January 2018

Drug Information Update

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NEWLY AVAILABLE GENERICS

GENERIC DRUG NAME	STRENGTH & DOSAGE FORM	GENERIC MANUFACTURER	BRAND NAME
TENOFOVIR DISOPROXIL FUMARATE	300MG TABLET	TEVA USA	VIREAD
EFAVIRENZ	50MG CAPSULE	RISING PHARM	SUSTIVA
EFAVIRENZ	200MG CAPSULE	RISING PHARM	SUSTIVA
CARBINOXAMINE MALEATE	6MG TABELT	FOXLAND PHARMAC	RYVENT
ATAZANAVIR SULFATE	150MG CAPSULE	GREENSTONE LLC	REYATAZ
ATAZANAVIR SULFATE	200MG CAPSULE	GREENSTONE LLC	REYATAZ
ATAZANAVIR SULFATE	300MG CAPSULE	GREENSTONE LLC	REYATAZ
BOCASAL	538MG POWDER PACK	WISCONSIN PHARM	NEUTRASAL
ESTRADIOL	0.01% CREAM	MYLAN	ESTRACE
ROMIDEPSIN	10MG/2ML VIAL	PFIZER US PHARM	ISTODAX
REMIFENTANIL HCL	5MG VIAL	FRESENIUS KABI	ULTIVA
REMIFENTANIL HCL	2MG VIAL	FRESENIUS KABI	ULTIVA
REMIFENTANIL HCL	1MG VIAL	FRESENIUS KABI	ULTIVA

NEW DRUG ENTITIES/COMBINATIONS/STRENGTHS

DESCRIPTION	BRAND NAME	GENERIC NAME	STRENGTH	NOTES
NARCOTIC WITHDRAWAL THERAPY AGENTS	SUBLOCADE	BUPRENORPHINE	100 mg/0.5 mL	New Strength and Dosage Form
NARCOTIC WITHDRAWAL THERAPY AGENTS	SUBLOCADE	BUPRENORPHINE	300 mg/1.5 mL	New Strength and Dosage Form
TOPICAL ANTI-INFLAMMATORY, NSAIDS	DICLOPR	DICLOFENAC/MET SALICYL/MENTHOL	1 %-30 %-10 %	New Combination
LAXATIVES AND CATHARTICS	CLENPIQ	SOD PICOSULF/MAG OX/CITRIC AC	10 mg-3.5 gram-12 gram/160 mL	New Strength and Dosage Form
ANTIFIBRINOLYTIC AGENTS	FIBRYGA	FIBRINOGEN	1 gram (700 mg-1,300 mg)	New Strength
TX FOR ATTENTION DEFICIT-HYPERACT(ADHD)/NARCOLEPSY	METHYLPHENIDATE ER	METHYLPHENIDATE HCL	72 mg	New Strength no pricing available, claims will not process till pricing is provided.
NEUROMUSCULAR BLOCKING AGENTS	SUCCINYLCHOLINE CHLORIDE-NACL	SUCCINYLCHOLINE/SOD CLR,ISO/PF	140 mg/7 mL (20 mg/mL)	New Strength no pricing available, claims will not process till pricing is provided.
NEUROPATHIC AGENTS	LYRICA CR	PREGABALIN	82.5 mg	New Strength and Dosage Form
NEUROPATHIC AGENTS	LYRICA CR	PREGABALIN	165 mg	New Strength and Dosage Form
NEUROPATHIC AGENTS	LYRICA CR	PREGABALIN	330 mg	New Strength and Dosage

DESCRIPTION	BRAND NAME	GENERIC NAME	STRENGTH	NOTES
				Form
ANTINEOPLASTIC,ANTI-PROGRAMMED DEATH-1 (PD-1) MAB	OPDIVO	NIVOLUMAB	240 mg/24 mL	New Strength
2ND GEN. ANAEROBIC ANTIPROTOZOAL-ANTIBACTERIAL	SOLOSEC	SECNIDAZOLE	2 gram	New Entity, no pricing available until 01/31/2018, claims will not process till pricing is provided.
SYSTEMIC ENZYME INHIBITORS	PROLASTIN-C	ALPHA-1-PROTEINASE INHIBITOR	1,000 mg (+/-)/20 mL	New Dosage form, no pricing available until 01/09/2018, claims will not process till pricing is provided.
ANTINEOPLASTIC - ANTIMETABOLITES	GEMCITABINE HCL	GEMCITABINE HCL	100 MG/ML	New Strength
ANTINEOPLASTIC SYSTEMIC ENZYME INHIBITORS	ALUNBRIG	BRIGATINIB	90 MG	New Strength
ANTINEOPLASTIC SYSTEMIC ENZYME INHIBITORS	BORTEZOMIB	BORTEZOMIB	3.5 MG IV	New Route
ANTIHYPERGLYCEMIC-SOD/GLUC COTRANSPORT2(SGLT2)INHIBITORS	STEGLATRO	ERTUGLIFLOZIN PIDOLATE	5 MG	New Entity
ANTIHYPERGLYCEMIC-SOD/GLUC COTRANSPORT2(SGLT2)INHIBITORS	STEGLATRO	ERTUGLIFLOZIN PIDOLATE	15 MG	New Entity
RETINAL ENZYME REPLACEMENT	LUXTURNA	VORETIGENE NEPARVOVEC-RZYL	$1.5X10^{11}$	New Entity
ANTIHYPERGLYCEMIC-SGLT2 INHIBITOR-BIGUANIDE	XIGDUO XR	DAPAGLIFLOZIN/METFORMIN HCL	2.5-1000MG	New Strength

DESCRIPTION	BRAND NAME	GENERIC NAME	STRENGTH	NOTES
COMBS.				
ANTINEOPLASTIC SYSTEMIC ENZYME INHIBITORS	ALUNBRIG	BRIGATINIB	180 MG	New Strength
ANTINEOPLASTIC SYSTEMIC ENZYME INHIBITORS	ALUNBRIG	BRIGATINIB	90MG-180MG	New Strength and Dosage Form
ADRENERGICS, AROMATIC, NON-CATECHOLAMINE	ADZENYS ER	AMPHETAMINE	1.25 mg/mL	New Strength and Dosage Form
TOPICAL ANTI-INFLAMMATORY STEROIDAL	IMPOYZ	CLOBETASOL PROPIONATE	0.025 %	New Strength

NEW INDICATIONS (EXISTING DRUGS)

XGEVA®

January 5, 2018

Amgen (NASDAQ:AMGN) today announced that the U.S. Food and Drug Administration (FDA) has approved the supplemental Biologics License Application (sBLA) for XGEVA® (denosumab) to expand the currently approved indication for the prevention of skeletal-related events in patients with bone metastases from solid tumors to include patients with multiple myeloma. The approval is based on data from the pivotal Phase 3'482 study, the largest international multiple myeloma clinical trial ever conducted, which enrolled 1,718 patients.

Source: Amgen

FDA NEWS/BULLETINS/ADVISORIES/SAFETY ALERTS

Long-Acting Beta Agonists (LABAs) and Inhaled Corticosteroids (ICS): Drug Safety Communication - Boxed Warning About Asthma-Related Death Removed

[Posted 12/20/2017]

ISSUE: FDA's most prominent warning, the Boxed Warning, about asthma-related death has been removed from the drug labels of medicines that contain both an ICS and LABA. A FDA review of four large clinical safety trials shows that treating asthma with long-acting beta agonists (LABAs) in combination with inhaled corticosteroids (ICS) does not result in significantly more serious asthma-related side effects than treatment with ICS alone. A description of the four trials is now also included in the Warnings and Precautions section of the drug labels. These trials showed that LABAs, when used with ICS, did not significantly increase the risk of asthma-related hospitalizations, the need to insert a breathing tube known as intubation, or asthma-related deaths, compared to ICS alone.

BACKGROUND: In 2011, FDA required the drug companies manufacturing fixed-dose combination drugs containing an ICS and LABA (GlaxoSmithKline, Merck, Astra Zeneca) to conduct several large, 26-week, randomized, double-blind, active-controlled clinical safety trials to evaluate the risk of serious asthma-related events when long-acting beta agonists (LABAs) were used in fixed dose combination with an inhaled corticosteroid (ICS) compared to ICS alone in patients with asthma. FDA reviewed the results of four trials involving 41,297 patients. The results demonstrate that the use of ICS/LABA in fixed-dose combination does not result in a significant increase in the risk of serious asthma-related events compared to ICS alone. The results of subgroup analyses for gender, adolescents 12-18 years, and African Americans are consistent with the primary endpoint results.

The four trials also assessed efficacy of the ICS/LABA products. The primary efficacy endpoint was asthma exacerbation, defined as a deterioration of asthma requiring the use of systemic corticosteroids for at least 3 days, or an in-patient hospitalization or emergency department visit due to asthma that required systemic corticosteroids. The results showed that the ICS/LABA combination reduced asthma exacerbations compared to ICS alone, noting that the majority of these exacerbations were those that required at least 3 days of systemic corticosteroids. This efficacy information has been added to the Clinical Studies section of the ICS/LABA drug labels.

RECOMMENDATION: Health care professionals should refer to the most recently approved drug labels for recommendations on using ICS/LABA medicines (see links in Table 1 of the Drug Safety Communication). Patients and parents/caregivers should talk to your health care professional if you have any questions or concerns. Do not stop taking your asthma medicines without first talking to your health care professional. Also read the patient information leaflet that comes with every prescription.

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: Department of Health and Human Services

Pantoprazole Sodium for Injection 40 Mg Per Vial: Recall - Presence of Glass Particles

[Posted 12/20/2017]

ISSUE: AuroMedics Pharma LLC is voluntarily recalling one lot of Pantoprazole Sodium for Injection 40 mg per vial, to the hospital level. The product was found to contain glass particles in the vial. This problem was discovered as a result of a product complaint in which the contents of one vial from one batch was found to contain a piece of glass.

The administration of a glass particulate, if present in an intravenous drug, may result in local irritation or swelling in response to the foreign material. More serious potential outcomes would include blockage and clotting in blood vessels, which may be life-threatening.

The affected Pantoprazole Sodium for Injection lot being recalled is CPO170035, EXP. May 2019. AuroMedics commenced shipping the product to customers on August 7, 2017 and was distributed to wholesalers and/or hospitals nationwide. See the press release for product photo.

BACKGROUND: Pantoprazole Sodium for Injection 40 mg per vial, is used for short term treatment of gastroesophageal reflux disease associated with a history of erosive esophagitis and pathological hypersecretion including zollinger-ellison syndrome and is packaged in a carton containing 10 vials, NDC: 55150-202-10.

RECOMMENDATION: AuroMedics Pharma LLC is notifying its distributors and customers by recall letters and is arranging for return/replacement etc. of all recalled product. Consumers/distributors/retailers that have the product lot which is being recalled should immediately stop using and return to place of purchase/contact their doctor as appropriate.

Consumers with questions regarding this recall can contact Aurobindo Customer Service weekdays 9:00AM to 5:00PM EST at 866-850-2876 Option 1. If you need assistance in returning your product or have questions about the recall process, contact Inmar at 800-967-5952 weekdays Monday through Friday 8:30 AM to 5:00 PM EST. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

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

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

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

Linezolid Injection by Auromedics Pharma: Voluntary Recall - Due to Presence White Particle Matter That Has Been Identified as Mold

[Posted 12/26/2017]

ISSUE: AuroMedics Pharma is voluntarily recalling one lot of Linezolid Injection 600mg/300mL flexible bags, NDC 55150 -242 -51 batch CLZ160007 expiration August 2018 to the hospital level. This batch was distributed May 15 through August 14, 2017. The product was found to contain white particulate matter that has been identified as mold.

BACKGROUND: Linezolid injection is an oxazolidinone-class antibacterial indicated in adults and children for the treatment of the following infections caused by susceptible Gram-positive bacteria:

- Nosocomial pneumonia
- Community-acquired pneumonia
- Complicated skin and skin structure infections, including diabetic foot infections, without concomitant osteomyelitis
- Uncomplicated skin and skin structure infections
- Vancomycin-resistant Enterococcus faecium infections.

Linezolid injection is supplied as a ready-to-use sterile, clear colorless to slightly yellow color isotonic solution for intravenous infusion. Each 300 mL contains 600 mg of linezolid. Inactive ingredients are sodium citrate, citric acid, and dextrose in an aqueous vehicle for intravenous administration. The sodium (Na+) content is 0.38 mg/mL (5 mEq/300 mL bag). It is available in single-use, ready-to-use flexible plastic infusion bags in a foil laminate overwrap.

RECOMMENDATION: Healthcare professionals patients and consumers who have the product lot which is being recalled should immediately stop using and return to place of purchase/contact their doctor as appropriate.

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 preaddressed form, or submit by fax to 1-800-FDA-0178

Source: Department of Health and Human Services

Compounded Sterile Products by PharMEDium Services: Recall - Lack of Sterility Assurance
[Posted 1/2/2018]

ISSUE: PharMEDium Services is voluntarily recalling certain lots of drug products to the hospital/user level due to a lack of assurance of sterility. Administration of a drug product intended to be sterile that is not sterile could result in serious infections that may be life-threatening.

See the press release for a listing of affected products.

BACKGROUND: PharMEDium conducted a retrospective review of all commercially distributed product lots compounded in the Memphis location currently within their labeled expiration date in response to an FDA request regarding microbial control program during recent inspection to provide verification of acceptable microbiological testing results of the ISO5 environment, personnel glove sampling results, media fill results, sterility testing results, and endotoxin results. The review indicated that a total of 55 lots of different products impacting 25,327 units had two unsuccessful media fills. The remaining lots were associated with environmental monitoring or personnel monitoring excursions in the ISO 5 space on hood/surface and glove tip. Finished product release testing for both sterility and endotoxin were acceptable. Although there were no defects identified in these products, as a conservative measure, a recall is being initiated.

The recalled products were distributed nationwide in the USA to hospitals/clinics.

RECOMMENDATION: PharMEDium Services is notifying customers of the voluntary recall by phone. Customers that have any of the affected medications that are being recalled should immediately quarantine the product, discontinue use and destroy per their hospital protocol. Customers with any of the affected medications can also reference PharMEDium Services website for more information on the specific lot numbers affected and contact information: www.pharmedium.com.

Patients and healthcare providers with questions regarding this recall can contact PharMEDium Services Clinical Pharmacist at (847) 457-2220, Monday through Friday, between 8am and 5pm Central Standard Time or via e-mail at dantonio@pharmedium.com.

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

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

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

Ampicillin and Sulbactam for Injection USP 1.5 g/vial by Auromedics: Recall – Presence of Glass Particles in Vial
[Posted 1/4/2018]

ISSUE: AuroMedics Pharma is voluntarily recalling one lot of Ampicillin and Sulbactam for Injection USP, 1.5 g in a Single-Dose vial (equivalent to 1 g ampicillin as the sodium salt plus 0.5 g Sulbactam as the

sodium salt), to the hospital level. Lot AFO l 17001-A, Expiry date Dec 2018 has been found to contain glass particles.

The affected Ampicillin and Sulbactam for Injection lot is packaged in a carton containing 10 vials, NDC: 55150-116-20. The product can be identified as a 'clear vial stoppered with grey rubber stopper and sealed with aluminum seals having a Royal Blue color polypropylene disc'. AuroMedics shipped the entire lot to wholesalers and/or hospitals nationwide on February 9, 2017.

The administration of a glass particulate, if present in an intravenous drug, may result in local irritation or swelling in response to the foreign material. More serious potential outcomes would include blockage and clotting in blood vessels, which may be life-threatening.

BACKGROUND: The product Ampicillin and Sulbactam for Injection is used for treatment of infections due to susceptible strains of designated microorganism in skin and skin structure infections, intra¬abdominal infections and gynecological infections in adults and for in treatment of skin and skin structure infection in pediatric patient one year and older.

RECOMMENDATION: AuroMedics Pharma LLC is notifying its distributors and customers by recall letters and is arranging for return/replacement etc. of all recalled product. Consumers/distributors/retailers that have the product lot which is being recalled should immediately stop using and return to place of purchase/contact their doctor as appropriate.

Consumers with questions regarding this recall can contact AuroMedics Customer Service Monday through Friday from 9:00AM to 5:00PM EST at 888-238-7880 Option 1. If you need assistance in returning your product or have questions about the recall process, contact Inmar at 800-967-5952, Monday through Friday from 8:30 AM to 5:00 PM 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 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: Department of Health and Human Services

Clopidogrel Tablets USP, 75 mg by International Laboratories: Recall – Product Mislabeling

[Posted 01/10/2018]

ISSUE: International Laboratories, LLC is voluntarily recalling Lot# 117099A of Clopidogrel Tablets, USP 75 mg, packaged in bottles of 30 tablets, to the consumer level due to mislabeling. The product is labeled as Clopidogrel Tablets USP, 75 mg but may contain Clopidogrel 75mg or Simvastatin Tablets USP 10 mg.

Missed doses of Clopidogrel increases the risk of heart attack and stroke which can be life threatening. Patients should not stop taking clopidogrel without talking to their prescribing physician. Additionally, unintentional consumption of simvastatin could include the common side effects associated with its use and may cause fetal harm when administered to a pregnant woman. Simvastatin occasionally causes

myopathy which is a disease of the muscles. Finally, allergic reactions are also possible and could also be life threatening.

- NDC# 54458-888-16
- Lot# 117099A

BACKGROUND: Clopidogrel Tablets USP 75 mg are a platelet inhibitor (blood thinner) indicated for the use in patients with acute coronary syndrome, recent myocardial infarction (MI), recent stroke, or established peripheral arterial disease. Clopidogrel tablets have been shown to reduce the rate of MI and stroke.

The product was distributed nationwide and delivered to the distribution centers in Arkansas, Georgia, Indiana, California and Maryland, and distributed to retail stores in all US States.

RECOMMENDATION: International Laboratories, LLC is notifying distributors and customers by letter and is arranging for return of all recalled products. Consumers who have purchased this product should stop using and return the product to the location of purchase for a full refund. For questions regarding return of product please call Inmar at 855-258-7280 or via email internationallabs@inmar.com or by using mailing address Recall Coordinator, 635 Vine St., Winston Salem, NC 27101. Inmar's business hours are (Monday – Friday 9 AM – 5 PM EST).

Consumers should also contact their physician or healthcare provider if they are experiencing any health concerns that may be related to taking or using this drug product.

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

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

Source: Department of Health and Human Services

Certitude Delivery System by Edwards Lifesciences: Class I Recall - Mold Overflow Defect Which May Obstruct Blood Flow

[Posted 1/11/2018]

Model/Item Numbers: 9600CT20A, 9600CT23A, 9600CT26A, 9600CT29A, 9600SDS20A, 9600SDS23A, 9600SDS26A, 9600SDS29A

ISSUE: Edwards LifeSciences is recalling its Certitude Delivery System due to a molding overflow defect in the button valve within the loader. The overflow material could detach during placement of the delivery system and potentially embolize into the patient.

Such an embolism could obstruct blood flow to critical organs, leading to serious injury and/or a need to surgically extract the overflow material from the patient. In dire situations, severe neurologic, cardiac, limb, renal, or gastrointestinal injury may result.

- Lot Numbers: Select lot numbers between 60677270 and 60990824.
- Manufacturing Dates: November 22, 2016 to July 10, 2017
- Distribution Dates: January 9, 2017 to July 17, 2017

BACKGROUND: The Edwards LifeSciences Certitude Delivery System is used for delivery of the Edwards SAPIEN 3 transcatheter heart valve (THV), typically used during a transcatheter aortic valve replacement.

The Certitude Delivery System includes a balloon catheter that expands a compressed (crimped) THV, a loader that delivers the THV through the guiding tube, and extension tubing. During a procedure, the physician will first crimp the THV onto the balloon of the Certitude Delivery System. The Certitude Delivery System is then inserted into the body, usually during a transapical (inserted through small incision under left breast) or transaortic (inserted through small incision in the top right side of the chest) approach. The THV is then deployed through the guiding tube to the site of the native stenotic aortic valve, where it is expanded and fixed in place.

RECOMMENDATION: On July 21, 2017, Edwards LifeSciences sent affected customers a "Recall Notification Letter" informing them of the device's risks. In the letter, Edwards LifeSciences directed customers to:

- Complete the "Acknowledgement Form" that accompanied the Recall Notification Letter.
- Check all inventory for affected models of the Certitude Delivery System.
- Return the "Acknowledgement Form" and all affected models of the Certitude Delivery System to Edwards LifeSciences as indicated in the Recall Notification Letter.

Customers with questions regarding this recall may contact Edwards Customer Service at 1-800-424-3278, from 6:00 AM to 4:30 PM (Pacific Time).

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 preaddressed form, or submit by fax to 1-800-FDA-0178

Source: Department of Health and Human Services

Prescription Opioid Cough and Cold Medicines: Drug Safety Communication – FDA Requires Labeling Changes

[Posted 1/11/2018]

ISSUE: FDA is requiring safety labeling changes for prescription cough and cold medicines containing codeine or hydrocodone to limit the use of these products to adults 18 years and older because the risks of these medicines outweigh their benefits in children younger than 18. FDA is also requiring the addition of safety information about the risks of misuse, abuse, addiction, overdose, death, and slowed or difficult breathing to the Boxed Warning, the most prominent warning, of the drug labels for prescription cough and cold medicines containing codeine or hydrocodone.

Some codeine cough medicines are available OTC in a few states, and FDA is also considering regulatory action for these products.

FDA is taking this action after conducting an extensive review and convening a panel of outside experts. Both of these determined the risks of slowed or difficult breathing, misuse, abuse, addiction, overdose, and death with these medicines outweigh their benefits in patients younger than 18.

