September 2017

Drug Information Update

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NEWLY AVAILABLE GENERICS

GENERIC DRUG NAME	STRENGTH & DOSAGE FORM	GENERIC MANUFACTURER	BRAND NAME
CHLORZOXAZONE	250 MG TABLET	SOLUBIOMIX, LLC	CHLORZOXAZONE
LIDOCAINE HCL/PF	200 MG/20 ML (1 %) SYRINGE	PHARMEDIUM/OF	LIDOCAINE HCL
GLYCOPYRROLATE	1.5 MG TABLET	SOLUBIOMIX, LLC	GLYCOPYRROLATE
EPHEDRINE SULFATE/0.9% NACL/PF	10 MG/5 ML (2 MG/ML) SYRINGE	PHARMEDIUM/OF	EPHEDRINE SULFATE-0.9% NACL
EPINEPHRINE HCL IN 0.9 % NACL	200 MCG/10 ML (20 MCG/ML) SYRINGE	PHARMEDIUM/OF	EPINEPHRINE HCL-0.9% NACL
DIAZEPAM	5 MG-7.5 MG-10 MG KIT	OCEANSIDE PHARM	DIASTAT ACUDIAL
DIAZEPAM	12.5 MG-15 MG-17.5 MG-20 MG KIT	OCEANSIDE PHARM	DIASTAT ACUDIAL
DIAZEPAM	2.5 MG KIT	OCEANSIDE PHARM	DIASTAT
VIGABATRIN	500 MG POWD PACK	PAR PHARM.	SABRIL
LIDOCAINE/PRILOCAINE	4 %-2.5 %-2.5 % KT CRM GEL	TALEOS PHARMA C	DOLOTRANZ
LANTHANUM CARBONATE	500 MG TAB CHEW	PRASCO LABS	FOSRENOL
LANTHANUM CARBONATE	750 MG TAB CHEW	PRASCO LABS	FOSRENOL
LANTHANUM CARBONATE	1000 MG TAB CHEW	PRASCO LABS	FOSRENOL

NEW DRUG ENTITIES/COMBINATIONS/STRENGTHS

DESCRIPTION	BRAND NAME	GENERIC NAME	STRENGTH	NOTES
PRENATAL VITAMIN PREPARATIONS	NESTABS ONE	PNV NO.111/IRON/FOLATE/DHA	38 MG iron-1 MG-225 MG	NEW COMBINATION
DIRECT FACTOR XA INHIBITORS	BEVYXXA	BETRIXABAN MALEATE	40 MG	NEW ENTITY
DIRECT FACTOR XA INHIBITORS	BEVYXXA	BETRIXABAN MALEATE	80 MG	NEW ENTITY
LHRH(GNRH)AGNST PIT.SUP-CENTRAL PRECOCIOUS PUBERTY	TRIPTODUR	TRIPTORELIN PAMOATE	22.5 MG	NEW DOSAGE FORM
ANTINEOPLASTIC-CD19 DIR. CAR-T CELL IMMUNOTHERAPY	KYMRIAH	TISAGENLECLEUCEL	NONE	NEW ENTITY
ANTINEOPLASTIC- CD33 ANTIBODY-CYTOTOXIC ANTIBIOTIC	MYLOTARG	GEMTUZUMAB OZOGAMICIN	4.5 MG (1 MG/ML initial concentration)	NEW STRENGTH
INSULINS	HUMALOG JUNIOR KWIKPEN	INSULIN LISPRO	45 MCG (15 MCG x 3)/0.5 ML SYRINGE	NEW DOSAGE FORM
ANTIHYPERLIPIDEMIC - HMG COA REDUCTASE INHIBITORS	FLOLIPID	SIMVASTATIN	20 MG/5 ML (4 MG/ML)	NEW STRENGTH AND DOSAGE FORM
ANTIHYPERLIPIDEMIC - HMG COA REDUCTASE INHIBITORS	FLOLIPID	SIMVASTATIN	40 MG/5 ML (8 MG/ML)	NEW STRENGTH AND DOSAGE FORM
GLUCOCORTICOIDS	LIDOCILONE I	TRIAMCINOLONE/LIDOCAINE	20 MG-20 MG/4 ML	NEW STRENGTH, ROUTE AND SOAGE FORM
TOPICAL LOCAL ANESTHETICS	WOUND DEBRIDEMENT-	LIDOCAINE/GAUZE/ALGINATE	4%	NEW COMBINATION

DESCRIPTION	BRAND NAME	GENERIC NAME	STRENGTH	NOTES
	LIDOCAINE			
TOPICAL LOCAL ANESTHETICS	DOLOTRANZ	LIDOCAINE/PRILOCAINE	4 %-2.5 %-2.5 %	NEW STRENGTH AND DOSAGE FORM
ANTINEOPLASTIC - ANTIBIOTIC AND ANTIMETABOLITE	VYXEOS LIPOSOME	DAUNORUBICIN/CYTARABINE LIPOS	44 MG-100 MG	NEW ENTITY
PANCREATIC ENZYMES	PERTZYE	LIPASE/PROTEASE/AMYLASE	24,000 UNIT-86,250 UNIT-90,750 UNIT	NEW STRENGTH
TOPICAL LOCAL ANESTHETICS	L.E.T. (LIDO-EPINEPH-TETRA)	LIDOCAINE/RACEPINEP/TETRACAINE	4 %-0.05 %-0.5 %	NEW COMBINATION
ANTINEOPLASTIC SYSTEMIC ENZYME INHIBITORS	LYNPARZA	OLAPARIB	150 MG	NEW STRENGTH AND DOSAGE FORM
ANTINEOPLASTIC SYSTEMIC ENZYME INHIBITORS	LYNPARZA	OLAPARIB	100 MG	NEW STRENGTH AND DOSAGE FORM
ANTINEOPLASTIC- CD22 ANTIBODY-CYTOTOXIC ANTIBIOTIC	BESPONSA	INOTUZUMAB OZOGAMICIN	0.9 MG (0.25 MG/ML INITIAL CONCENTRATION)	NEW ENTITY
ANTIHEMOPHILIC FACTORS	NUWIQ	ANTIHEMOPH.FVIII,HEK B-DELETE	2,500 (+/-) UNIT RANGE	NEW STRENGTH
ANTIHEMOPHILIC FACTORS	NUWIQ	ANTIHEMOPH.FVIII,HEK B-DELETE	3,000 (+/-) UNIT RANGE	NEW STRENGTH
ANTIHEMOPHILIC FACTORS	NUWIQ	ANTIHEMOPH.FVIII,HEK B-DELETE	4,000 (+/-) UNIT RANGE	NEW STRENGTH
POTASSIUM SPARING DIURETICS	CAROSPIR	SPIRONOLACTONE	25 MG/5 ML	NEW STRENGTH AND DOSAGE FORM

DESCRIPTION	BRAND NAME	GENERIC NAME	STRENGTH	NOTES
URICOSURIC AND XANTHINE OXIDASE INHIBITOR COMB.	DUZALLO	LESINURAD/ALLOPURINOL	200 MG-200 MG	NEW COMBINATION
URICOSURIC AND XANTHINE OXIDASE INHIBITOR COMB.	DUZALLO	LESINURAD/ALLOPURINOL	200 MG-200 MG	NEW COMBINATION

NEW INDICATIONS (EXISTING DRUGS)

LYNPARZA®

August 17, 2017

Sean Bohen, Executive Vice President, Global Medicines Development and Chief Medical Officer, AstraZeneca, said: “Physicians have almost three years of clinical experience with Lynparza on the market and we are now pleased to bring this important medicine, in a new tablet formulation, to a broader group of women. Today’s approvals validate more than 10 years of dedicated research behind Lynparza, the world’s first PARP inhibitor, which now provides oncologists with the greater flexibility for use in terms of treatment settings. It builds on our recently-announced collaboration with Merck, which aims to further increase the number of treatment options available to patients.”

Source: AstraZeneca

VICTOZA®

August 25, 2017

Bagsværd, Denmark - The U.S. Food and Drug Administration (FDA) has approved a new indication for Victoza® (liraglutide) to reduce the risk of major adverse cardiovascular (CV) events in adults with type-2 diabetes and established CV disease. The FDA's decision is based on the results from the landmark LEADER trial, which demonstrated that Victoza® statistically significantly reduced the risk of cardiovascular death, non-fatal heart attack or non-fatal stroke by 13% vs placebo, when added to standard of care, with an absolute risk reduction of 1.9%. The overall risk reduction was derived from a statistically significant 22% reduction in cardiovascular death with Victoza® treatment vs placebo, with an absolute risk reduction of 1.3%, and non-significant reductions in non-fatal heart attack and non-fatal stroke.

Source: Novo Nordisk

FASLODEX ®

August 28, 2017

AstraZeneca today announced that the US Food and Drug Administration (FDA) has approved Faslodex (fulvestrant) 500mg as monotherapy for expanded use in women with hormone receptor positive (HR+), human epidermal growth factor receptor 2 negative (HER2-) advanced breast cancer, who have gone through menopause and have not received previous endocrine therapy.

Source: AstraZeneca

AUSTEDO®

August 30, 2017

JERUSALEM--(BUSINESS WIRE)-- Teva Pharmaceutical Industries Ltd. (NYSE and TASE: TEVA) today announced that the U.S. Food and Drug Administration (FDA) has approved AUSTEDO® (deutetrabenazine) tablets for the treatment of tardive dyskinesia in adults. AUSTEDO® was previously approved for the treatment of chorea associated with Huntington's disease in April 2017.

Source: Teva Pharmaceutical Industries Ltd.

ACTEMRA®

August 30, 2017

Genentech, a member of the Roche Group (SIX: RO, ROG; OTCQX: RHHBY), announced today that the U.S. Food and Drug Administration (FDA) has approved Actemra® (tocilizumab) intravenous injection for the treatment of chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome (CRS) in patients two years of age and older. CRS, which is caused by an overactive immune response, has been identified as a potentially severe and life-threatening side effect of CAR T cell therapy for certain cancers.

Source: Genentech

FDA NEWS/BULLETINS/ADVISORIES/SAFETY ALERTS

Lorazepam Oral Concentrate, USP 2mg/mL by Amneal Pharmaceuticals: Recall - Misprinted Dosing Droppers

[Posted 8/16/2017]

ISSUE: Amneal Pharmaceuticals LLC is voluntarily recalling 13 lots of Lorazepam Oral Concentrate, USP 2mg/mL, to the Consumer level due to a defect in the dropper markings. The Lorazepam Oral Concentrate, USP 2mg/mL, product is packaged with a dosing dropper, supplied to Amneal by a third party. In a few instances, the dropper is printed with the dose markings in reverse number order, has no dose markings or has dose markings that are shifted. Amneal learned about the issue from a Consumer's report. To date no adverse events related to these dropper defects have been reported to Amneal. See the press release for product photos and a listing of affected lot numbers. There is a significant likelihood that the dropper marking errors will result in dispensing either less than, or more than, the prescribed dose. There is a significant probability of a serious health consequence if more than the prescribed dose is dispensed and potential serious adverse events include: drowsiness causing trauma; increased anxiety; increased accidental injury to self or others (e.g., hip fracture, motor vehicle accident); which in the most serious circumstances could result in permanent decreased function or death.

BACKGROUND: The product is indicated for the management of anxiety disorders for the short-term relief of the symptoms of anxiety or anxiety associated with depressive symptoms. It is packaged in an individual carton, identified with the code: NDC 65162-687-84, which contains a 30mL amber glass bottle of liquid produced by Amneal, a package insert with patient information, and a plastic dropper sealed in a clear plastic bag. The product can be identified by the lot number printed on the bottom-right side of the blue and white label, with the Amneal logo, on the amber bottle supplied with the dropper, in a blue and white carton, with the Amneal logo. The Lorazepam Oral Concentrate, USP 2mg/mL was distributed nationwide to wholesalers.

RECOMMENDATION: Amneal Pharmaceuticals has notified its wholesale customers by a Recall Letter to return all recalled lots. Amneal is notifying pharmacies by providing a Recall Letter and a supply of replacement droppers to all pharmacies that may have received any of the recalled lots. There is no safety issue with the bottled product itself. To avoid any interruption in supply or access to the medication by the patient, pharmacies are instructed to immediately discard the dropper included with the recalled lots and replace it with the dropper included with the Recall Letter. Amneal also is providing the pharmacist with a sticker which the pharmacist is required to place on the box to alert the patient and other pharmacists that the dropper has been replaced. Pharmacists are instructed to notify all Consumers impacted by the recall of the potential defect and the need to exchange a defective dropper. Consumers are instructed to discontinue use of any defective dropper and return it to the place of purchase for a replacement. If Consumers are unsure whether their droppers are defective they are encouraged to confirm with their dispensing pharmacy.

Consumers with questions regarding this recall can contact Amneal Pharmaceuticals at 631.952.0214 x338 or amnealreg@amneal.com on Monday through Friday from 9AM through 5PM Eastern Time. 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)

Sterile Drug Products by Bella Pharmaceuticals: Recall - Lack of Sterility Assurance
[Posted 8/18/2017]

ISSUE: Bella Pharmaceuticals is voluntarily recalling all lots of unexpired sterile drug products due to lack of sterility assurance. The recalled products were distributed to health care facilities nationwide.

Administration of a drug product intended to be sterile that is not sterile could result in serious infections that may be life-threatening. To date, Bella Pharmaceuticals has not received any reports of adverse events.

BACKGROUND: The affected products include all lots distributed April 17, 2017, to August 10, 2017, remaining within expiry, and they would be packaged in a syringe, vial or eye dropper. For a list of products affected by this recall see the Firm Press Release.

RECOMMENDATION: Bella Pharmaceuticals is notifying its customers by email and phone, and is arranging for the return of all recalled products. Anyone with product subject to the recall should stop using it and contact the company. To return medication or request assistance related to this recall, contact Bella Pharmaceuticals at 877-235-5279, Monday through Friday, between 9 a.m. and 5 p.m. CST.

Health care professionals are encouraged to report any adverse events to FDA’s MedWatch 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)

Ninjacof and Ninjacof A: Recall - Potential Burkholderia Cepacia Contamination
[Posted 8/23/17]

ISSUE: Centurion Labs is voluntarily recalling 1 lot of Ninjacof (Lot# 200N1601) and 1 lot of Ninjacof A (Lot# 201NA1601) manufactured by Vilvet and distributed by Centurion Labs to the retail level due to potential contamination with Burkholderia cepacia. Centurion was notified by the FDA regarding the potential contamination as they discovered this product may have been manufactured in a Pharmatech, FDA registered facility, in Davie, FL. that was found to have a product that contained B. cepacia.

Products are sold in 473 mL bottles with the expiration date of 11/2018. The affected products are Ninjacof with Lot# 200N1601 (NDC 23359-032-16) and Ninjacof A with Lot#201NA1601 (NDC 23359-033-16) and both were distributed within the following states: Alabama, Arkansas, Florida, Georgia, Louisiana, Missouri, Mississippi, New Jersey, North Carolina, Ohio, Oklahoma, South Carolina, Tennessee, and Texas. See press release for product photos.

Use of a product that may contain B. cepacia, could result in infections in patients with compromised immune systems and in patients with chronic lung conditions such as cystic fibrosis. Some of these infections may be serious or even life threatening in the at-risk patient population.

BACKGROUND: Ninjacof and Ninjacof A are used to temporarily relieve symptoms due to the common cold, allergic rhinitis or other respiratory allergies.

RECOMMENDATION: Centurion Labs is notifying its distributors and customers by recall letter. To date Centurion Labs has not found any B. cepacia or received any complaints for the products or lots listed. However, it is recommended that patients, pharmacies, and healthcare facilities that have the recalled product on hand stop their use immediately.

Consumers with questions regarding this recall can contact the company at Centurion Customer Support: recall@centurionlabs.com or 601-852-3681 (M-F 8am – 5pm Central Standard 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 pre-addressed form, or submit by fax to 1-800-FDA-0178

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

Doctor Manzanilla Cough & Cold and Doctor Manzanilla Allergy & Decongestant Relief Syrup: Recall - Potential Contamination with Burkholderia cepacia

[Posted 8/30/2017]

ISSUE: Mid Valley Pharmaceutical is recalling lot# 23221701 of Doctor Manzanilla Cough & Cold and lot# 23221701 of Doctor Manzanilla Allergy & Decongestant Relief syrup to the consumer level. The products may potentially be contaminated with the bacteria Burkholderia cepacia. Contaminated products with Burkholderia cepacia can potentially result in serious infections, may be life-threating in patients with compromised immune systems. To date, Mid Valley Pharmaceutical, LLC has not received any reports of adverse events related to this recall.

