for injection on shortage due to shipping delays.
- Sagent has doxorubicin solution for injection on back order due to manufacturing delays.
- Mylan Institutional could not provide a reason for the reason shortage.
- Actavis has doxorubicin injection available.
- FDA is allowing temporary importation of doxorubicin lyophilized powder for injection 50 mg vials. These vials were manufactured for Hospira UK Limited. The labeling as well as bar coding for the imported product is different from the US version. FDA has the Dear Healthcare Professional Letter linked on their website. The letter includes a link to both the US and United Kingdom package inserts to help explain the differences in labeling and packaging. Ordering can be done directly with Hospira Customer Care at 877-946-7747.

Estimated Resupply Dates

- Sagent has doxorubicin 2 mg/mL 25 mL and 100 mL vials on back order and the company cannot estimate a release date. The 5 mL vials are available with an expiration date of December 2016.

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

Vancomycin Hydrochloride Injection

December 19, 2016

Reason for the Shortage

- Pfizer has vancomycin injection available.
- Fresenius Kabi has vancomycin injection on shortage due to increased demand.
- Mylan Institutional has vancomycin injection available.
- Baxter is allocating vancomycin.
- Sagent has vancomycin injection on allocation due to manufacturing delays.

Estimated Resupply Dates

- Fresenius Kabi has vancomycin 5 gram and 10 gram vials on intermittent back order and the company is releasing product as it becomes available.
- Sagent has vancomycin 10 gram vials on allocation

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

Sodium Phosphate Injection

December 19, 2016

Reason for the Shortage

- American Regent has sodium phosphate injection on shortage due to manufacturing delay.
- Fresenius Kabi states the reason for the shortage was increased demand.
- Hospira had sodium phosphate injection on shortage due to manufacturing delay.

Estimated Resupply Dates

- American Regent has sodium phosphate 3 mmol/mL 5 mL, 15 mL, and 50 mL vials on back order and the company cannot estimate a release date.
- Fresenius Kabi has imported Glycophos available with an expiration date of <3 months.

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

Sodium Acetate Injection

December 19, 2016

Reason for the Shortage

- American Regent has sodium acetate injection on back order due to manufacturing delays.
- Fresenius Kabi has sodium acetate injection available.
- Pfizer has sodium acetate injection available.

Estimated Resupply Dates

- American Regent has sodium acetate 2 mEq/mL 20 mL vials and 4 mEq/mL 50 mL vials on long-term back order and the company cannot estimate a release date.

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

Potassium Acetate Injection

December 19, 2016

Reason for the Shortage

- American Regent has potassium acetate on shortage due to manufacturing delays.
- Hospira had potassium acetate on shortage due to increased demand.
- Exela received FDA approval for potassium acetate injection in late-December 2015. Exela has potassium acetate injection available.

Estimated Resupply Dates

- American Regent has potassium acetate 2 mEq/mL 20 mL vials and 4 mEq/mL 50 mL vials on back order and the company cannot estimate a release date.

http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=668

Phenobarbital Injection

December 19, 2016

Reason for the Shortage

- West-Ward has phenobarbital on allocation due to manufacturing delays.

Estimated Resupply Dates

- West-Ward has phenobarbital 65 mg/mL 1 mL vials on a weekly allocation.

http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=649

Morphine Injections

December 19, 2016

Reason for the Shortage

- Astramorph injection has been unavailable since 2012. Fresenius Kabi changed manufacturing sites and cannot estimate if Astramorph will return.
- Hospira states the shortage is due to manufacturing delays.
- West-Ward launched several new morphine sulfate products in late-September 2015. They are not actively marketing the 15 mg/mL 1mL vials.

Estimated Resupply Dates

- Hospira has morphine 25 mg/mL 4 mL and 10 mL ADD-Vantage vials on back order and the company cannot estimate a release date.

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

Lorazepam injectable presentations

December 19, 2016

Reason for the Shortage

- Bedford discontinued lorazepam injection in May, 2011.
- West-Ward had product on shortage due to manufacturing delays.
- Pfizer has product on shortage due to increased demand.
- Akorn has not provided a reason for the shortage.
- Amphastar has product available.

Estimated Resupply Dates

- Pfizer has lorazepam 4 mg/mL 10 mL vials on back order and the company estimates a release date of late-December 2016.

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

Indomethacin Capsules

December 19, 2016

Reason for the Shortage

- Glenmark had indomethacin 25 mg 100 count on shortage due to manufacturing delays.
- Heritage did not provide a reason for the shortage.
- Sandoz discontinued indomethacin in mid-2016.
- Teva did not provide a reason for the shortage.