See the FDA Drug Safety Communication for a list of prescription cough and cold medicines containing codeine or hydrocodone

BACKGROUND: Codeine and hydrocodone are available in combination with other medicines, such as antihistamines and decongestants, in prescription medicines to treat coughs and symptoms associated with allergies or the common cold. Other non-opioid prescription and OTC medicines are available to treat these symptoms.

RECOMMENDATION: Health care professionals should be aware that FDA is changing the age range for which prescription opioid cough and cold medicines are indicated. These products will no longer be indicated for use in children, and their use in this age group is not recommended. Health care professionals should reassure parents that cough due to a cold or upper respiratory infection is self-limited and generally does not need to be treated. For those children in whom cough treatment is necessary, alternative medicines are available. These include over-the-counter (OTC) products such as dextromethorphan, as well as prescription benzonatate products.

Parents and caregivers should be aware that prescription opioid cough and cold medicines that include codeine or hydrocodone should not be used in children. Codeine and hydrocodone are narcotic medicines called opioids and may carry serious risks when used in children. It is important for parents and caregivers to understand that a cough due to a common cold often does not need medicines for treatment. If a cough medicine is prescribed, ask your child's health care professional or a pharmacist if it contains an opioid such as codeine or hydrocodone. Always read the labels on prescription bottles. If the medicine prescribed for your child contains an opioid, talk to your child's health care professional about a different, non-opioid medicine, or if you have any questions or concerns.

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: Department of Health and Human Services

STUDIES AND RECENT TOPICS

Looking ahead: Some of FDA's major policy goals for 2018
December 14, 2017

Twice a year the federal government publishes the "Unified Agenda of Federal Regulatory and Deregulatory Actions" (Unified Agenda), which provides the American public with insight into regulations under development or review throughout the federal government. For the U.S. Food and Drug Administration (FDA), it gives us an opportunity to outline some of our efforts to modernize our approach to our work and improve our efficiency, while fulfilling our mandate to protect and promote the public health and uphold FDA's gold standard for regulatory decision making. While many of FDA's polices are advanced through guidance documents and other proposals, this annual list of proposed regulations provides one element of our policy agenda.

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

FDA Says Tech Can Open Up Access to Prescription Drugs
DECEMBER 15, 2017

Imagine downloading an app, answering a series of questions, and gaining access to a medication that is otherwise gated to the public by way of a prescription. In 2018, that could become the new reality, according to the FDA.

Source: hcanews.com

FDA Targets Insulin for Increased Competition to Lower Prices
December 15, 2017

The Food and Drug Administration will add insulin, a life-saving drug used by millions of diabetics, to its campaign to add generic competitors to brand-name products the agency believes are part of the U.S.'s medical cost problem.

Source: bloomberg.com

A Bipartisan Approach on Drug Prices Is Emerging
December 14, 2017

Congress has found little to agree on when it comes to health care, but lawmakers from both parties appear to be warming up to ideas for reining in drug prices. While soaring prescription costs have drawn fire from across the political spectrum, action has been scant. There are signs however that a consensus is forming on Capitol Hill on how to curtail tactics that shield blockbuster medicines from competition.

Source: bloomberg.com

Jump in H3N2 flu prompts CDC warning, antiviral reminder
Dec 27, 2017

The US Centers for Disease Control and Prevention (CDC) today warned clinicians that flu activity has increased significantly in recent weeks, much of it from H3N2, which poses a heightened threat, especially to seniors and young children, and elevates the importance of prompt antiviral treatment.

Source: cidrap.umn.edu

Pharmacists Play Key Role in Protecting Children from Prescription Meds
December 27, 2017

LONDON (Reuters) - Pfizer's big-selling erectile dysfunction drug Viagra has been given a green light for sale without a prescription in Britain, the first country to grant it over-the-counter status.

Source: reuters.com

Life Expectancy Drops Again As Opioid Deaths Surge In U.S.
December 21, 2017

Life expectancy in the U.S. fell for the second year in a row in 2016, nudged down again by a surge in fatal opioid overdoses, federal officials report Thursday. "I'm not prone to dramatic statements," says Robert Anderson, chief of the mortality statistics branch at the National Center for Health Statistics. "But I think we should be really alarmed. The drug overdose problem is a public health problem, and it needs to be addressed. We need to get a handle on it."

Source: npr.org

Patients With T2D Taking Metformin Have Lowest Adherence
December 19, 2017

Patients with type 2 diabetes (T2D) that are prescribed metformin, the most commonly prescribed diabetes medication, are the least likely to subscribe to medical advice regarding their prescription—because of the adverse effects (AEs).

Source: mdmag.com

Broad-Spectrum Antibiotics Not the Best Bet in Kids with RTIs
December 19, 2017

Broad-spectrum antibiotics were not associated with better clinical outcomes, but their use was associated with higher rates of adverse events, researchers reported.

Source: reuters.com

FDA proposes tighter norms to grant orphan status for children's treatments
December 19, 2017

The U.S. Food and Drug Administration on Tuesday sought to tighten the norms for granting orphan drug status to treatments for children in a bid to clamp down on companies trying to use the special status to bypass pediatric drug trials.

Source: reuters.com

Smoking cessation drug may increase risk of adverse cardiovascular event

December 20, 2017

Varenicline, one of the most commonly prescribed drugs for helping people quit smoking, may put them at higher risk for a cardiovascular event, according to new research published online in the American Journal of Respiratory and Critical Care Medicine.

Source: sciencedaily.com

FDA to target 'potentially harmful, unproven' homeopathic drugs under new proposal

December 18, 2017

The Food and Drug Administration is planning to more aggressively regulate homeopathic drugs that are potentially harmful and unproven, reversing nearly three decades of policy. Homeopathic remedies use ingredients that can be dangerous, but are so diluted they're said to be safe and even cure illnesses. The FDA decided in 1988 that it would not use all the enforcement authority within its power to regulate such products.

Source: cnbc.com

The top 10 prospective blockbuster drug launches slated for 2018 — Evaluate

December 14, 2017

Everybody in biopharma talks about unmet medical needs when they review their late-stage pipeline, but it’s the market potential that will either whip up investors or leave them cold about any innovation. The top 10 prospective drug launches looming in 2018 — as selected by Evaluate in its 2018 preview — underscores all the potential of the would-be blockbusters that always dominate biopharma R&D news.

Source: endpts.com

CMS to cover Abbott's glucose monitoring device

January 4, 2018

Abbott Laboratories said on Thursday its newly launched glucose monitoring device would be covered by the Centers for Medicare & Medicaid Services, expanding its usage to millions of diabetes patients in the United States.

Source: reuters.com

The First Effective Drugs For Preventing Migraine May Be Available Soon

January 7, 2018

I suffer from migraines. At least once a month, I have excruciating head pain, sensory problems and intermittent bouts of vomiting. The attacks can last for two weeks or more. Migraines have a huge impact on every aspect of my life, so it is with excited anticipation that I await the US Food and Drug

Administration's decision on a new drug that could prevent these attacks. The FDA's decision is expected in the first half of 2018.

Source: ibtimes.com

Cancer Deaths Fall to Lowest Rate in Decades

January 04, 2018

Fewer Americans are getting cancer, and more of those who do are surviving the disease, according to a new study. In 2015, the most recent year with available data, cancer deaths dropped to 158.6 per 100,000 people, according to a report released Thursday by the American Cancer Society. That rate is 26 percent lower than in 1991, according to the report, or about 2.4 million fewer deaths over that period.

Source: bloomberg.com

Neurontin prescriptions surge amid opioid crisis

January 04, 2018

Prescriptions for nerve pain medicines like Neurontin and Lyrica have more than tripled in recent years, driven by increased use among chronically ill older adults and patients already taking opioids, a U.S. study suggests.

Source: reuters.com

Deaths and hospitalizations rise as flu season hits full swing

January 10, 2018

With flu season now in full swing — causing widespread illness in 46 states — health officials across the country are reporting waves of misery, rising hospitalizations and some deaths.
It is still too soon to say just how bad this flu season will be, but there are troubling signs in some places.

Source: usatoday.com

Copay Accumulators: Costly Consequences of a New Cost-Shifting Pharmacy Benefit

January 03, 2018

Let's kick off 2018 with a Last Jedi-themed look at copay accumulator programs—a benefit design option that I expect to become highly controversial this year. Accumulator programs target specialty drugs for which a manufacturer provides copayment assistance. Unlike conventional benefit designs, the manufacturer's payments no longer count toward a patient's deductible or out-of-pocket maximum.

Source: drugchannels.net

FDA again delays Portola's BLA for bleeding antidote to Eliquis, Xarelto

December 28, 2017

Pfizer and Bristol-Myers Squibb, as well as Bayer and Johnson & Johnson, were hoping to hear that a bleeding antidote for their blood thinners Eliquis and Xarelto would be approved early next year. Instead

they will have to wait at least until spring after the FDA again delayed consideration of AndexXa, a universal bleeding reversal agent being developed by Portola Pharmaceuticals.

Source: fiercepharma.com

New cholesterol calculation may avoid need to fast before testing, study suggests

January 2, 2018

In a direct comparison study, Johns Hopkins researchers have added to evidence that a newer method of calculating so-called "bad cholesterol" levels in the blood is more accurate than the older method in people who did not fast before blood was drawn. The research results, published in print on Jan. 2 in Circulation, suggest that routine fasting for cholesterol tests could be eliminated for most people, making such screening more convenient.

Source: medicalxpress.com

Drug makers raise 2018 U.S. prices, stick to self-imposed limits

January 2, 2018

Drug makers opened the new year by raising U.S. prices on dozens of medicines, but early data showed the increases generally remained within a 10 percent self-imposed limit in response to a backlash from consumers and politicians.

Source: reuters.com

These developments in diabetes care will shape the industry next year

December 29, 2017

Companies are racing to develop technology that makes it easier and simpler for the estimated 30.3 million Americans with diabetes to manage their blood sugar. About 9 percent of the population has the disease, according to the Centers for Disease Control and Prevention.

Source: cnbc.com

RECALLS

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drug	Mitomycin 40 mg/mL Preservative Free Irrigation Volume: 10 mL SDV , Compounded by: Premier Pharmacy Labs 8265 Commercial Way, Weeki Wachee, FL 34613, NDC: 69623-160-35.	Not Yet Classified	Lot: MIT100217SVDS BUD: 03/01/2018	Labeling: Not Elsewhere Classified: Mitomycin 40 mg/10 mL labeled incorrectly as Mitomycin 40 mg/mL.	Premier Pharmacy Labs Inc 8265 Commercial Way Weeki Wachee, FL 34613-4511
Drugs	NitroGlycerin 1 mg/10 mL in 5% Dextrose Inj, USP QS 10mL (100 mcg per mL), 10 mL Sterile single dose syringe, packaged in 5 x 5 (TWENTY FIVE) syringes per box, Rx only, Advanced Pharma, 9265 Kirby Dr., Houston, TX 77054, NDC 15082-818-61.	I	Lot: 4/17/17 0857 81861S, BUD 08/15/2017	Subpotent Drug: found to be below the specification for labeled assay.	Advanced Pharma Inc. 9265 Kirby Dr Houston, TX 77054-2520 United States
Drugs	NitroGlycerin (1 mg/5 mL) 1 mg in 5% Dextrose Inj, USP QS 5 mL (200 mcg per mL), 5 mL Sterile single dose syringe, packaged in 8 x 5 (FORTY) syringes per box, Rx only, Advanced Pharma, 9265 Kirby Dr., Houston, TX 77054, NDC 15082-863-67.	I	Lot: 4/10/17 1441 257-86367S, BUD 6/9/17; 4/17/17 0950 86367S, BUD¿6/16/2017; 4/20/17 1505 257-86367S, BUD 6/19/2017; 4/24/17 0115 15-86367S, BUD ¿6/23/2017; 4/26/17 0301 387-86367S, BUD 6/25/2017	Subpotent Drug: found to be below the specification for labeled assay.	Advanced Pharma Inc. 9265 Kirby Dr Houston, TX 77054-2520 United States
Drugs	NitroGlycerin (2 mg/10 mL in 5% Dextrose Inj, USP QS 10mL (200 mcg per mL), 10 mL Sterile single dose syringe, packaged in 5 x 5 (TWENTY FIVE) syringes per box, Rx only, Advanced Pharma, 9265 Kirby Dr., Houston, TX 77054, NDC 15082-863-61.	I	Lot: 4/19/17 1445 248-86361S, BUD¿6/18/2017	Subpotent Drug: found to be below the specification for labeled assay.	Advanced Pharma Inc. 9265 Kirby Dr Houston, TX 77054-2520 United States
Drugs	LaBri's Body Health Atomic 60 Capsules Exclusively distributed worldwide by LaBri's Body Health.	I	All lots remaining within expiry.	Marketed Without An Approved NDA/ANDA: Tainted Product Marketed As a Dietary Supplements: products found to be tainted with sibutramine making these unapproved drugs.	EZWeightLossTX LLC 3333 S Padre Island Dr Suite 102 Corpus Christi, TX 78415-2904

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drugs	LaBri's Body Health XPLODE 30 capsules Exclusively distribute worldwide by LaBri's Body Health.	I	All lots remaining within expiry.	Marketed Without An Approved NDA/ANDA: Tainted Product Marketed As a Dietary Supplements: products found to be tainted with sibutramine making these unapproved drugs.	EZWeightLossTX LLC 3333 S Padre Island Dr Suite 102 Corpus Christi, TX 78415-2904
Drugs	NATURAL HERBAL COFFEE AMPT, sold in 25g packages (UPC 6942630905), 10-count packages per box (UPC 6942630912); Manufactured For: The Ampt Life, LLC.	I	All lots	Marketed Without An Approved NDA/ANDA: FDA analysis found the product to contain undeclared sildenafil and tadalafil and undeclared milk. The presence of sildenafil and tadalafil makes AMPT Natural Herbal Coffee an unapproved drug for which safety and efficacy have not been established and, therefore, subject to recall. Additionally, this product has been found to contain undeclared milk, milk is recognized as one of the foods reported to have caused deaths due to anaphylactic shock in persons with underlying hypersensitivities.	The Ampt Life, LLC 5134 Navajo Dr Frisco, TX 75034-1275
Drugs	Lorazepam Oral Concentrate, USP, 2 mg/mL, 30 mL bottle, Rx only, Manufactured by: Amneal Pharmaceuticals Branchburg, NJ 08876. Distributed by: Amneal Pharmaceuticals, Glasgow, KY 42141. NDC 65162-687-84	I	Lot 06876016A, 06876017A, 06876018A, Exp 08/2018; 06876019A, 06876020A, 06876021A, 06876022A, Exp 09/2018; 06876023A, Exp 11/2018; 06876024A, 06876025A, Exp 12/2018; 06877001A, 06877002A, Exp 02/2019; 06877003A, Exp 03/2019.	Defective Delivery System: the dropper measurement markings may be reversed, shifted or missing.	Amneal Pharmaceuticals of New York, LLC 50 Horseblock Rd Brookhaven, NY 11719-9509
Drugs	Vancomycin Hydrochloride for Injection, USP. 750 mg. Sterile Powder. Rx Only. Hospira, Inc., Lake Forest, IL 60045 USA. NDC: 0409-6531-02	I	Lot: 632153A; Exp. 03/18	Presence of Particulate Matter: glass particulate found in vial	Pfizer Inc. 235 E 42nd St New York, NY 10017-5703
Drugs	Enhanced Vegetal Vigra 200 mg Capsules, 8 count bottles, Manufacturer: Hand-shaking (Int'l) Cop. USA, ADD: Hand-shaking Mansion, the 5th Ave., Stanford, USA --- UPC# 8931028556885	I	All lots, Exp. 02/23/2020	Marketed without an Approved NDA/ANDA; FDA analysis found product to be tainted with Sildenafil	Natures Supplement 2525 N Dixie Hwy Lake Worth, FL 33460-6250

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drugs	diphenoxylate hydrochloride and atropine sulfate tablets, USP, 2.5 mg/0.025 mg, a) 100-count bottle (NDC 59762-1061-1), b) 1000-count bottle (NDC 59762-1061-2), Rx Only, Distributed by: Greenstone LLC. Peapack, NJ 07977	I	Lots: a) R83962, R93347, R93348, R93349, R93350, R93351, R93352, Exp. 2021 OCT 31; S57831, S57832, S57834, Exp. 2021 NOV 30 b) R93356, R93357, R93358, R97310, Exp. 2021 OCT 31.	SUPERPOTENT: Weight variations resulting in tablets that are sub and super potent	Pfizer Inc. 235 E 42nd St New York, NY 10017-5703
Drugs	Midazolam Injection, USP, Preservative Free, 2 mg / 2 mL (1 mg / mL), 24 X 2mL Prefilled single-use syringes per carton, Rx only, Fresenius Kabi Lake Zurich, IL 60047, NDC 76045-001-20	I	Lot: 6400048	Labeling: Label MIX-UP. Blister Packages, Labeled as Midazolam injection, USP, 2 mg / 2 ml, Containing Syringes of Ondansetron Injection, USP, 4 mg / 2 mL	Fresenius Kabi USA, LLC 5200 Corporate Pkwy Wilson, NC 27893-9412
Drugs	NitroGlycerin 1 mg/10 mL in 5% Dextrose Inj, USP QS 10mL (100 mcg per mL), 10 mL Sterile single dose syringe, packaged in 5 x 5 (TWENTY FIVE) syringes per box, Rx only, Advanced Pharma, 9265 Kirby Dr., Houston, TX 77054, NDC 15082-818-61.	II	Lot: 3/3/17 1830 81861S, BUD 07/01/17; 3/27/17 0658 81861S, BUD 7/25/17	Stability Data Does Not Support Expiry: lots do not have stability that supports the use of the container system.	Advanced Pharma Inc. 9265 Kirby Dr Houston, TX 77054-2520 United States
Drugs	NitroGlycerin 100 mcg/mL QS 5% Dextrose Inj, USP (2 mg per 20 mL) 20 mL Sterile single dose syringe, packaged in 10 x 5 (FIFTY) syringes per box, Rx only, Advanced Pharma, 9265 Kirby Dr., Houston, TX 77054, NDC 15082-818-62.	II	Lot: 5/31/17 0202 5-81862S, BUD 7/30/17	Stability Data Does Not Support Expiry: lots do not have stability that supports the use of the container system.	Advanced Pharma Inc. 9265 Kirby Dr Houston, TX 77054-2520 United States
Drugs	NitroGlycerin (1 mg/5 mL) 1 mg in 5% Dextrose Inj, USP QS 5 mL (200 mcg per mL), 5 mL Sterile single dose syringe, packaged in 8 x 5 (FORTY) syringes per box, Rx only, Advanced Pharma, 9265 Kirby Dr., Houston, TX 77054, NDC 15082-863-67.	II	Lot: 4/26/17 0730 20-86367S, BUD 6/25/17; 4/24/17 0106 241-86367S, BUD 6/23/17; 5/1/17 1500 45-86367S, BUD 6/30/17; 5/9/17 1103 241-86367S, BUD 7/8/17; 5/9/17 1104 257-86367S, BUD 7/8/17; 5/12/17 0839 15-86367S, BUD 7/11/17; 5/19/17 0109 15-86367S, BUD 7/18/17; 5/22/17 0828 387-	Stability Data Does Not Support Expiry: lots do not have stability that supports the use of the container system.	Advanced Pharma Inc. 9265 Kirby Dr Houston, TX 77054-2520 United States

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
			86367S, BUD 7/21/17; 5/23/17 0721 257-86367S, BUD 7/22/17; 5/24/17 0200 241-86367S, BUD 7/23/17; 5/24/17 0203 20-86367S, BUD 7/23/17; 5/26/17 0315 15-86367S, BUD 7/25/17; 5/31/17 1217 20-86367S, BUD 7/30/17		
Drugs	NitroGlycerin (2 mg/10 mL in 5% Dextrose Inj, USP QS 10mL (200 mcg per mL), 10 mL Sterile single dose syringe, packaged in 5 x 5 (TWENTY FIVE) syringes per box, Rx only, Advanced Pharma, 9265 Kirby Dr., Houston, TX 77054, NDC 15082-863-61.	II	Lot: 4/20/17 0307 265-86361S, BUD 6/19/17; 4/26/17 0732 265-86361S, BUD 6/25/17; 4/28/17 0215 265-86361S, BUD 6/27/17; 5/2/17 0310 248-86361S, BUD 7/1/17; 5/4/17 1422 248-86361S, BUD 7/3/17; 5/12/17 0841 248-86361S, BUD 7/11/17; 5/18/17 0206 250-86361S, BUD 7/17/17	Stability Data Does Not Support Expiry: lots do not have stability that supports the use of the container system.	Advanced Pharma Inc. 9265 Kirby Dr Houston, TX 77054-2520
Drugs	Neostigmine Methylsulfate (single dose syringe) 1 mg per mL 5 mg per 5 mL Injectable Hospital/Office Use Only Compounded by: Premier Pharmacy Labs., Inc. 8265 Commercial Way Weeki Wachee, FL 34613, NDC# 69623-234-15	II	Lot # NEO071317MMD SA BUD: 01/19/2018 Lot # NEO071317MMD SC BUD: 01/19/2018 Lot # NEO071317MMD SF BUD: 01/19/2018	Stability Date Doesn't Support Expiry: labeling error indicating a beyond use date that exceeds current stability data.	Premier Pharmacy Labs Inc 8265 Commercial Way Weeki Wachee, FL 34613-4511
Drugs	Maximum Strength Zephrex-D, Pseudoephedrine HCl, 30 mg, Nasal Decongestant. 24 softgel tablets per paper carton, Distributed by Perrigo, Allegan, MI 49010, NDC 70085-151-01	II	Lot # AF4273A; Exp. 02/18	Microbial Contamination of Non-Sterile Products	L. Perrigo Company 515 Eastern Ave Allegan, MI 49010-9070