BACKGROUND: Doctor Manzanilla Cough & Cold is sold over the counter for relief of cough, nasal decongestion, throat irritation, sneezing, itching watery eyes, and bronchial irritation. Doctor Manzanilla Allergy & Decongestant Relief is sold over the counter for relief of allergy, nasal decongestion, itchy throat, sneezing, itchy watery eyes, and as an antihistamine. Product was distributed locally in the Rio Grande Valley, Texas to retailers and pharmacies.

RECOMMENDATION: Consumers/distributors/retailers that have Doctor Manzanilla products which are being recalled should stop using/selling/distributing and return product to the place of purchase. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to using this product and are encouraged to report any adverse events to FDA's MedWatch 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)

Piyanping Anti-Itch Lotion: Recall - Incorrect Active Ingredient

[Posted 8/30/2017]

ISSUE: Lucky Mart Inc. is voluntarily recalling lots C14005, C16001 and C16002 of Piyanping Anti-Itch Lotion to the consumer level. The product was manufactured using the active pharmaceutical ingredient dexamethasone rather than hydrocortisone. Dexamethasone is not listed as an ingredient in the labeling.

Dexamethasone is a higher potency steroid than hydrocortisone and may have a longer half-life; it could potentially cause serious side effects in patients applying the cream multiple times daily. There is a reasonable probability of any or all of the following side effects of topical steroids which include but are not limited to skin changes (whitening, thinning), adrenal suppression (high blood sugar, weakened immunity, electrolyte imbalances, emotional lability, slowing of growth in children), glaucoma, and cataracts. To date Lucky Mart Inc. has not received any reports of adverse events related to this recall.

BACKGROUND: The product is an itch lotion and is indicated for the temporary relief of itching associated with minor skin irritations, inflammation, and rashes in adults and children ages two and older. Products are packaged in a 0.67 oz (20g) tube in a paper carton. Lots C14005 (Exp. 03/2017), C16001 (Exp. 12/2018), C16002 (Exp. 12/2018). NDC 68085-8012-4. Piyanping Anti-Itch Lotion was distributed Nationwide in the USA to herbal and ethnic grocery stores. Lot # and Expiration Date can be found on the right side of the box, opposite of the barcode.

RECOMMENDATION: Consumers that may have product which is being recalled should stop use and return to place of purchase. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to using this product and are encouraged to report any adverse events to FDA's MedWatch 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)

Keytruda (pembrolizumab) in Patients with Multiple Myeloma: FDA Statement – Two Clinical Trials on Hold

[Posted 8/31/2017]

ISSUE: Based on data from two recently halted clinical trials, the U.S. Food and Drug Administration today is issuing this statement to inform the public, health care professionals, and oncology clinical investigators about the risks associated with the use of Keytruda (pembrolizumab) in combination with dexamethasone and an immunomodulatory agent (lenalidomide or pomalidomide) for the treatment of patients with multiple myeloma. Keytruda (pembrolizumab) is not approved for treatment of multiple myeloma.

The FDA statement is based on review of data from two clinical trials (KEYNOTE-183 and KEYNOTE-185) evaluating the use of Keytruda (pembrolizumab) combined with other treatments in patients with multiple myeloma. On July 3, 2017, the FDA required that all patients in these trials be discontinued from further investigation with this drug, because interim results from both trials demonstrated an increased risk of death for patients receiving Keytruda (pembrolizumab) when it was combined with an immunomodulatory agent as compared to the control group (see statistical analysis section below). Merck & Co., Inc. was made aware of the issue through an external data monitoring committee recommendation and suspended the trials to enrollment on June 12, 2017.

BACKGROUND: This does not apply to patients taking Keytruda (pembrolizumab) for an approved indication. Patients on Keytruda (pembrolizumab) for an approved use should continue to take their medication as directed by their health care professional. Keytruda (pembrolizumab) is currently approved by the FDA for treatment of: Melanoma, Lung Cancer, Head and Neck Cancer, Classical Hodgkin Lymphoma, Urothelial Carcinoma, Microsatellite Instability-High (MSI-H) Cancer. For a summary of the statistical analysis and findings, please refer to the FDA Statement.

RECOMMENDATION: Other multiple myeloma clinical trials of Keytruda (pembrolizumab), other PD-1/PD-L1 cancer drugs and other combinations are currently undergoing clinical evaluation. The FDA will be working directly with sponsors of Keytruda and other PD-1/PD-L1 cancer drugs, as well as clinical investigators conducting clinical trials in patients with multiple myeloma, to determine the extent of the safety issue. The agency will communicate any new information to the public as soon as it is able.

Health care professionals and consumers are encouraged to report any adverse events or side effects related to the use of these products and other similar products to FDA's MedWatch 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)

Vancomycin Hydrochloride for Injection, USP, 750 mg/vial by Hospira: Recall - Presence of Particulate Matter

[Posted 8/31/2017]

ISSUE: Hospira is voluntarily recalling one lot of Vancomycin Hydrochloride for Injection, USP,

750 mg/vial (NDC 0409-6531-02) lot 632153A, to the hospital/retailer level. The recall was due to a confirmed customer report for the presence of particulate matter, confirmed as glass, within a single vial. To date, Hospira has not received reports of any adverse events associated with this issue for this lot. Hospira has initiated an investigation to determine the root cause and corrective and preventive actions.

In the event the particulate is administered to a patient, it may result in phlebitis, end-organ granuloma or micro-embolic effects, or gastrointestinal trauma. The risk is reduced by the possibility of detection. The label contains a clear statement directing the healthcare professional to visually inspect the product for particulate matter and discoloration prior to administration.

BACKGROUND: Vancomycin Hydrochloride is indicated for the treatment of serious or severe infections caused by susceptible strains of methicillin-resistant staphylococci. Vancomycin Hydrochloride USP, 750 mg/vial NDC: 0409-6531-02, Lot 632153A, Expiry Date 01 MAR 2018, is packaged in a carton containing 10 units. The lot was distributed from August 2016 through January 2017 nationwide in the United States and Puerto Rico.

RECOMMENDATION: Anyone with an existing inventory of the recalled lot should stop use and distribution and quarantine immediately. Inform Healthcare Professionals in your organization of this recall. If you have further distributed the recalled product, please notify any accounts or additional locations which may have received the recalled product from you. Further, please instruct entities that may have received the recalled product from you that if they redistributed the product, they should notify their accounts, locations or facilities of the recall to the hospital level. Hospira will be notifying its direct customers via a recall letter and is arranging for impacted product to be returned to Stericycle in the United States. For additional assistance, call Stericycle at 1-800-805-3093 between the hours of 8 a.m. to 5 p.m. ET, Monday through Friday.

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)

Alcohol Pads or Benzalkonium Chloride Antiseptic Towelettes by Foshan Flying Medical Products: FDA Alert - Lack of Sterility Assurance and Other Quality Issues

[Posted 9/1/2017]

ISSUE: The U.S. Food and Drug Administration is alerting health care professionals and patients not to use alcohol pads or benzalkonium chloride antiseptic towelettes made by Foshan Flying Medical Products Co. Ltd., located in China, due to the lack of sterility assurance and other quality issues. These products are distributed by Total Resources International, Walnut, California, and Simple Diagnostics Inc., Williston Park, New York. The use of these alcohol pads and antiseptic towelettes could cause infections.

BACKGROUND: FDA initially contacted Foshan on May 25, 2017, regarding a recall, and had several follow-up meetings with the company. However, Foshan has not taken action to remove its alcohol pads or antiseptic towelettes from the market.

FDA placed all drug products made by Foshan on import alert on May 23, 2107, to stop these products from entering the United States. However, FDA is concerned these products might still be in U.S. distribution. FDA also sent Foshan a warning letter on August 1, 2017, for violations of current good manufacturing practice regulations.

RECOMMENDATION: Patients, health care facilities and pharmacies that have alcohol pads and antiseptic towelettes labeled by Total Resource or Simple Diagnostics should immediately stop using them and discard the products. Patients should contact a doctor if they experienced any adverse reactions after using these products.

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)

Unexpired Lots of Oxytocin Compounded with Either Lactated Ringers or Lactated Ringers and Dextrose by PharMEDium - Recall - Sub-Potency

[Posted 9/1/2017]

ISSUE: PharMEDium Services, LLC (PharMEDium) is voluntarily recalling all unexpired lots of Oxytocin compounded with Lactated Ringers and all unexpired lots of Oxytocin compounded with Lactated Ringers and Dextrose products that were produced between July 6, 2017 and August 29, 2017 to the hospital/user level. The recall is being issued based on laboratory test results indicating a lower than expected potency on certain lots of Oxytocin compounded with Lactated Ringers and Oxytocin Compounded with Lactated Ringers and Dextrose which would lead to a lower dose being administered. Although oxytocin is titrated based on clinical response, an extreme and unexpected reduction in dose than expected could lead to a delay in treatment, disruption of clinical care of the patient, and worsening of patient's conditions.

BACKGROUND: These products were packaged in ready to use intravenous bags. All unexpired lots of Oxytocin compounded with Lactated Ringers and all unexpired lots of Oxytocin compounded with Lactated Ringers and Dextrose are included in this recall. The product can be identified by referring to the sample labels provided. These 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 shasan@pharmedium.com.

Patients should contact their physician or healthcare provider if they have experienced any problems that may be related to the use of these products.

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)

Kayexalate (sodium polystyrene sulfonate): Drug Safety Communication – FDA Recommends Separating Dosing

[Posted 9/6/2017]

ISSUE: FDA is recommending that patients avoid taking the potassium-lowering drug sodium polystyrene sulfonate (Kayexalate) at the same time as other medicines taken by mouth. A study found that sodium polystyrene sulfonate binds to many commonly prescribed oral medicines, decreasing the absorption and therefore effectiveness of those oral medicines. To reduce this likelihood, we recommend separating the dosing of sodium polystyrene sulfonate from other orally administered medicines by at least 3 hours. We are updating the sodium polystyrene sulfonate drug labels to include information about this dosing separation.

BACKGROUND: Sodium polystyrene sulfonate is used to treat hyperkalemia, a serious condition in which the amount of potassium in the blood is too high. It works by binding with potassium in the intestines so it can be removed from the body. Potassium is a mineral that helps the body function properly. Too much potassium in the blood can cause problems with heart rhythm, which in rare cases can be fatal. Sodium polystyrene sulfonate is available as the brand name Kayexalate, as generic brands, and also as non-branded generics.

RECOMMENDATION: Patients should take orally administered prescription and over-the-counter (OTC) medicines at least 3 hours before or 3 hours after taking sodium polystyrene sulfonate. Patients should not stop taking their potassium-lowering medicines without talking to their health care professional first. If you have questions or concerns, including about how to take sodium polystyrene sulfonate with other medicines, talk to a pharmacist or other health care professional.

When prescribing sodium polystyrene sulfonate, health care professionals should advise patients to separate dosing from other orally administered medicines by at least 3 hours. That time should be increased to 6 hours for patients with gastroparesis or other conditions resulting in delayed emptying of food from the stomach into the small intestine.

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)

Activase (alteplase) 100mg by Genentech: Recall - Lack of Sterility Assurance

[Posted 9/7/2017]

ISSUE: Genentech is voluntarily recalling three lots of Activase (alteplase) 100mg vials, that were co-packaged with Sterile Water for Injection, to the hospital level. The vials of Sterile Water for Injection, manufactured by Hospira Inc., a Pfizer company, and packaged with Activase 100 mg, may be cracked or chipped at the neck of the vial and leaking. See press release for affected lots.

The use of impacted Sterile Water for Injection could result in adverse events such as fever, chills, phlebitis, and granuloma or more severe adverse events such as sepsis or invasive systemic infections. To date, Genentech has not received reports of adverse events associated with use of impacted Sterile Water for Injection.

BACKGROUND: Activase is supplied directly to hospitals and used in a hospital setting. Activase is indicated for treating patients with acute ischemic stroke (AIS), which is caused by a blood clot in the brain's blood vessels, for treating an acute myocardial infarction (AMI), also known as a heart attack and to break apart an acute massive pulmonary embolism (PE), which is a large blood clot lodged in the blood vessels of the lung. Activase is supplied as a sterile, lyophilized powder in 100 mg vials without vacuum. Each 100 mg Activase vial (58 million IU) is packaged with diluent for reconstitution (100 mL Sterile Water for Injection, USP), and one transfer device: NDC 50242-085-27. The product was distributed nationwide to hospitals.

RECOMMENDATION: Genentech is notifying its distributors and customers by issuing a "Dear Customer" letter and arranging for the return of all recalled products. Healthcare providers that have lots of Activase that have been recalled should stop using the product and should return the affected lots to Genentech.

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

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

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

STUDIES AND RECENT TOPICS

2017 On Track to be a Record Breaking Year for Orphan Drug Approvals

August 09, 2017

It is only August but the U.S. Food and Drug Administration (FDA) is on track to set a record for orphan drugs approved this year. At last count, 42 orphan drugs have been approved between January 1, 2017 and August 9, 2017.At their current pace, the FDA will approve more than 60 orphan drugs by the end of the year. That is 20% above their last record breaking period in 2014 (49 approvals) and 2015 (48 approvals).

Source: raredr.com

One-third of US adults misused prescription drugs in 2015

August 10, 2017

More than one-third of the U.S. adult population misused prescription drugs at least once in the past year, according to a report from the Substance Abuse and Mental Health Services Administration.

“Prescription drug misuse is second only to marijuana use as the nation’s most commonly used illicit drug. Although prescription drug misuse is common in the United States, the majority of people (87.2%) who take prescription pain relievers do not misuse them,” Rachel N. Lipari, PhD, of SAMHSA, and colleagues wrote. “Understanding the prevalence of and reasons for prescription drug misuse has major public health implications. Policymakers can use this type of information to help inform their assessments of substance use prevention and treatment needs in their communities.”

Source: healio.com

13% of Americans Take Antidepressants

August 15, 2017

Antidepressants are some of the most popular drugs in the United States, and their usage shows no signs of waning.

A new report from the National Center for Health Statistics shows that from 2011 through 2014, the most recent data available, close to 13% of people 12 and older said they took an antidepressant in the last month. That number is up from 11% in 2005-2008.

Source: time.com

U.S. Antidepressant Use Jumps 65 Percent in 15 Years

August 15, 2017

The number of Americans who say they've taken an antidepressant over the past month rose by 65 percent between 1999 and 2014, a new government survey finds. By 2014, about one in every eight Americans over the age of 12 reported recent antidepressant use, according to a report released Tuesday from the U.S. Centers for Disease Control and Prevention.

Source: healthday.com

Flimsy evidence behind many FDA approvals
August 15, 2017

Many drugs granted accelerated approval by the U.S. Food and Drug Administration (FDA) lack clear evidence of safety and effectiveness, and the same is true for most high-risk medical devices, according to two new reports in the Journal of the American Medical Association.

Source: reuters.com

Noninvasive eye scan could detect key signs of Alzheimer's years before patients show symptoms
August 17, 2017

LOS ANGELES (Aug. 17, 2017) -- Cedars-Sinai neuroscience investigators have found that Alzheimer's disease affects the retina -- the back of the eye -- similarly to the way it affects the brain. The study also revealed that an investigational, noninvasive eye scan could detect the key signs of Alzheimer's disease years before patients experience symptoms.

Source: eurekalert.org

FDA May Limit 'Risk Info' in Direct-to Consumer TV Drug Ads
August 18, 2017

The U.S. Food and Drug Administration may shorten the list of caveats for drugs you see advertised on television. Prescription drug makers must now mention all benefits and risks in direct-to-consumer advertising, presenting viewers with a litany of potential harms, both major and minor. But a new approach being considered could trim those lists to feature only the most serious and potentially fatal side effects, the FDA said Friday.

Source: healthday.com

More children to be diagnosed with high blood pressure under new guidelines
August 21, 2017

More children and teens are likely to be diagnosed and treated for high blood pressure under new guidelines released today by the American Academy of Pediatrics (AAP). An estimated 3.5 percent of children and adolescents in the U.S. have hypertension, or abnormally high blood pressure, but experts say the actual prevalence is likely much higher as elevated blood pressure readings often go undetected.