Estimated Resupply Dates

- Heritage has indomethacin 50 mg capsules in 100 count and 500 count on back order and the company cannot estimate a release date. Heritage has indomethacin 25 mg capsules in 100 count and 1000 count on allocation.
- Teva has all indomethacin presentations temporarily unavailable and the company cannot estimate a release date.

http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1236

Etomidate Injection

December 19, 2016

Reason for the Shortage

- Ben Venue stopped production in its plant in Bedford, Ohio and closed in July 2014.
- Pfizer has Amidate on shortage due to manufacturing delays. Pfizer discontinued etomidate 20 mL ampules in October 2016.
- Mylan cannot provide a reason for the current back order.
- Par Sterile Products discontinued etomidate in early 2015.
- Sagent is no longer marketing etomidate.
- Zydus has etomidate 20 mL vials on back order due to an increase in demand.

Estimated Resupply Dates

- Pfizer has Amidate 20 mL LifeShield syringes and 10 mL ampules on back order and the company cannot estimate a release date.
- Zydus has etomidate 20 mL vials on back order and the company estimates a release date of mid-January 2017.

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

Epinephrine Injection

December 19, 2016

Reason for the Shortage

- American Regent discontinued both epinephrine presentations in early 2015.
- Amphastar has epinephrine available.
- BPI Labs has epinephrine available.
- Pfizer has epinephrine syringes on shortage due to manufacturing delays.
- Par has Adrenalin available.

Estimated Resupply Dates

- Pfizer has epinephrine 0.1 mg/mL 10 mL 18 gauge Abboject syringes on back order and the company cannot estimate a release date.

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

Dopamine Hydrochloride Injection

December 19, 2016

Reason for the Shortage

- American Regent has dopamine on shortage due to manufacturing delays.
- Baxter could not provide a reason for the shortage.
- Hospira states the shortage is due to manufacturing delays.

Estimated Resupply Dates

- American Regent has all dopamine presentations on back order and the company cannot estimate a release date.
- Hospira has dopamine in 5% dextrose 400 mg/500 mL premixed bags on back order and the company estimates a release date of late-December 2016.

http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1243

Dihydroergotamine Mesylate Injection

December 19, 2016

Reason for the Shortage

- Perrigo and Valeant did not provide a reason for the shortage

Estimated Resupply Dates

- Perrigo has dihydroergotamine 1 mg/mL 1 mL ampules in 5 count and 10 count on back order and the company estimates a release date of early-January 2017 for the 5 count and late-December 2016 for the 10 count presentations.
- Valeant has D.H.E. 45 1 mg/mL 1 mL ampules available with an expiration date of August 2017.

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

Cisplatin Injection

December 19, 2016

Reason for the Shortage

- Fresenius Kabi did not provide a reason for the shortage.
- Mylan Institutional could not provide a reason for the shortage.
- Teva was allocating cisplatin to prevent stockpiling.
- WG Critical Care could not provide a reason for the shortage.

Estimated Resupply Dates

- Mylan Institutional has cisplatin 50 mL and 100 mL vials on back order and the company cannot estimate a release date.
- Fresenius Kabi has cisplatin 50 mL vials available with short expiration dating (< 8 months).

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

Carboplatin Solution for Injection

December 19, 2016

Reason for the Shortage

- Bedford discontinued carboplatin in May, 2011 to concentrate on the manufacturing of other products.
- Fresenius Kabi has carboplatin on shortage due to increased demand for the product.
- Pfizer has carboplatin injection available.
- Mylan Institutional cannot provide a reason for the shortage.
- Sagent states the reason for the shortage is increased demand for the product.
- Sandoz has discontinued carboplatin injection.
- Teva states the reason for the shortage is increased demand for the product.

Estimated Resupply Dates

- Fresenius Kabi has carboplatin 45 mL vials available with an expiration date of <8 months.
- Mylan Institutional has all carboplatin injection on back order and the company cannot estimate a release date.
- Sagent has carboplatin 5 mL, 15 mL, 45 mL, and 60 mL vials on back order and the company cannot estimate a release date.
- Teva has carboplatin 45 mL and 60 mL vials on allocation.

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

Bupivacaine with epinephrine Injection

December 19, 2016

Reason for the Shortage

- Hospira has bupivacaine with epinephrine on shortage due to manufacturing delays.

Estimated Resupply Dates

- Fresenius Kabi has 0.25% Sensorcaine-MPF with epinephrine 10 mL vials and 0.5% Sensorcaine-MPF with epinephrine 10 mL vials on back order and the company estimates a release date of mid-April 2017. Fresenius Kabi has 0.25% Sensorcaine-MPF with epinephrine 30 mL vials on back order and the company estimates a release date of mid-January 2017. The 0.5% Sensorcaine-MPF with epinephrine 30 mL vials are on back order with intermittent releases. The 0.5% Sensorcaine-MPF with epinephrine 30 mL vials sterile packs are on back order and the company estimates a release date of late-January 2017.
- Hospira has 0.25% bupivacaine with epinephrine 30 mL vials and 0.5% bupivacaine with epinephrine 30 mL vials available in limited supply. The 0.25% bupivacaine with epinephrine 10 mL and 50 mL vials on back order and the company estimates a release date of late-December 2016. The 0.5% bupivacaine with epinephrine 50 mL vials are on back order and the company estimates a release date of early-January 2017.
- Hospira has 0.25% Marcaine with epinephrine 10 mL vials available in limited supply. The 0.25% Marcaine 50 mL vials are on back order and the company estimates a release date of late-January 2017. The 0.5% Marcaine 30 mL vials are on back order and the company estimates a release date of late-December 2016. The 0.5% Marcaine 50 mL vials are on back order and the company estimates a release date of early-February 2017.