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drugs	Amethyst (Levonorgestrel and Ethinyl Estradiol Tablets USP, 90mcg/20mcg), 28 tablet dispenser (blister foil unit), Rx only, Manufactured by: Warner Chilcott Company, LLC Fajardo, Puerto Rico 00738: Distributed by: Actavis Pharma, Inc. Parsippany, NJ 07054 USA, NDC-52544-295-28	II	Lot # 544637A	Labeling: Incorrect Instructions. "TABLETS IN WEEK 4 ARE INACTIVE" printed on the blister foil and package insert, however, all tablets are active.	Teva Pharmaceuticals USA 1090 Horsham Rd North Wales, PA 19454-1505
Drugs	0.25% Acetic Acid Irrigation USP, 500 mL Plastic Irrigation Container (PIC), B. Braun Medical Inc. Irvine CA 92614-5895 USA, NDC 0264-2304-10	II	Lot #: J7N965, Exp. 10/31/2020	Presence of Particulate Matter: identified as polyethylene, which is consistent with the material used to manufacture the contain cap	B. Braun Medical Inc 2525 McGaw Ave Irvine, CA 92614-5841
Drugs	Alcohol Prep Pads (Isopropyl Alcohol USP 70% v/v), 100 Individual Pads, Sterile, Distributed by Simple Diagnostics, Winston Park, NY NDC 98302-0001-05	II	Lot # SD2070420925 Exp. Date 09/2019, and Lot # SD2070421201 and Lot # SD2070420601, Exp. Date 12/2019	Lack of Assurance of Sterility and cGMP Deviations	Simple Diagnostics, Inc. 11555 Heron Bay Blvd Ste 200 Coral Springs, FL 33076-3362
Drugs	Fentanyl 10 mcg in 0.9% Sodium Chloride 1 mL, 1 mL Vial, Concentration: 10 mcg/mL, This is a compounded injectable drug; Rx only; Hospital/office use only. SSM St. Clare Outsourcing Facility, Fenton, MO. --- NDC: 88890-9010-81	II	Lot: 170614-006, exp 9/12/2017	Lack of sterility assurance: Microbial growth detected during a routine simulation of the manufacturing process. No batches of distributed product have been identified as actually containing microorganisms.	SSM Health Care St. Louis DBA SSM St. Clare Health Center 1015 Bowles Ave Fenton, MO 63026-2394
Drugs	Amiodarone 900 mg in dextrose 5% 500 mL, 500 mL bag, Concentration: 1.8 mg/mL, This is a compounded injectable drug; Rx only; Hospital/office use only. SSM St. Clare Outsourcing Facility, Fenton, MO. --- NDC: 88890-0333-01	II	Lot: 170711-005, 10/09/2017	Lack of sterility assurance: Microbial growth detected during a routine simulation of the manufacturing process. No batches of distributed product have been identified as actually containing microorganisms.	SSM Health Care St. Louis DBA SSM St. Clare Health Center 1015 Bowles Ave Fenton, MO 63026-2394
Drugs	Fentanyl 2 mcg/mL and ropivacaine 0.2% in 0.9% Sodium Chloride 150 mL, 150 mL bag, This is a compounded injectable drug; Rx only; Hospital/office use only. SSM St. Clare Outsourcing Facility, Fenton, MO. --- NDC: 88883-4272-01	II	Lot, exp: 170621-008, 09/19/2017; 170703-002, 10/01/2017; 170711-031, 10/09/2017	Lack of sterility assurance: Microbial growth detected during a routine simulation of the manufacturing process. No batches of distributed product have been identified as actually containing microorganisms.	SSM Health Care St. Louis DBA SSM St. Clare Health Center 1015 Bowles Ave Fenton, MO 63026-2394

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drugs	HYDROmorphone 10 mg in 0.9% Sodium Chloride 50 mL PCA, 50 mL Cartridge, Concentration: 0.2 mg/mL., This is a compounded injectable drug; Rx only; Hospital/office use only. SSM St. Clare Outsourcing Facility, Fenton, MO. --- NDC: 88883-0600-01	II	Lot, exp: 170615-004, 9/13/2017; 170720-009, 10/18/2017	Lack of sterility assurance: Microbial growth detected during a routine simulation of the manufacturing process. No batches of distributed product have been identified as actually containing microorganisms	SSM Health Care St. Louis DBA SSM St. Clare Health Center 1015 Bowles Ave Fenton, MO 63026-2394
Drugs	Morphine 50 mg in 0.9% Sodium Chloride 5 mL PCA, 50 mL Cartridge, Concentration: 1 mg/mL, This is a compounded injectable drug; Rx only; Hospital/office use only. SSM St. Clare Outsourcing Facility, Fenton, MO. --- NDC: 88887-6795-01	II	Lot, exp: 170627-012, 9/25/2017; 170629-019, 9/27/2017	Lack of sterility assurance: Microbial growth detected during a routine simulation of the manufacturing process. No batches of distributed product have been identified as actually containing microorganisms.	SSM Health Care St. Louis DBA SSM St. Clare Health Center 1015 Bowles Ave Fenton, MO 63026-2394
Drugs	Neostigmine Methylsulfate 5 mg/5 mL, 5 mL Syringe, Concentration: 1 mg/mL. This is a compounded injectable drug; Rx only; Hospital/office use only. SSM St. Clare Outsourcing Facility, Fenton, MO --- NDC: 88890-0329-01	II	Lot: 170705-002, 10/03/2017	Lack of sterility assurance: Microbial growth detected during a routine simulation of the manufacturing process. No batches of distributed product have been identified as actually containing microorganisms.	SSM Health Care St. Louis DBA SSM St. Clare Health Center 1015 Bowles Ave Fenton, MO 63026-2394
Drugs	Norepinephrine 8 mg in dextrose 5% 250 mL, 250mL IV Bag, Concentration: 0.032 mg/mL, This is a compounded injectable drug; Rx only; Hospital/office use only. SSM St. Clare Outsourcing Facility, , Fenton, MO --- NDC: 88890-0334-01	II	Lot, exp: 170614-007, 9/12/2017; 170628-001, 9/26/2017; 170703-017, 10/1/2017; 170706-009, 10/4/2017; 170719-007, 10/17/2017	Lack of sterility assurance: Microbial growth detected during a routine simulation of the manufacturing process. No batches of distributed product have been identified as actually containing microorganisms	SSM Health Care St. Louis DBA SSM St. Clare Health Center 1015 Bowles Ave Fenton, MO 63026-2394
Drugs	Oxytocin 30 units in 0.9% Sodium Chloride 500 mL, 500 mL IV Bag, Concentration: 0.06 units/mL. This is a compounded injectable drug; Rx only; Hospital/office use only. SSM St. Clare Outsourcing Facility, Fenton, MO --- NDC: 88890-0903-01	II	Lot, exp: 170619-011, 9/17/2017; 170707-007, 10/5/2017; 170713-009, 10/11/2017	Lack of sterility assurance: Microbial growth detected during a routine simulation of the manufacturing process. No batches of distributed product have been identified as actually containing microorganisms	SSM Health Care St. Louis DBA SSM St. Clare Health Center 1015 Bowles Ave Fenton, MO 63026-2394
Drugs	Phenylephrine 1000 mcg in 0.9% Sodium Chloride 10 mL, 10 mL syringe, Concentration: 100 mcg/mL. This is a compounded injectable drug; Rx only; Hospital/office use only. SSM St. Clare Outsourcing Facility, Fenton, MO --- NDC: 88890-0104-01	II	Lot, exp: 170622-007, 9/20/2017; 170710-007, 10/8/2017	Lack of sterility assurance: Microbial growth detected during a routine simulation of the manufacturing process. No batches of distributed product have been identified as actually containing microorganisms	SSM Health Care St. Louis DBA SSM St. Clare Health Center 1015 Bowles Ave Fenton, MO 63026-2394

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drugs	Succinylcholine chloride 100 mg in 5 mL syringe, Concentration: 20 mg/mL. This is a compounded injectable drug; Rx only; Hospital/office use only. SSM St. Clare Outsourcing Facility, Fenton, MO --- NDC: 88890-7536-01	II	Lot, exp: 170620-005, 9/18/2017; 170626-003, 9/24/2017	Lack of sterility assurance: Microbial growth detected during a routine simulation of the manufacturing process. No batches of distributed product have been identified as actually containing microorganisms	SSM Health Care St. Louis DBA SSM St. Clare Health Center 1015 Bowles Ave Fenton, MO 63026-2394
Drugs	Zoloft (sertraline HCl) tablets 25 mg* 30-count bottle, Rx only, Distributed by Roerig Division of Pfizer Inc., NY, NY, 10017 NDC 0049-4960-30	II	Lot: S84026	SUPERPOTENT: Weight variations resulting in tablets that are sub and super potent	Pfizer Inc. 235 E 42nd St New York, NY 10017-5703
Drugs	Sterile Eyewash (sterile isotonic phosphate buffered saline solution), 1 oz. 144 units per box. Manufactured by Medex Cardio-Pulmonary Inc. d.b.a. Smiths Medical Company, 300 Corporate Woods Pkwy, Vernon Hills. Illinois, USA 60061 Model Number: 32-005582.	II	Lot: Z516	Lack of sterility assurance: leaking containers which could lead to exposure to infectious agents.	Medex Cardio-Pulmonary Inc., d.b.a. Smiths Medical Company 330 Corporate Woods Pkwy Vernon Hills, IL 60061-3107
Drugs	Sterile Eyewash (sterile isotonic phosphate buffered saline solution), 4 oz. 24 units per box. Manufactured by Medex Cardio-Pulmonary Inc. d.b.a. Smiths Medical Company, 300 Corporate Woods Pkwy, Vernon Hills. Illinois, USA 60061. Model Number: 32-005583	II	Lot: A225	Lack of sterility assurance: leaking containers which could lead to exposure to infectious agents.	Medex Cardio-Pulmonary Inc., d.b.a. Smiths Medical Company 330 Corporate Woods Pkwy Vernon Hills, IL 60061-3107
Drugs	Sterile Eyewash (sterile isotonic phosphate buffered saline solution), 16 oz. 12 units per box. Manufactured by Medex Cardio-Pulmonary Inc. d.b.a. Smiths Medical Company, 300 Corporate Woods Pkwy, Vernon Hills. Illinois, USA 60061. Model Number: 32-005585	II	Lot: A259, A260, EXP 05-26-2018; A301, 06-23-2018; B117, B118, EXP 03-02-2019; C005, EXP 01-09-2020; C219, EXP 05-24-2020; Z521, EXP 10-06-2017	Lack of sterility assurance: leaking containers which could lead to exposure to infectious agents.	Medex Cardio-Pulmonary Inc., d.b.a. Smiths Medical Company 330 Corporate Woods Pkwy Vernon Hills, IL 60061-3107
Drugs	Sterile Eyewash (sterile isotonic phosphate buffered saline solution), 32 oz. 12 units per box. Manufactured by Medex Cardio-Pulmonary Inc. d.b.a. Smiths Medical Company, 300 Corporate Woods Pkwy, Vernon Hills. Illinois, USA 60061. Model Number: 32-005587	II	Lot: A257, EXP 05-20-2018; A258, EXP 05-19-2018; B017, EXP 01-12-2019; B116, B119, EXP 05-03-2019; B120, EXP 05-04-2019; B131, EXP 05-05-2019; Z535, EXP 10-13-2017; Z638, EXP 12-19-2017.	Lack of sterility assurance: leaking containers which could lead to exposure to infectious agents.	Medex Cardio-Pulmonary Inc., d.b.a. Smiths Medical Company 330 Corporate Woods Pkwy Vernon Hills, IL 60061-3107

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drugs	Anastrozole 0.5 mg Capsules, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.	II	Lots: 03092017@21 BUD: 3/9/2018; 03292017@33 BUD: 3/24/2018; 05092017@38 BUD: 5/4/2018; 05162017@31 BUD: 5/11/2018; 05182017@25 BUD: 5/13/2018; 07032017@40 BUD: 6/28/2018; 07142017@34 BUD: 7/9/2018; 07192017@32 BUD: 7/14/2018; 08282017@25 BUD: 8/23/2018; 09142017@8BUD: 9/9/2018; 09212017@23 BUD: 9/16/2018; 09272017@36 BUD: 9/ 22/2018; 10162017@39 BUD: 10/11/2018; 11032017@28 BUD: 10/29/2018	Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.	KRS Global Biotechnology, Inc 791 Park of Commerce Blvd Ste 600 Boca Raton, FL 33487-3633
Drugs	Amphotericin 60 mg/Chloramphenicol 600 mg/Hydrocortisone 10 mg Otic Powder packaged in jars, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.	II	Lot: 07282017@25 BUD: 1/24/2018	Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.	KRS Global Biotechnology, Inc 791 Park of Commerce Blvd Ste 600 Boca Raton, FL 33487-3633
Drugs	Anastrozole SR 1 mg Capsules, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.	II	Lots: 02022017@30 BUD: 1/28/2018; 04172017@29 BUD: 4/12/2018; 05082017@39 BUD: 5/3/2018; 05222017@23 BUD: 5/17/2018; 06072017@28 BUD: 6/2/2018; 06122017@42 BUD: 6/7/2018; 06192017@24 BUD: 6/14/2018; 06292017@25 BUD: 6/24/2018; 07112017@33 BUD: 7/6/2018; 07172017@35 BUD: 7/12/2018; 07282017@26	Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.	KRS Global Biotechnology, Inc 791 Park of Commerce Blvd Ste 600 Boca Raton, FL 33487-3633

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
			BUD: 7/23/2018; 08012017@25 BUD: 7/27/2018; 08112017@35 BUD: 8/9/2018; 08142017@30 BUD: 8/9/2018; 08172017@31 BUD: 8/12/2018; 09202017@21 BUD: 9/15/2018; 09142017@27 BUD: 9/9/2018; 10022017@38 BUD: 3/31/2018; 10102017@37 BUD: 4/8/2018; 10172017@26 BUD: 4/15/2018; 10202017@22 BUD: 4/18/2018; 10302017@29 BUD: 4/28/2018		
Drugs	Arginine 150 mg/ Lysine HCl 50 mg/ Glutamine 200 mg/g Topical Cream packaged in jars, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd Boca Raton, FL 33487.	II	Lot: 05242017@54 BUD: 11/20/2017	Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.	KRS Global Biotechnology, Inc 791 Park of Commerce Blvd Ste 600 Boca Raton, FL 33487-3633
Drugs	Benzocaine 20%, Lidocaine 6%, Tetracaine 4% Cream packaged in jars, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.	II	Lots: 06072017@22 BUD: 12/4/2017; 06222017@30 BUD: 12/19/2017; 08032017@31 BUD: 1/30/2018; 09212017@21 BUD: 3/20/2018; 10232017@20 BUD: 11/22/2017	Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.	KRS Global Biotechnology, Inc 791 Park of Commerce Blvd Ste 600 Boca Raton, FL 33487-3633
Drugs	Benzocaine 20%, Lidocaine 8%, Tetracaine 4% Topical Cream packaged in jars, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.	II	Lots: 07142017@31 BUD: 1/10/2018; 09202017@22 BUD: 3/19/2018; 10042017@25 BUD: 4/2/2018	Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.	KRS Global Biotechnology, Inc 791 Park of Commerce Blvd Ste 600 Boca Raton, FL 33487-3633
Drugs	Benzo/Lido/Tetracaine 20%-8%-8% Topical Cream packaged in jars, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.	II	Lots: 06072017@38 BUD: 12/4/2017; 07062017@48 BUD: 1/2/2018; 08012017@23 BUD: 1/28/2018; 08212017@36 BUD: 2/17/2018;	Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.	KRS Global Biotechnology, Inc 791 Park of Commerce Blvd Ste 600 Boca Raton, FL 33487-3633

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
			09182017@26 BUD: 3/17/2018		
Drugs	Bi-Est (Estriol/Estradiol) (80/20) + Progesterone 7.5 mg/200 mg Cream packaged in jars, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd Boca Raton, FL 33487.	II	Lot: 08172017@39 BUD: 12/15/2017	Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.	KRS Global Biotechnology, Inc 791 Park of Commerce Blvd Ste 600 Boca Raton, FL 33487-3633
Drugs	Chloramphenicol 50 mg/ Sulfamethoxazole 50 mg/ Amphotericin-B 5 mg capsules, For OTIC Use Only, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.	II	Lot: 08212017@24 BUD: 2/17/2018	Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.	KRS Global Biotechnology, Inc 791 Park of Commerce Blvd Ste 600 Boca Raton, FL 33487-3633
Drugs	Chloramphenicol 500 mg Amphotericin 50 mg Otic Powder packaged in jars, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.	II	Lot: 08162017@32 BUD: 2/12/2018	Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.	KRS Global Biotechnology, Inc 791 Park of Commerce Blvd Ste 600 Boca Raton, FL 33487-3633
Drugs	Chloramphenicol 500 mg Sulfamethoxazole 500 mg Amphotericin 50 mg Otic Powder packaged in jars, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.	II	Lots: 07282017@24 BUD: 1/24/2018; 08162017@33 BUD: 2/12/2018	Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.	KRS Global Biotechnology, Inc 791 Park of Commerce Blvd Ste 600 Boca Raton, FL 33487-3633
Drugs	Estriol 0.1% (1 mg/gm) Cream packaged in jars, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.	II	Lot: 07182017@45 BUD: 1/14/2018	Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.	KRS Global Biotechnology, Inc 791 Park of Commerce Blvd Ste 600 Boca Raton, FL 33487-3633
Drugs	Human Chorionic Gonadotropin 500 iu Orally Disintegrating Tablets (ODT), Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.	II	Lot: 06132017@22 BUD: 12/10/2017	Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.	KRS Global Biotechnology, Inc 791 Park of Commerce Blvd Ste 600 Boca Raton, FL 33487-3633
Drugs	Human Chorionic Gonadotropin 2,500 Units, Vial-Lyophilized, For SC Use, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.	II	Lots: 06212017@19 BUD: 12/18/2017; 10052017@1 BUD: 4/3/2018	Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.	KRS Global Biotechnology, Inc 791 Park of Commerce Blvd Ste 600 Boca Raton, FL 33487-3633

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drugs	Human Chorionic Gonadotropin 5,000 iu/ Vial Lyophilized, For SC Use, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.	II	Lots: 06132017@2 BUD: 12/10/2017; 07262017@17 BUD: 1/22/2018; 10032017@1 BUD: 4/1/2018	Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.	KRS Global Biotechnology, Inc 791 Park of Commerce Blvd Ste 600 Boca Raton, FL 33487-3633
Drugs	Human Chorionic Gonadotropin 6,000 iu/Vial, For SC Use - Lyophilized, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.	II	Lot: 08302017@11 BUD: 2/26/2018	Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.	KRS Global Biotechnology, Inc 791 Park of Commerce Blvd Ste 600 Boca Raton, FL 33487-3633
Drugs	Human Chorionic Gonadotropin 11,000 iu/Vial Lyophilized For SC Use, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.	II	Lots: 06222017@10 BUD: 12/19/2017; 09272017@14 BUD: 3/26/2018; 05312017@5 BUD: 11/27/2017; 07192017@8 BUD: 1/15/2018	Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.	KRS Global Biotechnology, Inc 791 Park of Commerce Blvd Ste 600 Boca Raton, FL 33487-3633
Drugs	Human Chorionic Gonadotropin 20,000 iu/Vial, Lyophilized - For SC Use, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.	II	Lots: 06082017@33 BUD: 12/5/2017; 06152017@4 BUD: 12/12/2017; 07272017@4 BUD: 1/23/2018; 10042017@22 BUD: 4/2/2018; 09282017@3 BUD: 3/27/2018	Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.	KRS Global Biotechnology, Inc 791 Park of Commerce Blvd Ste 600 Boca Raton, FL 33487-3633
Drugs	Hydroquinone 8%/ Tretinoin 0.1% Topical Ointment packaged in jars, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.	II	Lot: 08222017@37 BUD: 11/20/2017	Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.	KRS Global Biotechnology, Inc 791 Park of Commerce Blvd Ste 600 Boca Raton, FL 33487-3633
Drugs	Hydroxocobalamin 0.5 mg/mL For Diluent Purpose Only 10 mL Vial, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.	II	Lot: 10102017@9 BUD: 2/7/2018	Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.	KRS Global Biotechnology, Inc 791 Park of Commerce Blvd Ste 600 Boca Raton, FL 33487-3633
Drugs	Hydroxocobalamin 1 mg/mL 30 mL Vial For IM Use, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL	II	Lot: 10162017@20 BUD: 2/13/2018	Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make	KRS Global Biotechnology, Inc 791 Park of Commerce Blvd Ste 600