Source: cbsnews.com

FDA Committee to Review Safety of Hydrocodone, Codeine for Children

August 21, 2017

In its latest effort in the war against the opioid epidemic, the US Food and Drug Administration has announced an upcoming Pediatric Advisory Committee review of prescription medications containing hydrocodone or codeine that are currently approved to treat children.

Source: mdmag.com

Dying At Home In An Opioid Crisis: Hospices Grapple With Stolen Meds

August 22, 2017

Nothing seemed to help the patient — and hospice staff didn't know why. They sent home more painkillers for weeks. But, the elderly woman, who had severe dementia and incurable breast cancer, kept calling out in pain.

Source: khn.org

Steroid Pills Usually Ineffective Against Bronchitis, Study Finds

August 23, 2017

Doctors sometimes prescribe a steroid for patients with bronchitis or other troublesome chest infections, but a new British study says the approach isn't warranted. "Our study does not support the continued use of steroids as they do not have a clinically useful effect on symptom duration or severity," said study lead researcher Dr. Alastair Hay, who teaches primary care medicine at the University of Bristol.

Source: healthday.com

Afinitor Effective in Neuroendocrine Tumors; Quality of Life Scores Not Significantly Improved

August 23, 2017

In February 2016, the FDA approved Afinitor (everolimus) tablets for the treatment of adult patients with progressive, well-differentiated, nonfunctional neuroendocrine tumors (NETs) of gastrointestinal or lung origin that are unresectable, locally advanced or metastatic.

Neuroendocrine tumors arise from cells in the endocrine or nervous system, and most commonly occur in the intestine. They can also, however, derive from the lung, pancreas, and other parts of the body.

Source: raredr.com

Researchers find only slight decline in pediatric flu shots without nasal spray option

August 24, 2017

HERSHEY, Pa. — Influenza vaccination rates in children may have decreased for the 2016-17 influenza season because of a recommendation by the Centers for Disease Control and Prevention that the nasal spray version of the vaccine not be used, according to Penn State College of Medicine researchers.

Source: drugstorenews.com

Google Rolls Out Tool To Help Diagnose Depression

August 24, 2017

Google is getting involved with people's mental health, rolling out a tool to help steer people who may have depression toward treatment. They've partnered up with the National Alliance on Mental Illness (NAMI) to reach out to people who may be depressed, by asking a simple question: Are you depressed? The hope is that getting people to begin to assess their own mental health will act as a catalyst to seeking treatment.

Source: forbes.com

A New Drug Lowers Risk of Heart Attack and Cancer

August 27, 2017

It turns out that cholesterol isn't the only thing you have to worry about to keep your heart healthy. In recent years, doctors have started to focus on inflammation — the same process that makes cuts red and painful — as an important contributor to a heart attack. It's the reason doctors recommend low-dose aspirin to prevent recurrent heart attacks in people who have already had them, why they also prescribe statins, which lower both cholesterol and inflammation, and why they have started to measure inflammation levels in the blood.

Source: time.com

Boosting immunotherapy by targeting cells' recycling centers

August 28, 2017

A subpopulation of cells in the immune system called CD8+ T cells are vital for the proper functioning of both vaccines and cancer immunotherapy treatments. When these cells divide, they become one of two types of pathogen-destroying soldiers: those that kill right away or those that remember the offender and provide long-term protection. Finding a way to boost the second variety of immune cells, called "memory" CD8+ T cells, could improve both vaccines and immunotherapies.

Source: fiercebiotech.com

Lupin seed extract could provide potent diabetes treatment, researchers say
August 29, 2017

Curtin University researchers say they are close to developing a food supplement which could prove more potent than some pharmaceutical drugs in tackling diabetes.

Research team leader Professor Philip Newsholme said lupin seed extract was being used in laboratory trials to regulate blood glucose levels.

Source: abc.net.au

SSRIs, SNRIs Provide Modest Benefit to Kids with Mental Disorders
August 30, 2017

Selective serotonin reuptake inhibitors (SSRIs) and serotonin-norepinephrine reuptake inhibitors (SNRI) had a small, but significant benefit, for children and adolescents with common mental disorders compared to placebo, a systematic review and meta-analysis found.

Source: medpagetoday.com

Groups seek ban on high-dose opioids citing overdose danger
August 31, 2017

CHICAGO (AP) -- Safety advocates and state health officials are formally calling on the Food and Drug Administration to ban high-dose opioid painkillers to prevent accidental overdose deaths among patients and people who abuse drugs.

A petition filed Thursday asks the FDA to ban opioid pills that, when taken as directed, would add up to a daily dose of more than 90 milligrams of morphine. The Centers for Disease Control and Prevention has said that level is dangerous for most patients and doesn't improve pain control or the ability to function.

Source: ap.org

Vaginal estrogen not tied to cancer or heart disease risks
September 5, 2017

Using vaginally applied estrogen to ease menopause symptoms likely doesn’t increase a woman’s risk of heart disease or certain cancers, a U.S. study suggests.

Many women have been reluctant to use hormone replacement therapy (HRT) for menopause symptoms since 2002, when the federally funded Women’s Health Initiative (WHI) study linked pills containing man-made versions of the female hormones estrogen and progestin to an increased risk for breast cancer, heart attacks and strokes. Some women have also been reluctant to use vaginally applied estrogens, which can ease symptoms like dryness and painful intercourse.

Source: reuters.com

RECALLS

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drugs	UPROAR All Natural Male Enhancement Herbal Dietary Supplement Capsules, supplied in 2, 4 and 10 count packages, Distributed by AH Distribution, DelRay, Beach, FL ---- UPC Code 680474229260	Class I	All lots and package si zes	Marketed without an Approved NDA/ANDA; FDA analysis found the presence of undeclared tadalafil, sildenafil and/or their analogues and Flibanserin	Organic Herbal Supply 8303 Sierra College Blvd Ste 128 Roseville, CA 95661-9420
Drugs	Cummor Natural Male Enhancement, Herbal Dietary Supplement Capsules, 500 mg, supplied in 2, 4 and 10 count packages, Made in Malaysia, Distributed by Naturally Hard Supplements, Reno, NV --- UPC code #680474229116	Class I	All lots and package si zes	Marketed without an Approved NDA/ANDA; FDA analysis found the presence of undeclared tadalafil, sildenafil and/or their analogues and Flibanserin	Organic Herbal Supply 8303 Sierra College Blvd Ste 128 Roseville, CA 95661-9420
Drugs	ZRECT Male Enhancement Herbal Dietary Supplement Capsules, 500 mg, supplied in 2, 4 and 10 count packages, Made in Malaysia, Distributed by Organic Herbal Supply, Roseville, CA --- UPC Code 852675999451	Class I	All lots and packag e sizes	Marketed without an Approved NDA/ANDA; FDA analysis found the presence of undeclared tadalafil, sildenafil and/or their analogues and Flibanserin	Organic Herbal Supply 8303 Sierra College Blvd Ste 128 Roseville, CA 95661-9420
Drugs	Xrect Male Enhancement Herbal Dietary Supplement Capsules, 500 mg supplied in 2, 4 and 10 count packages, Distributed by Organic Herbal Supply, Roseville, CA ---- UPC Code 680474015795	Class I	All lots and package si zes	Marketed without an Approved NDA/ANDA; FDA analysis found the presence of undeclared tadalafil, sildenafil and/or their analogues and Flibanserin	Organic Herbal Supply 8303 Sierra College Blvd Ste 128 Roseville, CA 95661-9420
Drugs	RECTALIS Male Enhancement Herbal Dietary Supplement Capsules, 500 mg, supplied in 2, 4 and 10 count packages, Made in Malaysia, Distributed by Organic Herbal Supply, Cheyenne, WY --- UPC Code 680474228782	Class I	All lots and package si zes	Marketed without an Approved NDA/ANDA; FDA analysis found the presence of undeclared tadalafil, sildenafil and/or their analogues and Flibanserin	Organic Herbal Supply 8303 Sierra College Blvd Ste 128 Roseville, CA 95661-9420

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drugs	GEC LX Laxoplex 60 capsules Dietary Supplement, 60 count bottle, Manufactured by GEC, McKinney, TX, 75070, UPC: 700580499842	Class I	All lots.	Marketed Without An Approved NDA/ANDA: Tainted Product Marketed As a Dietary Supplement: FDA analysis found the product to tainted with undeclared anabolic steroids and steroid like substances.	Genetic Edge Compounds LLC 2305 Brandywine McKinney, TX 75070-4563
Drugs	Mibelas 24 Fe (Norethindrone acetate and Ethinyl estradiol 1 mg/0.02 mg chewable and ferrous Fumarate 75 mg) Tablets, wallet of 28 tablets (NDC 68180-911-11), Carton of 3 wallets (NDC 68180-911-13), Rx Only, Manufactured by: Lupin Limited, India, Distributed by Lupin Pharmaceuticals, Inc., Baltimore, MD, 21202	Class I	Batch Number L600518; Exp. 05/18	Contraceptive Tablets Out of Sequence- First 4 pills of the packet are brown, instead of the last four pills and the expiry/lot was not printed on the package.	Lupin Limited (Unit 1) Unit 1, Plot 2, SEZ, Phase II, Misc Zone Apparel Park, Dist. Dhar Pithampur
Drugs	Biotech Underground Tri-Ton Hardcore Formula capsules, 90-count bottle, Distributed by: Dynamic Technical Formulations 12850 Hwy 9 Suite 600-441 Alpharetta, GA 30004	Class I	All lots	Marketed Without An Approved NDA/ANDA: Tainted Product Marketed As a Dietary Supplement: Product was tested by FDA and found to contain andarine and ostarine.	DYNAMIC TECHNICAL FORMULATIONS 660 Hembree Pkwy Ste 115 Roswell, GA 30076-4974
Drugs	ULTRA-STEN Rapid Size and Strength capsules, 10 mgs, 90 count bottle, Hardcore Formulations UPC: 7 48252 68763 0	Class I	All lots remaining with in expiry.	Marketed Without An Approved NDA/ANDA: Product contains Methylstenbolone or Dymethazine.	HARDCORE FORMULATIONS 3012 Fm 621 Ste B San Marcos, TX 78666-1668
Drugs	D-ZINE Rapid Size and Strength capsules, 10mgs, 90 count bottle, Hardcore Formulations, UPC: 7 48252 86193 1	Class I	All lots remaining with in expiry.	Marketed Without An Approved NDA/ANDA: Product contains Methylstenbolone or Dymethazine.	HARDCORE FORMULATIONS 3012 Fm 621 Ste B San Marcos, TX 78666-1668

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drugs	Phenobarbital Tablets USP, 15 mg, 1000 count bottles, Rx Only, Manufactured by West-ward Pharmaceutical Corp. Eatontown, NJ 07724, Distributed by Truxton, Inc., Bellmawr, NJ 08031, NDC 0463-6160-10	Class I	Lot # 70952A; Exp. 11/ 17	Labeling: Labeled Error on Declared Strength; report of a 1000 ct bottle labeled as Phenobarbital 15 mg tablets actually contained 30 mg tablets	C. O. Truxton 136 Harding Ave Bellmawr, NJ 08031-2412
Drugs	CaverFlo Natural Herbal Coffee, 25 g, supplied in boxes of 10 packets, manufacture for Caverflo Texas Trading -- UPC: 9555671709987	Class I	all lots within expiry.	Marketed without an Approved NDA/ANDA; FDA analysis result found product to contain sildenafil, tadalafil and undeclared milk	Brian P. Richardson 3410 Delafield Ln Dallas, TX 75227-5313
Drugs	ANDROPHARM STEN Z (2, 17a-Dimethyl-17b-hydroxy-5a-androst-1-en-3-one 10mg and 17b-hydroxy-2a, 17b-dimethyl-5a-androstan-3-one azine 10 mg) capsule, packaged in 60-count bottle, Andropharm.com, UPC: 6 42125 50294 8	Class I	All lots remaining within expiry.	Marketed without an approved NDA/ANDA: product label states it contains anabolic steroids.	Andropharm, LLC 1140 Holland Dr Ste 12 Boca Raton, FL 33487-2764
Drugs	ANDROPHARM M1 ALPHA (Methyl-1-Etiocholenolol-Epietiocholanollone 20 mg) capsule, packaged in 60-count bottle, Amazon.com, UPC 6 42125 50292 4	Class I	All lots remaining with in expiry.	Marketed without an approved NDA/ANDA: product label states it contains anabolic steroids.	Andropharm, LLC 1140 Holland Dr Ste 12 Boca Raton, FL 33487-2764
Drugs	New Kopi Jantan Tradisional Natural Herbs Coffee, packaged in 13 gram red packets, and each box contains 25 packets, Made in Malaysia, USA Distributor: Bestherbscoffee LLC (USA), Email: bestherbscoffee@yahoo.com	Class I	UPC 557205060083 ,E xp 5/24/18	Marketed without an approved NDA/ANDA: presence of undeclared desmethyl carbodenafil and undeclared milk.	BESTHERBS COFFEE LLC 2420 E Arkansas Ln Ste 216 Arlington, TX

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
					76014-1753
Drugs	Super Panther 7K Capsules 1250 mg blend, a) 1 count blister cards shipped in boxes of 30 (UPC# 6015577513247); and b) 6 count bottles (UPC# 601577513209), Distributed by SX Power CO., Brooklyn, NY	Class I	a) RO846356 Exp. 8/28/2020; b) RO246852 Exp. 8/28/2020	Marketed without an Approved NDA/ANDA;FDA analysis found product to be tainted with sildendafil and tadalafil	Chiavna Saffron LLC 14235 Boren St Apt 201 Huntersville, NC 28078-6516
Drugs	Caffeine Powder, Anhydrous, Pharmaceutical Grade, 100% Pure caffeine, 250 g (8.8 oz)., 1250 servings, Packed By: LifeLine Nutrients Corp, 1801 S. Canal St, Chicago, IL 60616, UPC 021754905076	Class II	Batch # 15121931, 15 121939, Exp 12/19	Marketed without an Approved NDA/ANDA: The product consists of pure, powdered caffeine and is an unapproved drug due to stimulant claims. The product is also misbranded as it fails to bear adequate directions for its intended use.	Global Marketing Enterprises, Inc. 1801 S Canal St Chicago, IL 60616-1522
Drugs	0.9% Sodium Chloride Injection, USP in 1000 mL Single Dose Flexible Container, Hospira, Inc., Lake Forest, IL 60045 USA ---- NDC# 0409-7983-09	Class II	Lot: 61-841-FW Exp. 0 1/01/2018	Presence of Particulate Matter; stainless steel	ICU Medical Inc 600 N Field Dr Lake Forest, IL 60045-4835
Drugs	Procrit Epoetin Alfa 40,000 units/mL single use vial For Intravenous or Subcutaneous Use Only, Rx only, Manufactured by: Amgen Inc., Thousand Oaks, CA 91320-1799, Manufactured for: Janssen Products, LP Horsham, PA 19044, NDC 59676-340-01	Class II	Lot #: G290491A, G29 0491B, Exp. 06/18	Presence of particulate matter: Visible glass flakes identified as lamellae in some drug product vials.	Amgen, Inc. 1 Amgen Center Dr Thousand Oaks, CA 91320-1730
Drugs	Phenobarbital Tablets USP, 60 mg, 1000 count bottles, Rx Only, Manufactured by West-ward Pharmaceutical Corp. Eatontown, NJ 07724, Distributed by Truxton, Inc., Bellmawr, NJ 08031, NDC 0463-6151-10	Class II	Lot # 71416A; Exp. 05/ 20 Lot # 70881A; Exp. 07/17 Lot # H15A68; E xp. 01/18 Lot # 70980 A; Exp. 02/18	Labeling: Label Mixup; potentially mislabeled	C. O. Truxton 136 Harding Ave Bellmawr, NJ 08031-2412
Drugs	Phenobarbital Tablets USP, 100 mg, a) 100 count bottles (NDC 0463-6152-01), b) 1000 count bottles (NDC 0163-6152-10), Rx Only, Manufactured by West-ward	Class II	a) Lot # 70989A; Exp. 02/18, Lot # 70973A; E xp. 01/18 b) Lot # 709 73A; Exp. 01/18, Lot #	Labeling: Label Mixup; potentially mislabeled	C. O. Truxton