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

Bupivacaine Injection

December 19, 2016

Reason for the Shortage

- AuroMedics has not provided a reason for the shortage.
- Fresenius Kabi has Sensorcaine on shortage due to increased demand for the product.
- Pfizer has bupivacaine on shortage due to manufacturing delays.

Estimated Resupply Dates

- AuroMedics has 0.25% bupivacaine 10 mL vials and 0.75% bupivacaine 30 mL vials on intermittent back order and the company is releasing product as it becomes available.
- Fresenius Kabi has 0.25% Sensorcaine 50 mL vials on back order and the company estimates a release date of late-December 2016.
- Pfizer has 0.25% Marcaine 50 mL and 0.5% Marcaine 50 mL vials available in limited supply.

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

Ammonium Molybdate Injection

December 19, 2016

Reason for the Shortage

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

Estimated Resupply Dates

- American Regent has ammonium molybdate injection on back order and the company cannot estimate a release date.

http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1003

Piperacillin Tazobactam Injection

December 20, 2016

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.
- Mylan Institutional launched piperacillin/tazobactam 3.375 gram and 4.5 gram vials in early-June 2016.
- Pfizer has Zosyn on shortage due to manufacturing delays.
- Sagent has piperacillin/tazobactam on shortage due to increased demand.
- WG Critical Care states the reason for the shortage is increased demand.

Estimated Resupply Dates

- Apotex has piperacillin/tazobactam 2.25 gram, 3.375 gram, 4.5 gram, and 40.5 gram vials on back order and the company estimates a release date of early- to mid-January 2017 for the 3.375 gram vials, mid-January 2016 for the 2.25 gram vials, January 2017 for the 4.5 gram vials, and late-January 2017 for the 40.5 gram vials.
- AuroMedics has piperacillin/tazobactam on intermittent back order and the company is releasing product as it becomes available. Check wholesalers for inventory.
- Baxter has all frozen piperacillin/tazobactam presentations available in limited supply.
- Fresenius Kabi has piperacillin/tazobactam 2.25 gram, 3.375 gram, and 4.5 gram vials on intermittent back order and the company is releasing product as it becomes available. The 40.5 gram vials are on back order and the company estimates a release date of late-February to early-March 2017.
- Pfizer has piperacillin/tazobactam 3.375 gram and 4.5 gram vials on allocation.
- Pfizer has Zosyn 2.25 gram vials, 3.375 gram vials, 4.5 gram vials, and 40.5 gram vials on back order and the company estimates a release date of January 2018.
- Sagent has piperacillin/tazobactam 3.375 gram vials on back order and the company estimates a release date of December 2016. The 4.5 gram vials are on allocation.
- Sandoz has all piperacillin/tazobactam presentations available in in limited supply.
- WG Critical Care has piperacillin/tazobactam 2.25 gram, 3.375 gram, 4.5 gram, and 40.5 gram vials on back order and the company cannot estimate a release date.

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

Ampicillin Sulbactam

December 20, 2016

Reason for the Shortage

- Mylan Institutional discontinued ampicillin sulbactam 1.5 gram and 3 gram vials.
- Pfizer has discontinued generic ampicillin sulbactam.
- Sandoz cannot provide a reason for the shortage.

- Sagent has ampicillin sulbactam vials on allocation due to increased demand for the product.
- WG Critical Care states the shortage was due to increased demand.

Estimated Resupply Dates

- AuroMedics has ampicillin sulbactam 3 gram and 15 gram vials on intermittent back order and the company is releasing product as it becomes available.
- Fresenius Kabi has ampicillin sulbactam 1.5 gram, 3 gram, and 15 gram vials on back order and the company cannot estimate a release date.
- Sagent has ampicillin sulbactam 1.5 gram, 3 gram, and 15 gram vials on back order and the company estimates a release date of January 2017.
- Sandoz has ampicillin sulbactam 1.5 gram, 3 gram, and 15 gram vials temporarily unavailable and the company cannot estimate a release date.
- West-Ward has ampicillin sulbactam 3 gram vials on a weekly allocation. The 15 gram vials are available with an expiration date of October 2017.

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

*Please refer to ASHP website for more information at:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/