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
	33487.			final product.	Boca Raton, FL 33487-3633
Drugs	Iodochlorhydroxyquin 3%/ Boric Acid 10%/ Amphotericin 5% Otic Powder packaged in jars, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.	II	Lot: 07282017@23 BUD: 1/24/2018	Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.	KRS Global Biotechnology, Inc 791 Park of Commerce Blvd Ste 600 Boca Raton, FL 33487-3633
Drugs	Liothyronine SR (T3) 20 mcg Capsule, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd Boca Raton, FL 33487.	II	Lots: 05022017@24 BUD: 4/27/2018; 10122017@21 BUD: 4/10/2018; 11062017@38 BUD: 5/5/2018; 08252017@28 BUD: 8/20/2018	Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.	KRS Global Biotechnology, Inc 791 Park of Commerce Blvd Ste 600 Boca Raton, FL 33487-3633
Drugs	Methylene Blue (PF) 10 mg/mL (1%) Injectable Vial, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.	II	Lot: 09252017@7 BUD: 12/24/2017	Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.	KRS Global Biotechnology, Inc 791 Park of Commerce Blvd Ste 600 Boca Raton, FL 33487-3633
Drugs	Nicotinamide Adenine Dinucleotide 500 mg packaged in vials, Lyophilized-For IV Use, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.	II	Lot: 06062017@3 BUD: 12/3/2017	Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.	KRS Global Biotechnology, Inc 791 Park of Commerce Blvd Ste 600 Boca Raton, FL 33487-3633
Drugs	Oxytocin 30 Units in 0.9% Sodium Chloride Solution (PF) IV Bag, For IV Infusion Use, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.	II	Lots: 10112017@10 BUD: 1/9/2018; 10252017@9 BUD: 1/23/2018	Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.	KRS Global Biotechnology, Inc 791 Park of Commerce Blvd Ste 600 Boca Raton, FL 33487-3633
Drugs	PrednisoLONE 10 mg Tablet, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.	II	Lot: 07172017@40 BUD: 1/13/2018	Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.	KRS Global Biotechnology, Inc 791 Park of Commerce Blvd Ste 600 Boca Raton, FL 33487-3633
Drugs	Progesterone 3% Topical Cream packaged in jars, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.	II	Lot: 09212017@22 BUD: 3/20/2018	Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.	KRS Global Biotechnology, Inc 791 Park of Commerce Blvd Ste 600 Boca Raton, FL 33487-3633

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drugs	QUADMIX #16, 5 mL Vial, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.	II	Lot: 05242017@27 BUD: 11/20/2017	Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.	KRS Global Biotechnology, Inc 791 Park of Commerce Blvd Ste 600 Boca Raton, FL 33487-3633
Drugs	QUADMIX #18, 5 mL Vial, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.	II	Lot: 05242017@29 BUD: 11/20/2017	Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.	KRS Global Biotechnology, Inc 791 Park of Commerce Blvd Ste 600 Boca Raton, FL 33487-3633
Drugs	Savinase 100 mcg/mL Topical Solution, 1 mL in a 3 mL Droptainer, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487	II	Lot: 06262017@31 BUD: 6/26/2018	Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.	KRS Global Biotechnology, Inc 791 Park of Commerce Blvd Ste 600 Boca Raton, FL 33487-3633
Drugs	Sermorelin 500 mcg Orally Disintegrating Tablets (ODT), Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.	II	Lot: 07112017@32 BUD: 1/7/2018	Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.	KRS Global Biotechnology, Inc 791 Park of Commerce Blvd Ste 600 Boca Raton, FL 33487-3633
Drugs	Valsartan Tablets, USP, 160 mg, 90-count bottles, Rx Only, Manufactured by: Zhejiang Huahai Pharmaceutical Co., Ltd, Xunqiao, Linhai, Zhejiang 317024, China; Distributed by: Solco Healthcare US, LLC, Cranbury, NJ 08512, USA; NDC 43547-369-09.	II	Lot #: 343B17025, Exp 03/31/19	Failed Tablet/Capsule Specifications: confirmed customer complaint of thicker and heavier tablets in bottle.	Prinston Pharmaceutical Inc 2002 Eastpark Blvd Cranbury, NJ 08512-3514
Drugs	Viokace (pancrelipase) tablets, 20,880 USP units, 100-count bottle, Rx only, Distributed by; Allergan USA Inc., Irvine, CA 92612, Manufactured in Canada, NDC 58914-117-10	II	Lot #: 160741A, Exp 02/18	Subpotent Drug: One lot of Viokace is being recalled since product stability testing results did not meet the specifications for enzyme profile.	ALLERGAN 1 Giralda Farms Madison, NJ 07940-1027
Drugs	FOR EXPORT ONLY Atorvastatin calcium Film-Coated Tablets a) 80 mg SMT Tabs Bulk, b) 40 mg SMT G EP PR KR, c) 20 mg SMT G EP PR, d) 20 mg SMT G EP PR KR, FOR MANUFACTURING, PROCESSING OR REPACKAGING	II	Bulk Product Batch # (Packaged Lot#) a) S55350 Exp. 20 APR 2018, S55378 Exp. 07 MAR 2018, S55386 Exp. 14 MAR 2018, S53284 Exp.14 FEB 2018, S53283 Exp. 10 FEB 2018; b) S53287 Exp. 16 FEB 2018,	Microbial Contamination of Non-Sterile Products	Pfizer Manufacturing Deutschland GmbH Pfizer GmbH Arzneimittelwerk Godecke (Betriebsstatte Freiburg) Freiburg im Breisgau

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
			S33417 Exp. 03 FEB 2018; c) S33445 Exp. 17 FEB 2018, S33452 Exp. 24 FEB 2018; d) S33397 Exp. 07 FEB 2018		
Drugs	Gabapentin Tablets, USP, 800 mg, 500-count, Rx only, Made in India, PONDRUGS/16 134193, Distributed by: Solco Healthcare US, LLC, Cranbury, NJ, 08512, USA. NDC 43547-0333-50	II	Lot # 7700656A	Labeling: Label Mix-Up. Some bottles labeled as Gabapentin 800 mg contain Gabapentin 600 mg	Solco Healthcare US LLC 2002 Eastpark Blvd Ste A Cranbury, NJ 08512-3514
Drugs	Sermorelin, 3 mg/ GHRP6, 1.8 mg/ GHRP2, 1.8 mg/mL in 3 mL Cartridge, For SC Use, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.	II	Lot: 10122017@8 BUD: 2/9/2018	Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.	KRS Global Biotechnology, Inc 791 Park of Commerce Blvd Ste 600 Boca Raton, FL 33487-3633
Drugs	Sermorelin, 3 mg/ GHRP6, 3 mg/GHRP2, 3 mg, Vial - Lyophilized, For SC Use, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.	II	Lots: 06162017@12 BUD: 12/13/2017; 08042017@1 BUD: 1/31/2018	Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.	KRS Global Biotechnology, Inc 791 Park of Commerce Blvd Ste 600 Boca Raton, FL 33487-3633
Drugs	Sermorelin Acetate 3 mg/ GHRP6 3 mg, Lyophilized Vial, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.	II	Lot: 06272017@4 BUD: 12/24/2017	Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.	KRS Global Biotechnology, Inc 791 Park of Commerce Blvd Ste 600 Boca Raton, FL 33487-3633
Drugs	Sincalide 5 mcg Lyophilized Vials, For IV Use, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.	II	Lot: 07052017@2 BUD: 1/1/2018	Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.	KRS Global Biotechnology, Inc 791 Park of Commerce Blvd Ste 600 Boca Raton, FL 33487-3633
Drugs	Trimix #22F (Prostaglandin E1 25 mcg/ Papaverine HCl 30 mg/ Phentolamine Mesylate 2 mg/mL), For Intracavernous Use, 5 mL Vial, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.	II	Lot: 05262017@21 BUD: 11/22/2017; 07132017@2 BUD: 1/9/2018	Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.	KRS Global Biotechnology, Inc 791 Park of Commerce Blvd Ste 600 Boca Raton, FL 33487-3633
Drugs	Trimix #23F (Prostaglandin E1 6 mcg/ Papaverine HCl 17.8 mg/ Phentolamine Mesylate 0.6 mg/mL), For Intracavernous Use, 5 mL Vial, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL	II	Lot: 06142017@6 BUD: 12/11/2017	Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.	KRS Global Biotechnology, Inc 791 Park of Commerce Blvd Ste 600 Boca Raton, FL 33487-3633

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
	33487.				
Drugs	T-105 (Prostaglandin E1, 10 mcg/ Papaverine 30 mg/ Phentolamine 1 mg/mL), For Intracavernous Use, 5 mL Vial, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.	II	Lot: 07122017@2 BUD: 1/8/2018	Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.	KRS Global Biotechnology, Inc 791 Park of Commerce Blvd Ste 600 Boca Raton, FL 33487-3633
Drugs	Cyclopentolate HCl/ Phenylephrine HCl/ Tropicamide/ Ketorolac 1%/ 2.5%/ 1%/ 0.5% Ophthalmic Solution, 3 mL Multi Dose Droptainer, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.	II	Lot: 09192017@20 BUD: 12/18/2017	Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.	KRS Global Biotechnology, Inc 791 Park of Commerce Blvd Ste 600 Boca Raton, FL 33487-3633
Drugs	Cyclopentolate HCl/ Phenylephrine HCl/ Tropicamide/ Ketorolac 1%/ 10%/ 1%/ 0.5% Ophthalmic Soln, 5 mL Multi Dose Droptainer, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.	II	Lot: 10042017@34 BUD: 1/2/2018	Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.	KRS Global Biotechnology, Inc 791 Park of Commerce Blvd Ste 600 Boca Raton, FL 33487-3633
Drugs	Vitamin 9 Lyophilized Vial, For IM Use, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487..	II	Lot: 07102017@4 BUD: 1/6/2018	Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.	KRS Global Biotechnology, Inc 791 Park of Commerce Blvd Ste 600 Boca Raton, FL 33487-3633
Drugs	Vitamin 9 A/B Lyophilized Vial, For IM Use, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.	II	Lots: 06092017@2 BUD: 12/6/2017; 07212017@16 BUD: 1/17/2018; 07312017@26 BUD: 1/27/2018; 08182017@5 BUD: 2/14/2018; 09222017@2 BUD: 3/21/2018; 09292017@2 BUD: 3/28/2018; 10062017@2 BUD: 4/4/2018	Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.	KRS Global Biotechnology, Inc 791 Park of Commerce Blvd Ste 600 Boca Raton, FL 33487-3633

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drugs	Vitamin 10 B Lyophilized Vial, For IM Use, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.	II	Lots; 05232017@13 BUD: 11/19/2017; 05262017@2 BUD: 11/22/2017; 06022017@1 BUD: 11/29/2017; 06092017@1 BUD: 12/6/2017; 06162017@10 BUD: 12/13/2017; 08142017@10 BUD: 2/10/2018; 08252017@1 BUD: 2/21/2018; 09222017@1 BUD: 3/21/2018; 09292017@1 BUD: 3/28/2018; 10062017@1 BUD: 4/4/2018; 10132017@2 BUD: 4/11/2018	Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.	KRS Global Biotechnology, Inc 791 Park of Commerce Blvd Ste 600 Boca Raton, FL 33487-3633
Drugs	7-Ketodehydroepiandrosterone (7-Keto DHEA) 100 mg Capsule, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.	II	Lot: 08012017@35 BUD: 1/28/2018	Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.	KRS Global Biotechnology, Inc 791 Park of Commerce Blvd Ste 600 Boca Raton, FL 33487-3633
Drugs	7-Keto DHEA 25mg Capsule, Rx Only, KRS Global Biotechnology, 791 Park of Commerce Blvd, Boca Raton, FL 33487.	II	Lot: 06082017@36 BUD: 12/5/2017	Labeling: Incorrect or Missing Lot and/or Exp Date: Beyond Use Date (BUD) exceed the BUD/EXP of at least one ingredient used to make final product.	KRS Global Biotechnology, Inc 791 Park of Commerce Blvd Ste 600 Boca Raton, FL 33487-3633
Drugs	Ephedrine sulfate 5 mg/mL in 0.9% Sodium Chloride 10 mL in Single Dose Syringe, Total Volume 10 mL, Rx only, SCA Pharmaceuticals, 8821 Knoedl Ct. Little Rock, AR 72205, NDC 70004-0600-12	II	Lot#: 20171013@30, Exp 12/27/2017	Labeling: Incorrect or Missing Lot and/or Exp Date - product label was missing lot number and beyond use date.	SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205-4600
Drugs	Moexipril Hydrochloride and Hydrochlorothiazide Tablets USP, 7.5 mg/12.5 mg, 100-count bottle, Rx only, Distributed By: TEVA PHARMACEUTICALS USA, INC., North Wales, PA 19454, NDC 0093-5213-01.	II	Lot # 30229439A, Exp 12/17	Failed Impurities/Degradation Specifications: High out of specification test result for the Moexipril Diketopiperazine impurity was obtained during routine stability testing.	Teva Pharmaceuticals USA 1090 Horsham Rd North Wales, PA 19454-1505

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drugs	Codeine-Guaifenesin Oral Solution 10-100 mg/5 mL Antitussive Expectorant ,16 fl. oz. , Manufactured For: Method Pharmaceuticals, LLC Arlington, TX 76006, NDC 58657-500-16	II	Lot: 08616; Exp. 07/18	Microbial Contamination of Non-Sterile Products: potentially contamination with the bacteria Burkholderia cepacia	Woodfield Pharmaceutical, LLC 10863 Rockley Rd Houston, TX 77099-3405
Drugs	Docetaxel Injection USP, 20 mg/mL, One-Vial Formulation, Rx Only, Mfd. By: Dr. Reddy's Laboratories Limited, Visakhapatnam - 530 046 INDIA, NDC 43598-611-11	II	Lot #: H7044, Exp 05/19	Defective Container: Product complaints received of defect in the seal of the Docetaxel injection vials that the aluminum seal and/or stopper is removed when the cap is flipped off.	Dr. Reddy's Laboratories, Inc. 107 College Rd E Princeton, NJ 08540-6623
Drugs	Rugby Diocto Liquid, Docusate Sodium 50 mg/ 5 mL, Stool Softener Laxative, One Pint (473 mL) plastic bottles, Dist. by: Rugby Laboratories, 17177 N. Laurel Park Dr., Suite 233, Livonia, MI 48152 ---- NDC: 0536-0590-85, Manufactured by PharmaTech LLC, Davie, FL	II	All lots remaining within expiry.	Microbial Contamination of Non Sterile Product; presence of yeast and potential B. cepacia contamination	Pharmatech LLC 4131 SW 47th Ave Ste 1403 Davie, FL 33314-4036
Drugs	ePHEDrine Sulfate In 0.9% Sodium Chloride, 5 mg per mL (50 mg per 10 mL), 10 mL Total Volume pre-filled syringes, packaged in a) 5-count cartons, NDC 71030-0003-10 and NDC 71030-0003-20, and b) 25-count cartons, NDC 71030-0003-21 and NDC 71030-0003-12, Rx Only, PharMEDium Services, LLC, 913 N. Davis Ave, Cleveland, MS, Code 2R3304.	II	Lot #: 172950036M, Exp. 1/21/2018; 172940003M, Exp. 1/20/2018; 172880044M, Exp. 1/14/2018; 172840176M, Exp. 1/11/2018; 172920115M, Exp. 1/18/2018; 172840015D, Exp. 1/10/2018; 172930139M, Exp. 1/19/2018.	Subpotent Drug	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drugs	Phenylephrine HCL 100 mcg per mL (1 mg/10 mL) in 0.9% Sodium Chloride 10 mL syringes, PharMEDium Services, LLC 913 N Davis Ave Cleveland, MS, NDC 71019-263-20	II	Lot #: 172560019M, Exp. 12/13/2017	Superpotent Drug	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drugs	Rugby Diocto Syrup, Docusate Sodium 60 mg/15 mL, Stool Softener Laxative, One Pint (473 mL) plastic bottles, Dist. by: Rugby Laboratories, 17177 N. Laurel Park Drive, Suite 233, Livonia, MI 48152. NDC: 0536-1001-85, Manufactured by PharmaTech LLC, Davie, FL	II	All lots remaining within expiry.	Microbial Contamination of Non Sterile Product; presence of yeast and potential B. cepacia contamination	Pharmatech LLC 4131 SW 47th Ave Ste 1403 Davie, FL 33314-4036

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drugs	Rugby Senexon Liquid Natural Vegetable Stimulant,(Sennosides) 8.8 mg, 8 fl oz (237 mL) plastic bottles, Distributed by: Rugby Laboratories, 17177 N Laurel Park Drive, Suite 233, Livonia, MI 48152 --- NDC 0536-1000-59 ; ALSO LABELED AS Major Senna Syrup Natural Vegetable Laxative, Sennoside 8.8 mg, 8 fl. oz. (237mL) plastic bottles, Dist. by: Major Pharmaceuticals, 17177 N Laurel Park Drive, Suite 233, Livonia, MI 48152 USA. NDC: 00904-6289-09; Manufactured by PharmaTech LLC, Davie, FL	II	All lots remaining within expiry.	Microbial Contamination of Non Sterile Product; presence of yeast and potential B. cepacia contamination	Pharmatech LLC 4131 SW 47th Ave Ste 1403 Davie, FL 33314-4036
Drugs	Rugby Aller-chlor (Chlorpheniramine Maleate Syrup, USP), 2 mg, 4 fl. oz. (120 mL) plastic bottles, Distributed by: Rugby Laboratories 17177 N. Laurel Park Drive, Suite 233, Livonia, MI 48152 USA --- NDC: 0536-1025-47, Manufactured by PharmaTech LLC, Davie FL	II	All lots remaining within expiry.	Microbial Contamination of Non Sterile Product; presence of yeast and potential B. cepacia contamination	Pharmatech LLC 4131 SW 47th Ave Ste 1403 Davie, FL 33314-4036
Drugs	Divalproex Sodium Delayed Release Tablets USP, 500 mg, 100-count bottle, RX Only, Manufactured by: Unichem Laboratories Ltd. Ind. Area, Meerut Road, Ghaziabad-201 003, India. Marketed By: Unichem Pharmaceuticals (USA), Inc. Hasbrouck Heights, NJ 07604. NDC 29300-140-01	II	Lot: ZDPH17040	Cross Contamination With Other Products: metronidazole powder was found in one bottle of Divalproex Sodium.	Unichem Pharmaceuticals Usa Inc 777 Terrace Ave Suite 102 Hasbrouck Heights, NJ 07604-3102
Drugs	bareMinerals Broad Spectrum SPF 50 Daily Prep Lotion (zinc oxide 23.8%, titanium dioxide 4.1%), 40 mL/1.35 fl. oz. bottle, Dist. by Bare Escentuals Beauty, Inc. SF, CA 94105 USA, NDC 98132-761-01	II	SKU#: BE8047201	GMP Deviations: manufacturing of API material did not meet GMP and quality requirements.	SHISEIDO AMERICA INC. 366 Princeton Hightstown Rd East Windsor, NJ 08520-1411
Drugs	Shiseido Future Solution LX Universal Defense SPF 50+ (octinoxate 4.9%, octocrylebe 3.0%, oxybenzone 1.0% and zinc oxide 15.4%), packaged in a) 2mL, b) 15 mL and c) 50 mL tubes, Shiseido Americas Corporation Dist. New York, NY 10022. NDC 58411-256-60	II	SKU#: a) 8C52541, b) 8B41841, c) 1155840, 1155841, 1155842, 1155851, 0710341, 0710342	GMP Deviations: manufacturing of API material did not meet GMP and quality requirements.	SHISEIDO AMERICA INC. 366 Princeton Hightstown Rd East Windsor, NJ 08520-1411

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drugs	Lovastatin Tablets USP, 40 mg, 50 Tablets (5x10) Unit Dose carton, Rx only, Manufactured for AvKARE, Inc. Pulaski, TN 38478, NDC 50268-512-15.	II	Lot: 15270, Exp. 01/18	Failed Dissolution Specifications: Low out of specification results for dissolution during annual stability testing.	AVKARE Inc. 615 N 1st St Pulaski, TN 38478-2403
Drugs	Shiseido Future Solution LX Discovery Set contains SPF 50+ (octinoxate 4.9%, octocrylebe 3.0%, oxybenzone 1.0% and zinc oxide 15.4%), packaged in 15 mL tubes, Shiseido Americas Corporation Dist. New York, NY 10022,	II	SKU#: 95167	GMP Deviations: manufacturing of API material did not meet GMP and quality requirements.	SHISEIDO AMERICA INC. 366 Princeton Hightstown Rd East Windsor, NJ 08520-1411
Drugs	Shiseido Future Solution LX Luxurious Eye & Lip Collection contains SPF 50+ (octinoxate 4.9%, octocrylebe 3.0%, oxybenzone 1.0% and zinc oxide 15.4%), packaged in 15 mL tubes, Shiseido Americas Corporation Dist. New York, NY 10022	II	SKU#: 95393	GMP Deviations: manufacturing of API material did not meet GMP and quality requirements.	SHISEIDO AMERICA INC. 366 Princeton Hightstown Rd East Windsor, NJ 08520-1411
Drugs	Shiseido Future Solutions LX Triple Points Bonus contains SPF 50+ (octinoxate 4.9%, octocrylebe 3.0%, oxybenzone 1.0% and zinc oxide 15.4%), packaged in 15 mL tubes, Shiseido Americas Corporation Dist. New York, NY 10022, NDC 58411-256-60	II	SKU#: 95284	GMP Deviations: manufacturing of API material did not meet GMP and quality requirements.	SHISEIDO AMERICA INC. 366 Princeton Hightstown Rd East Windsor, NJ 08520-1411
Drugs	Ciprofloxacin in Dextrose (5%) Injection, USP 200 mg in 100 mL 5% Dextrose, Rx Only, (2 mg/mL), 100 mL Flexible Bag, Manufactured for: Claris LifeScience Inc. North Brunswick NJ 08902 by Claris Injectables Ltd. Gujarat, India UPC 336000008242 NDC 36000-008-249	III	A060192 01/2018; A060305 02/2018; A061038 08/2018; A0A0068 12/2018; A0A0404 04/2019	Superpotent	Claris Lifesciences Inc 1445 US Highway 130 North Brunswick, NJ 08902-3100
Drugs	Fluconazole Injection, USP, 2 mg/mL, a) 50 mL (NDC 336000-261-10) and b) 100 mL (NDC 33600-002-10), Rx Only, Manufactured for: Claris LifeSciences, Inc. North Brunswick, NJ 08902 By: Claris Injectables Ltd., Gujarat, India	III	a) A060174 01/13/2018, A060257 02/28/2018, A060692 05/31/2018, A061165 09/30/2018, A0A0143 01/31/2019, A0A0347 03/31/2019, and A0A0424 04/30/2019 ; b) A060027	Superpotent	Renaissance Lakewood, LLC 1200 Paco Way Lakewood, NJ 08701-5938