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
	Pharmaceutical Corp. Eatontown, NJ 07724, Distributed by Truxton, Inc., Bellmawr, NJ 08031		H15A76; Exp. 02/18, L ot # 71346A; Exp. 12/ 19, Lot # 70989A; Exp. 02/18		136 Harding Ave Bellmawr, NJ 08031-2412
Drugs	Amitriptyline HCL Tablets, USP 50 mg, 100 count bottles, Rx Only, Manufactured for: Qualitest Pharmaceuticals Huntsville, AL 35811, Distributed by: Truxton, Inc. Bellmawr, NJ 08031, NDC: 0463-6352-10	Class II	Lot # C0260416A; Exp. 03/18	Labeling: Label Mixup; potentially mislabeled	C. O. Truxton 136 Harding Ave Bellmawr, NJ 08031-2412
Drugs	Phenobarbital Tablets USP, 15 mg, 1000 count bottles, Rx Only, Manufactured by West-ward Pharmaceutical Corp. Eatontown, NJ 07724, Distributed by Truxton, Inc., Bellmawr, NJ 08031, NDC 0463-6160-10	Class II	Lot # 71162A; Exp. 10/ 18 Lot # 70915A; Exp. 08/17 Lot # H15A55; E xp. 11/17	Labeling: Label Mixup; potentially mislabeled	C. O. Truxton 136 Harding Ave Bellmawr, NJ 08031-2412
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	Class II	Item# 370010, Lot: 20 351701	Microbial contamination of Non-sterile Products; presence of yeast and potential B. cepacia contamination	The Harvard Drug Group 17177 N Laurel Park Dr Ste 233 Livonia, MI 48152-3951
Drugs	Rugby Diocto Syrup, Docusate Sodium 60 mg/15 mL, Stool Softener Laxative, One Pint (473 mL) plastic bottles, Dist. by: Rugby Laboratories, 31778 Enterprise Drive, Livonia, MI 48150. NDC: 0536-1001-85	Class II	Item# 370282, Lot: 22 941701	Microbial contamination of Non-sterile Products; presence of yeast and potential B. cepacia contamination	The Harvard Drug Group 17177 N Laurel Park Dr Ste 233 Livonia, MI 48152-3951
Drugs	Major Senna Syrup Natural Vegetable Laxative, Sennoside 8.8 mg, 8 fl. oz. (237 mL) plastic bottles, Dist. by: Major Pharmaceuticals, 17177 N Laurel Park Drive, Suite 233, Livonia, MI 48152 USA. NDC: 00904-6289-09	Class II	Item # 263923, all lots	Microbial contamination of Non-sterile Products; presence of yeast and potential B. cepacia contamination	The Harvard Drug Group 17177 N Laurel Park Dr Ste 233 Livonia, MI 48152-3951

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
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	Class II	Item # 370339, all lots	Microbial contamination of Non-sterile Products; presence of yeast and potential B. cepacia contamination	The Harvard Drug Group 17177 N Laurel Park Dr Ste 233 Livonia, MI 48152-3951
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	Class II	Item# 370281 all lots	Microbial contamination of Non-sterile Products; presence of yeast and potential B. cepacia contamination	The Harvard Drug Group 17177 N Laurel Park Dr Ste 233 Livonia, MI 48152-3951
Drugs	Morphine Sulfate Oral Solution, 100 mg/ 5 mL (20 mg/mL), packaged in a 1 oz. bottle containing 30 mL with an oral syringe, Rx Only, Manufactured by: Tris Pharma, Inc. Monmouth Junction, NJ 08852, NDC 27808-082-01	Class II	Lot #: 08215001A, Exp 6/30/2017; 08215002 A, 08215004A, Exp 7/ 31/2017	Defective container: Oral solution leaking from container.	Tris Pharma Inc. 2033 US Highway 130 Monmouth Junction, NJ 08852-3003
Drugs	Amoxicillin and Clavulanate Potassium for Oral Suspension, USP, 250/62.5 mg per 5 mL, 100 mL (when reconstituted) bottle, Rx Only, Manufactured By: Cipla Ltd. at Medispray Laboratories Pvt. Ltd., Kundaim Goa, India; Manufactured For: Wockhardt USA, LLC, Parsippany, NJ 07054, NDC 60432-065-00.	Class II	Batch #: KH60276, Exp 10/18	Presence of Foreign Substance: customer complaint of blue foreign material identified as a portion of a nitrile glove was discovered in product.	Morton Grove Pharmaceuticals, Inc. 6451 Main St Morton Grove, IL 60053-2633
Drugs	Ketorolac Tromethamine Injection, USP 30 mg/mL, packaged in 1 mL single-dose vials, Rx only, Amphastar Pharmaceuticals, Inc., Rancho Cucamonga, CA 91730, NDC 0548-9021-00	Class II	Lot # XI002A6, XI003A 6, Exp 12/17; XI004G6 , XI005G6, Exp 6/18; XI 007H6, Exp 7/18; XI00 816, XI00916, XI01016 , XI01116, Exp 8/18; XI 012J6, XI013J6, Exp 9/ 18; XI015K6, Exp 10/1 8; XI016L6, Exp 11/18; XL018A7, XI019A7, Ex p 12/18; XI020B7, XI0 21B7, Exp 1/19; XI022 C7, XI023C7, Exp 2/19;	Crystallization: Particulate matter (Ketorolac Calcium Salt) was observed from several lots of retained samples.	Amphastar Pharmaceuticals, Inc. 11570 6th St Rancho Cucamonga, CA 91730-6025

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
			XI025D7, Exp 3/19.		
Drugs	Curcumin Emulsion 10mg/ml Injection, Sterile 10 mL Multiple Dose Vial, For Slow IV Administration, Compounded for a licensed professional or patient use by ImprimisRx, Irvine, CA	Class II	03212017@21B Exp:6/19/2017; 03232017@19B Exp:6/21/2017; 03292017@27B Exp:6/27/2017; 03292017@9B Exp:6/27/2017; 04042017@21B Exp:7/3/2017; 04122017@22B Exp:7/11/2017; 04132017@14B Exp:7/12/2017; 04192017@37B Exp:7/18/2017; 04192017@17B Exp:7/18/2017; 04242017@18B Exp:7/23/2017	Incorrect/Undeclared Excipient; non-pharmaceutical grade PEG 40 Castor Oil was used due to a mislabeling by the supplier	ImprimisRx CA, Inc., dba ImprimisRx 9257 Research Dr Irvine, CA 92618-4286
Drugs	Latanoprost PF Solution, 0.005%, Ophthalmic Drops in Sterile 5ml Bottles, Compounded for a licensed professional or patient use, imprimisRx, Irvine, CA	Class II	0404017@32B, 10/01/2017	Incorrect/Undeclared Excipient; non-pharmaceutical grade PEG 40 Castor Oil was used due to a mislabeling by the supplier	ImprimisRx CA, Inc., dba ImprimisRx 9257 Research Dr Irvine, CA 92618-4286
Drugs	Timolol-Latanoprost PF Solution (0.5-0.005)%, Ophthalmic Drops, Sterile 5ml Bottle, Compounded for a licensed professional or patient use, imprimisRx, Irvine, CA	Class II	04042017@34B, 10/01/2017	Incorrect/Undeclared Excipient; non-pharmaceutical grade PEG 40 Castor Oil was used due to a mislabeling by the supplier	ImprimisRx CA, Inc., dba ImprimisRx 9257 Research Dr Irvine, CA 92618-4286
Drugs	Timolol-Brimonidine-Dorzolamide-Latanoprost (0.5/0.15/2/0.005)% Ophthalmic Drops, Sterile 5ml Bottle, Compounded for a licensed professional or patient use, imprimisRx, Irvine, CA	Class II	05092017@2B, 11/5/2017	Incorrect/Undeclared Excipient; non-pharmaceutical grade PEG 40 Castor Oil was used due to a mislabeling by the supplier	ImprimisRx CA, Inc., dba ImprimisRx 9257 Research Dr Irvine, CA 92618-4286
Drugs	Povidone Iodine, USP Prep Solution, 10%, packaged in 1 gallon bottle, OTC,	Class	Lot #: 3A176011, Exp	Labeling: Label mix-up. Finished product Povidone iodine 7	Degasa Sa De Cv

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
	Manufactured for PSS World Medical, Inc. Southpoint Blvd. Jacksonville, FL Made in Mexico, NDC 68345-350-09	II	10/18	.5% was labeled as Povidone i odine 10% , the outer box ha d the correct label.	Calle Centenario 15 Col. DEPORTIVA Jiutepec
Drugs	Vitamin A&D Ointment (petroleum 93.5%), Skin Protectant, NET Wt. 0.18 OZ (5g), Manufactured for Medline Industries, Inc., Northfield, IL 60093 USA. NDC: 53329-090-16	Class II	Lot Number: A-K-8383	Labeling Mixup; the individual A&D ointment foil packets ar e incorrectly labeled as petrol eum jelly. The boxes and oute r case are correctly labeled as A&D ointment.	MEDLINE INDUSTRIES INC 3 Lakes Dr Northfield, IL 60093-2753
Drugs	PF-Glutathione 200mg/ml, 30 mL vials, Rx only, Bella Pharma 3101 W. Devon Ave., Chicago, IL 60659 1 (877) BELLA.	Class II	Lot #: 070617GL, Exp. 1/6/18	Lack of Assurance of Sterility.	Bella Pharmaceuticals, Inc. 3101 W Devon Ave Chicago, IL 60659-1407
Drugs	Methylcobalamin 10mg, (1mg/ml), 30 mL vials, Rx only, Bella Pharma 3101 W. Devon Ave., Chicago, IL 60659, 1 (877) BELLA.	Class II	Lot #: 070717MC, Exp. 1/7/18	Lack of Assurance of Sterility.	Bella Pharmaceuticals, Inc. 3101 W Devon Ave Chicago, IL 60659-1407
Drugs	Mannitol 20%, 10 mL vials, Rx only, Bella Pharma 3101 W. Devon Ave., Chicago, IL 60659, 1 (877) BELLA.	Class II	Lot #: 070717ML, Exp. 1/7/18	Lack of Assurance of Sterility.	Bella Pharmaceuticals, Inc. 3101 W Devon Ave Chicago, IL 60659-1407
Drugs	G.A.C 25/100/250mg, 30 mL Vials, Rx only, Bella Pharma 3101 W. Devon Ave., Chicago, IL 60659, 1 (877) BELLA.	Class II	Lot #: 071217GAC, 1/12/18	Lack of Assurance of Sterility.	Bella Pharmaceuticals, Inc.

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
					3101 W Devon Ave Chicago, IL 60659-1407
Drugs	Calcium chloride 10%, 10 mL vials, Rx only, Bella Pharma 3101 W. Devon Ave., Chicago, IL 60659, 1 (877) BELLA.	Class II	Lot #: 071217CC, Exp. 10/12/18	Lack of Assurance of Sterility.	Bella Pharmaceuticals, Inc. 3101 W Devon Ave Chicago, IL 60659-1407
Drugs	B-Complex, 30 mL vials, Rx only, Bella Pharma 3101 W. Devon Ave., Chicago, IL 60659,1 (877) BELLA.	Class II	Lot #: BPBC3080517, Exp. 2/5/18	Lack of Assurance of Sterility.	Bella Pharmaceuticals, Inc. 3101 W Devon Ave Chicago, IL 60659-1407
Drugs	Methylcobalamin 10mg, (10mg/ml), 30 mL vials, Rx only, Bella Pharma 3101 W. Devon Ave., Chicago, IL 60659, 1 (877) BELLA.	Class II	Lot #: BPMC30072917, Exp. 1/29/18	Lack of Assurance of Sterility.	Bella Pharmaceuticals, Inc. 3101 W Devon Ave Chicago, IL 60659-1407
Drugs	Magnesium Chloride 200mg, 30m L vials, Rx only, Bella Pharma 3101 W. Devon Ave., Chicago, IL 60659, 1 (877) BELLA.	Class II	Lot #: BPMC08517, Exp. 2/5/18	Lack of Assurance of Sterility.	Bella Pharmaceuticals, Inc. 3101 W Devon Ave Chicago, IL 60659-1407
Drugs	L-Glutamine 100mg, 30 mL vials, Rx only, Bella Pharma 3101 W. Devon Ave.,	Class	Lot #: BPLG08517, Exp	Lack of Assurance of Sterility.	Bella Pharmaceuticals,

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
	Chicago, IL 60659, 1 (877) BELLA.	II	. 2/5/18		Inc. 3101 W Devon Lack of Assurance of Sterility. Ave Chicago, IL 60659-1407
Drugs	MIC 25/50/50, 30mL vials, Rx only, Bella Pharma 3101 W. Devon Ave., Chicago, IL 60659, 1 (877) BELLA.	Class II	Lot #: BPMIC3007291 7, Exp. 1/29/18	Lack of Assurance of Sterility.	Bella Pharmaceuticals, Inc. 3101 W Devon Ave Chicago, IL 60659-1407
Drugs	Lidocaine Ophthalmic Gel 3.5%, 15mL bottles, Rx only, Bella Pharma 3101 W. Devon Ave., Chicago, IL 60659,1(877) BELLA.	Class II	Lot #: BPLG3508717, E xp. 11/7/17	Lack of Assurance of Sterility.	Bella Pharmaceuticals, Inc. 3101 W Devon Ave Chicago, IL 60659-1407
Drugs	Phenylephrine2.5%/Tropicamide 1% Ophthalmic Solution, 15mL bottle, Rx only, Bella Pharma 3101 W. Devon Ave., Chicago, IL 60659, 1 (877) BELLA.	Class II	Lot #: BPPTC08717, Ex p. 11/7/17	Lack of Assurance of Sterility.	Bella Pharmaceuticals, Inc. 3101 W Devon Ave Chicago, IL 60659-1407
Drugs	Sodium Bicarbonate 8.4%, 10 mL vials, Rx only, Bella Pharma 3101 W. Devon Ave., Chicago, IL 60659, 1 (877) BELLA.	Class II	Lot #: BPSB8408717, E xp. 11/7/17	Lack of Assurance of Sterility.	Bella Pharmaceuticals, Inc. 3101 W Devon Ave Chicago, IL 60659-1407

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drugs	Fluorescein Sodium, 5mL vials, Rx only, Bella Pharma 3101 W. Devon Ave., Chicago, IL 60659, 1 (877) BELLA.	Class II	Lot #: BPFS41717, Exp. 4/1/18	Lack of Assurance of Sterility.	Bella Pharmaceuticals, Inc. 3101 W Devon Ave Chicago, IL 60659-1407
Drugs	Bevacizumab Prefilled 30g and 31 gram 1.25mg/0.05mL Syringes, Rx only, Bella Pharma 3101 W. Devon Ave., Chicago, IL 60659, 1 (877) BELLA	Class II	Lot #: 3141201, Exp. 9/13/17; 3146966, Exp. 9/20/17; 3160608, Exp. 10/5/17; 3146966, Exp. 11/1/17	Lack of Assurance of Sterility.	Bella Pharmaceuticals, Inc. 3101 W Devon Ave Chicago, IL 60659-1407
Drugs	Paroxetine tablets USP, 30mg, 30-count bottles, Rx Only, Manufactured by: Cadila Healthcare Ltd, Ahmedabad, India Distributed by: Zydus Pharmaceuticals USA, Inc., Pennington, NJ 08534, NDC 68382-099-06, UPC 3 6838209906 8	Class II	Lot #: Z701133, Exp 03/19	Presence of Foreign tablets/capsules: risperidone Tablets were found in bottle of paroxetine Tablets	Zydus Pharmaceuticals USA Inc 73 Route 31 N Pennington, NJ 08534-3601
Drugs	Ninjacof (Chlophedianol HCL 12.5 mg and Pyrilamine Maleate 12.5 mg) Oral Solution, 16 fl. oz. (473 mL), Cotton Candy Flavor, Manufactured for: Centurion Labs, LLC Birmingham, AL 35243 --- NDC 23359-032-16	Class II	Lot: 200N1601 Exp. 11/2018	Microbial contamination of Non-sterile Products; potential B. cepacia contamination	Centurion Labs, LLC 3100 Bowling Dr Suite 1 Birmingham, AL 35242-6588
Drugs	Ninjacof-A (Acetaminophen 160 mg, Chlophedianol HCL 12.5 mg and Pyrilamine Maleate 12.5 mg) Oral Solution, 16 fl. oz. (473 mL), Cotton Candy Flavor, Manufactured for: Centurion Labs, LLC Birmingham, AL 35243 --- NDC 23359-033-16	Class II	Lot: 23221701, Exp. 05/19	Microbial contamination of Non-sterile Products; potential B. cepacia contamination	Centurion Labs, LLC 3100 Bowling Dr Suite 1 Birmingham, AL 35242-6588

