September 2016

Drug Information Update

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NEWLY AVAILABLE GENERICS

GENERIC DRUG NAME	STRENGTH & DOSAGE FORM	GENERIC MANUFACTURER	BRAND NAME
PNV No.80/Iron/MFolate/DSS/DHA	38mg iron-1 mg-25mg- 225mg Capsule	SEYER INC.	Folet One
Phentermine HCL	8mg Tablet	KVK-TECH, INC.	Lomaira
Sodium Polystyrene Sulfon/Sorb	15 gram/60 mL Oral Suspension	PERRIGO CO.	Kionex

NEW DRUG ENTITIES/COMBINATIONS/STRENGTHS

DESCRIPTION	BRAND NAME	GENERIC NAME	STRENGTH	NOTES
ELECTROLYTE DEPLETERS	KIONEX	SODIUM POLYSTYRENE SULFON/SORB	15 gram/60 mL-19.3 gram/21.5 mL	New Formulation
ELECTROLYTE DEPLETERS	SPS	SODIUM POLYSTYRENE SULFON/SORB	30 gram/120 mL-40 gram/43 mL	New Formulation, Route and Dosage Form
ELECTROLYTE DEPLETERS	SPS	SODIUM POLYSTYRENE SULFON/SORB	15 gram/60 mL-20 gram/21.5 mL	New Formulation
ALZHEIMER'S THX,NMDA RECEPT ANTAG & CHOLINES INHIB	NAMZARIC	MEMANTINE HCL/DONEPEZIL HCL	7 mg-10 mg	New Strength
ALZHEIMER'S THX,NMDA RECEPT ANTAG & CHOLINES INHIB	NAMZARIC	MEMANTINE HCL/DONEPEZIL HCL	21 mg-10 mg	New Strength
GLUCOCORTICOIDS	BETALOAN SUIK	BETAMETH AC,NA PH/R 134A,245FA	6 mg/mL	New Combination
INFLUENZA VIRUS VACCINES (Vial)	AFLURIA QUAD 2016-2017	FLU VACC QS 2016-17 (18 YR UP)	60 mcg (15 mcg x 4)/0.5 mL	New Entity
INFLUENZA VIRUS VACCINES (Syringe)	AFLURIA QUAD 2016-2017	FLU VACC QS 2016-17 (18 YR UP)	60 mcg (15 mcg x 4)/0.5 mL	New Entity
METABOLIC DEFICIENCY AGENTS	SOD POLYSULTHIONATE-FOLIC ACID	SULFUR/SOD SUL/SOD THIOSULF/FA	400 mg-1 mg	New Strength
ACID AND ALKALI POISON ANTIDOTES	PROVAYBLUE	METHYLENE BLUE	50 mg/10 mL (5 mg/mL,	New Strength and

DESCRIPTION	BRAND NAME	GENERIC NAME	STRENGTH	NOTES
			0.5 %)	Dosage Form
BICARBONATE PRODUCING/ CONTAINING AGENTS	VAXCHORA BUFFER COMPONENT	CHOLERA VAC BUFFER COMP 1 OF 2	N/A	New Combination
LOCAL ANESTHETICS	MARVONA SUIK	BUPIVACAINE/PF/NORFLU/HFC245FA	5 mg/mL	New Combination
SYMPATHOMIMETIC AGENTS	EPHEDRINE SULFATE-WATER	EPHEDRINE SULFATE IN WATER/PF	50 mg/mL	New Dilution
ANTI-OBESITY SEROTONIN 2C RECEPTOR AGONISTS	BELVIQ XR	LORCASERIN HCL	20 mg	New Strength and Dosage Form
GLUCOCORTICOIDS	MEDROLOAN SUIK	ME-PREDNIS/NORFLURAN/HFC 245FA	40 mg/mL	New Combination
GLUCOCORTICOIDS	MEDROLOAN II SUIK	ME-PREDNIS/NORFLURAN/HFC 245FA	40mg/mL	New Combination
TOPICAL ANTI-INFLAMMATORY, NSAIDS	NUDICLO	DICLOFENAC SODIUM/CAPSAICIN	1.5 %-0.025 %	New Combination

NEW INDICATIONS (EXISTING DRUGS)

DRUG	NEW INDICATION	DATE OF APPROVAL	SOURCE
ARZERRA® (Ofatumumab)	Use in combination with Fludarabine and Cyclophosphamide for Relapsed CLL	August 31, 2016	Genmab
AFLURIA® QUADRIVALENT (Influenza Virus Vaccine)	Immunization for people 18 years of age and older	August 29, 2016	Seqirus

FDA NEWS/BULLETINS/ADVISORIES/SAFETY ALERTS

Drug Safety Labeling Changes

July 2016

The MedWatch Safety Labeling Changes posting includes 52 products with safety labeling changes to the following sections: BOXED WARNING, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, ADVERSE REACTIONS, or PATIENT PACKAGE INSERT/MEDICATION GUIDE.

The "Summary Page" table provides a listing of product names and safety labeling sections revised:

http://www.fda.gov/Safety/MedWatch/SafetyInformation/ucm514705.htm

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

- Avelox (moxifloxacin hydrochloride)
- Acetadote (acetylcysteine) Injection
- Alinia (nitazoxanide)
- Aromasin (exemestane)
- Asmanex HFA (mometasone furoate)
- Caprelsa (vandetanib)
- Cipro (ciprofloxacin hydrochloride) Tablets, Solution, Oral Suspension
- Cipro XR (ciprofloxacin extended release) Tablets
- Clinolipid (lipid injectable emulsion)
- Dexilant (dexlansoprazole delayed-release capsules)
- Dulera (formoterol fumarate, mometasone furoate)
- Dysport (abobotulinumtoxinA)
- Effient (prasugrel)
- Eliquis (apixaban)
- Epivir (lamivudine) Tablets and Oral Solution
- Evotaz (atazanavir/cobicistat)
- Factive (gemifloxacin mesylate)
- Faslodex (fulvestrant)
- Flovent Diskus (fluticasone propionate inhalation powder)
- Flovent HFA (fluticasone propionate)
- Glyxambi (empagliflozin and linagliptin)
- Hicon (for the preparation of sodium iodide I 131 solution or sodium iodide I 131 capsules)
- Humulin R U-500 (insulin human injection)
- Ilaris (canakinumab)
- Isoniazid Tablets
- Jardiance (empagliflozin)
- Kadcyla (ado-trastuzumab emtansine)
- Kepivance (palifermin) Injection

- Lamprene (clofazimine)
- Levaquin (levofloxacin)
- Mirapex (pramipexole)
- Mirapex ER (pramipexole) extended-release
- Mirvaso (brimonidine)
- Moxifloxacin Injection
- Namzaric (memantine and donepezil hydrochlorides) Extended-release
- Noroxin (norfloxacin)
- Plegridy (peginterferon beta-1a)
- Pravachol (pravastatin sodium)
- Prismasol and Phoxillum Renal Replacement Solution
- Synjardy (empagliflozin and metformin hydrochloride)
- Tarka (trandolapril/verapamil hydrochloride ER tablets)
- Thallous Chloride T1201 Injection
- Xolair (omalizumab) Lyophilized Powder
- Yondelis (trabectedin)
- Source: U.S. Food and Drug Administration

Source: U.S. Food & Drug Administration

Cetylev (acetylcysteine) Effervescent Tablets for Oral Solution: Recall - Inadequate Seal of Blister Pack

August 18, 2016

ISSUE: Arbor Pharmaceuticals, LLC announced a voluntary recall of three (3) lots of Cetylev (acetylcysteine) effervescent tablets for oral solution, 500 mg, due to an inadequate seal of the blister pack. An inadequate seal could result in an increase of oxygen and moisture entering the blister cavity which can start the effervescent process. This results in enlarged and swelled tablets which could also completely dissolve within the blister pack. The improper seal of the product can lead to a potentially sub-therapeutic dose as well as potential microbial contamination. Because the effectiveness of acetylcysteine to prevent or lessen hepatic injury after ingestion of acetaminophen is delayed with decreased therapy, sub-therapeutic dosing could lead to increased risk of liver injury. With regards to the potential microbial contamination due to moisture ingress into the tablets, the risk of serious infection is increased in certain patient populations such as children, pregnant women, immunosuppressed patients, and patients on gastric acid suppression therapy such as proton pump inhibitors.

Three lots of the 500 mg strength (Lot Numbers 005C16, 006C16, and 007C16, expiration date 02/2018) with NDC 24338-700-10 are included in the recall.

BACKGROUND: Cetylev (acetylcysteine) effervescent tablets for oral solution are indicated as an antidote for acetaminophen overdose indicated to prevent or lessen hepatic injury after ingestion of a potentially hepatotoxic quantity of acetaminophen in patients with acute ingestion or from repeated supratherapeutic ingestion.

RECOMMENDATION: Healthcare facilities should immediately discontinue use from these lots of product and return all unused Cetylev to Arbor. Consumers with questions regarding this recall should contact Arbor Pharmaceuticals, LLC at 1-866-516-4950, Monday through Friday, during business hours of 9:00 am to 5:00 pm,

Eastern Standard Time (EST). 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 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

Oxacillin for Injection, USP, 10g by Sagent: Recall - Iron Oxide Particulate Matter

August 19, 2016

ISSUE: Sagent Pharmaceuticals, Inc. announced the voluntary nationwide recall of one lot of Oxacillin for Injection, USP, 10 g (NDC 25021-163-99) Lot OXT512 (Exp. Date March 2017) manufactured by Astral SteriTech Private Limited and distributed by Sagent. Sagent initiated this recall to the user level due to the receipt of a product complaint for a single vial containing small, dark particulate matter found within the solution after reconstitution. The particulate matter has been identified as iron oxide. If metal particulate in an injectable product is administered to a patient, it may result in local swelling, irritation of blood vessels or tissue, or blockage of blood vessels. Blockage of blood vessels can lead to serious events, which may be life-threatening, such as stroke, heart attack, respiratory failure, kidney failure, or liver failure.

BACKGROUND: The product is packaged in cartons containing 10 x 10 gram Pharmacy Bulk Package bottles identified by NDC 25021-163-99. The lot number being recalled is Lot OXT512 which was distributed to hospitals, wholesalers and distributors nationwide from June 2016 through July 2016. Oxacillin for Injection, USP, 10 g is indicated in the treatment of infections caused by penicillinase producing staphylococci which have demonstrated susceptibility to the drug. It is available by prescription only.

RECOMMENDATION: Customers are being notified by fax, email, FedEx, and/or certified mail that includes arrangements for the return of all recalled product. Customers have been instructed to examine their inventory immediately and to quarantine, discontinue distribution of and return the recalled lot of product. Customers who may have further distributed this product have been requested to identify their customers and notify them at once of this product recall. The necessary form by which to document this information as well as other information regarding this recall is available at www.Sagentpharma.com.

Any questions about returning unused product should be directed to the Customer Call Center at (866) 625-1618 M-F 8am-7pm CST. Healthcare workers who have medical questions about Oxacillin for Injection, USP may contact Sagent Medical Affairs (866-625-1618, Option 3) M-F 8am-5pm 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

Eyesaline Eyewash by Honeywell: Recall – Microbial Contamination

August 22, 2016

ISSUE: Honeywell is voluntarily recalling one production lot of 32-ounce bottles of Eyesaline Eyewash solution, which is used for emergency eye rinsing after an injury. Although no injuries have been reported and no contamination was found in batch testing, there is a risk of product contamination with Klebsiella pneumoniae. Although found in the normal flora of the mouth and skin, if the contaminant were present in a bottle, there is a potential for it to result in infections that may be sight-threatening. Approximately 9,700 32-ounce bottles with lot number F16091-61 are subject to recall. No other lot number of the product is subject to this recall.