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
			12/31/2017		
Drugs	Methylphenidate Hydrochloride Extended-release Tablets, USP 27 mg, 100-count bottles, Rx Only, Trigen Laboratories, LLC. Bridgewater, NJ 08807, NDC 13811-707-10	III	Lot #: 170027A, Exp. 02/2019	Subpotent Drug	Osmotica Pharmaceutical Corp 895 Sawyer Rd Marietta, GA 30062-2257
Drugs	Bayer Chewable Low Dose Aspirin 81 mg Orange Flavored 36 tablets, Made in Spain, Distributed by: Bayer Healthcare LLC Morristown, NJ 07962 NDC 0280-2160-36 UPC 3128431310577	III	Lot # NAA3T0X; Exp. 07/18	Failed Stability Specifications	Bayer HealthCare Pharmaceuticals, Inc. 100 Bayer Blvd Whippany, NJ 07981-1544
Drugs	morphine Sulfate in 0.9% Sodium Chloride Injection 2 mL Total Volume 1 mg per mL (2 mg per 2 mL), For IV Use, Rx Only, Compounded by: PharMEDium Services LLC. 913 N Davis Ave Cleveland, MS 38732, NDC# 61553-259-28	III	Lot: 172360026C; Exp. 11/23/2017	Labeling: Incorrect or Missing Lot and/or Exp. Date	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drugs	morphine Sulfate in 0.9% Sodium Chloride Injection 1 mL Total Volume 2 mg per mL , For IV Use, Rx Only, Compounded by: PharMEDium Services LLC. 913 N Davis Ave Cleveland, MS 38732, NDC# 61553-455-78	III	Lot:172410028C; Exp. 11/28/2017 Lot: 172470030C; Exp. 12/04/2017	Labeling: Incorrect or Missing Lot and/or Exp. Date	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drugs	HYDROmorphone HCl in 0.9% Sodium Chloride Injection, 1 mL Total Volume 1 mg per mL, For IV Use Only, Rx Only, Compounded by: PharMEDium Services LLC. 913 N Davis Ave Cleveland, MS 38732, NDC# 61553-165-78	III	Lot: 172410025C; Exp. 11/27/2017	Labeling: Incorrect or Missing Lot and/or Exp. Date	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drugs	Auryxia (ferric citrate) tablets, 210 mg , 200-count bottles, RX ONLY, Manufactured for and distributed by: Keryx Biopharmaceuticals, Inc. One Marina Park Drive, 12th Floor, Boston, MA 02210 USA. NDC 59922-631-01	III	Lot # AH3842	Presence of Foreign Substance: Reports have been received of damaged StripPax packets containing silica gel desiccant potentially allowing the silica gel granules to make contact with Auryxia tablets in the bottle.	Keryx Biopharmaceuticals, Inc. 1 Marina Park Dr Fl 12 Boston, MA 02210-1832

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drugs	Enoxaparin Sodium, Injection 120 mg/0.8 mL, pre-filled, packaged in 10-count cartons, Rx Only, Winthrop US., a business of Sanofi-Aventis, U.S. LLC Bridgewater, NJ 08807, NDC 0955-1012-10	III	Lot #: 7S572, Exp. 04/2019	Labeling: Label Error on Declared Strength. A single syringe labeled as 150 mg/1.0 mL was found packaged in a blister labeled as 120 mg/mL	Sanofi-Aventis U.S. LLC 55 Corporate Dr Bridgewater, NJ 08807-1265
Drugs	Gabapentin Oral Solution, 250 mg/5 mL (50 mg/mL) in a 470 mL amber-colored bottle, Rx Only. Manufactured by: Hi-Tech Pharmacal Co., Inc. Amityville, NY 11701. NDC: 50383-311-47	III	Batch# 359774; Exp. 09/02/19	CGMP Deviations: Inadvertent release of a drug product with unapproved active ingredient manufacturer	Akorn Inc 1925 W Field Ct Ste 300 Lake Forest, IL 60045-4862
Drugs	Simvastatin Tablets, USP, 40 mg, 1000-count bottle, Rx only, Manufactured for: Camber Pharmaceuticals, Inc., Piscataway, NJ 08854, Manufactured by: Hetero (trademark), Hetero Labs Limited, Jeedimetla, Hyderabad - 500 055, India, NDC 31722-513-10	III	Lot #: E171280, Exp 06/19	Presence of foreign substance: metallic razor blade was found in one bottle.	Hetero Labs, Ltd. - Unit III Plot 22-110, Part Ii, Ida Rangareddy, Jeedimetla Hyderabad
Drugs	Mefenamic Acid Capsules, USP, 250 mg, 30-count bottle, Rx only, Distributed by Prasco Laboratories, Mason, OH 45040, Manufactured by Halo Pharmaceutical Inc., Whippany, NJ 07981, NDC 66993-070-30	III	Lot#: 7H66200103G, Exp 12/19	Presence of foreign substance: The recall was initiated due to black particles being observed while performing routine post-release stability testing on Mefenamic acid capsules	Shionogi Inc. 5770 Shiloh Rd Alpharetta, GA 30005-8408

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

CURRENT DRUG SHORTAGES

Acetylcysteine Oral and Inhalation Solution
January 22, 2018

Reason for the Shortage

- American Regent has acetylcysteine oral and inhalation solution on shortage due to manufacturing delays.
- Fresenius Kabi has acetylcysteine oral and inhalation solution available.
- Pfizer has acetylcysteine oral and inhalation solution on shortage due to manufacturing delays.
- Roxane Labs discontinued acetylcysteine oral and inhalation solution in April 2014.

Estimated Resupply Dates

- American Regent has acetylcysteine solution 100 mg/mL 10 mL vials available in limited supply. The 200 mg/mL 4 mL, 10 mL, and 30 mL vials are on back order and the company cannot estimate a release date.
- Fresenius Kabi has acetylcysteine solution 200 mg/mL 4 mL and 10 mL vials on back order and the company estimates a release date of late-February to early-March 2018 for the 4 mL vials and late-March 2018 for the 10 mL vials. The 200 mg/mL 10 mL vials are intermittent back order and the company is releasing product as it becomes available. The 100 mg/mL 10 mL and 30 mL vials are on back order and the company estimates a release date of late-January 2018. The 100 mg/mL 4 mL vials are on back order and the company estimates a release date of early- to mid-April 2018.
- Pfizer has acetylcysteine solution 100 mg/mL 30 mL and 200 mg/mL 30 mL vials on back order and the company estimates a release date of late-April 2018 for the 100 mg/mL 30 mL vials and mid-February 2018 for the 200 mg/mL 30 mL vials.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=932

Bupivacaine with epinephrine Injection
January 22, 2018

Reason for the Shortage

- Fresenius Kabi has bupivacaine and epinephrine on shortage due to increased demand and manufacturing delays.
- Pfizer 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 intermittent back order and the company is releasing product as it becomes available. The 0.25% Sensorcaine-MPF with epinephrine 10 mL vials are on back order and the company estimates a release date of mid-February 2018. The 0.25% Sensorcaine with epinephrine 50 mL vials are on back order and the company estimates a release date of late-January 2018. The 0.5% Sensorcaine-MPF with epinephrine 30 mL vials are on intermittent back order and the company is releasing product as it becomes available. The 0.5% Sensorcaine-MPF with epinephrine 10 mL vials are on back order and the company estimates a release date of mid- to late-February 2018. The 0.5% Sensorcaine-MPF with epinephrine 30 mL sterile packs are on back order and the company cannot estimate a

release date. The 0.5% Sensorcaine with epinephrine 50 mL vials are on back order and the company estimates a release date of mid- to late-March 2018. The 0.75% Sensorcaine with epinephrine 30 mL vials are on back order and the company cannot estimate a release date.

- Pfizer has 0.25% bupivacaine with epinephrine 10 mL and 30 mL preservative-free vials on back order and the company estimates a release date of June 2018 for the 10 mL vials and mid-February 2018 for the 30 mL vials. The 0.25% bupivacaine with epinephrine 50 mL vials are on back order and the company estimates a release date of June 2018. The 0.5% bupivacaine with epinephrine 10 mL preservative-free vials are on back order and the company estimates a release date of late-January 2018. The 0.5% bupivacaine with epinephrine 30 mL preservative-free vials are available in limited supply. The 0.5% bupivacaine with epinephrine 50 mL vials are on back order and the company estimates a release date of June 2018.
- Pfizer has 0.25% Marcaine with epinephrine 10 mL and 30 mL preservative-free vials on back order and the company estimates a release date of March 2019. The 0.25% Marcaine with epinephrine 50 mL vials are on back order and the company estimates a release date of March 2019. The 0.5% Marcaine with epinephrine 10 mL and 30 mL preservative-free vials are on back order and the company estimates a release date of March 2019. The 0.5% Marcaine with epinephrine 50 mL vials are on back order and the company estimates a release date of March 2019.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=937

Calcium Gluconate Injection

January 22, 2018

Reason for the Shortage

- American Regent has calcium gluconate on shortage due to manufacturing delays.
- Fresenius Kabi has calcium gluconate available with alternating short-dating due to manufacturing process of the vials.
- American Regent has issued a statement that all lots of calcium gluconate may contain glass particles and filters must be used. Do not use if there are visible glass particles and filter all other product.

Estimated Resupply Dates

- American Regent has calcium gluconate 100 mg/mL 50 mL and 100 mL vials on back order and the company cannot estimate a release date.
- Fresenius Kabi has calcium gluconate 100 mg/mL 10 mL vials on back order and the company estimates a release date of mid-February 2018.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=48

Carbidopa and Levodopa Extended-Release Tablets

January 22, 2018

Reason for the Shortage

- Accord has discontinued carbidopa and levodopa 25 mg/100 mg extended-release tablets due to problems obtaining active ingredient. The 50 mg/ 200 mg tablets remain available.

- Caraco refuses to provide availability information. However, per FDA, Caraco has carbidopa and levodopa extended-release tablets available.
- Merck could not provide a reason for the Sinemet CR shortage.
- Mylan could not provide a reason for the shortage

Estimated Resupply Dates

- Mylan Institutional has carbidopa and levodopa 25 mg/100 mg and 50 mg/200 mg extended-release tablets in 100 count bottles on back order and the company estimates a release date of late-January 2018.
- Merck has Sinemet CR 25 mg/100 mg extended-release tablets in 100 count bottles on back order and the company estimates a release date of late-January 2018.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1181

Dextrose (25%) Injection

January 22, 2018

Reason for the Shortage

- Pfizer has 25% dextrose injection on shortage due to manufacturing delays.

Estimated Resupply Dates

- Pfizer has 25% dextrose 10 mL Ansyr syringes on back order and the company estimates a release date of mid-February 2018.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1011

Dextrose (50%) Injection

January 22, 2018

Reason for the Shortage

- Amphastar has 50% dextrose injection on shortage due to increased demand.
- Pfizer has 50% dextrose injection on shortage due to manufacturing delays.

Estimated Resupply Dates

- Amphastar has 50% dextrose 50 mL syringes on allocation and is regularly releasing product.
- Pfizer has 50% dextrose 50 mL LifeShield syringes and 50 mL Ansyr II syringes on back order and the company estimates a release date of late-January 2018. The 50% dextrose 50 mL vials are on back order and the company estimates a release date of mid-February 2018.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1012

Dopamine Hydrochloride Injection

January 22, 2018

Reason for the Shortage

- American Regent has dopamine on shortage due to manufacturing delays.
- Baxter has all dopamine presentations on shortage due to manufacturing delays.

- Pfizer states the shortage is due to manufacturing delays. The dopamine 200 mg/250 mL and 400 mg/500 mL premixed bags were discontinued in August 2017.

Estimated Resupply Dates

- American Regent has all dopamine presentations on back order and the company cannot estimate a release date.
- Baxter has all dopamine premixed bags on allocation only through direct orders. Product is not available through wholesalers.
- Pfizer has dopamine 40 mg/mL 10 mL vials on back order and the company estimates a release date of 2018. The 400 mg/250 mL bags are on back order and the company estimates a release date of early-February 2018. The 800 mg/500 mL premixed bags are on back order and the company estimates a release date of late-January 2018. The 800 mg/250 mL premixed bags are on back order and the company estimates a release date of mid-February 2018. The 40 mg/mL 5 mL vials are on back order and the company estimates a release date of late-March 2018.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1243

Lidocaine with Epinephrine Injection

January 22, 2018

Reason for the Shortage

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

Estimated Resupply Dates

- Pfizer has 0.5% lidocaine with epinephrine (1:200,000) 50 mL on back order and the company estimates a release date of June 2018. The 1% lidocaine with epinephrine (1:100,000) 20 mL vials are on back order and the company estimates a release date of late-March 2018. The 1% lidocaine with epinephrine (1:100,000) 30 mL vials are on intermittent back order and the company is releasing product as it becomes available. The 1.5% lidocaine with epinephrine (1:200,000) 30 mL vials are on back order and the company estimates a release date of June 2018. The 1.5% lidocaine with epinephrine (1:200,000) 5 mL ampules are available in limited supply. The 2% lidocaine with epinephrine (1:200,000) 20 mL vials are on back order and the company estimates a release date of March 2018. The 2% lidocaine with epinephrine (1:100,000) 20 mL, 30 mL, and 50 mL vials are on back order and the company estimates a release date of June 2018 for the 20 mL and 30 mL vials and late-January 2018 for the 50 mL vials.
- Fresenius Kabi has 0.5% Xylocaine with epinephrine (1:200,000) 50 mL vials on back order and the company cannot estimate a release date. The 1% Xylocaine with epinephrine (1:200,000) 20 mL and 50 mL vials are on intermittent back order and the company is releasing product as it becomes available. The 1% Xylocaine with epinephrine (1:200,000) 10 mL vials are on back order and the company estimates a release date of late-February to early-March 2018. The 1% Xylocaine-MPF with epinephrine (1:200,000) 10 mL and 30 mL vials are on back order and the company estimates a release date of mid- to late-February 2018. The 1% Xylocaine-MPF with epinephrine (1:200,000) 30 mL vials in sterile packs are on back order and the company cannot estimate a release date. The 1.5% Xylocaine-MPF with epinephrine (1:200,000) 10 mL and 30 mL

vials are on back order and the company cannot estimate a release date. The 1.5% Xylocaine-MPF with epinephrine (1:200,000) 30 mL vials in sterile packs are on back order and the company cannot estimate a release date. The 2% Xylocaine with epinephrine (1:200,000) 20 mL vials are on intermittent back order and the company is releasing product as it becomes available. The 2% Xylocaine with epinephrine (1:200,000) 50 mL vials are on back order and the company cannot estimate a release date. The 2% Xylocaine-MPF with epinephrine (1:200,000) 10 mL vials are on back order and the company estimates a release date of late-February to early-March 2018. The 2% Xylocaine-MPF with epinephrine (1:200,000) 20 mL vials are on intermittent back order and the company is releasing product as it becomes available. The 2% Xylocaine-MPF with epinephrine (1:200,000) 20 mL vials in sterile packs are on back order and the company cannot estimate a release date.

- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=860

Meperidine Hydrochloride Injection

January 22, 2018

Reason for the Shortage

- Pfizer has Demerol injection on shortage due to manufacturing delays.

Estimated Resupply Dates

- Pfizer has Demerol 100 mg/mL 20 mL vials on back order and the company estimates a release date of March 2019. The 25 mg/mL 1 mL Carpuject syringes, 50 mg/mL 1 mL Carpuject syringes, 75 mg/mL 1 mL Carpuject syringes, and 100 mg/mL 1 mL Carpuject syringes are on back order and the company estimates a release date of June 2019. The 50 mg/mL 30 mL vials are on back order and the company estimates a release date of September 2018. The 100 mg/mL 1 mL ampules are on back order and the company estimates a release date of mid-February 2018.
- West-Ward has meperidine 25 mg/mL 1 mL vials on back order and the company estimates a release date of February 2018.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1285

Potassium Acetate Injection

January 22, 2018

Reason for the Shortage

- American Regent has not had product available for several years. It is unclear if they will market potassium acetate again in the future.
- Pfizer has potassium acetate on shortage due to manufacturing delays.

Estimated Resupply Dates

- Pfizer has potassium acetate 2 mEq/mL 20 mL vials on back order and the company estimates a release date of late-January 2018.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=668

Selenium Injection
January 22, 2018

Reason for the Shortage
- American Regent did not provide a reason for the shortage.

Estimated Resupply Dates
- American Regent has selenium 40 mcg/mL 10 mL vials on back order and the company estimates a release date of early-February 2018.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=784

Sodium Acetate Injection
January 22, 2018

Reason for the Shortage
- American Regent has had sodium acetate on long-term back order for several years.
- Fresenius Kabi had sodium acetate on shortage due to increased demand.
- Pfizer has sodium acetate on shortage due to manufacturing delays.

Estimated Resupply Dates
- Pfizer has sodium acetate 2 mEq/mL 20 mL vials on back order and the company estimates a release date of late-January 2018. The 100 mL vials are available in limited supply. https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=762

Hydromorphone Hydrochloride Injection
January 19, 2018

Reason for the Shortage
- Akorn has hydromorphone injection on shortage due to increased demand.
- Fresenius Kabi has Dilaudid syringes on shortage due to increased demand.
- Pfizer did not provide a reason for the shortage.
- Purdue discontinued Dilaudid and Dilaudid HP in May 2017 for marketing reasons.
- Teva did not provide a reason for the shortage.
- West-Ward did not provide a reason for the shortage.

Estimated Resupply Dates
- Akorn has hydromorphone 10 mg/mL 1 mL ampule in limited quantities. Hydromorphone 10 mg/mL 5 mL ampules and 50 mL vials are on back order and the company estimates a release date of mid- to late-February 2018 for the 5 mL ampules and late-January to early-February 2018 for the 50 mL vials.
- Fresenius Kabi has Dilaudid 0.5 mg/mL 0.5 mL syringes on back order and the company estimates a release date of mid-February 2018. The 1 mg/mL 1 mL syringes are on back order and the company estimates a release date of 2nd quarter 2018. The 2 mg/mL 1 mL syringes and 4 mg/mL 1 mL syringes are on back order and the company cannot estimate a release date.

- Pfizer has hydromorphone 0.5 mg/0.5 mL 0.5 mL iSecure syringes are on back order and the company estimates a release date of early-February 2018. The 1 mg/mL 1 mL Carpuject syringes are on back order and the company estimates a release date of late-February 2018. The 2 mg/mL 1 mL Carpuject syringes are on back order and the company estimates a release date of mid-March 2018. The 1 mg/mL 1 mL iSecure syringes are on back order and the company estimates a release date of mid-February 2018. The 2 mg/mL 1 mL vials are on back order and the company estimates a release date of late-January 2018. The 10 mg/mL 1 mL vials are on back order and the company estimates a release date of September 2018. The 1 mg/mL 1 mL ampules, 2 mg/mL 1 mL ampules, and 4 mg/mL 1 mL ampules are on back order and the company cannot estimate a release date. The 2 mg/mL 1 mL iSecure syringes and 4 mg/mL 1 mL Carpuject syringes are on back order and the company estimates a release date of June 2019.
- Teva has hydromorphone 10 mg/mL 1 mL and 5 mL vials on intermittent back order and the company is allocating product upon release. The 10 mg/mL 50 mL vials are on allocation.
- West-Ward has hydromorphone 2 mg/mL 20 mL vials on back order and the company estimates a release date of February 2018. The 2 mg/mL 1 mL vials are on allocation.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=856

Morphine Injections

January 19, 2018

Reason for the Shortage

- Fresenius Kabi procured morphine syringes from BD in 2016.
- Astramorph injection has been unavailable since 2012. Fresenius Kabi changed manufacturing sites and cannot estimate if Astramorph will return.
- Pfizer states the shortage is due to manufacturing delays. Pfizer discontinued morphine ADD-Vantage vials in January 2017.
- Pfizer anticipates a shortage of several prefilled syringe products, including morphine, starting in late-July 2017 due to issues at a manufacturing facility. To minimize the impact of the shortage, Pfizer is prioritizing production of certain morphine Carpuject syringes. Pfizer expects the shortage of prefilled syringe products to recover by late-first quarter 2018.
- West-Ward launched several new morphine sulfate products in late-September 2015. They are not actively marketing the 15 mg/mL 1 mL vials or the 8 mg/mL 1 mL vials (NDC 00641-6075-25). They are still marketing the 8 mg/mL 1 mL vials with NDC 00641-6126-25.

Estimated Resupply Dates

- Fresenius Kabi has morphine 2 mg/mL 1 mL syringes and 4 mg/mL 1 mL syringes on intermittent back order and the company is releasing product as it becomes available. The morphine 5 mg/mL 1 mL, 8 mg/mL, and 10 mg/mL 1 mL syringes are on back order and the company cannot estimate a release date.
- Pfizer has morphine 2 mg/mL 1 mL Carpuject syringes on back order and the company estimates a release date of early-February 2018. The 4 mg/mL 1 mL Carpuject syringes are on back order and the company estimates a release date of mid-February 2018. The 0.5 mg/mL 10 mL preservative-free vials are available in limited supply. The 1 mg/mL 10 mL preservative-free vials are on back order and the company estimates a release date of late-January 2018. The 2 mg/mL 1 mL iSecure syringes, 4 mg/mL 1 mL iSecure syringes, 8 mg/mL 1 mL Carpuject syringes, 8

mg/mL 1 mL iSecure syringes, 10 mg/mL 1 mL iSecure syringes, and 10 mg/mL 1 mL Carpuject syringes are on back order and the company estimates a release date of June 2019.
- West-Ward has morphine 4 mg/mL 1 mL, 8 mg/mL 1 mL, and 10 mg/mL 1 mL vials on allocation.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=664

Potassium Chloride Injection

January 19, 2018

Reason for the Shortage

- Baxter has their highly concentrated potassium chloride in sterile water on shortage because a manufacturing facility has been affected by Hurricane Maria. Baxter has removed these products from distribution and they can be purchased directly if they are in stock. Baxter is also adjusting the allocation of these products. Baxter did not provide a reason for the shortage of their other potassium chloride products.
- Fresenius Kabi did not provide a reason for the shortage.
- Pfizer has potassium chloride injection on shortage due to increase demand and manufacturing delays.