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drugs	Doctor Manzanilla Cough & Cold (diphenhydramine hydrochloride and phenylephrine hydrochloride) Syrup, 12.5 mg and 5 mg in each 5 mL, 4 fl oz. (118 mL) bottle, Distributed by: Midvalley Pharmaceuticals, Raymondville, TX 78580, UPC 7 62558 00316 1.	Class II	Lot: 23221701, Exp. 05/19	CGMP Deviations: Recall initiated as a precautionary measure due to a potential risk of product contamination with the bacteria B. cepacia.	Mid Valley Pharmaceutical 910 E Hidalgo Ave Suite 3 Raymondville, TX 78580-4095
Drugs	BevaDex (bevacizumab) 0.06mL Prefilled 32 g (1.25mg/1mg) Syringes, Rx only, Bella Pharma 3101 W. Devon Ave., Chicago, IL 60659 (877) BELLA.	Class II	Lot #: 08152017, Exp. 11/15/17	Lack of Assurance of Sterility.	Bella Pharmaceuticals, Inc. 3101 W Devon Ave Chicago, IL 60659-1407
Drugs	Voriconazole Tablets, 200 mg, 20-count cartons (4 x 5) Unit Dose, Rx only, Manufactured for: AvKARE, Inc. Pulaski, TN 38478, NDC 50268-804-12	Class III	Lot #: 16933, Exp 07/2018; 17054, Exp 08/2018	Failed impurities/degradation specifications: Out of specification for a related compound C.	AVKARE Inc. 615 N 1st St Pulaski, TN 38478-2403
Drugs	Chlorhexidine Gluconate Oral Rinse, 0.12%, 15 mL Unit Dose Cup, a) unit dose cup (NDC 50383-720-15), b) 100-count tray (NDC 50383-720-19), Rx Only, Hi-Tech Pharmacal Co. Inc., Amityville, NY 11701.	Class III	Lot: 353394, Exp 10-2018	Crystallization with subpotent out of specification assay results for chlorhexidine.	Akorn Inc 1925 W Field Ct Lake Forest, IL 60045-4862
Drugs	Halyard 24-Hour Oral Care Kit q2, contains 2x15 mL Unit Dose Cups 0.12% Chlorhexidine Gluconate Oral Rinse. Manufactured by Halyard Health Inc., 5405 Windward Parkway, Alpharetta, GA 30004. Distributed by Halyard Sales, LLC Alpharetta, GA 30004. REF # 97012	Class III	Lots: 0202623109, 0202623110, 0202623111, 0202630207, 0202630208, 0202630209, EXP 06-2018; 0202642227, 0202642228, 0202647413, 0202647414, 0202653433, 0202653434, EXP 07-2018.	Crystallization with subpotent out of specification assay results for chlorhexidine.	Akorn Inc 1925 W Field Ct Lake Forest, IL 60045-4862
Drugs	Halyard 24-Hour Oral Care Kit q4, contains 2x15 mL Unit Dose Cups 0.12% Chlorhexidine Gluconate Oral Rinse. Manufactured by Halyard Health Inc., 5405 Windward Parkway, Alpharetta, GA 30004. Distributed by Halyard Sales, LLC Alpharetta, GA 30004. REF # 97014	Class III	Lots: 0202635072, 0202635073, EXP 06-2018; 0202630205, 0202630206, EXP 07-2018; 0202630203, 0202630204, 0202642217, 0202642218, 0202642219, 0202647410, 0202647411, EXP 08-2018; 0202647409, 0202647412, 0202653431, 0202653432, EXP 09-	Crystallization with subpotent out of specification assay results for chlorhexidine.	Akorn Inc 1925 W Field Ct Lake Forest, IL 60045-4862

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
			2018.		
Drugs	Beautipharm All Day Moisturizing Balm SPF 10 (Octocrylene 4% and Octyl methoxycinnamide 4%) Facial Cream, 1.66 oz. Net. Wt. 50 ml bottle, Art. 03120 Made in Germany, Doctor Eckstein, Linde Eckstein GMBH Co. Kg, 90522 Oberasbach, Germany. UPC 4 035219 032005.	Class III	Lot #: 240817, Exp 08/24/17; 061217, Exp 12/06/17; 290318, Exp 03/29/18; 160818, Exp 08/16/18; 231118, Exp 11/23/18; 160119, Exp 01/16/19; 080819, Exp 08/08/19	Subpotent Drug: products are labeled as having SPF 10 protection; however, this claim cannot be 100% guaranteed.	Linde Eckstein Gmbh + Co KG Flurstrasse 27a-35 Oberasbach
Drugs	Beautipharm Body Moisturizing Balm SPF 10 (Octocrylene 4% and Octyl methoxycinnamide 4%) Body Lotion, 8.3 oz. Net. Wt. 250 ml bottle, Art. 03150 Made in Germany, Doctor Eckstein, Linde Eckstein GMBH Co. Kg, 90522 Oberasbach, Germany. UPC 4 035219 031503.	Class III	Lot #: 201017, Exp 10/20/17; 290618, Exp 06/29/18; 040419, Exp 04/04/19.	Subpotent Drug: products are labeled as having SPF 10 protection; however, this claim cannot be 100% guaranteed.	Linde Eckstein Gmbh + Co KG Flurstrasse 27a-35 Oberasbach
Drugs	Beautipharm Eye Care Balm SPF 10 (Octocrylene 4% and Octyl methoxycinnamide 4%) Eye cream, 1 oz. Net. Wt. 30 ml bottle, Art. 03190 Made in Germany, Doctor Eckstein, Linde Eckstein GMBH Co. Kg, 90522 Oberasbach, Germany. UPC 4 035219 031909.	Class III	Lot #: 280318, Exp 03/28/2018; 020918, Exp 09/02/2018; 131019, Exp 10/13/19	Subpotent Drug: products are labeled as having SPF 10 protection; however, this claim cannot be 100% guaranteed.	Linde Eckstein Gmbh + Co KG Flurstrasse 27a-35 Oberasbach
Drugs	Make Up Transparent ivory (Titanium Dioxide) SPF 10 liquid make-up, 1 oz. Net Wt. 30 ml bottle, Art. 03200, Made in Germany, Doctor Eckstein, Linde Eckstein GMBH Co. Kg, 90522 Oberasbach, Germany, UPC 4 035219 032005.	Class III	Lot #: 180318, Exp 03/18/2018	Subpotent Drug: products are labeled as having SPF 10 protection; however, this claim cannot be 100% guaranteed.	Linde Eckstein Gmbh + Co KG Flurstrasse 27a-35 Oberasbach
Drugs	Make Up Transparent pastel (Titanium Dioxide) SPF 10 liquid make-up, 1 oz. Net Wt. 30 ml bottle, Art. 03210, Made in Germany, Doctor Eckstein, Linde Eckstein GMBH Co. Kg, 90522 Oberasbach, Germany, UPC 4 035219 032104.	Class III	Lot #: 130917, Exp 09/13/2017; 310318, Exp 03/31/2018; 270718, Exp 07/27/2018; 081118, Exp 11/08/2018.	Subpotent Drug: products are labeled as having SPF 10 protection; however, this claim cannot be 100% guaranteed.	Linde Eckstein Gmbh + Co KG Flurstrasse 27a-35 Oberasbach
Drugs	Make Up Transparent sand (Titanium Dioxide) SPF 10 liquid make-up, 1 oz. Net Wt. 30 ml bottle, Art. 03220, Made in Germany, Doctor Eckstein, Linde Eckstein GMBH Co. Kg, 90522 Oberasbach, Germany, UPC 4 035219 032203.	Class III	Lot #: 300817, Exp 08/30/2017; 291217, Exp 12/29/2017; 010918, Exp 09/01/2018.	Subpotent Drug: products are labeled as having SPF 10 protection; however, this claim cannot be 100% guaranteed.	Linde Eckstein Gmbh + Co KG Flurstrasse 27a-35 Oberasbach
Drugs	Make Up Perfect caramel (Titanium Dioxide) SPF 10 liquid make-up, 1 oz. Net Wt. 30 ml bottle, Art. 03330, Made in Germany, Doctor Eckstein, Linde Eckstein GMBH Co. Kg, 90522 Oberasbach, Germany, UPC 4 035219 032302.	Class III	Lot #: 130917, Exp 09/13/2017; 010818, Exp 08/01/2018.	Subpotent Drug: products are labeled as having SPF 10 protection; however, this claim cannot be 100% guaranteed.	Linde Eckstein Gmbh + Co KG Flurstrasse 27a-35 Oberasbach
Drugs	Make Up Transparent dark tan (Titanium Dioxide) SPF 10 liquid make-up, 1 oz. Net Wt. 30 ml bottle, Art. 03240, Made in Germany, Doctor Eckstein, Linde Eckstein GMBH Co. Kg, 90522 Oberasbach, Germany, UPC 4 035219 032401.	Class III	Lot #: 040318, Exp 03/04/2018; 261018, Exp 10/26/2018.	Subpotent Drug: products are labeled as having SPF 10 protection; however, this claim cannot be 100% guaranteed.	Linde Eckstein Gmbh + Co KG Flurstrasse 27a-35 Oberasbach
Drugs	Make Up Transparent terra (Titanium Dioxide) SPF 10 liquid make-up, 1 oz. Net Wt. 30 ml bottle, Art. 03250, Made in Germany, Doctor Eckstein, Linde Eckstein GMBH Co. Kg, 90522 Oberasbach, Germany, UPC 4 035219 032500.	Class III	Lot #: 060917, Exp 09/06/2017.	Subpotent Drug: products are labeled as having SPF 10 protection; however, this claim cannot be 100% guaranteed.	Linde Eckstein Gmbh + Co KG Flurstrasse 27a-35 Oberasbach

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drugs	Make Up Perfect ivory (Titanium Dioxide) SPF 10 liquid make-up, 1 oz. Net Wt. 30 ml bottle, Art. 03300, Made in Germany, Doctor Eckstein, Linde Eckstein GMBH Co. Kg, 90522 Oberasbach, Germany, UPC 4 035219 033002.	Class III	Lot #: 310318, Exp 03/31/2018.	Subpotent Drug: products are labeled as having SPF 10 protection; however, this claim cannot be 100% guaranteed.	Linde Eckstein Gmbh + Co KG Flurstrasse 27a-35 Oberasbach
Drugs	Make Up Perfect pastel (Titanium Dioxide) SPF 10 liquid make-up, 1 oz. Net Wt. 30 ml bottle, Art. 03310, Made in Germany, Doctor Eckstein, Linde Eckstein GMBH Co. Kg, 90522 Oberasbach, Germany, UPC 4 035219 033101.	Class III	Lot #: 210917, Exp 09/21/2017; 010918, Exp 09/01/2018.	Subpotent Drug: products are labeled as having SPF 10 protection; however, this claim cannot be 100% guaranteed.	Linde Eckstein Gmbh + Co KG Flurstrasse 27a-35 Oberasbach
Drugs	Make Up Perfect sand (Titanium Dioxide) SPF 10 liquid make-up, 1 oz. Net Wt. 30 ml bottle, Art. 03320, Made in Germany, Doctor Eckstein, Linde Eckstein GMBH Co. Kg, 90522 Oberasbach, Germany, UPC 4 035219 033200.	Class III	Lot #: 200917, Exp 09/20/2017; 230218, Exp 02/23/2018; 010918, Exp 09/01/2018; 140219, Exp 02/14/2019.	Subpotent Drug: products are labeled as having SPF 10 protection; however, this claim cannot be 100% guaranteed.	Linde Eckstein Gmbh + Co KG Flurstrasse 27a-35 Oberasbach
Drugs	Make Up Perfect dark tan (Titanium Dioxide) SPF 10 liquid make-up, 1 oz. Net Wt. 30 ml bottle, Art. 03340, Made in Germany, Doctor Eckstein, Linde Eckstein GMBH Co. Kg, 90522 Oberasbach, Germany, UPC 4 035219 033408.	Class III	Lot #: 310318, Exp 03/31/2018; 180718, Exp 07/18/2018; 020219, Exp 02/02/2019.	Subpotent Drug: products are labeled as having SPF 10 protection; however, this claim cannot be 100% guaranteed.	Linde Eckstein Gmbh + Co KG Flurstrasse 27a-35 Oberasbach
Drugs	Make Up Perfect terra (Titanium Dioxide) SPF 10 liquid make-up, 1 oz. Net Wt. 30 ml bottle, Art. 03350, Made in Germany, Doctor Eckstein, Linde Eckstein GMBH Co. Kg, 90522 Oberasbach, Germany, UPC 4 035219 033507.	Class III	Lot #: 221217, Exp 12/22/2017; 270718, Exp 07/27/2018.	Subpotent Drug: products are labeled as having SPF 10 protection; however, this claim cannot be 100% guaranteed.	Linde Eckstein Gmbh + Co KG Flurstrasse 27a-35 Oberasbach
Drugs	Phentermine HCL Capsules, USP 15 mg, packaged in a) 100-count bottles (NDC 10702-026-01), and b) 1000-count bottles (NDC 10702-026-10), Rx only, mfd. by: KVK-TECH, INC. NEWTOWN, PA 18940	Class III	Lot # a):12322A, 12323B, 12324A, Exp. Sep 2017; 12455A, Exp. Dec 2017; b) 12323A, Exp. Sep 2017; 12456A, Exp. Dec 2017	Failed Impurities/Degradation Specifications: out-of-specification results obtained for individual unknown impurities found at 30 month Room Temperature Retained Sample stability test.	KVK-Tech, Inc. 110 Terry Dr Newtown, PA 18940-3427
Drugs	Phentermine Capsules, 15 mg, a) 7-count bottle (NDC 55289-791-07), b) 14-count bottle (NDC 55289-791-14), c) 21-count bottle (NDC 55289-791-21), d) 30-count bottle (NDC 55289-791-30), e) 60-count bottle (NDC 55289-791-60), Packaged by PD-Rx Pharmaceuticals, Incorporated, Oklahoma City, OK. 73127 Mfg: KVK-Tech, Inc. Newtown, PA 18940	Class III	Lots: a) H15E22, Exp. 8 /31/17; J15E02, Exp. 1 0/31/17. b) J15A53, Ex p. 10/31/17; D16C78, Exp.12/31/17; c)J15D5 4, Exp. 10/31/17; d)H1 5B60, Exp. 8/31/17; e) J15A49, Exp. 10/31/17 ; C16A14, Exp. 12/31/ 17.	Failed Impurities/Degradation Specifications: Out of specification results for individual unknown impurities at 30th month Room Temperature Retained Sample stabilities test .	PD-Rx Pharmaceuticals, Inc. 727 N Ann Arbor Ave Oklahoma City, OK 73127-5822
Drugs	Propafenone Hydrochloride tablets, 150 mg, packaged in 10 x 10 unit dose cards (100-count box), Rx only, Manufactured By: Watson Pharmaceuticals 311 Bonnie Circle Corona, CA 92880, NDC 63739-509-10	Class III	Lot#: 0112313 Exp. 12 /2017; 0113376 Exp. 0 6/2018; 0113645 Exp. 02/2019.	Failed moisture limits: Out of specification for moisture content.	McKesson Packaging Services 7101 Weddington Rd NW Concord, NC 28027-3412

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drugs	Famotidine for Oral Suspension USP, 40 mg/5 mL, 50 mL bottle, Rx only, Manufactured for: Lupin Pharmaceuticals, Inc., Baltimore, Maryland 21202; Manufactured by: Lupin Limited, Goa 403 722 INDIA, NDC 68180-150-01	Class III	Lot #: G606950, Exp 07/18	CGMP Deviations	Lupin Pharmaceuticals Inc. 111 S Calvert St Fl 21ST Baltimore, MD 21202-6174
Drugs	AMLODIPINE BESYLATE TABLET, USP, 10 mg, 1000 count bottle, Rx Only, Manufactured by: Alkem Laboratories Ltd., Mumbai - 400 013, India, Distributed by: Ascend Laboratories, LLC Montvale, NJ 07645, NDC 67877-217-10	Class III	Lot #: 6142626, Exp 09/19	PRESENCE OF FOREIGN TABLETS/CAPSULES: A 2.5 mg Amlodipine Besylate tablet was found co-mingled with 10 mg Amlodipine Besylate tablets in a bottle labeled as Amlodipine Besylate 10 mg.	Ascend Laboratories LLC 180 Summit Ave Ste 200 Montvale, NJ 07645-1722
Drugs	Hydrocodone Bitartrate and Acetaminophen Oral Solution 7.5 mg/325 mg per 15 mL (Cherry Flavored), 473 mL bottles, Rx only, Manufactured by: VistaPharm, Inc. Largo, FL 33771 ---- NDC 66689-023-16	Class III	Lot: 494700 Exp. 10/2018	Labeling: Not Elsewhere Classified; product is incorrectly labeled as Class III controlled substance instead of Class II controlled substance	VistaPharm, Inc. 7265 Ulmerton Rd Largo, FL 33771-4809
Drugs	Phentermine, USP Capsules, 15 mg, 30 count bottles, Rx only, Packaged By: Aidarex Pharmaceuticals, Corona, CA, MFG: KVK-TECH INC. Newtown. PA ---33261-0361-30	Class III	Batch 47262-2, 47262-3, exp 8/31/2017; 47262-4, exp 12/30/17, 47262-5, 47262-6, 47262-7, exp 12/31/17	Failed Impurities/Degradation Specification; out-of-specification results for individual unknown impurities at the 30 month Room Temperature Retained Sample stability test	Aidarex Pharmaceuticals LLC 595 N Smith Ave Ste B Corona, CA 92880-6920

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

CURRENT DRUG SHORTAGES

Ceftazidime Injection

August 22, 2017

Reason for the Shortage

- Pfizer has Tazicef available.
- Sagent has ceftazidime injection on shortage due to manufacturing delays.
- Sandoz discontinued ceftazidime 1 gram and 2 gram vials in 2015.
- BBraun had ceftazidime on allocation due to increased demand.
- WG Critical Care has ceftazidime on shortage due to manufacturing delays.