BACKGROUND: Eyesaline Eyewash is sold through industrial sales distributors. The affected product and lot number can be identified as follows:

- Product: 32 ounce Eyesaline Eyewash
- Lot number: F16091-61 (no other lot number is subject to recall)
- The lot number can be found on the outside of the product case, and on individual bottles.

See the press release for product photos.

RECOMMENDATION: All of Honeywell's distributors who received this lot have been notified by phone, e-mail and certified mail, and have been instructed to notify their customers. Distributors must stop distribution of the affected product and return it to Honeywell for credit or replacement. Commercial-industrial users of the product should also check whether their Eyesaline Eyewash is subject to recall. If it is, customers should stop using the solution and contact their distributor for replacement or credit.

- 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

Lamotrigine Orally Disintegrating Tablet 200 mg by Impax: Recall - Incorrect Labeling of Blister Cards

August 29, 2016

ISSUE: Impax Laboratories, Inc. issued a voluntary nationwide retail level recall on August 19, 2016 for one lot of Lamotrigine Orally Disintegrating Tablet (ODT) 200 mg, NDC 0115- 1529-08, Lot # 502240. The affected lot was distributed between June 13, 2016 and August 10, 2016 to wholesale distributors and retail pharmacies nationwide. Unit-of-use blister packs (a 10 count blister card contained in a single plastic shell-pack) may contain 100 mg product instead of 200 mg product. Each blister card within the unitof- use blister pack is properly labeled as 100 mg ODT, however the plastic shell pack containing the 100 mg blister cards is labeled as 200 mg ODT. Shell-packs from the affected lot may contain 100 mg ODT instead of 200 mg ODT, and as a result, it is possible that consumers could take less than their intended lamotrigine dose. A reduction in dose may lead to reduced therapeutic effects of lamotrigine and reemergence of epilepsy or bipolar disorder symptoms.

BACKGROUND: Lamotrigine is indicated for the treatment of epilepsy or bipolar disorders. The lot number can be found on the side of the manufacturer's carton as well as on the blister cards within the unit-of-use blister packs. See the press release for product label Photos.

RECOMMENDATION: Consumers are being asked to carefully inspect their medication. If they have the affected lot or any questions or concerns regarding this recall they should contact Stericycle at 1-866-300-2207 (Monday through Friday 8:00 a.m. through 5:00 p.m. EST). Consumers who are unsure if they have the affected lot number or have any concerns about their product should consult their pharmacy or health care professional.

Pharmacists and wholesalers are being asked to check their inventories for the affected lot, segregate any material from the lot, and to then contact Stericycle at 1-866-300-2207 for instructions on product return. Pharmacies that received the affected lot will receive a copy of this press release with their recall notification information to be prominently posted in the pharmacy area. 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

Opioid Pain or Cough Medicines Combined With Benzodiazepines: Drug Safety Communication - FDA Requiring Boxed Warning About Serious Risks and Death

August 31, 2016

ISSUE: FDA review has found that the growing combined use of opioid medicines withbenzodiazepines or other drugs that depress the central nervous system (CNS) has resulted in serious side effects, including slowed or difficult breathing and deaths. Opioids are used to treat pain and cough; benzodiazepines are used to treat anxiety, insomnia, and seizures. In an effort to decrease the use of opioids and benzodiazepines, or opioids and other CNS depressants, together, FDA is adding Boxed Warnings, our strongest warnings, to the drug labeling of prescription opioid pain and prescription opioid cough medicines, and benzodiazepines. See the Drug Safety Communication for a listing of all approved prescription opioid pain and cough medicines, and benzodiazepines and other CNS depressants. FDA conducted and reviewed several studies showing that serious risks are associated with the combined use of opioids and benzodiazepines, other drugs that depress the CNS, or alcohol (see the FDA Drug Safety Communication for a Data Summary). Based on these data, FDA is requiring several changes to reflect these risks in the opioid and benzodiazepine labeling, and new or revised patient Medication Guides. These changes include the new Boxed Warnings and revisions to the Warnings and Precautions, Drug Interactions, and Patient Counseling Information sections of the labeling.

FDA is continuing to evaluate the evidence regarding combined use of benzodiazepines or other CNS depressants with medication-assisted therapy (MAT) drugs used to treat opioid addiction and dependence. FDA is also evaluating whether labeling changes are needed for other CNS depressants, and will update the public when more information is available.

BACKGROUND: Opioids are powerful prescription medicines that can help manage pain when other treatments and medicines cannot be taken or are not able to provide enough pain relief. Benzodiazepines are a class of medicines that are widely used to treat conditions including anxiety, insomnia, and seizures.

RECOMMENDATION: Healthcare professionals should limit prescribing opioid pain medicines with benzodiazepines or other CNS depressants only to patients for whom alternative treatment options are inadequate. If these medicines are prescribed together, limit the dosages and duration of each drug to the minimum possible while achieving the desired clinical effect. Warn patients and caregivers about the risks of slowed or difficult breathing and/or sedation, and the associated signs and symptoms. Avoid prescribing prescription opioid cough medicines for patients taking benzodiazepines or other CNS depressants, including alcohol. Patients taking opioids with benzodiazepines, other CNS depressant medicines, or alcohol, and caregivers of these patients, should seek medical attention immediately if they or someone they are caring for experiences symptoms of unusual dizziness or lightheadedness, extreme sleepiness, slowed or difficult breathing, or unresponsiveness. 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

Eye Wash/Eye Irrigating Solutions Distributed by Major Pharmaceuticals and Rugby Laboratories: Recall - Microbial Contamination

September 7, 2016

ISSUE: United Exchange Corp. of Cerritos, CA, a primary source vendor of the Rugbybranded Eye Irrigating Solution and Major-branded Eye Wash, is voluntarily recalling products due to microbial contamination. These products consist of a purified water solution. Use of a contaminated product could be calamitous for any population since there is a reasonable probability of a potentially sight-threatening eye infection.

BACKGROUND: Eye Wash/Eye Irrigating Solution is used to flush the eye to relieve irritation, stinging, or itching by removing foreign material such as air pollutants or chlorinated water. It is packaged in 4 oz (118mL) bottles. Rugby-branded Eye Irrigating Solution and Majorbranded Eye Wash were distributed nationwide to wholesale and retail facilities including hospitals and pharmacies. The company learned of the potential issue through the receipt of a product complaint regarding this product. For a table of affected lots and expiration dates please see firm press release.

RECOMMENDATION: Consumers, pharmacies, and healthcare facilities that have product which is being recalled should stop using and dispensing them immediately. Healthcare professionals and consumers may report adverse reactions or quality problems they experienced using these devices to FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report.htm

- 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

Family Care Eye Wash by United Exchange Corp: Recall - Microbial Contamination

September 8, 2016

ISSUE: United Exchange Corp. is voluntarily recalling specific lots of Family Care Eye Wash 4 oz due to microbial contamination. These products consist of a purified water solution. Use of a contaminated product could be calamitous for any population since there is a reasonable probability of a potentially sight threatening eye infection.

See the Press Release for a list of affected Lot numbers.

BACKGROUND: Eye Wash/Eye Irrigation Solution is used to flush the eye to relieve irritation, stinging, or itching by removing foreign material such as air pollutants or chlorinated water. It is packaged in 4 oz (118mL) bottles. Family Care Eye Wash was distributed nationwide to wholesale and retail facilities.

RECOMMENDATION: United Exchange Corp. is notifying its distributors and customers by recall letter and is arranging for return or disposal of all recalled products. Consumers and businesses that have product which is being recalled should stop using and selling them Immediately.

Consumers with questions regarding this recall should contact the Customer Service Department at 800-814-8028, available Monday through Friday from 8:30 am to 5:30 pm (Pacific Time). Consumers can contact their physician or healthcare provider if they have additional questions about this 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

Source: U.S. Food and Drug Administration

STUDIES and RECENT TOPICS

Statins Act As a Shield Against Diabetic Macular Edema

August 11, 2016

It's been a long history when it comes to statins and the effects on the heart and diabetic health. Evidence backs statins as an effective preventive measure against cardiovascular events like heart attack and stroke. On the other hand, the drugs increase insulin resistance and impact glucose metabolism, as well as associated with new onset of type 2 diabetes. It's been unclear whether statins affect the development of diabetic microvascular complications, therefore, Alam Park, MD, from the Ajou University School of Medicine in Korea, and colleagues set out to uncover just that.

Source: hcplive.com

Soy supplements may be good for women with PCOS

Aug 11, 2016

Women with a common hormone disorder known as polycystic ovary syndrome (PCOS) may have a lower risk of diabetes and heart disease when they take soy supplements, a small study suggests.

Source: reuters.com

Most seniors won't abuse opioids after surgery

August 12, 2016

Seniors who receive prescriptions for opioid drugs to control pain after major surgery don't usually end up addicted to them, research from Canada shows. One year after having major surgery, less than 1 percent of patients over age 66 were still taking opioids, according to a report in JAMA Surgery.

Source: ocregister.com

Biosimilar names may affect pharmacist dispensing habits

August 15, 2016

What's in a name? An awful lot when it comes to biosimilars. A newly released survey suggests variations in how biosimilars are named may affect the willingness of pharmacists to substitute a so-called interchangeable biosimilar for a more expensive biologic. While a biosimilar is supposed to be highly similar to a biologic, interchangeability confers a higher threshold — it's a distinct regulatory description for a biosimilar producing the very same clinical result as a biologic.

Source: statnews.com

‘America’s other drug problem’: Giving the elderly too many prescriptions

August 15, 2016

Dominick Bailey sat at his computer, scrutinizing the medication lists of patients in the geriatric unit. A doctor had prescribed blood pressure medication for a 99-year-old woman at a dose that could cause her to faint or fall. An 84-year-old woman hospitalized for knee surgery was taking several drugs that were not meant for older patients because of their severe potential side effects.

Source: washingtonpost.com

Acetaminophen use in pregnancy linked to kids' behavioral problems

August 15, 2016

Acetaminophen, long the mainstay of a pregnant woman’s pain-relief arsenal, has been linked to behavioral problems in children born to mothers who used it during pregnancy. Research published Monday by the journal JAMA Pediatrics found that a woman’s use of acetaminophen at 18 and 32 weeks of pregnancy was associated with greater odds that when the resulting child was 7 years old, his or her mother would report a range of problematic behaviors.

Source: latimes.com

Study Says FluMist Vaccine Does Indeed Work, Contradicting CDC

August 15, 2016

It came as a surprise this June when the Centers for Disease Control and Prevention recommended against using the nasal flu vaccine for the 2016-2017 flu season, citing a lack of evidence that it works. Now, findings from a Canadian study appear at first blush to contradict the research that led the Advisory Committee on Immunization Practices to recommend against that live attenuated vaccine.

Source: npr.org

Prices of drugs to treat rare diseases soar

August 15, 2016

Drugs approved to treat rare disorders have been spiking in price over the past few years, with a new report from the insurance industry raising questions about their affordability. America's Health Insurance Plans, the leading lobbying group for the industry, released a report on the costs for orphan drugs. Last year, nearly half of all drugs approved by the Food and Drug Administration were orphan drugs, which are intended to treat rare diseases.

Source: washingtonexaminer.com

Do Angioplasty Patients Really Need Beta-Blocker Drugs?

August 16, 2016

Doctors might be overprescribing beta-blocker medications to heart patients who aren't seriously ill, a new study contends. Beta blockers such as Inderal (propranolol) and Lopressor (metoprolol) reduce blood pressure and control abnormal heart rhythms. They're lifesaving when given to patients who've had a heart attack or have heart failure, said study co-author Dr. Valay Parikh. He is a cardiology fellow with North Shore LIJ-Staten Island University Hospital, in Staten Island, N.Y.