Estimated Resupply Date

- Baxter has potassium chloride 10 mEq/1000 mL in 5% dextrose and 0.45% sodium chloride, potassium chloride 20 mEq/1000 mL in 5% dextrose and 0.2% sodium chloride, and potassium chloride 20 mEq/1000 mL in 0.45% sodium chloride available in limited quantities. Potassium chloride 20 mEq/1000 mL in 5% dextrose and 0.9% sodium chloride and potassium chloride 40 mEq/1000 mL in 5% dextrose and 0.9% sodium chloride on back order and the company cannot estimate a release date.
- Baxter has all potassium chloride in sterile water presentations in sterile water on allocation.
- Pfizer has potassium chloride 10 mEq/5 mL vials and 20mEq/10 mL vials on back order and the company estimates a release date of early-April 2018 for the 10 mEq/5 mL vials and late-March 2018 for the 20 mEq/10 mL vials.
- ICU Medical has the 10 mEq/100 mL in sterile water, 20 mEq/50 mL in sterile water, 20 mEq/1000 mL in 0.9% sodium chloride premixed bags, and 20 mEq/1000 mL in lactated ringer's and 5% dextrose premixed bags on intermittent back order and the company is releasing supplies as they become available. Potassium chloride 10 mEq/500 mL in 5% dextrose and 0.225% sodium chloride premixed bags are on long-term back order. Several potassium chloride presentations are on allocation.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=696

Remifentanil Injection

January 19, 2018

Reason for the Shortage

- Mylan Institutional did not provide a reason for the shortage.
- Fresenius Kabi launched generic remifentanil in January 2018.

Estimated Resupply Date

- Mylan Institutional has Ultiva 1 mg and 2 mg vials on back order and the company estimates a release date of April 2018.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1299

0.9% Sodium Chloride Small Volume Bags (<150 mL)

January 18, 2018

Reason for the Shortage

- Baxter has 0.9% sodium chloride small volume bags on shortage due to manufacturing delays.
- BBraun has 0.9% sodium chloride small volume bags on shortage due to increased demand.
- ICU Medical has 0.9% sodium chloride small volume bags on shortage due to increased demand.

Estimated Resupply Date

- Baxter has all 0.9% sodium chloride small volume bags on allocation.
- BBraun has all 0.9% sodium chloride small volume bags on allocation to current customers only.
- Pfizer has 0.9% sodium chloride 50 mL and 100 mL ADD-Vantage bags on back order and the company estimates a release date in early-February 2018 for the 50 mL bags and late-January 2018 for the 100 mL bags.
- ICU Medical has 0.9% sodium chloride 50 mL VisIV bags, 25 mL bags, and 50 mL preservative - free bags on back order and the company estimates release dates of mid-January 2018 for the 50 mL VisIV bag, mid-March 2018 for the 25 mL bag, and late-February 2018 for the 50 mL preservative free bags. All other 0.9% sodium chloride small volume bags are on intermittent back order and the company is releasing supplies as they become available.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1287

0.9% Sodium Chloride Large Volume Bags Injection Bags

January 17, 2018

Reason for the Shortage

- Baxter discontinued 0.9% sodium chloride 250 mL and 500 mL AVIVA bags. The Viaflex bags and Viaflo bags are on back order.1
- BBraun did not provide a reason for the shortage.2
- Pfizer cited increased demand as the reason for the shortage.3
- Fresenius Kabi is no longer importing product.7
- Baxter has received FDA approval for 0.9% sodium chloride in Viaflo containers manufactured in an FDA-approved facility in Spain.

Estimated Resupply Date

- Baxter has 0.9% sodium chloride 500 mL Viaflex bags on back order and the company cannot estimate a release date. The 250 mL, 500 mL, and 1,000 mL PVC/DEHP-free bags are on back order and the company cannot estimate a release date.
- BBraun has 0.9% sodium chloride 250 mL, 500 mL, and 1,000 mL PVC/DEHP-free bags on allocation to current customers.
- Pfizer has 0.9% sodium chloride 500 mL , 500 mL 2-port, and 1,000 mL bags on allocation. The 250 mL, 250 mL PVC/DEHP-free, 250 mL 2-port bags are on intermittent back order and the

company is releasing supplies as they become available. The 150 mL bags are on back order and the company estimates a release date in late-February 2018.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1288

Ethiodized Oil
January 17, 2018

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

Estimated Resupply Date
- Guerbet is shipping supplies of Lipiodol Ultra-Fluide.2 Lipiodol Ultra-Fluide is not FDA approved. In order to prevent a drug shortage, FDA is allowing Guerbet to import Lipiodol Ultra-Fluide, a product manufactured for Guerbet in France by Delpharm Tours.
- Customers must order Lipiodol Ultra-Fluide directly from Guerbet by calling 1-877-729-6679. Lipiodol Ultra-Fluide is non-refundable and may not be resold.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=618

Haloperidol Lactate Injection
January 17, 2018

Reason for the Shortage
- Mylan Institutional has haloperidol lactate injection available.
- Patriot Pharmaceuticals has haloperidol lactate available.
- Sagent has discontinued haloperidol 5 mg/mL 10 mL vials. The company plans to relaunch the product in May 2018.
- Teva is not currently marketing haloperidol lactate.
- West-Ward is not actively marketing haloperidol lactate at this time.
- Janssen has Haldol injection available.

Estimated Resupply Date
- Sagent has discontinued haloperidol lactate 5 mg/mL 10 mL vials. The company plans to relaunch the product in May 2018.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=527

Lactated Ringer's Injection
January 17, 2018

Reason for the Shortage
- Baxter did not provide a reason for the shortage.
- BBraun states the reason for the shortage is increased demand.
- ICU Medical states the reason for the shortage is increased demand.

Estimated Resupply Date

- Baxter has lactated ringer's 500 mL and lactated ringer's with 5% dextrose 500 mL and 1000 mL on back order and the company cannot estimate a release date. Lactated ringer's 250 mL injection solution is available in limited quantities.
- BBraun has lactated ringer's injection solution and lactated ringer's with 5% dextrose injection solution products on allocation to current customers.
- ICU Medical has lactated ringer's 250 mL and 500 mL bags on back order and the company estimates a release date of early-February 2018 for the 250 mL bags and mid-January 2018 for the 500 mL bags. Lactated ringer's with 5% dextrose 500 mL bags are on back order and the company estimates a release date in mid-January 2018. Lactated ringer's 1000 mL and lactated ringer's with 5% dextrose 1000 mL bags are available in limited quantities.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1294

Sincalide Injection

January 17, 2018

Reason for the Shortage

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

Estimated Resupply Date

- Bracco has Kinevac on back order and the company cannot estimate a release date
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1032

Talc, Sterile

January 17, 2018

Reason for the Shortage

- Lymol has Sclerosol and talc powder on shortage due to manufacturing delays.
- Novatech SA has Steritalc powder available.

Estimated Resupply Date

- Lymol has Sclerosol and talc powder on long-term back order and the company cannot estimate a release date
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1248

Bumetanide Injection

January 16, 2018

Reason for the Shortage

- Pfizer has bumetanide injection on shortage due to manufacturing delays.
- West-Ward did not provide a reason for the shortage.

Estimated Resupply Date

- Pfizer has bumetanide 0.25 mg/mL 4 mL and 10 mL vials on back order and the company estimates a release date of June 2019.
- West-Ward has bumetanide 0.25 mg/mL 4 mL vials on back order and the company estimates a release date of January 2018. The 10 mL vials are on a weekly allocation.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=674

Chlorothiazide Sodium Injection

January 16, 2018

Reason for the Shortage

- Akorn has chlorothiazide injection on shortage due to manufacturing delays.
- Sagent has chlorothiazide injection on shortage due to increased demand.
- Sun Pharma refuses to provide availability information on any of their products.

Estimated Resupply Date

- Akorn has chlorothiazide 500 mg vials on back order and the company estimates a release date of mid-February 2018. Akorn has Sodium Diuril injection on back order and the company cannot estimate a release date.
- American Regent has chlorothiazide 500 mg vials available in limited supply.
- Fresenius Kabi has chlorothiazide 500 mg vials on back order and the company estimates a release date of late-February to early-March 2018.
- Mylan Institutional has chlorothiazide 500 mg vials on back order and the company estimates a release date of mid-January 2018.
- Sagent has chlorothiazide 500 mg vials on back order and the company estimates a release date of December 2017.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1296

Clindamycin Injection

January 16, 2018

Reason for the Shortage

- Akorn did not provide a reason for the shortage.
- Alvogen did not provide a reason for the shortage.
- Fresenius Kabi did not provide a reason for the shortage.
- Pfizer has Cleocin available.
- Sagent has clindamycin on shortage due to manufacturing delays.
- Sandoz has clindamycin injection available.

Estimated Resupply Date

- Alvogen has clindamycin 150 mg/mL 2 mL, 4 mL, and 6 mL ADD-Vantage presentations on back order and the company cannot estimate a release date.
- Sagent has clindamycin 150 mg/mL 2 mL and 4 mL vials on back order and the company estimates a release date of January 2018. The 6 mL vials are available with an expiration date of July 2018.

- Pfizer has Cleocin 150 mg/mL 2 mL ADD-Vantage vials on back order and the company estimates a release date of early-February 2018. Cleocin 150 mg/mL 4 mL vials are available in limited quantities.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1029

Dexrazoxane Injection

January 16, 2018

Reason for the Shortage

- Cumberland Pharmaceuticals relaunched Totect in late-July 2017.
- Mylan Institutional did not provide a reason for the shortage.
- Pfizer states manufacturing delay as the reason for the shortage.
- West-Ward is not actively marketing dexrazoxane injection at this time.

Estimated Resupply Date

- Pfizer has Zinecard 250 mg and 500 mg vials on back order and the company estimates a release date of March 2018 for the 250 mg vials and September 2018 for the 500 mg vials.
- Mylan has dexrazoxane 250 mg and 500 mg vials on intermittent back order and the company is releasing product as it becomes available.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=415

Dipyridamole Injection

January 16, 2018

Reason for the Shortage

- West-Ward did not provide a reason for the shortage.

Estimated Resupply Date

- West-Ward has dipyridamole 5 mg/mL 10 mL vials on back order and the company estimates a release date of late-January to mid-February 2018.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=465

Disopyramide Phosphate Controlled-release Capsules

January 16, 2018

Reason for the Shortage

- Pfizer has disopyramide controlled-release capsules on shortage due to manufacturing delays.

Estimated Resupply Date

- Pfizer has Norpace CR 100 mg capsules in 500 count and 150 mg capsules in 500 count on back order and the company estimates a release date of January 2018
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1139

Hepatitis B Vaccine Recombinant

January 16, 2018

Reason for the Shortage

- Merck has Recombivax HB on shortage due to increase in global demand.
- GlaxoSmithKline discontinued Engerix B pediatric vials in October 2017.

Estimated Resupply Date

- Merck has Recombivax HB adult formulation vials and syringes on back order and the company estimates this will continue through 2018.
- Merck has Recombivax HB pediatric/adolescent formulation syringes and pediatric/adolescent vials on back order and the company estimates a release date of early-April 2018.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=520

Ketorolac Tromethamine Injection

January 16, 2018

Reason for the Shortage

- Amphastar did not provide a reason for the shortage.
- BD RX is now part of Fresenius Kabi.
- Fresenius Kabi did not provide a reason for the shortage.
- Pfizer has ketorolac injection on back order due to manufacturing delays.
- 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 Date

- Amphastar has ketorolac 30 mg/mL 1 mL vials on back order and the company cannot estimate a release date.
- Fresenius Kabi has ketorolac 30 mg/mL 1 mL prefilled syringes on intermittent back order and the company is releasing product as it becomes available. The 15 mg/mL 1 mL vials are on back order and the company estimates a release date of mid-February 2018.
- Pfizer has ketorolac 30 mg/mL 2 mL Carpuject syringes for intramuscular injection on back order and the company estimates a release date of June 2019. The 30 mg/mL 1 mL vials are on back order and the company estimates a release date of late-January 2018.
- Sagent has ketorolac 30 mg/mL 2 mL vials for intramuscular injection and 30 mg/mL 1 mL vials on allocation.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=593

Leucovorin Calcium Injection

January 16, 2018

Reason for the Shortage

- Fresenius Kabi has leucovorin available.
- Sagent had leucovorin on shortage due to manufacturing delay.
- Teva has leucovorin available.
- West-Ward did not provide a reason for the current shortage.

Estimated Resupply Date

- Fresenius Kabi has leucovorin 500 mg vials on intermittent back order and the company is releasing product as it becomes available.
- West-Ward has leucovorin 200 mg and 350 mg vials on allocation.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=488

Methotrexate Injection

January 16, 2018

Reason for the Shortage

- Accord did not provide a reason for the shortage.
- Fresenius Kabi has methotrexate injection available.
- Mylan Institutional did not provide a reason for the shortage. Mylan Institutional discontinued the 40 mg/mL 2 mL and 4 mL vials in late-2017.
- Pfizer has methotrexate injection available.
- Teva had methotrexate injection on shortage due to increased demand.

Estimated Resupply Date

- Accord has methotrexate 25 mg/mL 2 mL, 10 mL, and 40 mL vials on back order and the company cannot estimate a release date.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=26

Metoclopramide Injection

January 16, 2018

Reason for the Shortage

- Pfizer has metoclopramide injection on shortage due to manufacturing delays.
- Teva has metoclopramide injection on shortage due to increased demand.

Estimated Resupply Date

- Fresenius Kabi has metoclopramide 5 mg/mL 2 mL syringes on back order and the company estimates a release date of early-March 2018.
- Pfizer has metoclopramide 5 mg/mL 2 mL vials on back order and the company estimates a release date of late-January 2018.
- Teva has metoclopramide 5 mg/mL 2 mL vials on allocation.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=611

Mitoxantrone Hydrochloride Injection
January 16, 2018

Reason for the Shortage

- Fresenius Kabi has mitoxantrone available.
- Pfizer has mitoxantrone injection on shortage due to manufacturing delays.
- Teva has mitoxantrone injection available except for the 10 mL vials which are temporarily discontinued.

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Estimated Resupply Date

- Fresenius Kabi has mitoxantrone 2 mg/mL 15 mL vials available with an expiration date of <5 months. The mitoxantrone 2 mg/mL 10 mL vials are on back order and the company estimates a release date of early-February 2018.
- Pfizer has mitoxantrone 2 mg/mL 15 mL vials on back order and the company estimates a release date of March 2018.
- Teva has temporarily discontinued mitoxantrone 10 mL vials and the company cannot estimate a release date.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1212

23.4% Sodium Chloride Injection
January 14, 2018

Reason for the Shortage

- Fresenius Kabi has 23.4% sodium chloride injection on shortage due to increased demand.
- Pfizer has 23.4% sodium chloride injection on shortage due to increased demand.

Estimated Resupply Date

- Fresenius Kabi has 23.4% sodium chloride 30 mL vials on back order and the company estimates a release date of early-February 2018. The 100 mL and 200 mL vials are on back order and the company estimates a release date of mid- to late-February 2018.
- Pfizer has 23.4% sodium chloride 200 mL vials on back order and the company estimates a release date of late-January 2018.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1279

Azithromycin Injection
January 14, 2018

Reason for the Shortage

- Pfizer has azithromycin injection on shortage due to manufacturing delays.
- AuroMedics did not provide a reason for the shortage.

Estimated Resupply Date

- Pfizer has azithromycin 500 mg ADD-Vantage vials on back order and the company estimates a release date of June 2018.

- AuroMedics has azithromycin 500 mg vials on intermittent back order and the company is releasing product as it becomes available.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=936

Nitroglycerin Injection

January 14, 2018

Reason for the Shortage

- American Regent did not provide a reason for the shortage.
- The premixed bags are not affected by this shortage.

Estimated Resupply Date

- American Regent has nitroglycerin 50 mg/mL 10 mL vials available in limited supply.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=786

Norepinephrine Bitartrate Injection

January 14, 2018

Reason for the Shortage

- Claris has norepinephrine injection available.
- Pfizer has Levophed on shortage due to manufacturing delays.
- Teva has norepinephrine injection on allocation due to increased demand.

Estimated Resupply Date

- Pfizer has Levophed 1 mg/mL 4 mL ampules and 4 mL vials on back order and the company estimates a release date of mid-February 2018.
- Teva has norepinephrine 1 mg/mL 4 mL vials on allocation.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1262

Pantoprazole Injection

January 14, 2018

Reason for the Shortage

- Pfizer has Protonix injection on shortage due to manufacturing delays.
- AuroMedics has pantoprazole injection available.
- West-Ward has pantoprazole injection available.

Estimated Resupply Date

- Pfizer has Protonix 40 mg vials in 25 count packs on back order and the company estimates a release date of early-February 2018.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1153

Clonidine Extended-Release Tablets
January 12, 2018

Reason for the Shortage
- Concordia did not provide a reason for the shortage of Kapvay tablets.

Estimated Resupply Date
- Concordia has Kapvay 0.1 mg extended-release tablets on long-term back order and the company cannot estimate a release date.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1303

Oxacillin Sodium Injection
January 12, 2018

Reason for the Shortage
- AuroMedics did not provide a reason for the shortage.
- Baxter has oxacillin on shortage due to manufacturing delays.
- Sagent has oxacillin on shortage due to manufacturing delays.

Estimated Resupply Date
- AuroMedics has all oxacillin presentations on back order and the company cannot estimate a release date.
- Baxter has oxacillin 1gram/50 mL and 2 gram/50 mL premixes on allocation.
- Sagent has oxacillin 10 gram bulk vials on allocation.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1121

Penicillamine
January 12, 2018

Reason for the Shortage
- Mylan did not provide a reason for the shortage.

Estimated Resupply Date
- Mylan has Depen tablets on allocation.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1304

Sufentanil Injection
January 12, 2018

Reason for the Shortage
- Pfizer has sufentanil injection on shortage due to manufacturing delays.
- Akorn has Sufenta injection on shortage due to increased demand for the product.
- West-Ward did not provide a reason for the shortage

Estimated Resupply Date

- Pfizer has sufentanil 50 mcg/mL 2 mL vials on back order and the company estimates a release date of March 2018.
- West-Ward has sufentanil 50 mcg/mL 5 mL ampules on allocation.
- Akorn has Sufenta 50 mcg/mL 2 mL ampules on back order and the company estimates a release date of mid-February 2018.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=823

Ampicillin Sulbactam

January 11, 2018

Reason for the Shortage

- Pfizer has discontinued generic ampicillin sulbactam.
- Sandoz cannot provide a reason for the shortage.
- Sagent has ampicillin sulbactam vials on allocation due to manufacturing delays.
- WG Critical Care states the shortage was due to increased demand.

Estimated Resupply Date

- AuroMedics has ampicillin sulbactam 1.5 gram and 3 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 long-term back order and the company cannot estimate a release date.
- Sagent has ampicillin sulbactam 1.5 gram and 15 gram vials on back order and the company estimates a release date of January 2018. Short-dated product is available.
- 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 15 gram vials on allocation.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=805

Fluconazole Injection

January 11, 2018

Reason for the Shortage

- Baxter, Claris Lifesciences, and West-Ward did not provide a reason for the fluconazole injection shortage.
- Pfizer has fluconazole injection on shortage due to manufacturing delays.

Estimated Resupply Date

- Baxter has 200 mg/100 mL and 400 mg/200 mL in 0.9% sodium chloride premixed bags on back order and the company cannot estimate a release date.
- Claris Lifesciences has fluconazole injection 100 mg/50 mL in 0.9% sodium chloride in 6 count, 400 mg/200 mL in 0.9% sodium chloride in 6 count, 200 mg/100 mL in 5% dextrose in 6 count, and 400 mg/200 mL in 5% dextrose in 6 count on back order and the company cannot estimate a release date. Fluconazole injection 400 mg/200 mL in 5% dextrose in 10 count is available in limited supply.

- West-Ward has all presentations on back order. The company cannot estimate a release date for any of the presentations except for the 200 mg/100 mL in 5% dextrose premixed bags which have an estimated release date of February to March 2018.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=644

Furosemide Tablets

January 11, 2018

Reason for the Shortage

- Major states the shortage is due to supply and demand issues.
- Mylan and Teva did not provide a reason for the shortage.
- West-Ward states the shortage is due to manufacturing delays.
- Sandoz discontinued furosemide tablets in late-August 2017.