Estimated Resupply Dates

- Teligent has Fortaz 2 gram and 6 gram vials on back order and the company cannot estimate a release date.
- WG Critical Care has ceftazidime 1 gram vials on back order and the company estimates a release date of late-October 2017.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=869

Magnesium Sulfate Injection

August 25, 2017

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 Dates

- Pfizer has magnesium sulfate 500 mg/mL 20 mL vials on back order and the company estimates a release date of 2nd quarter 2018. The 500 mg/mL 10 mL Ansyr syringes are available in limited supply

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=757

Hepatitis B Vaccine Recombinant

August 25, 2017

Reason for the Shortage

- Merck has Recombivax HB on shortage due to increase in global demand.

Estimated Resupply Dates

- 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 does not anticipate these products will be available in 2017.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=520

Fludarabine Injection

August 25, 2017

Reason for the Shortage

- Actavis has fludarabine available.
- Fresenius Kabi had fludarabine on shortage due to increased demand.
- Pfizer has fludarabine on shortage due to increased demand.
- Sagent had fludarabine 25 mg/mL 2 mL vials on shortage due to manufacturing delays.

Estimated Resupply Dates

- Pfizer has fludarabine lyophilized powder 50 mg vials on back order and the company estimates a release date of late-September 2017

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=648

Etoposide Injection

August 25, 2017

Reason for the Shortage

- Bristol-Myers Squibb had Etopophos on back order due to a shortage of the active ingredient
- Etoposide solution for injection is not affected by this shortage

Estimated Resupply Dates

- Bristol-Myers Squibb has Etopophos available

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=652

Thiotepa for Injection

August 29, 2017

Reason for the Shortage

- West-Ward launched thiotepa in August 2015.
- FDA was allowing temporary importation of Tepadina (thiotepa), from Adienne SA in Italy. There may still be product available at some healthcare centers but importation stopped in December 2015.

Estimated Resupply Dates

- West-Ward has thiotepa available with an expiration date of May 2018.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=589

Sodium Nitroprusside Injection

August 29, 2017

Reason for the Shortage

- Valeant has Nitropress available but short-dated.
- Nexus has sodium nitroprusside 25 mg/mL 2 mL vials available.
- Sagent has sodium nitroprusside 25 mg/mL 2 mL vials available.
- Exela launched Nipride RTU 0.5 mg/mL 100 mL vials in March 2017.

Estimated Resupply Dates

- Valeant has Nitropress 25 mg/mL 2 mL vials available with an expiration date of May 2018.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1223

Reteplase Injection

August 29, 2017

Reason for the Shortage

- Chiesi USA acquired Cornerstone Therapeutics in March 2014.
- Cornerstone Therapeutics acquired EKR Therapeutics in June 2012. EKR Therapeutics had previously purchased Retavase from PDL BioPharma.
- Cornerstone Therapeutics was seeking FDA approval of a new supplier of the active pharmaceutical ingredient for Retevase.

Estimated Resupply Dates

- Chiesi USA has Retavase 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=569

Penicillin G Procaine Injection

August 29, 2017

Reason for the Shortage

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

Estimated Resupply Dates

- 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 4th quarter 2017.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1238

Penicillin G Benzathine/Penicillin G Procaine

August 29, 2017

Reason for the Shortage

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

Estimated Resupply Dates

- Pfizer has Bicillin C-R 1,200,000 units/2 mL prefilled syringes and 1,200,000 units/2 mL pediatric prefilled syringes on allocation.
- Pfizer has Bicillin C-R 900/300 2 mL pediatric prefilled syringes on allocation.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1249

Penicillin G Benzathine

August 29, 2017

Reason for the Shortage

- Pfizer states the shortage is due to a delay in the manufacturing process.

Estimated Resupply Dates

- Pfizer has Bicillin L-A 600,000 unit/ 1 mL syringes, 1,200,000 unit/ 2 mL syringes, and 2,400,000 unit/ 4 mL syringes on allocation.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1232

Papaverine Injection

August 29, 2017

Reason for the Shortage

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

Estimated Resupply Dates

- American Regent has papaverine 30 mg/mL 2 mL vials available.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=781

Multiple Vitamins for Infusion

August 29, 2017

Reason for the Shortage

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

Estimated Resupply Dates

- Pfizer has M.V.I. adult 50 mL Dual vials on back order and the company estimates a release date of September 2017.
- Pfizer has M.V.I. pediatric 5 mL vials on back order and the company estimates a release date of October 2017.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=831

Ketorolac Tromethamine Injection

August 29, 2017

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 Dates

- Amphastar has ketorolac 30 mg/mL 1 mL vials on back order and the company cannot estimate a release date.
- Fresenius Kabi has ketorolac15 mg/mL 1 mL vials on back order and the company estimates a release date in early-September 2017. Ketorolac 30 mg/mL 1 mL prefilled syringes are available with short expiration dating (< 9 months).
- Sagent has ketorolac 15 mg/mL 1 mL vials, 30 mg/mL 1 mL vials, and 30 mg/mL 2 mL vials for intramuscular injection on back order and the company cannot estimate a release date.
- Pfizer has ketorolac 30 mg/mL 1 mL Carpuject syringes on back order and the company estimates a release date of October 2017. The 30 mg/mL 1 mL iSecure syringes and 30 mg/mL 2 mL Carpuject syringes for intramuscular injection are on 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=593

Indigo Carmine Injection

August 29, 2017

Reason for the Shortage

- American Regent launched indigo carmine in July 2017.
- Akorn has discontinued production of indigo carmine due to shortage of raw material.

Estimated Resupply Dates

- American Regent has indigo carmine 8 mg/mL 5 mL ampules available.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=861

Fluconazole Injection

August 29, 2017

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 Dates

- 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.
- Pfizer has fluconazole injection 400 mg/200 mL in 0.9% sodium chloride premixed bags on back order and the company estimates a release date of early-November 2017. The fluconazole injection 400 mg/200 mL in 5% dextrose premixed bags are on back order and the company estimates a release date of October 2017.

- 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 September to October 2017.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=644

Epinephrine Injection

August 29, 2017

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 Dates

- 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 late-September 2017.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=685

Cefpodoxime Oral Suspension

August 29, 2017

Reason for the Shortage

- Sandoz did not provide a reason for the shortage of cefpodoxime.
- Aurobindo discontinued cefpodoxime oral suspension in 2016.
- Cefpodoxime tablets are not affected by this shortage.

Estimated Resupply Dates

- Sandoz has cefpodoxime 100 mg/5 mL 100 mL bottles on back order and the company estimates a release date of mid- to late-September 2017.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1284

Cefotaxime Injection

August 29, 2017

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 Dates

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

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

Bumetanide Injection

August 29, 2017

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 Dates

- Pfizer has bumetanide 0.25 mg/mL 4 mL and 10 mL vials on back order and the company estimates a release date of early-April 2018.
- West-Ward has bumetanide 0.25 mg/mL 4 mL vials on a weekly allocation.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=674

Etomidate Injection

August 30, 2017

Reason for the Shortage

- Pfizer has Amidate on shortage due to manufacturing delays. Pfizer discontinued etomidate ampules in October 2016.
- Mylan has etomidate available.
- Par Sterile Products discontinued etomidate in early 2015.
- Sagent is no longer marketing etomidate.
- Zydus had etomidate on shortage due to an increase in demand.
- AuroMedics launched etomidate in mid-2017 and product is available.

Estimated Resupply Dates

- American Regent has etomidate 2 mg/mL 10 mL and 20 mL vials available with an expiration date of November 2017.
- Mylan Institutional has etomidate 2 mg/mL 10 mL and 20 mL vials available with an expiration date of March 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 mid-September 2017.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=419

Metronidazole Hydrochloride Injection

September 1, 2017

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 Dates

- 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 24 count and 80 count on back order and the company estimates a release date of mid-September 2017 for the 24 count size and early-September 2017 for the 80 count size.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1272

Metoclopramide Injection

September 1, 2017

Reason for the Shortage

- Fresenius Kabi has metoclopramide 2 mL syringes available.
- Pfizer has metoclopramide injection on shortage due to manufacturing delays.
- Teva has metoclopramide injection on shortage..

Estimated Resupply Dates

- Fresenius Kabi has metoclopramide 5 mg/mL 2 mL syringes available with an expiration date of <2 months.
- Pfizer has metoclopramide 5 mg/mL 2 mL vials on back order and the company estimates a release date of September 2017.
- Teva has metoclopramide 5 mg/mL 2 mL vials on intermittent back order and the company is allocating product upon release.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=611

Lorazepam Injection

September 1, 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.
- Akorn has not provided a reason for the shortage.
- Amphastar has product available.

Estimated Resupply Dates

- Pfizer has lorazepam 2 mg/mL 1 mL Carpuject syringes on back order and the company estimates a release date of early-December 2017. The 2 mg/mL 1 mL and 10 mL vials are on back order and the company estimates a release date of late-September 2017 for the 1 mL vials and 4th quarter 2017 for the 10 mL vials. The 4 mg/mL 1 mL vials are on back order and the company estimates a release date of mid-September 2017. The 4 mg/mL 1 mL Carpuject syringes are on back order and the company estimates a release date of 2nd quarter 2018.
- West-Ward has lorazepam 2 mg/mL 1 mL vials on back order and the company estimates a release date of September 2017.
- West-Ward has Ativan 2 mg/mL 10 mL vials available with an expiration date of August 2018

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1270

Dextrose (50%) Injection

September 1, 2017

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-September 2017. The 50% dextrose 50 mL vials are on back order and the company estimates a release date of early-October 2017.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1012

Calcium Chloride Injection

September 1, 2017

Reason for the Shortage

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

- 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-September 2017. The 100 mg/mL 10 mL LifeShield syringes are on back order and the company estimates a release date of late-October 2017.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=941

70% Dextrose Injection Large Volume Bags

September 5, 2017

Reason for the Shortage

- Baxter had 70% dextrose 2,000 mL bags on shortage due to manufacturing delays.
- BBraun discontinued 70% dextrose in 1,000 mL glass bottles in 2016. The 70% dextrose 2,000 mL bags were on allocation due to increased demand.
- Pfizer has 70% dextrose 500 mL in 1000 mL partial fill bags on back order due to manufacturing delays.

Estimated Resupply Dates

- Baxter has 70% dextrose 2,000 mL bags available.
- BBraun has 70% dextrose 2,000 mL bags available to current customers.
- Pfizer has 70% dextrose 500 mL in 1000 mL partial-fill bags on back order and the company estimates a release date in early-September 2017.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1133

Yellow Fever Vaccine Injection

September 6, 2017

Reason for the Shortage

- Sanofi Pasteur states the shortage is due to production delays.
- There are no other suppliers of yellow fever vaccine.
- Additional information on the yellow fever shortage.

Estimated Resupply Dates

- Sanofi Pasteur has YF-Vax multi-dose vials and single dose vials on back order and the company cannot estimate a release date.1
- FDA accepted an investigational new drug application in October 2016. This is for the importation of another yellow fever vaccine from France. The trade name of the imported product is Stamaril.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=383

Torsemide Injection

September 6, 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 Dates

- 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

Topotecan Capsules

September 6, 2017

Reason for the Shortage

- Novartis did not provide a reason for the current shortage.

Estimated Resupply Dates

- Novartis has Hycamtin 0.25 mg and 1 mg capsules available with new NDCs.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1266

Tolmetin Capsules and Tablets

September 6, 2017

Reason for the Shortage

- Mylan did not provide a reason for the shortage.

- Sun Pharma has not had tolmetin available since 2015. They refuse to provide availability information on any product.

Estimated Resupply Dates

- Mylan has tolmetin 400 mg capsules and 600 mg tablets on back order and the company estimates a release date of early-October 2017 for the 400 mg capsules and late-December 2017 for the 600 mg tablets.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1278

Tobramycin Injection

September 6, 2017

Reason for the Shortage

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

Estimated Resupply Dates

- Akorn has tobramycin 40 mg/mL 2 mL vials on back order and the company cannot estimate a release date.
- Fresenius Kabi has tobramycin 1.2 gram preservative-free powder 50 mL vials on back order and the company estimates a release date of mid-October 2017.
- Mylan Institutional has tobramycin 40 mg/mL 2 mL vials on intermittent back order and the company is releasing product as it becomes available.
- X-Gen has tobramycin 1.2 gram preservative-free powder 50 mL vials in 1 count on back order and the company estimates a release date of mid-October 2017.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=701

Procainamide Hydrochloride Injection

September 6, 2017

Reason for the Shortage

- Pfizer did not provide a reason for the shortage.

Estimated Resupply Dates

- Pfizer has procainamide 100 mg/mL 10 mL 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=868

Potassium Acetate Injection

September 6, 2017

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 and 50 mL vials on back order and the company estimates a release date of early-December 2017 for the 20 mL vials and early-October 2017 for the 50 mL vials.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=668

Ofloxacin Ophthalmic Solution

September 6, 2017

Reason for the Shortage

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

Estimated Resupply Dates

- Valeant has temporarily discontinued ofloxacin ophthalmic solution in 5 mL and 10 mL bottles and the company cannot estimate a release date.
- Akorn has ofloxacin ophthalmic solution in 5 mL vials on allocation.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1235

Methylene Blue Injection

September 6, 2017

Reason for the Shortage

- Akorn has methylene blue on shortage due to manufacturing delays.
- American Regent has recently launched an FDA approved presentation, ProvayBlue and product is available.

Estimated Resupply Dates

- Akorn has methylene blue 10 mg/mL 1 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=27

Gentamicin Injection

September 6, 2017

Reason for the Shortage

- Pfizer has discontinued all premixed bags.
- Baxter did not provide a reason for the shortage.

Estimated Resupply Dates

- Fresenius Kabi has gentamicin 40 mg/mL 2 mL vials on back order and the company estimates a release date in mid-to late-September 2017.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=728

Furosemide Tablets

September 6, 2017

Reason for the Shortage

- Major states the shortage is due to supply and demand issues.
- Mylan, Sandoz, and Teva did not provide a reason for the shortage.
- West-Ward states the shortage is due to manufacturing delays.