Source: healthday.com

Osteoporosis, a Disease With Few Treatment Options, May Soon Have One More

August 16, 2016

A large clinical trial of a new osteoporosis drug found that it stimulates bone growth and prevents fractures at least as well as the only other such drug on the market. The new drug, expected to win approval from federal regulators, would offer another much-needed treatment for some of the 10 million Americans, 80 percent of them women, who have a disease that weakens bones and often leads to years of pain, disability and early death.

Source: nytimes.com

FDA Advisors: Over-the-Counter Tests for STIs Offer Benefits

August 16, 2016

An FDA panel agreed that benefits would most likely outweigh the risks for over-the-counter (OTC) tests to detect sexually transmitted infections, but panel members were less sure about the benefits of OTC influenza testing.

Source: medpagetoday.com

Most antipsychotic drugs not tied to birth defects

August 18, 2016

Pregnant women on antipsychotic drugs can continue taking most of those medications without worrying the pills will increase the risk of their newborns having birth defects, a new study suggests. "We did not see a meaningful increase in risk for any of the drugs with the exception of risperidone," said lead author Krista Huybrechts, of Brigham and Women’s Hospital and Harvard Medical School in Boston

Source: reuters.com

EpiPen corporation drastically jacks up the price of life-saving product by 400%, sending patients scrambling

August 18, 2016

Saving the life of your allergic child has gotten a lot more expensive. Doctors and patients are blasting the Mylan pharmaceutical corporation for hiking up the price of their signature EpiPen product from around $100 in 2008 to a staggering $500 and up today — a 400% increase.

Source: nydailynews.com

After a fracture, patients often continue meds that boost fracture risk

August 22, 2016

Older people who break a bone are often receiving medications that can increase the risk of a fracture - and even after an accident, less than 10 percent of them stop taking those drugs, according to a new study. “One would expect that a significant health event like a fracture would result in some change in the use of prescription drugs that might have contributed to that event,” said lead author Dr. Jeffrey C. Munson of the Geisel School of Medicine at Dartmouth in Lebanon, New Hampshire. “In contrast to this expectation, we observed that for the overwhelming majority of patients we studied, a fragility fracture did not lead to any change in medications that have been linked to fracture risk.”

Source: reuters.com

Interleukin-Blocking RA Drugs Leave Patients More Exposed to Flesh-Eating Strep Infections

August 22, 2016

Interleukin-1β (IL-1beta), a cytokine that plays in important role in the body’s immune response, turns out to be part of the body’s early defense system for bacterial infections. Anti-inflammation treatments for autoimmune conditions like rheumatoid arthritis (RA) often times inhibit IL-1beta to mitigate the inflammation that it initiates when infection is detected.

Source: hcplive.com

Why it's bad to skip prescribed drugs after a heart attack

August 24, 2016

Many patients who have clogged arteries or survive a heart attack don’t consistently take medications prescribed to prevent life-threatening complications, a study confirms. Taking drugs at least every four out of five days lowered the odds death, heart attack, stroke or surgery to restore blood flow, the study found. But less than half of patients took their meds that often.

Source: reuters.com

Survey: Consumers lax in using OTC pain relievers safely

August 29, 2016

Many consumers don't heed safety factors when choosing and using over-the-counter pain relievers, a national survey supported by McNeil Consumer Healthcare finds. Of 1,292 U.S. adults who have used an OTC pain reliever in the last 90 days, 65% don't consider other OTC medicines they are taking and 45% don't take into account their prescription medications, according to the online and telephone poll, conducted by APCO Insight for McNeil and the U.S. Pain Foundation.

Source: chaindrugreview.com

Mylan to launch generic EpiPen at half the price of original

August 29, 2016

Mylan said it would launch the first generic version of its allergy auto-injector EpiPen for $300, half the price of the branded product, the drugmaker's second step in less than a week to counter the backlash over the product's steep price. The company reduced the out-of-pocket costs of EpiPen for some patients on Thursday, but kept the list price at about $600, a move that U.S. lawmakers and Presidential candidate Hillary Clinton said was not enough. EpiPen cost about $100 in 2008.

Source: reuters.com

Study leads to insulin injection recommendations

September 1, 2016

Many people who inject themselves with insulin to control diabetes are improperly performing this vital task, according to a large new study. Based on the results, experts have crafted recommendations for people who use insulin that touch on everything from what type of needle to use to where the shot should be administered.

Source: reuters.com

Reliability of at-home wrist blood pressure monitoring questioned

September 6, 2016

People with high blood pressure who monitor it regularly at home may be getting incorrect readings with devices that take measurements on the wrist, a new study suggests. Researchers found that self-measurement at home with wrist devices often led to false reports of elevated blood pressure when compared to measurements in a doctor's office. Accurate readings often depended on correct positioning of the wrist, which patients either didn't understand or didn't remember how to do.

Source: reuters.com

Vitamin D May Cut Risk of Severe Asthma Attacks

September 6, 2016

Taking vitamin D supplements alongside asthma medication helps cut the risk of severe asthma attacks, according to a review of scientific studies. But it isn't yet clear whether the benefits are only seen in people who are low in vitamin D, and the benefit to people with severe asthma is unclear.

Source: webmd.com

RECALLS

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drug	Albuterol Sulfate Syrup, 2 mg/ 5 mL, 473 mL bottle, Rx only, Manufactured in Canada by Contract Pharmaceuticals Limited, Canada, Manufactured For: Teva Pharmaceuticals USA, Sellersville, PA --- NDC 0093-0661-16	Class II	Lot # 95113, exp 01/2017	Presence of Foreign Substance; presence of black particles describes generically as cellulose-based bundles of brown fibrous material.	Teva North America 425 Privet Rd Horsham, PA 19044-1220
Drug	Zinc Acetate, Crystal, USP, packaged in 500 gram bottles, Spectrum Chemical MFG, CORP., New Brunswick, NJ 08901	Class II	Lot # 2EH0257	Does not meet monograph: product exhibits lead levels in excess of the USP monograph limits.	Spectrum Laboratory Products, Inc. 755 and 769 Jersey Ave New Brunswick, NJ 08901-3605
Drug	Betamethasone Acetate / Betamethasone Sodium Phosphate Injectable Suspension, 7 mg/ mL,10 mL Multi-Dose vial for injection, Rx Only, Isomeric Pharmacy Solution, 2401 Foothill Dr., Salt Lake City, UT 84109	Class II	Lot# 03037, Exp 8/17/16; 03042, 03043, Exp 8/31/16; 04043, Exp 9/29/16; 04047, 04048, Exp 10/1/16; 04052, 04053, Exp10/2/16; 05042, Exp 10/29/16; 05046, Exp 11/2/16; 05048, 05049, Exp 11/3/16; 05050 Exp 11/4/16	Lack of processing controls: Isomeric Pharmacy Solution, LLC is recalling Betamethasone Acetate / Betamethasone Sodium Phosphate 7 mg/mL INJ SUSP because of the potential of drug clumps in the vial of the sterile drug product and larger particle sizes.	Isomeric Pharmacy Solution, LLC 2401 S Foothill Dr Salt Lake City, UT 84109-1479
Drug	Glipizide 2.5 mg Extended-release tablets, 30-count bottle, Rx Only, Manufactured By: Patheon Pharmaceuticals Inc Cincinnati, OH 45237, NDC 00591-0900-30 NDC 00591-0900-30	Class II	Lot # 3132593, 3132594, 3134420, 3134421,3134422, Exp. 02/17	Failed dissolution specifications: Glipizide 2.5 mg ER Tablets exceeded dissolution specification rates for the 10 hour testing point.	Actavis Inc 400 Interpace Pkwy Parsippany, NJ 07054-1120
Drug	Venlafaxine HCL ER Capsule USP, 150mg, packaged in a) 30-count bottles (NDC 68382-036-	Class II	Lot #: a) MR10518, Exp. 9/2017; MR11051, MR11052, MR11053, MR11054, Exp.	Failed Dissolution Specifications: out of specification dissolution	Zydus Pharmaceuticals

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
	06), b) 90-count bottles (NDC 68382-036-16), and c) 1000-count bottles, (NDC 68382-036-10), Rx only, Manufactured by : Cadila Healthcare Ltd. Ahmedabad, India, Distributed by: Zydus Pharmaceuticals USA Inc. Pennington, NJ 08534.		10/2017; MR11403, Exp. 11/2017. Lot #: b) MR10197, MR10195, Exp. 09/2017; MR11482, Exp.10/2017; MR11479, MR11480, MR11481, MR11483, MR11665 Exp. 11/2017. Lot #: c) MR10404, MR10406, MR10521, Exp. 09/2017; MR10744, MR11055, MR11228, MR11287, MR11285, MR11288, MR11289, MR11286, Exp.10/2017; MR11567, Exp.11/2017.	results in retained samples	USA Inc 73 Route 31 N Pennington, NJ 08534-3601
Drug	Venlafaxine Hydrochloride Extended-Release Capsules, 150 mg, a) 30 capsules per bottle, NDC # 60429-123-30, b) 90 capsules per bottle, NDC # 60429-123-90, Rx Only, GSMS.	Class II	Lot #: a) GS011931, Exp 10/2017; GS011932, Exp 11/2017 b) GS010773, GS011242, 09/2017; GS011061, GS011315, GS011357, GS011585, GS011586, GS011588, GS011591, Exp 10/2017; GS011933, Exp 11/2017	Failed Dissolution Specifications: Out-of-specificati on results in retained sample.	Golden State Medical Supply Inc. 5187 Camino Ruiz Camarillo, CA 93012-8601
Drug	Venlafaxine Hydrochloride Extended-Release Capsules, 75 mg, 90 capsules per bottle, Rx Only, GSMS, NDC # 60429-122-90	Class II	Lot #: GS011692, GS011938, Exp 10/2017; GS012638, GS012639, Exp 11/2017	Failed Dissolution Specifications: Out-of-specificati on results in retained sample.	Golden State Medical Supply Inc. 5187 Camino Ruiz Camarillo, CA 93012-8601
Drug	Venlafaxine HCL ER Capsule USP, 75mg, packaged in a) 30-count bottles (NDC 68382-035-06), b) 90-count bottles (NDC 68382-035-16), and c) 1000-count bottles, (NDC 68382-035-10), Rx only, Manufactured by : Cadila Healthcare Ltd. Ahmedabad, India, Distributed by: Zydus Pharmaceuticals USA Inc. Pennington, NJ 08534.	Class II	Lot #: a) MS1217, MS1218 , Exp.12/2017. Lot #: b) MS1215, Exp.12/2017 Lot #: c) MR11150, MR11151, MR11854, Exp. 10/2017; MR11798, MR11799, MS1214, Exp.11/2017	Failed Dissolution Specifications: out of specification dissolution results in retained samples	Zydus Pharmaceuticals USA Inc 73 Route 31 N Pennington, NJ 08534-3601