Estimated Resupply Date

- Mylan has furosemide 20 mg tablets in 1000 count on intermittent back order and the company is releasing product as it becomes available. The 40 mg tablets in 100 count are on back order and the company estimates a release date of mid-March 2018. The 40 mg tablets in 1000 count bottles are on intermittent back order and the company is releasing product as it becomes available. The 80 mg tablets in 100 count and 1000 count bottles are on back order and the company estimates a release date of mid-March 2018.
- Teva has furosemide 20 mg and 40 mg tablets in 100 and 1000 count bottles temporarily unavailable and the company cannot estimate a release date.
- West-Ward has furosemide 20 mg tablets n 100 count and 1000 count bottles on allocation. The 40 mg tablets in 100 count and 1000 count bottles are on allocation.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1281

Piperacillin Tazobactam Injection

January 11, 2018

Reason for the Shortage

- Apotex has piperacillin/tazobactam on shortage due to regulatory delays.
- AuroMedics and Sandoz could not provide a reason for the shortage.
- 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 single dose vials and piperacillin/tazobactam on shortage due to manufacturing delays.
- Sagent has piperacillin/tazobactam on shortage due to increased demand.
- Sandoz has piperacillin/tazobactam available for contracted customers.
- WG Critical Care states the reason for the shortage is increased demand.
- FDA in conjunction with SteriMax was allowing temporary importation of piperacillin/tazobactam 3.375 gram, 4.5 gram, and 40.5 gram vials from Canada. This was being distributed through X-Gen Pharmaceuticals. These are no longer being imported with the launch of the products from X-Gen. The product codes on these items will not be recognized by U.S.

systems so institutions will need to implement alternative plans to assure the dose is being given correctly. More information can be found here on the FDA site.
- Wockhardt has piperacillin/tazobactam injection available.
- X-Gen has piperacillin/tazobactam injection available.

Estimated Resupply Date
- Apotex has piperacillin/tazobactam 3.375 gram and 40.5 gram vials on back order and the company estimates a release date of late-January 2018.
- Baxter has Zosyn 3.375 gram/50 mL premixed bags available in limited supply.
- Mylan has piperacillin/tazobactam 3.375 gram vials available with a short expiration date (expiration September 2018). The 4.5 gram vials are on back order and the company cannot estimate a release date.
- Pfizer has Zosyn 2.25 gram vials, 3.375 gram vials, 4.5 gram vials, and 40.5 gram vials on back order and the company estimates a release date of January 2018. Pfizer has piperacillin/tazobactam 3.375 gram and 4.5 gram ADD-Vantage vials available in limited supply.
- WG Critical Care has piperacillin/tazobactam 40.5 gram vials on back order and the company estimates a release date in April 2018.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1075

Vecuronium Bromide Injection
January 11, 2018

Reason for the Shortage
- Pfizer has vecuronium on shortage due to manufacturing delays.
- Teva has vecuronium available.
- 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.
- Sun Pharma refuses to provide information on availability of any of their products.
- Sagent is not marketing vecuronium 10 mg and 20 mg vials.
- Fresenius Kabi has vecuronium on shortage due to manufacturing delays.

Estimated Resupply Date
- Mylan Institutional has vecuronium 10 mg and 20 mg vials on back order with an estimated release date of late-January to early-February 2018 for the 10 mg vials and late-February to early-March 2018 for the 20 mg vials.
- Pfizer has vecuronium 10 mg and 20 mg vials on back order and the company estimates a release date of March 2019.
- Fresenius Kabi has vecuronium 10 mg and 20 mg vials on back order and the company estimates a release date of late-March 2018.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=490

Bupivacaine Injection
January 10, 2018

Reason for the Shortage

- AuroMedics has not provided a reason for the shortage.
- Fresenius Kabi had Sensorcaine on shortage due to increased demand for the product.
- Pfizer has bupivacaine on shortage due to manufacturing delays. Pfizer discontinued 0.5% bupivacaine 30 mL glass ampules in December 2017.

Estimated Resupply Date

- AuroMedics has 0.25% bupivacaine 30 mL preservative-free vials on intermittent back order and the company is releasing product as it becomes available. The 0.5% bupivacaine 10 mL and 30 mL preservative-free vials are on intermittent back order and the company is releasing product as it becomes available.
- Pfizer has 0.25% bupivacaine and 0.5% bupivacaine 10 mL preservative-free vials on back order and the company estimates a release date of late-February. The 0.25% bupivacaine and 0.5% bupivacaine 30 mL preservative-free vials are on back order and the company estimates a release date in early-April 2018.
- Pfizer has all Marcaine presentations on back order and the company estimates a release date in March 2019.
- Fresenius Kabi has 0.25% Sensorcaine 50 mL vials on back order and the company estimates a release date of mid-January 2018. The 0.5% Sensorcaine 10 mL preservative-free vials are on back order and the company estimates a release date of early-February 2018. The 0.5% Sensorcaine 50 mL vials are on back order and the company estimates a release date of late-January to early-February 2018.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=864

Calcium Chloride Injection

January 10, 2018

Reason for the Shortage

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

- American Regent has calcium chloride 100 mg/mL 10 mL vials on back order and the company cannot estimate a release date.
- Amphastar has calcium chloride 100 mg/mL 10 mL syringes on intermittent back order with regular releases.
- Pfizer has calcium chloride 100 mg/mL 10 mL Ansyr syringes on back order and the company estimates a release date of late-February 2018. The 100 mg/mL 10 mL LifeShield syringes are on back order and the company estimates a release date of late-January 2018.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=941

Cefoxitin Sodium Injection
January 10, 2018

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

Estimated Resupply Date
- Apotex has cefoxitin 1 gram, 2 gram, and 10 gram vials on back order and the company estimates a release date in late-January 2018.
- Fresenius Kabi has cefoxitin 10 grams on back order and the company estimates a release date in late-January 2018.
- Sagent has cefoxitin 1 gram on allocation.
- West-Ward has cefoxitin 10 gram vials on back order and the company cannot estimate a release date. The 2 gram vials are on allocation.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1256

Dobutamine Injection
January 10, 2018

Reason for the Shortage
- Baxter has dobutamine on shortage due to manufacturing delays.
- Pfizer has dobutamine on shortage due to manufacturing delays.

Estimated Resupply Date
- Baxter has all dobutamine premixed bags on allocation only through direct orders. Product is not available through wholesalers.
- Pfizer has dobutamine 12.5 mg/mL 20 mL and 40 mL latex-free vials on back order with an estimated release date of March 2019 for the 20 mL vials and 2018 for the 40 mL vials. The 12.5 mg/mL 20 mL regular vials in 10 count are on back order and the company estimates a release date of mid-February 2018. The 12.5 mg/mL 20 mL regular vials in single count are available in limited supply.
- Pfizer has dobutamine 1 mg/mL in 250 mL bags on back order and the company estimates a release date of April 2018. The dobutamine 2 mg/mL 250 mL bags are on back order and the company estimates a release date of early-May 2018. The dobutamine 4 mg/mL 250 mL bags are on back order and the company estimates a release date of early-May 2018.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=929

Dorzolamide 2% and Timolol 0.5% Ophthalmic Solution
January 10, 2018

Reason for the Shortage
- Akorn has dorzolamide and timolol ophthalmic solution on shortage due to manufacturing delays.

- Sandoz did not provide a reason for the shortage.
- Teva did not provide a reason for the shortage.
- Valeant did not provide a reason for the shortage.

Estimated Resupply Date

- Akorn has dorzolamide 2% and timolol 0.5% ophthalmic solution on allocation. The company has Cosopt 2%/0.5% ophthalmic solution available but with < 8 months until the expiration date. Cosopt PF 0.2 mL preservative-free vials are available.
- Sandoz has dorzolamide 2% and timolol 0.5% ophthalmic solution on back order and the company estimates a release date of early-February 2018.
- Teva has dorzolamide 2% and timolol 0.5% ophthalmic solution on back order and the company estimates a release date of late-February 2018.
- Valeant has dorzolamide 2% and timolol 0.5% ophthalmic solution on back order and the company estimates a release date of mid-January 2018.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1292

Etoposide Injection

January 10, 2018

Reason for the Shortage

- Accord has etoposide on back order due to increased demand.
- Fresenius Kabi has etoposide on back order due to increased demand.
- Teva did not provide a reason for the current shortage.
- Etoposide phosphate powder for injection (Etopophos) is unaffected by this shortage.

Estimated Resupply Date

- Accord has etoposide 20 mg/mL 5 mL, 25 mL, and 50 mL vials on back order and the company estimates a release date of January 2018.
- Fresenius Kabi has etoposide 20 mg/mL 5 mL, 25 mL, and 50 mL vials on back order and the company estimates a release date of late-January 2018 for the 5 mL vials, mid-February 2018 for the 25 mL vials, and late-January to early-February for the 50 mL vials.
- Teva has Toposar 20 mg/mL 5 mL, 25 mL, and 50 mL vials on intermittent back order and is allocating product upon release.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=652

Magnesium Sulfate Injection

January 10, 2018

Reason for the Shortage

- American Regent has had magnesium sulfate unavailable since late 2012.
- Fresenius Kabi had magnesium sulfate injection on shortage due to increased demand for the product.
- Pfizer has magnesium sulfate injection on shortage due to manufacturing delays.
- X-Gen has magnesium sulfate injection available.

Estimated Resupply Date

- Fresenius Kabi has magnesium sulfate 500 mg/mL 10 mL, 20 mL, and 50 mL vials on back order and the company estimates a release date of mid-February 2018 for the 10 mL vials, mid- to late-February 2018 for the 20 mL vials, and late-January 2018 for the 50 mL vials. The 40 mg/mL 100 mL premixed bags are on back order and the company estimates a release date of late-January 2018.
- Pfizer has magnesium sulfate 500 mg/mL 20 mL vials on back order and the company estimates a release date of June 2018. The magnesium sulfate 40 mg/mL 50 mL and 1000 mL bags are on back order and the company estimates a release date of late-January 2018 for the 50 mL bags and early-February 2018 for the 1000 mL bags. The 40 mg/mL 500 mL bags are available in limited supply.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=757

Mannitol Injection

January 10, 2018

Reason for the Shortage

- American Regent did not provide a reason for the mannitol shortage.
- Baxter did not provide a reason for the mannitol shortage.
- Fresenius Kabi did not provide a reason for the mannitol shortage.
- Pfizer has mannitol on shortage due to manufacturing delays

Estimated Resupply Date

- American Regent has mannitol 250 mg/mL 50 mL vials on back order and the company cannot estimate a release date.
- Baxter has Osmitrol 50 mg/mL 1000 mL premixed bags on back order and the company cannot estimate a release date. The 200 mg/mL 250 mL and 500 mL premixed bags are available in limited supply.
- Fresenius Kabi has mannitol 250 mg/mL 50 mL vials on back order and the company estimates a release date of early-February 2018.
- ICU Medical has mannitol 200 mg/mL 250 mL and 500 mL premixed bags available in limited supply.
- Pfizer has mannitol 250 mg/mL 50 mL vials on back order and the company estimates a release date of late-January 2018.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=863

Mepivacaine Injection

January 10, 2018

Reason for the Shortage

- Fresenius Kabi has Polocaine and Polocaine-MPF available.
- Pfizer states the reason for the shortage is manufacturing delays.

Estimated Resupply Date

- Pfizer has Carbocaine 1% 50 mL multiple-dose vials on back order and the company estimates a release date of mid-February 2018. Carbocaine 1% 30 mL preservative-free vials are available in limited supply. Carbocaine 1.5% 30 mL preservative-free vials are on back order and the company estimates a release date of March 2019. Carbocaine 2% 50 mL multiple-dose vials are back order and the company estimates a release date of early-February 2018.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=954

Moxifloxacin Injection

January 10, 2018

Reason for the Shortage

- Bayer did not provide a reason for the shortage.
- Fresenius Kabi has moxifloxacin injection on shortage due to increased demand.

Estimated Resupply Date

- Fresenius Kabi has moxifloxacin 400 mg/250 mL premixed bags on back order and the company estimates a release date of mid- to late-March 2018.
- Bayer has Avelox I.V. 400 mg/250 mL premixed bags on back order and the company cannot estimate a release date.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1151

Multiple Vitamins for Infusion

January 10, 2018

Reason for the Shortage

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

Estimated Resupply Date

- Pfizer has M.V.I. adult 50 mL Dual vials on back order and the company estimates a release date of mid-March 2018.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=831

Mupirocin Calcium 2% Cream

January 10, 2018

Reason for the Shortage

- GlaxoSmithKline is looking for an alternative supply source.
- Prasco discontinued mupirocin calcium 2% cream in February 2016.

Estimated Resupply Date

- GlaxoSmithKline has Bactroban 2% cream in 15 gram and 30 gram sizes on long-term back order and the company cannot estimate a release date.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1206

Mupirocin Calcium 2% Nasal Ointment

January 10, 2018

Reason for the Shortage

- GlaxoSmithKline states the shortage is due to manufacturing issues. GlaxoSmithKline is looking for an alternative supply source.

Estimated Resupply Date

- GlaxoSmithKline has Bactroban Nasal 2% Ointment in 1 gram tubes on long-term back order and the company cannot estimate a release date
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1094

Potassium Phosphate Injection

January 10, 2018

Reason for the Shortage

- American Regent has not had potassium phosphate injection available since 2012. It is unclear if and when product will return to market.
- Fresenius Kabi had potassium phosphate injection on shortage due to increased demand.
- Pfizer has potassium phosphate injection on shortage due to manufacturing delays.

Estimated Resupply Date

- Pfizer has potassium phosphate 3 mmol/mL 15 mL vials on back order and the company estimates a release date of mid-March 2018.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=709

Sodium Phosphate Injection

January 10, 2018

Reason for the Shortage

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

Estimated Resupply Date

- 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 sodium phosphate 3 mmol/mL 5 mL and 15 mL vials on back order and the company estimates a release date of late-January 2018.
- Pfizer has sodium phosphate 3 mmol/mL 15 mL vials available in limited supply.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=770

0.9% Sodium Chloride 10 mL, 20 mL, and 50 mL Preservative Free Vials and Syringes

January 9, 2018

Reason for the Shortage

- Fresenius Kabi did not provide a reason for the shortage.
- Pfizer has 0.9% sodium chloride preservative-free vials on shortage due to manufacturing delays.

Estimated Resupply Date

- Fresenius Kabi has 0.9% sodium chloride preservative free 10 mL and 20 mL vials on back order and the company estimates a release date of mid-January 2018 for the 10 mL vials and late-February to early-March 2018 for the 20 mL vials.
- Pfizer has 0.9% sodium chloride preservative free 10 mL and 20 mL vials on back order and the company estimates a release date of late-February 2018 for the 10 mL vials and mid-February 2018 for the 20 mL vials. The 50 mL vials are also on back order and the company estimates a release date of late-February 2018.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1276

Amiodarone Injection

January 6, 2018

Reason for the Shortage

- Baxter has Nexterone premixed bags on shortage due to manufacturing delays.
- Fresenius Kabi did not provide a reason for the shortage.
- Mylan Institutional did not provide a reason for the shortage.

Estimated Resupply Date

- Baxter has Nexterone 150 mg/100 mL and 360 mg/200 mL premixed bags on back order and the company cannot estimate a release date.
- Fresenius Kabi has amiodarone 50 mg/mL 9 mL vials in intermittent back order and the company is releasing product as it becomes available.
- Mylan Institutional has amiodarone 50 mg/mL 9 mL vials on back order and the company estimates a release date of late-January 2018. The 18 mL vials are available with an expiration date of October 2018.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1300

Atropine Sulfate Injection

January 6, 2018

Reason for the Shortage

- American Regent has atropine injection on shortage due to market demand.
- Pfizer has atropine injection on shortage due to manufacturing delays.

Estimated Resupply Date

- American Regent has atropine 0.4 mg/mL 1 mL ampules on back order and the company cannot estimate a release date.
- Pfizer has atropine 0.1 mg/mL 10 mL Ansyr syringes available on back order and the company estimates a release date of early-January 2018. The 0.1 mg/mL 5 mL LifeShield syringes and 0.1 mg/mL 10 mL LifeShield syringes are on back order and the company estimates a release date of March 2018 for the 5 mL LifeShield syringes and early-January 2018 for the 10 mL LifeShield syringes.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=814

Cefuroxime Sodium Injection

January 6, 2018

Reason for the Shortage

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

Estimated Resupply Date

- Sagent has cefuroxime 750 mg and 1.5 gram vials on back order and the company estimates a release date of January 2018. The 7.5 gram vials on back order and the company cannot estimate a release date.
- Teligent has Zinacef 750 mg vials, 750 mg ADD-Vantage vials, 1.5 gram vials, and 7.5 gram vials on long-term back order and the company cannot estimate a release date.
- West-Ward has cefuroxime 750 mg vials and 7.5 gram vials on allocation. The 1.5 gram vials are on back order and the company estimates a release date of January 2018.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=990

Dexamethasone Sodium Phosphate

January 6, 2018

Reason for the Shortage

- American Regent has dexamethasone sodium phosphate on shortage due to manufacturing delays.
- AuroMedics has dexamethasone sodium phosphate on intermittent back order.
- Fresenius Kabi has dexamethasone sodium phosphate presentations available.
- Mylan Institutional did not provide a reason for the shortage.
- West-Ward has dexamethasone sodium phosphate available.

Estimated Resupply Date

- American Regent has dexamethasone sodium phosphate 4 mg/mL products on back order and the company cannot estimate a release date.
- AuroMedics has dexamethasone sodium phosphate 4 mg/mL 1 mL vials on intermittent back order and the company is releasing product as it becomes available.
- Fresenius Kabi has dexamethasone sodium phosphate 4 mg/mL 1 mL prefilled syringes available with an expiration date of <7 months.

- West-Ward has dexamethasone sodium phosphate 4 mg/mL 1 mL and 5 mL vials on back order and the company estimates a release date of February to March 2018.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=751

Diltiazem Hydrochloride Injection

January 6, 2018

Reason for the Shortage

- Akorn states the reason for the shortage was increased demand due to market conditions.
- Pfizer states the reasons for the shortage is manufacturing delays and increases in demand.
- West-Ward has diltiazem injection on shortage due to manufacturing delays caused by increased demand due to current market conditions.

Estimated Resupply Date

- Akorn has diltiazem 5 mg/mL 10 mL vials and 25 mL vials in 10 count available with short-dating.
- Pfizer has 100 mg ADD-Vantage vials available in limited supply. The 5 mg/mL 5 mL and 10 mL vials are on back order and the company estimates a release date of March 2018.
- West-Ward has diltiazem 5 mg/mL 10 mL and 25 mL vials on back order and the company estimates a release date of January to February 2018.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1271

Doxorubicin Injection

January 6, 2018

Reason for the Shortage

- West-Ward has Adriamycin available.
- Teva has doxorubicin solution for injection available.
- Fresenius Kabi has doxorubicin solution for injection available.
- Caraco has discontinued doxorubicin solution for injection 25 mL and 100 mL vials.
- Pfizer has doxorubicin solution for injection available.
- Sagent has doxorubicin solution for injection on back order due to manufacturing delays.
- Mylan Institutional has doxorubicin lyophilized powder for injection available.
- Actavis had doxorubicin on shortage due to increased demand.
- FDA is allowing temporary importation of doxorubicin lyophilized powder for injection 50 mg vials. These vials were manufactured for Hospira UK Limited. The labeling as well as bar coding for the imported product is different from the US version. FDA has the Dear Healthcare Professional Letter linked on their website. The letter includes a link to both the US and United Kingdom package inserts to help explain the differences in labeling and packaging. Ordering can be done directly with Hospira Customer Care at 877-946-7747.

Estimated Resupply Date

- Mylan Institutional has doxorubicin lyophilized powder 10 mg vials available with an expiration date of August 2018.
- Sagent has doxorubicin 2 mg/mL 5 mL, 25 mL, and 100 mL vials on back order and the company cannot estimate a release date.

- Pfizer has doxorubicin 2 mg/mL 10 mL and 100 mL vials on back order and the company estimates a release date of late-February 2018 for the 10 mL vials and March 2018 for the 100 mL vials.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=464

Epinephrine Injection

January 6, 2018

Reason for the Shortage

- Amphastar stopped distributing epinephrine 1 mg/mL 30 mL vials on May 10, 2017. They are continuing to supply 0.1 mg/mL 10 mL syringes. These are on shortage due to increased demand.
- Pfizer stopped distributing epinephrine 1 mg/mL presentations on May 10, 2017.
- BPI has epinephrine 1 mg/mL 2 mL ampules available.
- Par has Adrenalin 1 mg/mL 1 mL and 30 mL vials available.

Estimated Resupply Date

- Amphastar has epinephrine 0.1 mg/mL 10 mL syringes on allocation.
- Pfizer has epinephrine 0.1 mg/mL 10 mL syringes on back order and the company estimates a release date of early-February 2018.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=685

etomidate Injection

January 6, 2018

Reason for the Shortage

- American Regent did not provide a reason for the current shortage.
- AuroMedics did not provide a reason for the current shortage.
- Mylan did not provide a reason for the current shortage.
- Par Sterile Products discontinued etomidate in early 2015.
- Pfizer has Amidate on shortage due to manufacturing delays. Pfizer discontinued etomidate ampules in October 2016.
- Sagent is no longer marketing etomidate.
- West-Ward did not provide a reason for the current shortage.
- Zydus had etomidate on shortage due to an increase in demand.

Estimated Resupply Date

- American Regent has etomidate 2 mg/mL 10 mL and 20 mL vials on back order and the company cannot estimate a release date.
- AuroMedics has 2 mg/mL 20 mL vials on intermittent back order.
- Mylan Institutional has etomidate 2 mg/mL 10 mL and 20 mL vials on back order and the company estimates a release date of late-July to early-August 2018.
- Pfizer has Amidate 2 mg/mL 20 mL LifeShield syringes on back order and the company cannot estimate a release date. The 2 mg/mL 10 mL and 20 mL vials are on back order and the company estimates a release date of early-January 2018.

- West-Ward has etomidate 2 mg/mL 20 mL vials on allocation.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=419

Furosemide Injection

January 6, 2018

Reason for the Shortage

- American Regent is not actively marketing furosemide injection.
- Pfizer has furosemide injection on shortage due to manufacturing delays and increased demand.
- Claris has furosemide injection available.
- Fresenius Kabi has furosemide injection available.