Estimated Resupply Dates

- Major has furosemide 20 mg tablets in 100 count unit-dose blister packs on back order and the company cannot estimate a release date.
- Mylan has furosemide 20 mg and 40 mg tablets in 100 count bottles on back order and the company estimates a release date of late-September 2017. The furosemide 20 mg and 40 mg tablets in 1000 count bottles are on back order and the company estimates a release date of early-September 2017.
- Sandoz has furosemide 20 mg tablets in 1000 count bottles and 80 mg tablets in 500 count bottles on back order and the company cannot estimate a release date.
- Teva has furosemide 20 mg and 40 mg tablets in 100 and 1000 count bottles on back order and the company cannot estimate a release date.
- West-Ward has furosemide 40 mg in 100 count bottles and 20 mg 100 count unit-dose blister packs on back order and the company estimates a release date of mid-September 2017 for the 40 mg tablets and early-October 2017 for the 20 mg tablets.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1281

Alcohol Dehydrated Injection (Ethanol)

September 6, 2017

Reason for the Shortage

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

Estimated Resupply Dates

- 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

Sodium Acetate Injection

September 8, 2017

Reason for the Shortage

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

Estimated Resupply Dates

- Fresenius Kabi has sodium acetate 4 mEq/mL 100 mL vials on back order and the company estimates a release date of late-October to early-November 2017.
- Pfizer has sodium acetate 2 mEq/mL 20 mL vials on back order and the company estimates a release date of mid-September 2017. The 50 mL and 100 mL vials are on back order and the company estimates a release date of early-October 2017.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=762

Rocuronium Injection

September 8, 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.
- X-Gen has rocuronium on shortage due to increased demand.
- AuroMedics launched rocuronium in mid-2017.

Estimated Resupply Dates

- Fresenius Kabi has rocuronium 10 mg/mL 10 mL vials on back order and the company estimates a release date of early-October 2017.
- Pfizer has rocuronium 10 mg/mL 5 mL and 10 mL vials on back order and the company estimates a release date of late-September 2017 for the 5 mL vials and mid-October 2017 for the 10 mL vials.
- Sagent has rocuronium 10 mg/mL 5 mL vials on back order and the company estimates a release date of November 2017. The 10 mL vials are on allocation.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=434

Pantoprazole Injection

September 8, 2017

Reason for the Shortage

- Pfizer did not provide a reason for the back order.
- AuroMedics did not provide a reason for the back order.

Estimated Resupply Dates

- Pfizer has Protonix 40 mg vials in 10 count and 25 count packs available in limited supply.
- AuroMedics has pantoprazole 40 mg vials on intermittent back order and the company and the company is releasing product as it becomes available.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1153

Lidocaine with Epinephrine Injection

September 8, 2017

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 1% lidocaine with epinephrine (1:100,000) 20 mL on back order and the company estimates a release date of 2nd quarter 2018. The 1% lidocaine with epinephrine (1:100,000) 30 mL vials are on back order and the company estimates a release date of mid-September 2017. The 1% lidocaine with epinephrine (1:100,000) 50 mL vials are on back order and the company cannot estimate a release date.

The 0.5% lidocaine with epinephrine (1:200,000) 50 mL vials are on back order and the company estimates a release date of 1st quarter 2018. The 1.5% lidocaine with epinephrine (1:200,000) 30 mL vials are on back order and the company estimates a release date of October 2017. The 2% lidocaine with epinephrine (1:200,000) 20 mL vials are on back order and the company estimates a release date of early-September 2017. 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 October 2017 for the 20 mL and 50 mL vials and 1st quarter 2018 for the 30 mL vials.

- •Fresenius Kabi has 0.5% Xylocaine with epinephrine (1:200,000) 50 mL vials on back order and the company estimates a release date of late-September 2017. The 1% Xylocaine with epinephrine (1:200,000) 10 mL, 20 mL , and 50 mL vials are on back order and the company estimates a release date of late-September 2017 for the 10 mL vials and mid-to late-September 2017 for the 20 mL vials, and mid-September 2017 for the 50 mL vials. The 1% Xylocaine-MPF with epinephrine (1:200,000) 10 mL and 30 mL vials are on back order and the company estimates a release date of mid-September 2017 for the 30 mL vials and cannot estimate a release date for the 10 mL vials. The 1% Xylocaine-MPF with epinephrine (1:200,000) 30 mL vials in sterile packs are on back order and the company estimates a release date of early- to mid-October 2017. 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 2% Xylocaine with epinephrine (1:200,000) 20 mL and 50 mL vials are on back order and the company cannot estimate a release date for the 20 mL vials and estimates a release date of late-September 2017 for the 50 mL vials. The 2% Xylocaine-MPF with epinephrine (1:200,000) 10 mL vials are on back order and the company cannot estimate a release date. The 2% Xylocaine-MPF with epinephrine (1:200,000) 20 mL vials are on back order and the company estimates a release date of mid- to late-September 2017. 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

Leucovorin Calcium Injection

September 8, 2017

Reason for the Shortage

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

Estimated Resupply Dates

- Fresenius Kabi has leucovorin 500 mg vials on back order and the company estimates a release date of early- to mid-October 2017.
- Sagent has leucovorin 50 mg, 100 mg, 200 mg, and 350 mg vials on back order and the company estimates a release date of September 2017.
- West-Ward has leucovorin 350 mg vials on allocation.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=488

Labetalol Injection

September 8, 2017

Reason for the Shortage

- Akorn has labetalol injection available.

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

Estimated Resupply Dates
- Pfizer has labetalol 5 mg/mL 20 mL and 40 mL vials on intermittent back order and the company is releasing product as it becomes available. The 5 mg/mL 4 mL syringes are on back order and the company estimates a release date of mid-October 2017.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=397

Furosemide Injection

September 8, 2017

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 Dates
- Claris has furosemide 10 mg/mL 10 mL vials in 5 count and 25 count on back order and the company cannot estimate a release date.
- Fresenius Kabi has furosemide 10 mg/mL 10 mL vials on back order and the company estimates a release date of 4th quarter 2017.
- Pfizer has furosemide 10 mg/mL 10 mL syringes on back order and the company estimates a release date of late-September 2017. The 10 mg/mL 4 mL and 10 mL vials are on back order and the company estimates a release date of mid- to late-September 2017 for the 4 mL vials and late-September 2017 for the 10 mL vials. The 10 mg/mL 4 mL syringes are available in limited supply.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=636

Fentanyl Citrate Injection

September 8, 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.

Estimated Resupply Dates
- Akorn has fentanyl 50 mcg/mL 5 mL ampules in 10 count and 25 count on back order and the company cannot estimate a release date. The fentanyl 50 mcg/mL 2 mL ampules are available in limited supply.
- Pfizer has fentanyl 50 mcg/mL 5 mL ampules on back order and the company estimates a release date of early-October 2017. The 2 mL ampules are on back order and the company estimates a release date of late-September 2017. The 2 mL Carpuject syringes are on back order and the company estimates a release date of 2nd quarter 2018. The 5 mL, 10 mL, and 20 mL vials are on back order and the company estimates a release date of late-September 2017. The 50 mL vials are on back order and the company estimates a release date of mid-September 2017.
- West-Ward has fentanyl 50 mcg/mL 50 mL vials on allocation. The 2 mL, 5 mL, and 20 mL vials are on back order and the company estimates a release date of September 2017 for the 2 mL and 5 mL vials and

September to October 2017 for the 20 mL vials. 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=1273

Dobutamine Injection

September 8, 2017

Reason for the Shortage

- Baxter did not provide a reason for the shortage.
- Pfizer has dobutamine on shortage due to manufacturing delays.

Estimated Resupply Dates

- Baxter has all dobutamine premixed bags on back order and the company cannot estimate a release date.
- Pfizer has dobutamine 12.5 mg/mL 20 mL and 40 mL latex-free vials on back order with an estimated release date of 2018. The 12.5 mg/mL 20 mL regular vials in single count are on back order and the company estimates a release date of September 2017.
- Pfizer has dobutamine 1 mg/mL in 250 mL bags on back order and the company estimates a release date of late-September 2017. The dobutamine 4 mg/mL 250 mL bags are on back order and the company estimates a release date of late-September 2017.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=929

Clindamycin Injection

September 8, 2017

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 Dates

- Alvogen has clindamycin 150 mg/mL 2 mL, 4 mL, and 6 mL ADD-Vantage vials on back order and the company cannot estimate a release date.
- Fresenius Kabi has clindamycin 150 mg/mL 2 mL, 6 mL, and 60 mL vials on back order and the company estimates a release date in mid-October 2017.
- Sagent has clindamycin 150 mg/mL 2 mL vials on back order and the company estimates a release date of September 2017. The clindamycin 150 mg/mL 4 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=1029

Cisplatin Injection

September 8, 2017

Reason for the Shortage

- Fresenius Kabi did not provide a reason for the shortage.
- Mylan Institutional could not provide a reason for the shortage.
- Teva has cisplatin on allocation due to increased demand.
- WG Critical Care has cisplatin available.

Estimated Resupply Dates

- Fresenius Kabi has cisplatin 200 mL vials on back order and the company estimates a release date of late-September 2017.
- Mylan Institutional has cisplatin 50 mL and 100 mL vials temporarily unavailable and the company cannot estimate a release date.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=57

Cefoxitin Sodium Injection

September 8, 2017

Reason for the Shortage

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

Estimated Resupply Dates

- Sagent has cefoxitin 1 gram and 10 gram vials on back order and the company estimates a release date of September 2017. The 2 gram vials are on back order and the company cannot estimate a release date.
- 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

Cefepime Injection

September 8, 2017

Reason for the Shortage

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

Estimated Resupply Dates

- BBraun has cefepime 1 gram and 2 gram premixed bags on allocation.

- Pfizer has Maxipime 1 gram ADD-Vantage vials on back order and the company estimates a release date of mid-October 2017. The 2 gram ADD-Vantage vials are on back order and the company estimates a release date of late-September 2017.
- Sagent has cefepime 1 gram vials on allocation.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1176

Carboplatin Solution for Injection

September 8, 2017

Reason for the Shortage

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

Estimated Resupply Dates

- Mylan Institutional has all carboplatin injection on back order and the company cannot estimate a release date.
- Sagent has carboplatin 10 mg/mL 5 mL and 15 mL vials on back order and the company cannot estimate a release date.
- Teva has carboplatin 10 mg/mL 15 mL, 45 mL, and 60 mL vials on allocation. Please check wholesaler for inventory.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1005

Bupivacaine with epinephrine Injection

September 8, 2017

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 10 mL and 30 mL vials on back order and the company estimates a release date of mid-September 2017. The 0.25% Sensorcaine with epinephrine 50 mL vials are on back order and the company estimates a release date of mid- to late-September 2017. The 0.5% Sensorcaine-MPF with epinephrine 30 mL vials are on back order and the company estimates a release date of late-September 2017. The 0.5% Sensorcaine-MPF with epinephrine 10 mL vials are on back order and the company cannot estimate a release date. The 0.5% Sensorcaine-MPF with epinephrine 30 mL vials and 30 mL sterile packs are on back order and the company estimates a release date of late-September 2017. The 0.5% Sensorcaine with epinephrine 50 mL vials are on back order and the company cannot estimate a release date. 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 January 2018 for the 10 mL vials and 3rd quarter 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 2nd quarter 2018. The 0.5% bupivacaine with epinephrine 10 mL and 30 mL preservative-free vials are on back order and the company estimates a release date of 1st quarter 2018 for the 10 mL vials and 3rd quarter 2018 for the 30 mL vials. The 0.5% bupivacaine with epinephrine 50 mL vials are on back order and the company estimates a release date of 2nd quarter 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 October 2017 for the 10 mL vials and late-September 2017 for the 30 mL vials. The 0.25% Marcaine with epinephrine 50 mL vials are on back order and the company estimates a release date of 1st quarter 2018. 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 1st quarter 2018 for the 10 mL vials and October 2017 for the 30 mL vials. The 0.5% Marcaine with epinephrine 50 mL vials are on back order and the company estimates a release date of 1st quarter 2018.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=937

Ampicillin Sulbactam

September 8, 2017

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 Dates

- 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 3 gram vials available with short expiration dating. The 15 gram vials are on back order and the company estimates a release date of September 2017.
- Sandoz has ampicillin sulbactam 1.5 gram, 3 gram, and 15 gram vials temporarily unavailable and the company cannot estimate a release date.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=805

Amino Acid Products

September 8, 2017

Reason for the Shortage

- Baxter has all amino acid products available.
- BBraun has all amino acid products available.
- 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 Dates

- Pfizer has all Aminosyn presentations on back order and the company cannot estimate a release date.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=671

Morphine Injections

September 11, 2017

Reason for the Shortage

- 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 on back order and the company estimates a release date of mid-September 2017. The 4 mg/mL 1 mL syringes are on back order and the company estimates a release date of mid-October 2017.
- Pfizer has morphine 0.5 mg/mL 10 mL preservative-free vials on back order and the company estimates a release date of early-October 2017. The 1 mg/mL 10 mL preservative-free vials are on back order and the company estimates a release date of late-September 2017. The 2 mg/mL 1 mL Carpuject syringes and 4 mg/mL 1 mL Carpuject syringes are on back order and the company estimates a release date of September 2017. The 50 mg/mL 20 mL and 50 mL vials are on back order and the company estimates a release date of mid-September 2017. The 25 mg/mL 1 mL preservative-free vials are on back order and the company estimates a release date of early-December 2017. The 2 mg/mL 1 mL iSecure syringes, 4 mg/mL 1 mL iSecure syringes, and 8 mg/mL 1 mL Carpuject syringes are on back order and the company estimates a release date of 3rd quarter 2018.
- West-Ward has Duramorph 0.5 mg/mL 10 mL ampules and 1 mg/mL 10 mL ampules are on a weekly allocation. Morphine 4 mg/mL 1 mL vials are on back order and the company estimates a release date of September 2017. Morphine 8 mg/mL 1 mL vials are on allocation.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=664

Methotrexate Injection

September 11, 2017

Reason for the Shortage

- Accord did not provide a reason for the shortage.
- Fresenius Kabi has methotrexate injection on shortage due to increased demand.
- Mylan did not provide a reason for the shortage.
- Pfizer has methotrexate injection on shortage due to increased demand.
- Teva has methotrexate injection on shortage due to increased demand.

Estimated Resupply Dates

- 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.
- Mylan Institutional has methotrexate injection temporarily unavailable and the company cannot estimate a release date.
- Pfizer has methotrexate 25 mg/mL 2 mL preservative-free vials available in limited supply.

- Teva has methotrexate 25 mg/mL 2 mL, 10 mL, and 40 mL preservative-free vials on allocation. Please check wholesaler for inventory.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=26

Hydromorphone Hydrochloride Injection

September 11, 2017

Reason for the Shortage

- 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

- Fresenius Kabi has Dilaudid 1 mg/mL 1 mL syringes on back order and the company estimates a release date in late-September 2017.
- Pfizer has hydromorphone 0.5 mg/0.5 mL 0.5 mL iSecure syringes and 1 mg/mL 1 mL Carpuject syringes on back order and the company estimates a release date of early-October 2017. The 1 mg/mL 1 mL iSecure syringes, 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 3rd quarter 2018. The 2 mg/mL 1 mL vials are on back order and the company estimates a release date of late-October 2017. The 10 mg/mL 5 mL vials are on back order and the company estimates a release date of mid-October 2017.
- Teva has hydromorphone 10 mg/mL 1 mL and 5 mL vials on allocation.
- West-Ward has hydromorphone 2 mg/mL 1 mL vials on back order and the company estimates a release date in mid- to late-September 2017.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=856

Dopamine Hydrochloride Injection

September 11, 2017

Reason for the Shortage

- American Regent has dopamine on shortage due to manufacturing delays.
- Baxter could not provide a reason for the shortage.
- 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.
- 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 late-September 2017. The 800 mg/500 mL premixed bags are on back order and the company estimates a release date of early-October 2017. The 800 mg/250 mL premixed bags are on back order and the company estimates a release date of mid-October 2017.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1243

Calcium Gluconate Injection

September 11, 2017

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, 50 mL, and 100 mL vials on back order and the company estimates a release date of mid- to late-September 2017. Check wholesalers for inventory.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=48

Atropine Sulfate Injection

September 11, 2017

Reason for the Shortage

- American Regent did not provide a reason for the shortage of atropine injection.
- Pfizer states the shortage was due to manufacturing delays.