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drug	Amlodipine Besylate Tablets, USP, 2.5 mg*, packaged in a)100-count (10 x 10) unit dose blisters per carton, NDC 51079-450-20 and b) 30-count tablets per dosage card in a carton, NDC 51079-450-63, Rx only, Manufactured by: Mylan Pharmaceuticals Inc., Morgantown, WV 26505; Packaged and Distributed By: UDL Laboratories, Inc., Rockford, IL 61103.	Class II	Lot #: a) 3039792, Exp 04/14; 3037880, Exp 01/14; 3043938, Exp 07/14; b) 3036811, Exp 10/13; 3037514, Exp 01/14; 3039975, Exp 04/14; 3042583, Exp 07/14	CGMP Deviations: Pharmaceuticals were produced and distributed with active ingredients not manufactured according to Good Manufacturing Practices.	Mylan Institutional, Inc. (d.b.a. UDL Laboratories) 1718 Northrock Ct Rockford, IL 61103-1201
Drug	Amlodipine Besylate Tablets, USP, 5 mg*, packaged in a) 100-count (10 x 10) unit dose blisters per carton, NDC 51079-451-20; b) 300-count (10 x 30) unit dose blisters per carton, NDC 51079-451-56, c) 25-count (25 x 1) Robot-Rx Ready Packages in a carton, NDC 51079-451-19; and d) 30-count tablets per dosage card in a carton, NDC 51079-451-69, Rx only, Manufactured by: Mylan Pharmaceuticals Inc., Morgantown, WV 26505; Packaged and Distributed By: UDL Laboratories, Inc., Rockford, IL 61103.	Class II	Lot #: a) 3038339, Exp 02/14; 3043618, Exp 06/14; b) 3041862, Exp 05/14; 3044258, Exp 06/14; c) 2120031, Exp 01/14; 2120067, Exp 06/14; d) 3035787, 3035834, 3035835, Exp 10/13; 3037125, 3037126, 3037127, 3037511, 3037512, 3037513, Exp 01/14; 3038113, 3038114, 3038115, 3038116, 3039641, 3039642, 3039643, 3039974, Exp 02/14; 3040567, 3040977, Exp 04/14; 3041253, 3041800, 3041801, Exp 05/14; 3042446, 3042624, 3043015, Exp 06/14; 3043401, 3043466, Exp 08/14; 3044590, Exp 09/14; 3044591, Exp 10/14; 3045063, 3045064, Exp 11/14	CGMP Deviations: Pharmaceuticals were produced and distributed with active ingredients not manufactured according to Good Manufacturing Practices.	Mylan Institutional, Inc. (d.b.a. UDL Laboratories) 1718 Northrock Ct Rockford, IL 61103-1201
Drug	Amlodipine Besylate Tablets, USP, 10 mg*, packaged in a) 100-count (10 x 10) unit dose blisters per carton, NDC 51079-452-20; b) 300-count (10 x 30) unit dose blisters per carton, NDC 51079-452-56; and c) 25-count (25 x 1) Robot-Rx Ready Packages in a carton, NDC 51079-452-19; Rx only, Manufactured by: Mylan Pharmaceuticals Inc., Morgantown, WV 26505; Packaged and Distributed By: UDL Laboratories, Inc., Rockford, IL 61103.	Class II	Lot #: a) 3039795, 3042896, Exp 04/14; b) 3039793, 3042892, Exp 04/14; c) 2120054, Exp 02/14; 2120090, Exp 05/14	CGMP Deviations: Pharmaceuticals were produced and distributed with active ingredients not manufactured according to Good Manufacturing Practices.	Mylan Institutional, Inc. (d.b.a. UDL Laboratories) 1718 Northrock Ct Rockford, IL 61103-1201

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drug	Amoxicillin for Oral Suspension USP, 400 mg/ 5 mL, 50 mL bottle, Rx only, Manufactured In Canada by: Teva Canada Limited, Toronto, Canada, NDC 0093-4161-76	Class II	Lot # 35434158A, Exp 6/17	Superpotent drug: Out of specification test result for assay during stability testing.	Teva North America 425 Privet Rd Horsham, PA 19044-1220
Drug	Human Chorionic Gonadotropin Injection (a) 2500 iu, (b) 2500 iu with B12, (c) 3500 iu, (d) 5000 iu, (e) 5000 iu with B12, (f) 6000 iu, (g) 7500 iu, (h) 7500 iu with B12, (i)11,000 iu, (j)11,000 iu with B12, (k) 15,000 iu, (l) 20,000 iu, (m) 20,000 iu with B12, 10 mL sterile, depyrogenated vials, Rx Only, Compounded by Talon Compounding Pharmacy, San Antonio, TX 78247 less...	Class II	Lot numbers: 12312015:45 12222015:91 01152016:91 01152016:91 01152016:91 01152016:91 12232015:37 12232015:37 12232015:37 12012015:03 01152016:91 12232015:37 12232015:37 12232015:37 01152016:91 01152016:91 01152016:91 01152016:91 01152016:91 01152016:41 01152016:91 01152016:91 01152016:41 01152016:91 01152016:41 01152016:41 01152016:91 01152016:41 01152016:41 01152016:41 01152016:41 01152016:41 01152016:41 01152016:41 01112016:51 01112016:51 01112016:51 01152016:41 01112016:51 01112016:51	Lack of Assurance of Sterility	Talon Compounding Pharmacy 2950 Thousand Oaks Dr Ste 25 San Antonio, TX 78247-3347
Drug	Sermorelin 6 mg and Sermorelin 6 mg/GHRP-2 Injection, 12 mg, 10 ml depyrogenated vials, Rx Only, Compounded by Talon Compounding Pharmacy, San Antonio, TX 78247	Class II	Lot numbers: 01082016:58 01082016:58 01082016:58 01082016:58 01082016:58 01082016:58 01082016:58 01082016:58 01202016:78 01202016:78 01202016:78 01202016:78 01202016:78 01202016:78 01202016:78 01202016:78 01202016:78 01202016:78 01202016:78 01202016:78 02012016:61 02012016:61 02012016:61 02012016:61 02012016:61 02012016:61 02012016:61 02012016:61 02012016:61 02012016:61	Lack of Assurance of Sterility	Talon Compounding Pharmacy 2950 Thousand Oaks Dr Ste 25 San Antonio, TX 78247-3347

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
			02012016:61 02012016:61 02012016:61 02012016:61		
Drug	Bromocriptine Mesylate Capsules USP, 5 mg, 30-count bottles, Rx only, Manufactured by: Cadila Healthcare ltd., Ahmedabad, India Distributed by: Zydus Pharmaceuticals USA Inc., Pennington, NJ 08534, NDC 68382-110-06	Class II	Lot # MP993, Exp10/16; MR2704, Exp 02/17; MR6851, MR8100; Exp 07/17 and MR1210, Exp 12/17	Failed impurities/degradation specifications: Out of specification results noticed in related substance test during analysis of 24 months long term (25 degree Celsius /65% RH) stability samples of two batches.	Zydus Pharmaceuticals USA Inc 73 Route 31 N Pennington, NJ 08534-3601
Drug	ARGATROBAN Injection in 0.9% Sodium Chloride 250 mg/250 mL (1 mg/mL) , Rx Only, Manufactured in Hungary for TEVA PHARMACEUTICALS USA, INC., North Wales, PA 19454, NDC# 0703-0020-31 (Single Use Bag), NDC # 0703-0020-32 (5 Single Use Bags in One Carton).	Class II	All lots within Expiry. Lot # 4720915, 6790315, 6800315, 6810315, 6820315	CGMP Deviations	Teva Pharmaceuticals USA 1090 Horsham Rd North Wales, PA 19454-1505
Drug	Linezolid Injection 600 mg/300 mL Rx Only, Manufactured in Hungary for TEVA PHARMACEUTICALS USA, INC., North Wales, PA 19454, NDC# 0703-9060-31- (Single Use Container), NDC# 0703-9060-33 (Box of 10 Singe Use Containers)	Class II	All Lots Within Expiry	CGMP Deviations	Teva Pharmaceuticals USA 1090 Horsham Rd North Wales, PA 19454-1505
Drug	Eptifibatide Injection 75 mg/100 mL (0.75 mg/mL) single use vial, For Intravenous Use Only, Rx Only, Manufactured in Hungary for TEVA PHARMACEUTICALS USA, INC., North Wales, PA 19454, NDC# 0703-1179-01.	Class II	All Lots Within Expiry Lot# 2710715, 2720715, 2730715, 3110715, 3120715	CGMP Deviations	Teva Pharmaceuticals USA 1090 Horsham Rd North Wales, PA 19454-1505
Drug	Ondansetron Injection USP 40 mg/20 mL (2 mg/mL), Rx Only, Manufactured in Hungary for TEVA PHARMACEUTICALS USA, INC., North Wales, PA 19454 NDC # 0703-7226-01 (20 mL-	Class II	All Lots Within Expiry Lot # 2930614, 2940614, 2950614	CGMP Deviations	Teva Pharmaceuticals USA 1090 Horsham

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
	Multi-dose Vial), NDC # 0703-72263-03 (10 Multi-dose Vials per carton)				Rd North Wales, PA 19454-1505
Drug	Methylprednisolone Acetate/Lidocaine HCl 40/10 mg/mL Injection, 10 mL multi dose vial, sterile. Rx only. Compounded by Isomeric Pharmacy Solutions, Salt Lake City, UT 84109,	Class II	Lots# 03045 and 03046; Exp. 10/16	Lack of Processing Controls: Isomeric Pharmacy Solution, LLC announces a voluntary field action for the Methylprednisolone Acetate/Lidocaine HCl 40/10 mg/mL Injection because the sterile injectable products were sterilized too long leading to potential difficulty re suspending particles.	Isomeric Pharmacy Solution, LLC 2401 S Foothill Dr Salt Lake City, UT 84109-1479
Drug	Ephedrine Sulfate Injection, USP, 50 mg/mL, Single Dose Vial, packaged in a) 1 mL fill in a 2 mL Vial (NDC: 69053-008-01); and b) 25 x 2 mL Vials (NDC 69053-008-02), Rx only, Manufactured for: Andersen Pharmaceutical, White Plains, NY 10605.	Class II	Lot #s: 102814, 102914, 103014, 103114, Exp 10/16; 110314, 110414, 110514, 110614, 110714, 111014, Exp 11/16; 121014, 121114, 121214, 121514, Exp 12/16; 011415, 011515, 011615, 012015, 012115, Exp 01/17; 021315, 021715, 021815, 021915, 022015, Exp 02/17; 030415, 030515, 030615, 031015, 031715, Exp 03/17; 042415, 042815, 042915, 043015, Exp 04/17; 050115	Lack of Assurance of Sterility: An FDA inspection at the facility raised concerns that product sterility was potentially impacted.	Allergy Laboratories, Inc. 1005 SW 2nd St Oklahoma City, OK 73109-1006
Drug	Dextroamphetamine Saccharate, Amphetamine Aspartate Monohydrate, Dextroamphetamine Sulfate, and Amphetamine Sulfate Tablets (Mixed Salts of a Single Entity Amphetamine Product) CII 5 mg, 30 UD Tablets (5 x 6), Rx, Packaged and Distributed by: American Health Packaging, Columbus, OH --- Carton NDC 68084-874-25; Blister NDC 68084-874-95	Class II	Lot 163220, exp. 10/31/17 and lot 164194, exp. 11/20/17	Unit Dose Mispackaging; blister cavities may contain more than one tablet /capsule	Amerisource Health Services 2550 John Glenn Ave Ste A Columbus, OH 43217-1188