Estimated Resupply Date

- Claris has furosemide 10 mg/mL 4 mL and 10 mL vials in 5 count on back order and the company cannot estimate a release date. The 10 mg/mL 2 mL vials in 5 count are available with an expiration date of May 2018.
- Pfizer has furosemide 10 mg/mL 4 mL syringes on back order and the company is releasing product as it becomes available. The 2 mL vials and 10 mL syringes are available in limited supply.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=636

Methylphenidate Extended-Release Oral Suspension and Chewable Tablets

January 6, 2018

Reason for the Shortage

- Pfizer has Quillivant XR and Quillichews on shortage due to manufacturing delays.

Estimated Resupply Date

- Pfizer has Quillivant XR 5 mg/mL extended-release oral suspension in 60 mL, 120 mL, 150 mL, and 180 mL bottles on back order and the company cannot estimate a release date.
- Pfizer has QuilliChews 20 mg and 30 mg extended-release chewable tablets in 100 count on back order and the company cannot estimate a release date.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1301

Metoprolol Injection

January 6, 2018

Reason for the Shortage

- Alvogen has metoprolol injection available.
- American Regent has had metoprolol injection on long-term back order for several years.
- Athenex has metoprolol injection available.
- Claris has metoprolol injection available.
- Fresenius Kabi has metoprolol injection available.
- Mylan Institutional acquired metoprolol injection from Sagent.

- Pfizer has metoprolol injection on shortage due to manufacturing delays.
- West-Ward has metoprolol injection available.

Estimated Resupply Date
- Mylan Institutional has metoprolol 1 mg/mL 5 mL vials available with an expiration date of July 2018.
- Pfizer has metoprolol 1 mg/mL 5 mL vials available in limited supply. The 1 mg/mL 5 mL ampules are on back order and the company estimates a release date of September 2018. The 1 mg/mL 5 mL Carpuject syringes are on back order and the company estimates a release date of June 2019.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=813

Metronidazole Hydrochloride Injection
January 6, 2018

Reason for the Shortage
- Pfizer has metronidazole injection on shortage due to manufacturing delay.
- Baxter, BBraun, and Claris did not provide a reason for the metronidazole injection shortage.

Estimated Resupply Date
- Baxter has metronidazole 100 mL bags on available only through direct orders.
- BBraun has metronidazole 100 mL bags on back order and the company cannot estimate a release date.
- Claris has metronidazole 100 mL bags on long-term back order and the company cannot estimate a release date.
- Pfizer has metronidazole 100 mL bags in 80 count on back order and the company estimates a release date of early-February 2018.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1272

Penicillin G Benzathine/Penicillin G Procaine
January 6, 2018

Reason for the Shortage
- Pfizer has Bicillin C-R on shortage due to manufacturing delays

Estimated Resupply Date
- Pfizer has Bicillin C-R 1,200,000 units/2 mL prefilled syringes and 1,200,000 units/2 mL pediatric prefilled syringes on allocation with weekly releases to wholesalers.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1249

Penicillin G Procaine Injection
January 6, 2018

Reason for the Shortage

- Pfizer has penicillin G procaine on shortage due to manufacturing delays.
- Pfizer is the sole supplier of penicillin G procaine.

Estimated Resupply Date
- Pfizer has penicillin G procaine 600,000 unit/mL 1 mL and 2 mL vials on back order and the company estimates a release date of June 2018.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1238

Sterile Water for Injection - Small Volume Vials
January 6, 2018

Reason for the Shortage
- Pfizer has sterile water for injection in vials on shortage due to manufacturing delays.
- Fresenius Kabi did not provide a reason for the shortage.

Estimated Resupply Date
- Fresenius Kabi has sterile water for injection 10 mL vials on intermittent back order and the company is releasing product as it becomes available. The 5 mL vials are on back order and the company cannot estimate a release date. The 20 mL, 50 mL, and 100 mL vials are on back order and the company estimates a release date of early-February 2018 for the 20 mL vials, late-January 2018 for the 50 mL vials, and early-January 2018 for the 100 mL vials.
- Pfizer has sterile water for injection 50 mL vials on back order and the company estimates a release date of late-January 2018. The 10 mL, 20 mL, and 100 mL vials are on back order and the company estimates a release date of March 2018.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1302

Flurbiprofen Sodium Ophthalmic Solution
January 5, 2018

Reason for the Shortage
- Allergan discontinued Ocufen ophthalmic solution in February 2017.
- Valeant had flurbiprofen sodium on shortage due to manufacturing delay.

Estimated Resupply Date
- Valeant has flurbiprofen sodium ophthalmic solution available in limited supply.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1283

5% Dextrose Injection (PVC-free and DEHP-free)
January 3, 2018

Reason for the Shortage
- ICU Medical states the shortage is due to increased demand and manufacturing delays. ICU Medical discontinued the 500 mL VisIV bags in 2011 due to leaking around the administration and medications ports.

- ICU Medical is now the IV fluid business of Pfizer after the acquisition of Hospira.
- Baxter is not currently marketing 5% dextrose PVC/DEHP-free bags.
- BBraun has 250 mL, 500 mL, and 1,000 mL PVC/DEHP-free bags on back order due to manufacturing delays.

Estimated Resupply Date

- BBraun has 5% dextrose 250 mL, 500 mL, and 1,000 mL PVC/DEHP-free bags on back order and the company cannot estimate a release date.
- ICU Medical has 5% dextrose in 50 mL, 100 mL, and 250 mL PVC/DEHP-free bags on back order and the company estimates a release date of mid-January 2018.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1269

Amino Acid Products

January 3, 2018

Reason for the Shortage

- Baxter has most amino acid products on allocation due to delays because of Hurricane Maria in Puerto Rico.
- BBraun has all amino acid on allocation due to increased demand.
- Pfizer has Aminosyn on back order due to an ingredient shortage which has caused a supply disruption. Pfizer has obtained the ingredient, but does not yet have an estimated date as to when manufacturing will resume.

Estimated Resupply Date

- Baxter has their amino acid products on allocation.1
- BBraun has their amino acid products on allocation.2
- Pfizer has all Aminosyn presentations on back order and the company cannot estimate a release date.3
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=671

Amino Acid Products with Electrolytes in Dextrose with Calcium (Clinimix E)

January 3, 2018

Reason for the Shortage

- Baxter has all Clinimix E with electrolytes plus calcium presentations on allocation due to delays because of the hurricane in Puerto Rico.
- To help alleviate the critical drug shortages resulting from the aftermath of Hurricane Maria, FDA has allowed Baxter to temporarily import the following amino acid products: Clinimix N9G15E, Clinimix N9G20E, and Clinimix N14G30E solutions for infusion. Additional information can be found in the Dear Healthcare Professional Letter.

Estimated Resupply Date

- Baxter has all amino acid products with electrolytes plus calcium on allocation.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1024

Amino Acids in Dextrose
January 3, 2018

Reason for the Shortage
- Baxter has all Clinimix presentations on allocation due to delays because of the hurricane in Puerto Rico.

Estimated Resupply Date
- Baxter has all Clinimix presentations on allocation
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1290

Belatacept Injection
January 3, 2018

Reason for the Shortage
- Bristol-Myers Squibb has Nulojix in short supply due to manufacturing delays.

Estimated Resupply Date
- Bristol-Myers Squibb has limited the distribution of Nulojix. They have product only for existing patients available through the US Nulojix Distribution Program. They have no estimated recovery date, but do not expect full recovery before the end of 2018. Nulojix is distributed by McKesson Plasma Biologics.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1265

Heparin Injection
January 3, 2018

Reason for the Shortage
- Fresenius Kabi did not provide a reason for the shortage.
- Pfizer did not provide a reason for the shortage.
- Sagent has all heparin presentations available.
- West-Ward did not provide a reason for the shortage.

Estimated Resupply Date
- Fresenius Kabi has 1,000 unit 2 mL vials on back order and the company estimates a release date of late-January 2018.
- Pfizer has 5,000 unit/mL 1 mL Carpuject syringes on back order and the company estimates a release date of June 2019. The 5,000 unit/mL 10 mL vials are on back order and the company estimates a release date in late-February 2018. The 1,000 unit/mL 10 mL glass vials and 30 mL glass vials are on back order and the company estimates a release date of mid-February 2018 for the 10 mL glass vials and late-January 2018 for the 30 mL glass vials. The 1,000 unit/mL 10 mL vials are on back order and the company cannot estimate a release date. The 10,000 unit/mL 1 mL vials and 1,000 unit/mL 30 mL vials are on back order and the company estimates a release date of January 2018.
- West-Ward has 1,000 mL 30 mL vials and 5,000 unit/mL 10 mL vials are on back order and the company cannot estimate a release date.

- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1289

Lidocaine Hydrochloride and 5% Dextrose injection

January 3, 2018

Reason for the Shortage

- Baxter did not provide a reason for the shortage.
- BBraun did not provide a reason for the shortage.

Estimated Resupply Date

- Baxter has lidocaine and 5% dextrose 4 mg/mL 500 mL premixed bags on allocation. The 8 mg/mL 250 mL premixed bags are on back order and the company cannot estimate a release date.
- BBraun has lidocaine and 5% dextrose 4 mg/mL 250 mL, 4 mg/mL 500 mL, and 8 mg/mL 250 mL premixed bags on intermittent back order and supplies are being allocated upon release.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1177

5% Lidocaine and 7.5% Dextrose Injection

January 2, 2018

Reason for the Shortage

- Pfizer has 5% lidocaine and 7.5% dextrose 2 mL ampules on shortage due to manufacturing delays.
- Pfizer is the sole supplier of this combination.

Estimated Resupply Date

- Pfizer has 5% lidocaine and 7.5% dextrose 2 mL ampules on long-term back order and the company estimates a release date of 2nd quarter 2018
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1245

Cefotaxime Injection

January 2, 2018

Reason for the 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 manufacturing and issues with raw material.

Estimated Resupply Date

- 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.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=826

Doxycycline Hyclate Injection
January 2, 2018

Reason for the Shortage
- Mylan Institutional temporarily discontinued doxycycline 100 mg vials in March 2016.
- Fresenius Kabi has doxycycline injection on shortage due to increased demand.

Estimated Resupply Date
- Fresenius Kabi has doxycycline 100 mg vials on intermittent back order with regular releases.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=431

Morrhuate Sodium Injection
January 2, 2018

Reason for the Shortage
- American Regent has morrhuate sodium injection on shortage due to manufacturing delays.

Estimated Resupply Date
- American Regent has morrhuate sodium 50 mg/mL 30 mL vials on long-term back order and the company cannot estimate a release date.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=903

Vancomycin Hydrochloride Injection
January 2, 2018

Reason for the Shortage
- Pfizer has vancomycin vials on back order due to manufacturing delays.
- Fresenius Kabi has vancomycin injection on shortage due to increased demand.
- Mylan Institutional has vancomycin injection available.
- Sagent has vancomycin injection on shortage due to manufacturing delays and increased demand.
- Baxter has vancomycin injection available.
- Samson Medical Technologies has vancomycin injection available.

Estimated Resupply Date
- Fresenius Kabi has vancomycin 500 mg, 750 mg, 1 gram, 5 gram and 10 gram vials on intermittent back order with regular releases.
- Pfizer has vancomycin 500 mg vials, 1 gram vials, 5 gram vials, and 10 gram vials available in limited supply. The 500 mg ADD-Vantage vials, 750 mg vials, 750 mg ADD-vantage vials, and 1 gram ADD-Vantage vials are on back order and the company estimates a release date of February 2018 for the 500 mg ADD-Vantage vials, mid-January 2018 for the 750 mg ADD-Vantage vials, early-February 2018 for the 750 mg vials, and January 2018 for the 1 gram ADD-Vantage vials.
- Sagent has vancomycin 5 gram and 10 gram vials on allocation.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=132

Erythromycin Lactobionate Injection
December 29, 2017

Reason for the Shortage
- Pfizer has Erythrocin on shortage due to manufacturing delays.

Estimated Resupply Date
- Pfizer has Erythrocin 500 mg ADD-Vantage vials and regular vials on back order and the company estimates a release date of late-January 2018 for the ADD-Vantage vials and September 2018 for the regular vials.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=546

Methyldopate Injection
December 29, 2017

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

Estimated Resupply Date
- American Regent has methyldopate injection on long-term back order and the company cannot estimate a release date.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=844

Procainamide Hydrochloride Injection
December 29, 2017

Reason for the Shortage
- Pfizer did not provide a reason for the shortage.
- Nexus Pharmaceuticals launched procainamide injection in October 2017.

Estimated Resupply Date
- Pfizer has procainamide 100 mg/mL 10 mL vials on back order and the company estimates a release date of late-January 2018.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=868

Sodium Bicarbonate Injection
December 29, 2017

Reason for the Shortage
- Amphastar has sodium bicarbonate injection on shortage due to increased demand.
- Pfizer has sodium bicarbonate injection on shortage due to manufacturing delays.
- Fresenius Kabi has reintroduced sodium bicarbonate injection in response to the shortage.

Estimated Resupply Date

- Amphastar has 8.4 % sodium bicarbonate 50 mL syringes on allocation.
- Pfizer has 8.4 % sodium bicarbonate 10 mL syringes and 7.5% sodium bicarbonate 50 mL syringes on back order and the company estimates a release date of mid-February 2018. The 4.2% sodium bicarbonate 10 mL syringes are on back order and the company estimates a release date of late-January 2018.
- Pfizer has Neut 4% additive solution in 5 mL vials on back order and the company estimates a release date of January 2018.
- To help alleviate the shortage, FDA is granting Athenex Pharmaceutical Division (APD) the ability to import 10 mL vials of sodium bicarbonate from Phebra, an Australian company. Supplies are limited and only available via direct orders. Orders may be placed by contacting customer service at 855-273-0154 or apdorders@dlss.com.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=788

Torsemide Injection

December 29, 2017

Reason for the Shortage

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

Estimated Resupply Date

- American Regent has torsemide injection on long-term back order and the company cannot estimate a release date.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=344

Trace Elements Injection

December 29, 2017

Reason for the Shortage

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

Estimated Resupply Date

- American Regent has trace elements-4 pediatric vials and Multitrace-5 Concentrate 10 mL vials on back order and the company cannot estimate a release date. The Multitrace-4 Pediatric 3 mL vials are available in limited supply.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=785

Alcohol Dehydrated Injection (Ethanol)

December 27, 2017

Reason for the Shortage

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

Estimated Resupply Date

- American Regent has dehydrated alcohol 1 mL and 5 mL ampules on back order and the company cannot estimate a release date.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=778

Aminocaproic Acid Injection

December 27, 2017

Reason for the Shortage

- Pfizer has aminocaproic acid on shortage due to manufacturing delays.

Estimated Resupply Date

- Pfizer has aminocaproic acid 250 mg/mL 20 mL vials on back order and the company estimates a release date of early-February 2018.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=789

Dexpanthenol Injection

December 27, 2017

Reason for the Shortage

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

Estimated Resupply Date

- American Regent has dexpanthenol injection on long-term back order and the company cannot estimate a release date.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1103

Diazepam Injection

December 27, 2017

Reason for the Shortage

- Pfizer has diazepam on shortage due manufacturing delays.

Estimated Resupply Date

- Pfizer has diazepam 5 mg/mL 2 mL Carpuject syringes on back order and the company estimates a release date of early-February 2018.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=492

Electrolyte Concentrate

December 27, 2017

Reason for the Shortage

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

Estimated Resupply Date

- American Regent has Nutrilyte and Nutrilyte II presentations on long-term back order and the company cannot estimate a release date.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1054

Hydroxyzine Hydrochloride Injection

December 27, 2017

Reason for the Shortage

- American Regent would not provide a reason for the shortage. They are the sole supplier of hydroxyzine injection.

Estimated Resupply Date

- American Regent has hydroxyzine 50 mg/mL 10 mL vials on back order and the company cannot estimate a release date. The 50 mg/mL 2 mL vials are available in limited supply.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1185

Indomethacin Capsules

December 27, 2017

Reason for the Shortage

- Glenmark had indomethacin on shortage due to manufacturing delays.
- Heritage did not provide a reason for the shortage. Heritage discontinued indomethacin 50 mg capsule presentations.
- Mylan did not provide a reason for the shortage.
- Sandoz discontinued indomethacin in mid-2016.
- Teva did not provide a reason for the shortage.

Estimated Resupply Date

- Glenmark has indomethacin 25 capsules in 100 count on back order and the company cannot estimate a release date.
- Heritage has indomethacin 25 mg capsules in 100 count and 1,000 count bottles on long-term back order, and the company cannot estimate a release date.
- Teva has all indomethacin presentations temporarily unavailable and the company cannot estimate a release date.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1236

Rocuronium Injection

December 27, 2017

Reason for the Shortage

- Fresenius Kabi has rocuronium on shortage due to delay of raw materials.
- Pfizer has rocuronium on shortage due to manufacturing delays.
- Sagent has rocuronium on shortage due to increased demand.
- AuroMedics launched rocuronium in mid-2017.

Estimated Resupply Date

- Auromedics has rocuronium 10 mg/mL 5 mL and 10 mL vials available with intermittent releases.
- Fresenius Kabi has rocuronium 10 mg/mL 5 mL and 10 mL vials on back order and the company estimates a release date of late-December 2017 for the 5 mL vials and early-January 2018 for the 10 mL vials.
- Sagent has rocuronium 10 mg/mL 5 mL and 10 mL vials on back order and the company estimates a release date of January 2018.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=434

Ammonium Molybdate Injection

December 22, 2017

Reason for the Shortage

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

Estimated Resupply Date

- American Regent has ammonium molybdate injection on back order and the company cannot estimate a release date.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1003

Fluorescein Sodium Ophthalmic Strips

December 22, 2017

Reason for the Shortage

- Hub did not provide a reason for the shortage.
- Akorn did not provide a reason for the shortage.

Estimated Resupply Date

- Akorn has Ful-Glo 0.6 mg and 1 mg strips on back order and the company cannot estimate a release date.
- Hub has Bio-Glo 1 mg strips on back order and the company cannot estimate a release date.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1295

Lorazepam Injection

December 22, 2017

Reason for the Shortage

- Bedford discontinued lorazepam injection in May, 2011.
- West-Ward has product on shortage due to manufacturing delays.
- Pfizer has product on shortage due to increased demand and manufacturing delays. Pfizer discontinued 4 mg/mL 10 mL vials in December 2017.
- Akorn has not provided a reason for the shortage.
- Amphastar has product available.

Estimated Resupply Date

- Pfizer has lorazepam 2 mg/mL 1 mL Carpuject syringes on back order and the company estimates a release date of mid-January 2018. The 2 mg/mL 1 and 10 mL vials are on back order and the company estimates a release date of early-January 2018. The 4 mg/mL 1 mL vials are on back order and the company estimates a release date of late-February 2018. The 4 mg/mL 1 mL Carpuject syringes are on back order and the company estimates a release date of June 2019.
- West-Ward has lorazepam 2 mg/mL 1 mL vials on back order and the company estimates a release date of January 2018. The 4 mg/mL 10 mL vials are on back order and the company estimates a release date of January to February 2018.
- West-Ward has Ativan 2 mg/mL 1 mL and 10 mL vials on back order and the company estimates a release date of January 2018 for the 1 mL vials and January to February 2018 for the 10 mL vials.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1270

Methadone Injection

December 22, 2017

Reason for the Shortage

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

Estimated Resupply Date

- Mylan Institutional has methadone 10 mg/mL 20 mL vials on back order and the company estimates a release date of mid-February 2018.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1291

Ceftriaxone Sodium Injection

December 21, 2017

Reason for the Shortage

- Apotex states the reason for the shortage is manufacturing delays. Apotex launched several products with new NDC numbers in June 2017.
- Fresenius Kabi states the reason for the shortage is increased demand.
- Pfizer has ceftriaxone injection available.
- Sagent states the reason for the shortage is manufacturing delay.
- Sandoz has most ceftriaxone available.
- West-Ward states the reason for the shortage is manufacturing delay.
- WG Critical Care states the reason for the shortage is increased demand.
- Wockhardt relaunched their ceftriaxone presentations in October 2017.

Estimated Resupply Date

- Apotex has ceftriaxone 250 mg and 500 mg on back order and the company cannot estimate a release date.
- Fresenius Kabi has ceftriaxone 500 mg vials on back order and the company cannot estimate a release date.
- Lupin has all ceftriaxone presentations on allocation.

- Pfizer has ceftriaxone 1 gram ADD-Vantage and 2 gram ADD-Vantage vials on allocation.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1101

Fentanyl Citrate Injection

December 21, 2017

Reason for the Shortage

- Akorn has fentanyl injection on shortage due to increased demand.
- West-Ward has fentanyl injection on shortage due to supply and demand issues.
- Pfizer has fentanyl injection on shortage due to manufacturing delays. The 20 mL ampules were discontinued in September 2017.

Estimated Resupply Date

- Akorn has Sublimaze 50 mcg/mL 2 mL ampules in 10 count and 25 count and 5 mL ampules in 10 count and 25 count on allocation.
- Pfizer has fentanyl 50 mcg/mL 2 mL and 5 mL ampules on back order and the company estimates a release date in early-January 2018. The 2 mL Carpuject syringes are on back order and the company estimates a release date of June 2019. The 5 mL, 20 mL, and 50 mL vials are on intermittent back order and the company is releasing product as it becomes available.
- West-Ward has fentanyl 50 mcg/mL 2 mL, 5 mL, and 50 mL vials on allocation. The 2 mL, 5 mL, and 20 mL ampules are on back order and the company cannot estimate a release date.
- https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1101

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