Estimated Resupply Dates

- American Regent has atropine 0.4 mg/mL 1 mL ampules and 1 mg/mL 1 mL vials available in limited supply.
- Pfizer has atropine 0.1 mg/mL 10 mL Ansyr syringes on back order and the company estimates a release date of mid-September 2017. The 0.1 mg/mL 10 mL LifeShield syringes are on back order and the company estimates a release date of late-September 2017. The 0.1 mg/mL 5 mL LifeShield syringes are on back order and the company estimates a release date of September 2017.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=814

23.4% Sodium Chloride Injection

September 11, 2017

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 Dates

- Fresenius Kabi has 23.4% sodium chloride 200 mL vials on back order and the company estimates a release date of mid- to late-September 2017.
- Pfizer has 23.4% sodium chloride 200 mL vials on back order and the company estimates a release date of late-October 2017.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1279

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

September 11, 2017

Reason for the Shortage

- Fresenius Kabi has 0.9% sodium chloride preservative free vials available.
- Pfizer could not provide a reason for the shortage.

Estimated Resupply Dates

- Pfizer has 0.9% sodium chloride preservative free Life Shield vials on back order and the company estimates a release date of mid-September 2017.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1276

Vancomycin Hydrochloride Injection

September 13, 2017

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.
- Baxter has vancomycin injection available.
- Samson Medical Technologies has vancomycin injection available.

Estimated Resupply Dates

- Fresenius Kabi has vancomycin 5 gram and 10 gram vials on intermittent back order with regular releases. The 750 mg vials are on back order and the company estimates a release date of mid-September 2017. The 500 mg vials are available with an expiration date of <1 months.
- Pfizer has vancomycin lyophilized powder 750 mg and 1 gram vials on back order and the company estimates a release date of January 2018 for the 750 mg vials and September 2017 for the 1 gram vials. The 500 mg, 5 gram, and 10 gram vials are available in limited supply. The 500 mg and 750 mg ADD-vantage vials are on back order and the company estimates a release date of early-October 2017 for the 500 mg vials and mid-October 2017 for the 750 mg vials.
- Sagent has vancomycin 5 gram and 10 gram vials on back order and the company estimates a release date of September 2017 for the 5 gram vials and October 2017 for the 10 gram vials.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=132

Talc, Sterile

September 13, 2017

Reason for the Shortage

- Lymol has Sclerosol and talc powder on shortage due to manufacturing delays.
- Novatech SA is launching Steritalc powder and the company estimates a release date in September 2017.

Estimated Resupply Dates

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

- Novatech SA is launching Steritalc powder and the company estimates a release date in September 2017 for the 2 gram/50 mL and 3 gram/10 mL vials.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1248

Promethazine Injection

September 13, 2017

Reason for the Shortage

- Teva is not marketing promethazine injection at this time.
- West-Ward states the shortage is due to manufacturing delays.
- Hospira discontinued promethazine in 2016.
- X-Gen has promethazine available.

Estimated Resupply Dates

- West-Ward has promethazine 50 mg/mL 1 mL ampules and 1 mL vials on back order and the company estimates a release date of 4th quarter 2017 or 1st quarter 2018 for the ampules and mid- to late-September 2017 for the vials.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=654

Potassium Phosphate Injection

September 13, 2017

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 has potassium phosphate injection on shortage due to increased demand.
- Pfizer had potassium phosphate injection on shortage due to manufacturing delays.

Estimated Resupply Dates

- Fresenius Kabi has potassium phosphate 3 mmol/mL 5 mL, 15 mL and 50 mL vials on back order and the company estimates a release date of late-September 2017 for the 5 mL vials, mid-September 2017 for the 15 mL vials, and early-October 2017 for the 50 mL vials.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=709

Potassium Chloride Injection

September 13, 2017

Reason for the Shortage

- Baxter did not provide a reason for the current shortage.
- Pfizer has potassium chloride injection on shortage due to increase demand and manufacturing delays.

Estimated Resupply Dates

- 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.
- Fresenius Kabi has potassium chloride 10 mEq/ 5 mL on back order and the company estimates a release date of early- to mid-October 2017.
- Pfizer has potassium chloride 2 mEq/mL 10 mL vials on back order and the company estimates resupply in late-September 2017. Potassium chloride 10 mEq/500 mL in 5% dextrose and 0.225% sodium chloride premixed bags are on long-term back order.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=696

Mepivacaine Injection

September 13, 2017

Reason for the Shortage

- Pfizer said the reason for the back order is manufacturing delays.

Estimated Resupply Dates

- Pfizer has all Carbocaine presentations on back order. Carbocaine 1% in 50 mL multiple-dose vials are on back order and the company estimates a release date of late-November 2017. Carbocaine 1% 30 mL preservative-free vials are on back order and the company estimates a release date of late-September 2017. Carbocaine 1.5% in 30 mL preservative-free vials are on back order and the company estimates a release date of mid-September 2017. Carbocaine 2% in 20 mL preservative-free vials are on back order and the company estimates a release date of mid-September 2017. Carbocaine 2% in 50 mL multiple-dose vials are back order and the company estimates a release date of late-October 2017.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=954

Liotrix Tablets

September 13, 2017

Reason for the Shortage

- Thyrolar tablets from Actavis (formerly Forest) are on shortage due to manufacturing changes.

Estimated Resupply Dates

- Actavis (formerly Forest) has all Thyrolar 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=24

Lidocaine Injection

September 13, 2017

Reason for the Shortage

- Amphastar had lidocaine 2% emergency syringes on shortage due to increase demand for the product.
- AuroMedics introduced lidocaine injection in February 2014.
- Fresenius Kabi had generic lidocaine presentations on shortage due to a supply interruption of raw ingredients.
- Pfizer has lidocaine presentations on shortage due to manufacturing delays.

Estimated Resupply Dates

- AuroMedics has 1% lidocaine 5 mL ampules on intermittent back order and the company is releasing product as it becomes available. AuroMedics has 2% lidocaine 2 mL ampules on intermittent back order and the company is releasing product as it becomes available.
- Fresenius Kabi has 1% Xylocaine 50 mL vials on back order and the company estimates a release date of mid- to late-September 2017. The 1% Xylocaine-MPF 30 mL vial sterile packs are on back order and the company estimates a release date of early-October 2017. The 2% Xylocaine 20 mL and 50 mL vials are on back order and the company estimates a release date of mid-September 2017. The 2% Xylocaine-MPF 5 mL vials and 10 mL ampules are on back order and the company estimates a release date of mid-September 2017.
- Pfizer has 1% lidocaine 50 mL vials on back order and the company estimates a release date in early-October 2017. The 2% lidocaine 5 mL vials are on back order and the company estimates a release date in mid-October 2017. The 2% lidocaine 10 mL ampules and 2% lidocaine 5 mL LifeShield syringes are on back order and the company estimates release dates of early-November 2017 for the ampules and mid-September 2017 for the syringes. The 2% lidocaine 5 mL Ansyr syringes are on back order and the company estimates a release date of early-October 2017.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=859

Dipyridamole Injection

September 13, 2017

Reason for the Shortage

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

Estimated Resupply Dates

- West-Ward has dipyridamole 5 mg/mL 10 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=465

C1-Esterase Inhibitor (Human) Injection

September 13, 2017

Reason for the Shortage

- Shire has Cinryze on back order due to manufacturing delay.
- The subcutaneous dosage form of C1-esterase inhibitor (human) is unaffected by this shortage.

Estimated Resupply Dates

- Shire has Cinryze 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=1282

Asparaginase Erwinia chrysanthemi

September 13, 2017

Reason for the Shortage

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

Estimated Resupply Dates

- Jazz Pharmaceuticals has Erwinaze unavailable. The company estimates a release date in mid-September 2017. The company requests that Erwinaze only be ordered for patients who are currently undergoing treatment or initiating treatment.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1252

Trace Elements Injection

September 18, 2017

Reason for the Shortage

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

Estimated Resupply Dates

- American Regent has trace elements-4 pediatric vials and Multitrace-4 Pediatric 3 mL vials on back order and the company cannot estimate a release date. The Multitrace-5 Concentrate 1 mL and 10 mL vials and Multitrace-5 regular 10 mL vials are available in limited supply.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=785

Hydroxyzine Hydrochloride Injection

September 18, 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 Dates

- American Regent has hydroxyzine 50 mg/mL 10 mL vials on back order and the company cannot estimate a release date. The 25 mg/mL 1 mL vials and 50 mg/mL 1 mL vials are available in limited supply.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1185

Electrolyte Concentrate

September 18, 2017

Reason for the Shortage

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

Estimated Resupply Dates

- 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

Disopyramide Phosphate Controlled-release Capsules

September 18, 2017

Reason for the Shortage

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

Estimated Resupply Dates

- Pfizer has Norpace CR 100 mg capsules in 100 count available but with an expiration date of October 2017. The 150 mg capsules in 100 count are available with an expiration date of July 2018. The 100 mg capsules in 500 count and 150 mg capsules in 500 count 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=1139

Dextrose (25%) Injection

September 18, 2017

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 available in limited supply.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1011

Dexamethasone Sodium Phosphate

September 18, 2017

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 Dates

- 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 and 30 mL vials on intermittent back order and the company is releasing product as it becomes available.
- West-Ward has dexamethasone sodium phosphate 4 mg/mL 1 mL and 5 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=751

Ammonium Molybdate Injection

September 18, 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 Dates

- 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

Sodium Phosphate Injection

September 19, 2017

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 Dates

- American Regent has sodium phosphate 3 mmol/mL 5 mL, 15 mL, and 50 mL vials on back order and the company cannot estimate a release date.
- Fresenius Kabi has sodium phosphate 3mmol/mL 5 mL and 15 mL vials on back order and the company estimates a release date of mid-November 2017.
- Pfizer has sodium phosphate 3 mmol/mL 15 mL vials on back order and the company estimates a release date of early-October 2017.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=770

Norepinephrine Bitartrate Injection

September 19, 2017

Reason for the Shortage

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

Estimated Resupply Dates

- Pfizer has Levophed 1 mg/mL 4 mL ampules and vials on allocation.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1262

Mitoxantrone Hydrochloride Injection

September 19, 2017

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.

Estimated Resupply Dates

- Fresenius Kabi has mitoxantrone 2 mg/mL 15 mL vials available with an expiration date of <9 months.
- Pfizer has all mitoxantrone presentations on long-term back order and the company estimates a release date of early-4th quarter 2017.
- 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

Meperidine Hydrochloride Injection

September 19, 2017

Reason for the Shortage

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

Estimated Resupply Dates

- Pfizer has limited supply of Demerol 50 mg/mL 1 mL Carpuject syringes and 50 mg/mL 1 mL ampules. The 50 mg/mL 0.5 mL and 2 mL ampules are on back order and the company estimates a release date of September 2017. The 50 mg/mL 1.5 mL ampules and 100 mg/mL 1 mL ampules are on back order and the company estimates a release date of mid-October 2017. The 100 mg/mL 20 mL vials are on back order and the company estimates a release date of 1st quarter 2018. The 100 mg/mL 1 mL Carpuject syringes are on back order and the company estimates a release date of 3rd quarter 2018. The 25 mg/mL 1 mL Carpuject syringes and 75 mg/mL 1 mL Carpuject syringes are on back order and the company estimates a release date of 2019. The 50 mg/mL 30 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=1285

Mannitol Injection

September 19, 2017

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 Dates

- 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 late-September 2017.
- Pfizer has mannitol 250 mg/mL 50 mL vials on back order and the company estimates a release date of late-September 2017.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=863

Diazepam Injection

September 19, 2017

Reason for the Shortage

- Pfizer has diazepam on shortage due manufacturing delays.

Estimated Resupply Dates

- Pfizer has diazepam 5 mg/mL 2 mL Carpuject syringes on back order and the company estimates a release date of October 2017. The diazepam 5 mg/mL 10 mL vials are available in limited supply.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=492

Sodium Bicarbonate Injection

September 20, 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 Dates

- Amphastar has 8.4 % sodium bicarbonate 50 mL syringes on allocation.
- Fresenius Kabi has 8.4% bicarbonate 50 mL vials on back order with an estimated release date of late-September 2017. Check wholesalers for inventory.
- Pfizer has 8.4 % sodium bicarbonate 50 mL syringes and 50 mL vials on back order and the company estimates a release date of early-September 2017 for the syringes and mid-September 2017 for the vials. The 8.4% sodium bicarbonate 10 mL syringes are on back order and the company estimates a release date of early-October 2017. The 4.2% sodium bicarbonate 10 mL syringes are on back order and the company estimates a release date of early-October 2017. The 7.5% sodium bicarbonate 50 mL syringes are on back order and the company estimates a release date of late-September 2017.
- Pfizer has Neut 4% additive solution in 5 mL vials on back order and the company estimates a release date of October 2017.
- 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

Sincalide Injection

September 20, 2017

Reason for the Shortage

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

Estimated Resupply Dates

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

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1032

Octreotide Injection

September 20, 2017

Reason for the Shortage

- Fresenius Kabi did not provide a reason for the shortage.
- Mylan Institutional has octreotide available.
- Sagent has octreotide on shortage due to manufacturing delays.
- Sun Pharma refuses to provide availability information for any of their products including octreotide.
- Teva has octreotide available.
- Novartis has Sandostatin available.

Estimated Resupply Dates

- Fresenius Kabi has octreotide 50 mcg/mL 1 mL vials on back order and the company estimates a release date of 1st quarter 2018. Octreotide 500 mcg/mL 1 mL vials are on back order and the company estimates a release date in mid-October 2017.
- Sagent has octreotide 50 mcg/mL 1 mL vials on back order and the company estimates a release date of September 2017. Octreotide 1000 mcg/mL 5 mL vials are short-dated. Additional supplies of 1000 mcg/mL 5 mL vials with regular dating are estimated to be available in October 2017.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=803

Haloperidol Lactate Injection

September 20, 2017

Reason for the Shortage

- Mylan Institutional has haloperidol lactate injection available.
- Patriot Pharmaceuticals has haloperidol lactate available.
- Sagent has haloperidol lactate on shortage due to manufacturing delays.
- 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 Dates

- Sagent has haloperidol lactate 5 mg/mL 10 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=527

Folic Acid Injection

September 20, 2017

Reason for the Shortage

- Fresenius Kabi has folic acid on shortage due to a delay in getting the active ingredient.

Estimated Resupply Dates

- Fresenius Kabi has folic acid 5 mg/mL 10 mL vials available with an expiration date of <4 months. The next estimated release date is November 2017.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=584

Ceftriaxone Sodium Injection

September 20, 2017

Reason for the Shortage

- Apotex states the reason for the shortage is manufacturing delays. Apotex has updated the NDC numbers for ceftriaxone 500 mg and 1 gram vials.
- 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 has discontinued ceftriaxone as of July 2017. The 500 mg vials will be available until inventory has been depleted.

Estimated Resupply Dates

- Apotex has ceftriaxone 10 gram vials on back order and the company estimates a release date in late-September to early-October 2017. The 2 gram and 250 mg vials are on allocation.
- 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.
- Sagent has ceftriaxone 2 gram vials on allocation.
- Sandoz has ceftriaxone 2 gram vials on back order and the company estimates a release date of November 2017.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1101

Belatacept Injection

September 20, 2017

Reason for the Shortage

- Bristol-Myers Squibb has Nulojix in short supply due to manufacturing delays.

Estimated Resupply Dates

- 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 2017. Nulojix is distributed by McKesson Plasma Biologics.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1265

Aminocaproic Acid Injection

September 20, 2017

Reason for the Shortage

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

Estimated Resupply Dates

- Pfizer has aminocaproic acid 250 mg/mL 20 mL 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=789

5% Dextrose Injection

September 20, 2017

Reason for the Shortage

- ICU Medical states the shortage is due to increased demand.
- ICU Medical is now the IV fluid business of Pfizer after the acquisition of Hospira.
- Baxter did not provide a reason for the shortage.
- 5% dextrose 1,000-mL bags are not affected at this time.

Estimated Resupply Dates

- Baxter has 5% dextrose 250 mL bags on back order and the company cannot estimate a release date.
- ICU Medical has 5% dextrose 500 mL bags on back order and the company estimates a release date of late-September 2017.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1268

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