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drug	Dextroamphetamine Saccharate, Amphetamine Aspartate Monohydrate, Dextroamphetamine Sulfate, and Amphetamine Sulfate Tablets (Mixed Salts of a Single Entity Amphetamine Product) CII 10 mg, 30 UD Tablets (5 x 6), Rx, Packaged and Distributed by: American Health Packaging, Columbus, OH ---- Carton NDC 68084-936-25; Blister NDC 68084-936-95	Class II	Lot 150130, exp. 10/31/16 and lot 161296, exp. 8/31/17	Unit Dose Mispackaging; blister cavities may contain more than one tablet /capsule	Amerisource Health Services 2550 John Glenn Ave Ste A Columbus,
Drugs	Dextroamphetamine Saccharate, Amphetamine Aspartate Monohydrate, Dextroamphetamine Sulfate, and Amphetamine Sulfate Tablets (Mixed Salts of a Single Entity Amphetamine Product) CII 15 mg, 30 UD Tablets (5 x 6), Rx, Packaged and Distributed by: American Health Packaging, Columbus, OH ---- Carton NDC 60687-133-25; Blister NDC 60687-133-95	Class II	Lot 150950, exp. 3/31/17 and lot 154813, exp. 5/31/2017	Unit Dose Mispackaging; blister cavities may contain more than one tablet /capsule	Amerisource Health Services 2550 John Glenn Ave Ste A Columbus, OH 43217-1188
Drug	Dextroamphetamine Saccharate, Amphetamine Aspartate Monohydrate, Dextroamphetamine Sulfate, and Amphetamine Sulfate Tablets (Mixed Salts of a Single Entity Amphetamine Product) CII 20 mg, 30 UD Tablets (5 x 6), Rx, Packaged and Distributed by: American Health Packaging, Columbus, OH --- Carton NDC 68084-943-25; Blister NDC 68084-943-95	Class II	Lot 162276, exp. 9/30/17	Unit Dose Mispackaging; blister cavities may contain more than one tablet /capsule	Amerisource Health Services 2550 John Glenn Ave Ste A Columbus, OH 43217-1188
Drug	Dextroamphetamine Saccharate, Amphetamine Aspartate Monohydrate, Dextroamphetamine Sulfate, and Amphetamine Sulfate Tablets (Mixed Salts of a Single Entity Amphetamine Product) CII 30 mg, 30 UD Tablets (5 x 6),	Class II	Lot 162278, exp. 10/31/17	Unit Dose Mispackaging; blister cavities may contain more than one tablet /capsule	Amerisource Health Services 2550 John Glenn Ave Ste A Columbus, OH

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
	Rx, Packaged and Distributed by: American Health Packaging, Columbus, OH --- Carton NDC 60687-154-25; Blister NDC 60687-154-95				43217-1188
Drugs	Dextroamphetamine Saccharate, Amphetamine Aspartate Monohydrate, Dextroamphetamine Sulfate, and Amphetamine Sulfate (Mixed Salts of a Single-Entity Amphetamine Product) Extended-Release Capsules CII 10 mg 30 UD Capsules (5 x 6), Rx, Packaged and Distributed by: American Health Packaging, Columbus, OH --- Carton NDC 68084-815-25; Blister NDC 68084-815-95	Class II	Lot 152254, exp. 12/31/16, lot 152324, exp. 3/31/17, lot 154833, exp. 5/31/17, lot 162406, exp. 12/31/17	Unit Dose Mispackaging; blister cavities may contain more than one tablet /capsule	Amerisource Health Services 2550 John Glenn Ave Ste A Columbus, OH 43217-1188
Drug	Dextroamphetamine Saccharate, Amphetamine Aspartate Monohydrate, Dextroamphetamine Sulfate, and Amphetamine Sulfate (Mixed Salts of a Single-Entity Amphetamine Product) Extended-Release Capsules CII 15 mg 20 UD Capsules (5 x 4), Rx, Packaged and Distributed by: American Health Packaging, Columbus, OH --- Carton NDC 68084-898-32; Blister NDC 68084-898-33	Class II	Lot 162489, exp. 9/30/17 and lot 162910, exp. 10/31/17	Unit Dose Mispackaging; blister cavities may contain more than one tablet /capsule	Amerisource Health Services 2550 John Glenn Ave Ste A Columbus, OH 43217-1188
Drug	Dextroamphetamine Saccharate, Amphetamine Aspartate Monohydrate, Dextroamphetamine Sulfate, and Amphetamine Sulfate (Mixed Salts of a Single-Entity Amphetamine Product) Extended-Release Capsules, CII 20 mg, 30 UD Capsules (5 x 6), Rx, Packaged and Distributed by: American Health Packaging, Columbus, OH --- Carton NDC 68084-832-25; Blister NDC	Class II	Lot 152325, exp. 12/31/16, lot 154834, exp. 5/31/17	Unit Dose Mispackaging; blister cavities may contain more than one tablet /capsule	Amerisource Health Services 2550 John Glenn Ave Ste A Columbus, OH 43217-1188

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
	68084-832-95				
Drug	Dextroamphetamine Saccharate, Amphetamine Aspartate Monohydrate, Dextroamphetamine Sulfate, and Amphetamine Sulfate (Mixed Salts of a Single-Entity Amphetamine Product) Extended-Release Capsules CII 25 mg 20 UD Capsules (5 x 4), Rx, Packaged and Distributed by: American Health Packaging, Columbus, OH ---- Carton NDC 68084-909-32; Blister NDC 68084-909-33	Class II	Lot 162490, exp. 9/30/17	Unit Dose Mispackaging; blister cavities may contain more than one tablet /capsule	Amerisource Health Services 2550 John Glenn Ave Ste A Columbus, OH 43217-1188
Drug	Dextroamphetamine Saccharate, Amphetamine Aspartate Monohydrate, Dextroamphetamine Sulfate, and Amphetamine Sulfate (Mixed Salts of a Single-Entity Amphetamine Product) Extended-Release Capsules CII 30 mg 20 UD Capsules (5 x 4), Rx, Packaged and Distributed by: American Health Packaging, Columbus, OH ---- Carton NDC 68084-887-32; Blister NDC 68084-887-33	Class II	Lot 152418, exp. 12/31/16, lot 153544, exp. 3/31/17, lot 154835, exp. 5/31/17	Unit Dose Mispackaging; blister cavities may contain more than one tablet /capsule	Amerisource Health Services 2550 John Glenn Ave Ste A Columbus, OH 43217-1188
Drug	Oxygen Nasal Wash (purified water, xylitol, stabilized oxygen, sodium chloride) solution, .75 oz (22mL) bottle, Distributed by: Let's Talk Health, Chula Vista, CA 91914.	Class III	Lot #15522	Marketed Without An Approved NDA/ANDA: product is an unapproved drug due to nasal decongestant claims as well as not complying with the nasal decongestant final monograph	Let's Talk Health, Inc. 2411 Fenton St Ste 102 Chula Vista, CA 91914-3517
Drug	Children's Qnasl 40 mcg (beclomethasone dipropionate) Nasal Aerosol, 40 mcg per spray, 60 Metered Sprays per canister, 4.9g Net Contents, Rx only; Professional Sample; Manufactured for Teva Respiratory, LLC, Horsham, PA	Class III	Lot # 150328, Exp 10/17	Failed Content Uniformity Specifications: out of specification test result for spray content uniformity.	Teva North America 425 Privet Rd Horsham, PA 19044-1220

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
	19044; By: 3M Drug Delivery Systems, Northridge, CA 91324; NDC 59310-206-08.				
Drug	Remeven Cream, (50% Urea in a Cream Base), a) 5.0 oz (142 g) and b) 9.0 oz (255 g) tubes, Rx only, Manufactured by Sonar Products Inc, Carlstadt, NJ. Distributed by Stratus Pharmaceuticals Inc., Miami, FL.	Class III	a) Lot (Exp): 8020 (02/17), 8096 (07/18), 8125 (08/18), 8169 (10/18). NDC 58980-680-50 b) Lot (Exp): 8020 (02/17), 8125 (08/18), 8170 (10/18). NDC 58980-680-90	Crystallization; Complaints that cream appears to have crystallized	Stratus Pharmaceuticals Inc 12379 SW 130th St Miami, FL 33186-6208
Drug	Urea (50% Urea in a Cream Base), a) Net Wt. 5 oz (142 g), (NDC 42808-0200-05) b) Net Wt. 9 oz (225 g) (NDC 42808-0200-09), Rx Only, Manufactured in the U.S.A. for Exact-Rx Inc., Melville, NY	Class III	Lot #'s: a) 8160, b) 8160 Exp Date: 9/2018	Crystallization; complaints received by the manufacturer of crystals forming in product	Exact-Rx Inc 105 Baylis Rd Melville, NY 11747-3833
Drug	Desoximetasone Gel USP, 0.05%, packaged in 60 gram aluminum tubes, Rx only, Marketed by: VersaPharm Incorporated Marietta, GA 30062, Manufactured by: Ei LLC Kannapolis, NC 28083, NDC 61748-205-60.	Class III	Lot#: 1967800, Exp10/2016	Failed impurities/degradation specifications: product was out of specification for unknown impurity at the 9 month stability time point	Akorn, Inc. 1925 W Field Ct Ste 300 Lake Forest, IL 60045-4862
Drug	Acetasol HC (hydrocortisone and acetic acid otic solution USP) , Rx Only, 10 mL bottle, Manufactured by: Actavis Midatlantic LLC 1877 Kawai Road Lincolnton, NJ 28092 USA, NDC 0472-0882-82	Class III	L503092, Exp 04/2016	Failed Impurities/Degradation Specifications: Out of specification (OOS) results for related compound G were obtained at 12-month (at expiry) stability time-point for room temperature sample(s).	Actavis Inc 400 Interpace Pkwy Parsippany, NJ 07054-1120
Drug	Hydrocortisone and acetic acid otic solution, Rx only, 10 mL bottle, Distributed by Actavis Inc. 60 Columbia Road Bldg B. Morristown, NJ 07560 USA , NDC 45963-412-61	Class III	L503092, Exp 04/2016	Failed Impurities/Degradation Specifications: Out of specification (OOS) results for related compound G were obtained at 12-month (at expiry) stability time-point for room temperature sample(s).	Actavis Inc 400 Interpace Pkwy Parsippany, NJ 07054-1120

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drug	CLINIQUE moisture surge tinted moisturizer broad spectrum SPF 15, 1 FL. OZ.LIQ./30 ml bottle within a carton, Clinique Labs., Dist. New York, N.Y., 10022; New York, London W1K 3BQ; Paris, UPC No. 20714-47476-8, Shade 01 (VF-N)	Class III	all lots	Subpotent Drug: Two of the active sunscreen ingredients, octinoxate and octisalate, are below the specifications for assay.	Clinique International 767 5th Ave New York, NY 10153-0023
Drug	CLINIQUE moisture surge tinted moisturizer broad spectrum SPF 15, 1 FL. OZ.LIQ./30 ml bottle within a carton, Clinique Labs., Dist. New York, N.Y., 10022; New York, London W1K 3BQ; Paris, UPC No. 20714-47477-5, Shade 02 (VF-N)	Class III	all lots	Subpotent Drug: Two of the active sunscreen ingredients, octinoxate and octisalate, are below the specifications for assay.	Clinique International 767 5th Ave New York, NY 10153-0023
Drug	CLINIQUE moisture surge tinted moisturizer broad spectrum SPF 15, 1 FL. OZ.LIQ./30 ml bottle within a carton, Clinique Labs., Dist. New York, N.Y., 10022; New York, London W1K 3BQ; Paris, UPC No. 20714-47478-2, Shade 03 (MF-N)	Class III	all lots	Subpotent Drug: Two of the active sunscreen ingredients, octinoxate and octisalate, are below the specifications for assay.	Clinique International 767 5th Ave New York, NY 10153-0023
Drug	CLINIQUE moisture surge tinted moisturizer broad spectrum SPF 15, 1 FL. OZ.LIQ./30 ml bottle within a carton, Clinique Labs., Dist. New York, N.Y., 10022; New York, London W1K 3BQ; Paris, UPC No. 20714-47479-9, Shade 04 (M-N)	Class III	all lots	Subpotent Drug: Two of the active sunscreen ingredients, octinoxate and octisalate, are below the specifications for assay.	Clinique International 767 5th Ave New York, NY 10153-0023
Drug	CLINIQUE moisture surge tinted moisturizer broad spectrum SPF 15, 1 FL. OZ.LIQ./30 ml bottle within a carton, Clinique Labs., Dist. New York, N.Y., 10022; New York, London W1K 3BQ; Paris, UPC No. 20714-48240-4, Shade 05 (D-G)	Class III	all lots	Subpotent Drug: Two of the active sunscreen ingredients, octinoxate and octisalate, are below the specifications for assay.	Clinique International 767 5th Ave New York, NY 10153-0023
Drug	CLINIQUE moisture surge tinted moisturizer broad spectrum SPF 15, 1 FL. OZ.LIQ./30 ml	Class III	all lots	Subpotent Drug: Two of the active sunscreen ingredients, octinoxate	Clinique International

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
	bottle within a carton, Clinique Labs., Dist. New York, N.Y., 10022; New York, London W1K 3BQ; Paris, UPC No. 20714-48241-1, Shade 06 (D-G)			and octisalate, are below the specifications for assay.	767 5th Ave New York, NY 10153-0023
Drug	Amlodipine Besylate Tablets USP, 2.5mg, 90-count bottles, Rx only, Manufactured for: Lupin Pharmaceuticals, Inc. Baltimore, Maryland 21202, Manufactured by: Lupin Limited Goa 403 722 INDIA, NDC 68180-750-09	Class III	Lot #: G304799, Exp. 4/2016	CGMP Deviations: finished products manufactured using active pharmaceutical ingredients whose intermediates failed specifications.	Lupin Limited 15-B, Phase 1A, Verna Industrial Area Verna, Salcette, Goa
Drug	Selegiline HCL Tablets USP 5mg, 60- count bottles, Rx only, Manufactured by: Stason Pharmaceuticals, Inc. Irvine, CA 92618 Distributed by: Libertas Pharma, Inc. Montgomery, AL 36117. NDC 51862-146-06	Class III	Lot #: 14F030, 14F031, 14F032, Exp. June 2017; 15G022, Exp. July 2018	Stason Pharmaceuticals is recalling Selegiline HCl tablets, USP 5mg 60 count bottle due to an out of specification result for dissolution of stability samples.	Stason Pharmaceuticals, Inc. 11 Morgan Irvine, CA 92618-2005
Drug	Amlodipine Besylate Tablets USP, 10mg, 1000-count bottles, Rx only, Manufactured for: Lupin Pharmaceuticals, Inc. Baltimore, Maryland 21202, Manufactured by: Lupin Limited Goa 403 722 INDIA, NDC 68180-752-03	Class III	Lot #: G304677, G304540, G304536, G304537, G304535, G304541, G304545, G304533, G304532, G304539, G304538, G304534, Exp. 4/2016	CGMP Deviations: finished products manufactured using active pharmaceutical ingredients whose intermediates failed specifications.	Lupin Limited 15-B, Phase 1A, Verna Industrial Area Verna, Salcette, Goa

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

CURRENT DRUG SHORTAGES

Indigo Carmine Injection

August 15, 2016

Reason of Shortage

- American Regent has indigo carmine on back order due to manufacturing delays.
- Akorn has discontinued production of indigo carmine due to shortage of raw material.

Estimated Resupply Dates

- American Regent has indigo carmine 8 mg/mL 5 mL ampules on back order and the company cannot estimate a release date.

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

Sufentanil Injection

August 15, 2016

Reason of Shortage

- West-Ward is no longer actively marketing sufentanil 1 mL and 2 mL ampules. The 5 mL ampules are available.
- Hospira has sufentanil on shortage due to manufacturing delays.
- Akorn has Sufenta available.

Estimated Resupply Dates

- Hospira has sufentanil 50 mcg/mL 1 mL, 2 mL, and 5 mL ampules on back order and the company cannot estimate a release date.

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

Theophylline Extended-Release Tablets

August 15, 2016

Reason of Shortage

- Major has discontinued theophylline extended-release tablets.
- Teva cannot provide a reason for the shortage.

Estimated Resupply Dates

- Teva has theophylline extended-release tablets temporarily unavailable and the company cannot estimate a release date.

Source: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1221

Clindamycin Injection

August 16, 2016

Reason of Shortage

- Akorn cannot provide a reason for the shortage.
- Pfizer states the Cleocin Add-Vantage vials are on shortage due to manufacturing delays.
- Hospira divested clindamycin injection to Alvogen in September 2015.
- Sandoz had clindamycin injection on shortage due to increased demand.
- Sagent has clindamycin injection on shortage due to manufacturing delays.

Estimated Resupply Dates

- Akorn has clindamycin 900 mg/50 mL premixed bottle available in limited supply.
- Fresenius Kabi has clindamycin 150 mg/mL 60 mL bulk vials on back order and the company estimates a release date of 3rd quarter 2016. The 150 mg/mL 6 mL vials are available with short expiration dating (< 8 months).

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

Diltiazem Injection

August 16, 2016

Reason of 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 available in limited supply.
- 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.

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

Hydralazine Injection

August 16, 2016

Reason of 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 10 count on back order and the company cannot estimate a release date.
- American Regent has hydralazine 20 mg/mL 1 mL vials on back order and the company cannot estimate a release date.
- X-Gen has hydralazine 20 mg/mL 1 mL vials on back order and the company estimates a release date of mid-September 2016.

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

Ampicillin Injection

August 18, 2016

Reason of Shortage

- Fresenius Kabi states the reason for the shortage is increased demand.
- Sagent states the reason for the shortage is manufacturing delay. Sagent stopped marketing the 10 gram vials in early 2016.
- Sandoz cannot provide a reason for the shortage.
- WG Critical Care discontinued ampicillin 250 mg vials in early 2016.

Estimated Resupply Dates

- AuroMedics has ampicillin 500 mg, 2 gram, and 10 gram vials on intermittent back order and the company is releasing product as it becomes available.

Source: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1226

Atropine Sulfate Injection

August 23, 2016

Reason of Shortage

- Hospira states the shortage was due to manufacturing delays.

Estimated Resupply Dates

- Hospira has atropine 0.1 mg/mL 10 mL Ansyr syringes on back order and the company estimates a release date of early-October 2016.

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

Vecuronium Bromide Injection

August 23, 2016

Reason of Shortage

- Hospira has vecuronium available.
- Teva states the shortage is due to manufacturing delays.
- Pfizer sold vecuronium injection to Mylan Institutional in December 2013.
- Ben Venue has stopped production in its plant in Bedford, Ohio and closed in 2014.
- Caraco cannot provide availability information at this time.
- Sagent is not marketing vecuronium 10 mg and 20 mg vials.

Estimated Resupply Dates

- Teva has both vecuronium presentations on back order and the company estimates a release date of December 2016.

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

Calcium Chloride Injection

August 24, 2016

Reason of 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 on back order and the company estimates a release date of late-October 2016.

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

Ciprofloxacin Oral Suspension

August 24, 2016

Reason of Shortage

- Lupin did not provide a reason for the shortage.

Estimated Resupply Dates

- Lupin has ciprofloxacin oral suspension on long-term back order and the company cannot estimate a release date.

Source: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1247

Dextrose (25%) Injection

August 24, 2016

Reason of Shortage

- Hospira has 25% dextrose syringes on shortage due to increased demand.
- Hospira is the sole supplier of 25% dextrose syringes.

Estimated Resupply Dates

- Hospira has 25% dextrose 10 mL Ansyr syringes on back order and the company estimates a release date of late-October 2016.

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

Dolasetron Mesylate Injection

August 24, 2016

Reason of 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.

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

Gadoteridol Injection

August 24, 2016

Reason of Shortage

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

Estimated Resupply Dates

- Bracco diagnostics has ProHance 10 mL, 15 mL, and 20 mL vials on allocation and the company is releasing supplies every 3 to 5 days.

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

Haemophilus B Conjugate Vaccine

August 24, 2016

Reason of Shortage

- GlaxoSmithKline relaunched Hiberix in August 2016.
- Sanofi Pasteur has ActHIB in short supply due to the shortage of other combination vaccines (eg, Pentacel).
- Merck has PedvaxHIB (Haemophilus b meningococcal protein conjugate vaccine) available.

Estimated Resupply Dates

- Sanofi Pasteur has ActHib vaccine on allocation.

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

Ampicillin Sulbactam

August 25, 2016

Reason of Shortage

- Mylan Institutional discontinued ampicillin sulbactam 1.5 gram and 3 gram vials.
- Pfizer (Hospira) has discontinued their generic ampicillin sulbactam products.
- 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 is due to increased demand.

Estimated Resupply Dates

- AuroMedics has ampicillin sulbactam 1.5 gram, 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 15 gram vials on back order and the company estimates a release date of September 2016. The 1.5 gram and 3 gram vials are on allocation.
- 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 1.5 gram and 15 gram vials on a weekly allocation. The 3 gram vials are on back order and the company cannot estimate a release date.
- WG Critical Care has ampicillin sulbactam 1.5 gram and 15 gram vials on back order and the company cannot estimate a release date.

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

Etomidate Injection

August 25, 2016

Reason of Shortage

- American Regent had etomidate injection on shortage due to manufacturing delays.
- Ben Venue stopped production in its plant in Bedford, Ohio and closed in July 2014.
- Hospira has Amidate on shortage due to manufacturing delays.

- Par Sterile Products discontinued etomidate in early 2015.
- Sagent is no longer marketing etomidate.

Estimated Resupply Dates

- Hospira has etomidate 20 mL LifeShield syringes and 20 mL ampules on back order and the company cannot estimate a release date.

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

Indomethacin Capsules

August 25, 2016

Reason of Shortage

- Mylan, Glenmark, and Teva did not provide a reason for the shortage.
- Sandoz discontinued indomethacin in mid-2016.

Estimated Resupply Dates

- Glenmark has all indomethacin presentations on intermittent back order and is releasing product as it becomes available.
- Heritage has indomethacin 50 mg capsules in 100 count and 500 count on back order and the company estimates a release date of mid-September 2016.
- Teva has all indomethacin presentations temporarily unavailable and the company cannot estimate a release date.
- Mylan Institutional has indomethacin 50 mg in 100 count unit-dose on back order and the company cannot estimate a release date.

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

Octreotide Injection

August 25, 2016

Reason of 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 Pharm did not provide a reason for the shortage.

Estimated Resupply Dates

- Fresenius Kabi has octreotide 50 mcg/mL 1 mL vials on back order and the company estimates a release date of late-October 2016.
- Sagent has octreotide 50 mcg/mL 1 mL vials, 200 mcg/mL 5 mL vials, and 500 mcg/mL 1 mL vials on allocation.
- Sun Pharma cannot provide availability information at this time.

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

Sodium Phosphate Injection

August 25, 2016

Reason of 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 <7 months.

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

23.4% Sodium Chloride Concentrated Solution for Injection

August 26, 2016

Reason of Shortage

- Fresenius Kabi had sodium chloride concentrated solution on shortage due to increased demand.
- Hospira has 23.4% sodium chloride solutions for injection on shortage due to increased demand.

Estimated Resupply Dates

- Hospira has 23.4% sodium chloride 250 mL bulk containers on back order and the company cannot estimate a release date.

Source: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1194

Fluorouracil Injection

August 26, 2016

Reason of Shortage

- Accord could not provide a reason for the shortage.
- Fresenius Kabi states the reason for the shortage was increased demand.
- Teva states the reason for the shortage is increased demand.

Estimated Resupply Dates

- Teva has fluorouracil 100 mL vials available on allocation.

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

Haloperidol Lactate Injection

August 26, 2016

Reason of Shortage

- Patriot Pharmaceuticals has haloperidol lactate available.
- Sagent has haloperidol lactate on shortage due to manufacturing delays.
- Teva has haloperidol lactate on shortage due to manufacturing delays.
- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired several products from Bedford Laboratories in July 2014 including haloperidol lactate injection. West-Ward is not actively marketing haloperidol lactate at this time.
- Janssen has Haldol injection available.

Estimated Resupply Dates

- Teva has haloperidol lactate 5 mg/mL 10 mL vials on back order and the company cannot estimate a release date.
- Sagent has haloperidol lactate 5 mg/mL 10 mL vials are on back order and the company cannot estimate a release date. The 5 mg/mL 1 mL vials are on allocation.

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

Magnesium Sulfate Injection

August 26, 2016

Reason of 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 has magnesium sulfate injection on shortage due to increased demand.

Estimated Resupply Dates

- Fresenius Kabi has magnesium sulfate 500 mg/mL 20 mL and 50 mL vials on back order and the company estimates a release date of late-August 2016. Magnesium 500 mg/mL 10 mL vials are on back order and the company estimates a release date of mid- to late-September 2016.
- Hospira has magnesium sulfate 500 mg/mL 20 mL vials on back order and the company estimates a release date of 1st quarter 2018.
- X-Gen has magnesium sulfate 500 mg/mL 10 mL vials on intermittent back order and the company is releasing product as it becomes available.

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

Etoposide Injection

August 30, 2016

Reason of Shortage

- Bristol-Myers Squibb did not provide a reason for the shortage of Etopophos.
- Etoposide solution for injection is not affected by this shortage.

Estimated Resupply Dates

- Bristol-Myers Squibb has Etopophos on back order and the company estimates a release date of July 2017.

Source: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=652

Nalbuphine Injection

August 30, 2016

Reason of Shortage

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

Estimated Resupply Dates

- Hospira has nalbuphine 10 mg/mL 1 mL ampules and 20 mg/mL 1 mL ampules on back order and the company estimates a release date in late.

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

Oxacillin Sodium Injection

August 30, 2016

Reason of Shortage

- Auromedics did not provide a reason for the shortage.
- Baxter has oxacillin on shortage due to a raw material supply disruption.
- Sagent has oxacillin injection on shortage due to manufacturing delays.

Estimated Resupply Dates

- Auromedics has oxacillin 2 gram vials and 10 gram bulk vials on intermittent back order and the company is releasing supplies as they become available.
- Baxter has oxacillin 2 gram/50 mL frozen premixed bags on back order and the company estimates a release date in October 2016.
- Sagent has oxacillin 1 gram, 2 gram, and 10 gram vials on back order and the company cannot estimate a release date.

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

Tetracaine Hydrochloride Ophthalmic Drops

August 30, 2016

Reason of Shortage

- Alcon, Valeant, 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 back order and the company cannot estimate a release date.
- Valeant has tetracaine 0.5% ophthalmic drops in 15 mL bottles on intermittent back order and the company is releasing supplies as they become available.
- OCuSOFT has Tetravisc 0.5% 0.6 mL unit-dose in 12 count on back order and the company cannot estimate a release date.

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

Caffeine and Sodium Benzoate Injection

August 31, 2016

Reason of Shortage

- American Regent could not provide a reason for the shortage of caffeine and sodium benzoate injection.
- American Regent is the sole manufacturer of caffeine and sodium benzoate injection.

Estimated Resupply Dates

- American Regent has caffeine and sodium benzoate 2 mL vials available.

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

Cefotaxime Injection

August 31, 2016

Reason of Shortage

- Hospira has discontinued Claforan. Sanofi-Aventis manufactured Claforan for Hospira and is no longer making the product.
- Baxter discontinued Claforan in late-2015.
- West-Ward has cefotaxime on shortage due to increased demand.

Estimated Resupply Dates

- West-Ward has cefotaxime 500 mg, 1 gram, 2 gram, and 10 gram vials on long-term back order and the company cannot estimate a release date.

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

Procainamide Hydrochloride Injection

August 31, 2016

Reason of 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 on back order and the company estimates a release date of 4th quarter 2018. The 500 mg/mL 2 mL vials are available in limited supply.

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

Scopolamine Transdermal Patch

August 31, 2016

Reason of Shortage

- Baxter has Transderm Scop on shortage due to a manufacturing hold. Sandoz has Transderm Scop on shortage due to increased demand.

Estimated Resupply Dates

- Baxter has Transderm Scop in 10 count on allocation. The 24 count presentation is on back order and the company estimates a release date of early-October 2016.
- Sandoz has Transderm Scop in 4 count on back order and the company estimates a release date of mid-September 2016.

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

Dihydroergotamine Mesylate Injection

September 2, 2016

Reason of 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 10 count on back order and the company estimates a release date of late-September to early-October 2016.
- Valeant has D.H.E. 45 1 mg/mL 1 mL ampules on back order and the company cannot estimate a release date.

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

Acetylcysteine Oral and Inhalation Solution

September 6, 2016

Reason of 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 on back order and the company cannot estimate a release date. Acetylcysteine 200 mg/mL 10 mL vials are available with a short expiration date (September 2016).

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

Cyclopentolate Hydrochloride and Phenylephrine Hydrochloride Ophthalmic Solution

September 6, 2016

Reason of Shortage

- Alcon had Cyclomydril ophthalmic solution on back order due to production delays.

Estimated Resupply Dates

- All presentations are available.

Source: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1214

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

September 6, 2016

Reason of Shortage

- Sanofi Pasteur states the reason for the shortage is manufacturing delay.

Estimated Resupply Dates

- Sanofi Pasteur has Pentacel vaccine on allocation.

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

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

September 6, 2016

Reason of Shortage

- Sanofi Pasteur has Daptacel in short supply due to the shortage of other combination vaccines (eg, Pentacel).
- GlaxoSmithKline has Infanrix available.

Estimated Resupply Dates

- Sanofi Pasteur has Daptacel vaccine on allocation.

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

Dopamine Hydrochloride Injection

September 6, 2016

Reason of 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 40 mg/mL 10 mL vials on back order and the company estimates a release date of late-September 2016.
- Hospira has dopamine in 5% dextrose 400 mg/500 mL premixed bags on back order and the company estimates a release date of 3rd quarter 2016.

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

Furosemide Injection

September 6, 2016

Reason of Shortage

- Fresenius Kabi has furosemide injection available.
- American Regent has furosemide injection on shortage due to manufacturing delays.
- Hospira has furosemide injection available.
- Wockhardt has discontinued all furosemide injection presentations.
- Claris has furosemide injection available.

Estimated Resupply Dates

- American Regent has furosemide 10 mg/mL 2 mL, 4 mL, and 10 mL vials on back order and the company cannot estimate a release date.

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

Ketorolac Tromethamine Injection

September 6, 2016

Reason of Shortage

- BD Rx has ketorolac injection available. BD RX is now part of Fresenius Kabi.
- Fresenius Kabi has ketorolac injection available.
- Hospira has ketorolac on shortage due to manufacturing delays for quality improvement activities and increased demand for the product.
- Sagent states the reason for the shortage is manufacturing delay.
- West-Ward is not actively marketing ketorolac injection.
- Ben Venue closed its plant in Bedford, Ohio in July 2014.
- FDA imposed an import ban in mid-2013 on several Wockhardt products including ketorolac.
- Sprix Nasal Spray is not affected by this shortage.

Estimated Resupply Dates

- Fresenius Kabi has 30 mg/mL 1 mL prefilled syringes and 30 mg/mL 2 mL syringes for intramuscular injection available with an expiration date of <7 months.
- Sagent has ketorolac 30 mg/mL 1 mL vials and 30 mg/mL 2 mL vials for intramuscular injection are on back order and the company estimates a release date of September 2016.

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

Leucovorin Calcium Injection

September 6, 2016

Reason of Shortage

- Fresenius Kabi has leucovorin on shortage due to increase demand.
- Teva has leucovorin on allocation due to increased demand.
- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired leucovorin calcium injection from Bedford in July 2014. West-Ward is not actively marketing leucovorin calcium injection at this time.
- Sagent has leucovorin on shortage due to manufacturing delay.

Estimated Resupply Dates

- Fresenius Kabi has leucovorin 200 mg and 500 mg vials on allocation.
- Sagent has leucovorin 50 mg vials on back order and the company estimates a release date in September 2016. Leucovorin 200 mg vials are on allocation.
- Teva has leucovorin 100 mg vials on allocation.

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

Methylphenidate Hydrochloride Chewable Tablets

September 6, 2016

Reason of Shortage

- Shionogi Pharma has Methylin chewable tablets on shortage due to manufacturing issues.
- Gavis launched methylphenidate chewable tablets in April 2015.

Estimated Resupply Dates

- Shionogi Pharma has all Methylin chewable tablets on long-term back order and the company cannot estimate a release date.

Source: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1163

Ofloxacin Ophthalmic Solution

September 6, 2016

Reason of Shortage

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

- Rising has ofloxacin ophthalmic solution available.
- 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 4th quarter 2016.
- Valeant has temporarily discontinued ofloxacin ophthalmic solution in 5 mL and 10 mL bottles and the company cannot estimate a release date.

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

Sodium Acetate Injection

September 6, 2016

Reason of Shortage

- American Regent has sodium acetate injection on back order due to manufacturing delays.
- Fresenius Kabi has sodium acetate injection available.
- Hospira had sodium acetate injection on back order due to increased demand.

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.

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

Sodium Bicarbonate Injection

September 6, 2016

Reason of Shortage

- Amphastar has sodium bicarbonate on shortage due to increased demand.
- Fresenius Kabi is not currently manufacturing sodium bicarbonate 4.2% 5 mL vials.
- Hospira had sodium bicarbonate on shortage due to manufacturing delays.
- Hospira is the sole supplier of the 4.2% 10 mL syringes used in pediatric patients.

Estimated Resupply Dates

- Amphastar (IMS) has sodium bicarbonate 8.4% 50 mL syringes on intermittent back order and the company is regularly releasing product.

Source: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=788

Talc, Sterile

September 6, 2016

Reason of Shortage

- Lymol has Sclerosol on shortage due to manufacturing delays.

Estimated Resupply Dates

- Lymol has Sclerosol on back order and the company cannot estimate a release date.

Source: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1248

Atropine Sulfate Ophthalmic Solution

September 7, 2016

Reason of 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 available in limited supply.

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

Bleomycin Sulfate Injection

September 7, 2016

Reason of Shortage

- Fresenius Kabi has bleomycin on back order due to shortage of active pharmaceutical ingredient.
- Hospira has bleomycin on shortage due to increase demand for the product.
- Teva has temporarily discontinued bleomycin.

- 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 and 30 unit vials on back order and the company estimates a release date of 2nd quarter 2017.
- Hospira has bleomycin 15 unit and 30 unit vials on allocation.
- Teva has temporarily discontinued bleomycin 15 unit and 30 unit vials and the company estimates a release date of late-September 2016 for the 30 unit vials and early-October 2016 for the 15 unit vials.

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

Bupivacaine Injection

September 7, 2016

Reason of Shortage

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

Estimated Resupply Dates

- AuroMedics has 0.5% bupivacaine 30 mL vials, and 0.75% bupivacaine 10 mL vials on intermittent back order and the company is releasing product as it becomes available.
- Hospira has 0.5% bupivacaine 20 mL ampule sterile packs on back order and the company cannot estimate a release date. The 0.5% bupivacaine 50 mL vials are available in limited supply.
- Fresenius Kabi has 0.5% Sensorcaine 50 mL vials on intermittent back order and the company is releasing product as it becomes available. The 0.75% Sensorcaine-MPF 30 mL preservative-free vials are on back order and the company estimates a release date of mid- to late-September 2016.

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

Cefepime Injection

September 7, 2016

Reason of Shortage

- Apotex could not provide a reason for the shortage.
- BBraun has cefepime on allocation due to increased demand.
- Baxter has cefepime on shortage due to increased demand.
- Fresenius Kabi has cefepime injection on shortage due to manufacturing delays.
- Sagent has cefepime injection on shortage due to manufacturing delays.
- WG Critical Care has cefepime injection on shortage due to increased demand.
- Hospira has Maxipime on shortage due to manufacturing delays.
- Sandoz discontinued cefepime injection in early 2016.

Estimated Resupply Dates

- Apotex has all presentations of cefepime on back order and the company cannot estimate a release date.
- 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 4th quarter 2016.
- Hospira has Maxipime 1 gram and 2 gram vials on allocation. The 1 gram and 2 gram ADD-Vantage vials are on back order and the company estimates a release date of December 2016.
- Sagent has cefepime 1 gram and 2 gram vials on back order and the company estimates a release date of September 2016.
- WG Critical Care has cefepime 1 gram and 2 gram vials on back order and the company cannot estimate a release date for the 1 gram vials and estimates a release date of October 2016 for the 2 gram vials.

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

Ceftazidime Injection

September 7, 2016

Reason of 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.

Estimated Resupply Dates

- Teligent has Fortaz 1 gram and 2 gram vials on back order and the company estimates a release date of September 2016. The Fortaz 6 gram vials are on back order and the company estimates a release date of 1st quarter 2017. The 1 gram/50 mL premixed bags are on back order and the company cannot estimate a release date.
- Sagent has ceftazidime 1 gram, 2 gram, and 6 gram vials on back order and the company estimates a release date of September 2016.
- WG Critical Care has ceftazidime 6 gram vials on back order and the company cannot estimate a release date.
- Hospira has Tazicef 1 gram ADD-Vantage vials on back order and the company estimates a release date of early-October 2016.

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

Hydroxyamphetamine Hydrobromide and Tropicamide Ophthalmic Solution

September 7, 2016

Reason of Shortage

- Akorn has Paremyd on shortage due to manufacturing delays.
- No clinical trial data were found to support the use of Paremyd in the diagnosis of Horner Syndrome.

Estimated Resupply Dates

- Akorn has Paremyd ophthalmic solution on back order and the company cannot estimate a release date.

Source: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1193

Lorazepam injectable presentations

September 7, 2016

Reason of Shortage

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

Estimated Resupply Dates

- Hospira has lorazepam 4 mg/mL 10 mL vials on intermittent back order and the company is releasing product as it becomes available. The 4 mg/mL 1 mL vials and 1 mL Carpuject syringes are on back order and the company estimates a release date of late-September 2016 for the 1 mL vials and early-October 2016 for the 1 mL syringes.
- West-Ward has Ativan 2 mg/mL 10 mL vials on back order and the company estimates a release date of September or October 2016.

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

Mannitol Injection

September 7, 2016

Reason of Shortage

- American Regent has mannitol injection on shortage due to manufacturing delays.
- Hospira has 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.
- Hospira has mannitol 250 mg/mL 50 mL vials on back order and the company estimates a release date of early-October 2016.

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

Mitoxantrone Hydrochloride Injection

September 7, 2016

Reason of 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

- 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 estimates a release date of October 2016.

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

Morphine Injections

September 7, 2016

Reason of 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 2 mg/mL 1 mL iSecure syringes on intermittent back order and the company is releasing product as it becomes available. Morphine 25 mg/mL 4 mL and 10 mL ADD-Vantage vials are on back order and the company cannot estimate a release date.
- West-Ward has 8 mg/mL 1 mL vials (NDC 00641-6075-25) on back order and the company cannot estimate a release date.
- BD Rx has morphine 8 mg/mL 1 mL syringes on back order and the company estimates a release date in early-October 2016.

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

Multiple Vitamins for Infusion

September 7, 2016

Reason of 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, MVI-12 without vitamin K 50 mL Dual vials, and MVI Adult 50 mL Dual vials on back order and the company cannot estimate a release date. The MVI Adult 5 mL Dual vials are on back order and the company estimates a release date of mid-September 2016.

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

Oxytocin Injection

September 7, 2016

Reason of 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 30 mL vials on back order and the company estimates a release date of mid-September 2016.

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

Thrombin Topical Solution (Bovine)

September 7, 2016

Reason of 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 syringe spray kits on back order and the company estimates a release date of mid- to late-September 2016. Thrombin JMI 5,000 unit epistaxis kits are on back order and the company estimates a release date of November 2016.

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

Tigecycline Injection

September 7, 2016

Reason of 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 1st quarter 2017. Tygacil 50 mg/5 mL vials are on allocation.

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

Tobramycin Injection

September 7, 2016

Reason of 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-September 2016.
- Teva has tobramycin 40 mg/mL solution for injection on long term back order and the company estimates a release date of October 2016.

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

Vinblastine Injection

September 7, 2016

Reason of Shortage

- Fresenius Kabi has vinblastine on shortage due to manufacturing delays.
- Fresenius Kabi is the sole supplier of vinblastine.

Estimated Resupply Dates

- Fresenius Kabi has vinblastine on allocation.

Source: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=883

Indocyanine Green

September 8, 2016

Reason of Shortage

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

Estimated Resupply Dates

- Akorn has IC-Green available in limited supply.

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

Benztropine Injection

September 8, 2016

Reason of Shortage

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

Estimated Resupply Dates

- Akorn has benztropine injection 1 mg/mL 2 mL ampules on back order and the company cannot estimate a release date.
- Fresenius Kabi has benztropine injection on back order and the company estimates a release date of mid-September 2016.

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

Gentamicin injection

September 9, 2016

Reason of Shortage

- Hospira has discontinued all premixed bags except for the 60 mg/50 mL size. This presentation is on long-term back order due to manufacturing delays.

Estimated Resupply Dates

- Hospira has gentamicin 60 mg/50 mL premixed bags on back order and the company cannot estimate a release date.

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

Leuprolide Acetate 14-Day Kit

September 9, 2016

Reason of Shortage

- Caraco cannot provide availability information at this time.
- 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.

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

Lidocaine Injection

September 9, 2016

Reason of 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 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 1% lidocaine 2 mL and 10 mL vials on back order and the company estimates a release date of mid-October 2016 for the 2 mL vials and late-September for the 10 mL vials. The 2% lidocaine 2 mL and 5 mL vials are on back order and the company estimates a release date of early-October 2016 for the 2 mL vials and mid-September 2016 for the 5 mL vials. The 1% Xylocaine 20 mL and 50 mL vials are on intermittent back order and the company is releasing product as it becomes available. The 2% Xylocaine 20 mL and 50 mL vials are on intermittent back order and the company is releasing product as it becomes available.
- 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 50 mL vials are available in limited supply.

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

Methylene Blue Injection

September 9, 2016

Reason of Shortage

- Akorn has methylene blue on shortage due to manufacturing delays.
- American Regent has methylene blue on back order due to manufacturing delays.

Estimated Resupply Dates

- Akorn has methylene blue available with short expiration dating.
- American Regent has all methylene blue presentations on back order and the company cannot estimate a release date.

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

Olanzapine Injection

September 9, 2016

Reason of Shortage

- American Regent cannot provide a reason for the shortage. Sandoz had olanzapine injection on shortage due to increase demand.

Estimated Resupply Dates

- American Regent has olanzapine 10 mg vials on back order and the company cannot estimate a release date.

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

Phenytoin Injection

September 9, 2016

Reason of Shortage

- Pfizer (Hospira) has discontinued phenytoin sodium injection.
- X-Gen is no longer marketing phenytoin sodium injection.

Estimated Resupply Dates

- West-Ward has phenytoin sodium 50 mg/mL 2 mL vials on a weekly allocation.

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

Piperacillin Tazobactam Injection

September 9, 2016

Reason of 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.
- Sandoz discontinued piperacillin/tazobactam in late 2015.
- 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 cannot estimate a release date.
- 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 Zosyn frozen premixes available on allocation.
- Fresenius Kabi has piperacillin/tazobactam 2.25 gram vials on back order and the company estimates a release date of mid- to late-September 2016. Piperacillin/tazobactam 3.375 gram and 40.5 gram vials are on intermittent back order and the company is releasing product as it becomes available. The 4.5 gram vials are on back order and the company estimates a release date of late-October 2016.
- Hospira has piperacillin/tazobactam 2.25 gram vials on intermittent back order and the company is releasing product as it becomes available. The 3.375 gram vials are available in limited supply.
- 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 October 2017.
- Sagent has piperacillin/tazobactam 2.25 gram, 3.375 gram, and 4.5 gram vials on allocation.

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

Potassium Chloride Injection

September 9, 2016

Reason of 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, 30 mEq/15 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. The 20 mEq/100 mL in sterile water is on back order and the company estimates a release date of mid-September 2016.

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

Testosterone Cypionate Intramuscular Injection

September 9, 2016

Reason of Shortage

- Actavis discontinued testosterone cypionate injection in 2015.
- Paddock had testosterone on shortage due to increased demand and shipping delays from their contract manufacturer.

- West-Ward had testosterone cypionate on shortage due to manufacturing delays.
- Sandoz discontinued testosterone cypionate 200 mg/mL 1 mL and 10 mL vials in September 2011. Sandoz discontinued final presentation in first half of 2012.
- Sun Pharma did not provide a reason for the shortage.

Estimated Resupply Dates

- Sun Pharma cannot provide any availability information at this time.
- West-Ward has testosterone cypionate 200 mg/mL 10 mL vials on allocation.

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

Bupivacaine with epinephrine Injection

September 13, 2016

Reason of Shortage

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

Estimated Resupply Dates

- Fresenius Kabi has 0.25% Sensorcaine-MPF with epinephrine 30 mL vials on back order and the company estimates a release date of mid- to late-September 2016.
- Hospira has 0.25% bupivacaine with epinephrine 10 mL vials and 30 mL vials on back order and the company estimates a release date of early-October 2016 for the 10 mL vials and mid-September 2016 for the 30 mL vials. The 0.5% bupivacaine with epinephrine 10 mL and 50 mL vials are on back order and the company estimates a release date of late-October 2016 for the 10 mL vials and mid-October 2016 for the 50 mL vials.
- Hospira has 0.25% Marcaine with epinephrine 10 mL and 30 mL vials on back order and the company estimates a release date of mid-October 2016 for the 10 mL vials and early-October 2016 for the 30 mL vials.

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

Dexamethasone Sodium Phosphate

September 13, 2016

Reason of Shortage

- American Regent has dexamethasone sodium phosphate on shortage due to manufacturing delays.
- AuroMedics has dexamethasone sodium phosphate is available.
- Fresenius Kabi has dexamethasone sodium phosphate is available.
- West-Ward has dexamethasone sodium phosphate is available.
- Mylan Institutional states the shortage is due to increased demand.

Estimated Resupply Dates

- American Regent has dexamethasone sodium phosphate 4 mg/mL products on back order and the company cannot estimate a release date.
- AuroMedics has all dexamethasone sodium phosphate presentations on intermittent back order and the company is releasing product as it becomes available.
- Fresenius Kabi has dexamethasone 4 mg/mL 1 mL vials on back order and the company estimates a release date of mid-September 2016.

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

Methylprednisolone Acetate Injection

September 13, 2016

Reason of Shortage

- Sandoz and Teva could not provide a reason for the shortage.
- Pfizer had Depo-Medrol injection on a short-term shortage due to increased demand for Solu-Medrol.

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 November 2016.

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

Penicillin G Benzathine/Penicillin G Procaine

September 13, 2016

Reason of 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 the company estimates a release date in 4th quarter 2016. Bicillin C-R 1,200,000 units/2 mL pediatric prefilled syringes are on back order and the company estimates a release date in late-December 2016.
- Pfizer has Bicillin C-R 900/300 2 mL pediatric prefilled syringes on allocation.

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

Potassium Acetate Injection

September 13, 2016

Reason of 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.

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