August 2017

Drug Information Update

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NEWLY AVAILABLE GENERICS

GENERIC DRUG NAME	STRENGTH & DOSAGE FORM	GENERIC MANUFACTURER	BRAND NAME
SEVELAMER CARBONATE	800 MG TABLET	GENZYME	RENVELA
ADAPALENE/BENZOYL PEROXIDE	0.1% - 2.5% GEL W/ PUMP	GALDERMA LABORA	EPIDUO
CASPOFUNGIN ACETATE	50 MG VIAL	FRESENIUS KABI	CANCIDAS
CASPOFUNGIN ACETATE	70 MG VIAL	FRESENIUS KABI	CANCIDAS
SCOPOLAMINE	1.5 MG (DELIVERS 1MG OVER 3 DAYS	PERRIGO CO.	TRANSDERM-SCOP
BUTALBITAL/ASPIRIN/CAFFEINE	50 MG-325 MG-40 MG TABLET	VENSUN PHARMACE	BUTALBITAL-ASPIRIN-CAFFEINE
CROMOLYN SODIUM	20 MG/2 ML AMPUL-NEB	TEVA USA	CROMOLYN SODIUM
PRASUGREL HCL	5 MG TABLET	MYLAN	EFFIENT
PRASUGREL HCL	10 MG TABLET	MYLAN	EFFIENT

NEW DRUG ENTITIES/COMBINATIONS/STRENGTHS

DESCRIPTION	BRAND NAME	GENERIC NAME	STRENGTH	NOTES
ANTIPSORIATIC AGENTS,SYSTEMIC	TREMFYA	GUSELKUMAB	100 MG/ML SYRINGE FOR INJ	NEW ENTITY
TOPICAL AGENTS,MISCELLANEOUS	NEURAPTINE	GABAPENTIN	10% CREAM	NEW STRENGTH, ROUTE AND DOSAGE FORM
ANTINEOPLASTIC SYSTEMIC ENZYME INHIBITORS	NERLYNX	NERATINIB MALEATE	40 MG	NEW ENTITY
INFLUENZA VIRUS VACCINES	FLULAVAL QUAD 2017-2018	FLU VACC QS2017-18(6MOS UP)/PF	60 MCG (15 MCG x 4)/0.5 ML SYRINGE	NEW ENTITY
INFLUENZA VIRUS VACCINES	AFLURIA QUAD 2017-2018	FLU VACC QS 2017-18 (18 YR UP)	60 MCG (15 MCG x 4)/0.5 ML VIAL	NEW ENTITY
INFLUENZA VIRUS VACCINES	AFLURIA QUAD 2017-2018	FLU VACC QS 2017 (18YRS UP)/PF	60 MCG (15 MCG x 4)/0.5 ML SYRINGE	NEW ENTITY
INFLUENZA VIRUS VACCINES	AFLURIA 2017-2018	FLU VACCINE TS2017-18(5 YR UP)	45 MCG (15 MCG x 3)/0.5 ML VIAL	NEW ENTITY
INFLUENZA VIRUS VACCINES	AFLURIA 2017-2018	FLU VACCINE TS2017-18(5 YR UP)	45 MCG (15 MCG x 3)/0.5 ML SYRINGE	NEW ENTITY
DRUGS TO TX CHRONIC INFLAMMATORY DISEASE OF COLON	RENFLEXIS	INFLIXIMAB-ABDA	100 MG VIAL	NEW ENTITY
HEP C - NS5A, NS3/4A, NUCLEOTIDE NS5B INHIB COMBO	VOSEVI	SOFOSBUVIR/VELPATAS/VOXILAPREV	400 MG-100 MG-100 MG	NEW ENTITY
IMMUNOMODULATOR,B-LYMPHOCYTE STIM(BLYS)-SPEC INHIB	BENLYSTA	BELIMUMAB	200 MG/ML AUTO INJCT	NEW STRENGTH AND DOSAGE FORM
IMMUNOMODULATOR,B-LYMPHOCYTE STIM(BLYS)-SPEC	BENLYSTA	BELIMUMAB	200 MG/ML SYRINGE	NEW STRENGTH AND DOSAGE

DESCRIPTION	BRAND NAME	GENERIC NAME	STRENGTH	NOTES
INHIB				FORM
EYE ANTI-INFLAMMATORY AGENTS	PREDNISOLONE-NEPAFENAC	PREDNISOLONE ACETATE/NEPAFENAC	1%-0.1% DROPS SUSP	NEW COMBINATION. NO PRICING
DRUGS TO TREAT HEREDITARY TYROSINEMIA	NITYR	NITISINONE	2 MG	NEW STRENGTH AND DOSAGE FORM
DRUGS TO TREAT HEREDITARY TYROSINEMIA	NITYR	NITISINONE	5 MG	NEW STRENGTH AND DOSAGE FORM
DRUGS TO TREAT HEREDITARY TYROSINEMIA	NITYR	NITISINONE	10 MG	NEW STRENGTH AND DOSAGE FORM
TX FOR ATTENTION DEFICIT-HYPERACT(ADHD)/NARCOLEPSY	COTEMPLA XR-ODT	METHYLPHENIDATE	8.6 MG	NEW STRENGTH AND DOSAGE FORM
TX FOR ATTENTION DEFICIT-HYPERACT(ADHD)/NARCOLEPSY	COTEMPLA XR-ODT	METHYLPHENIDATE	17.3 MG	NEW STRENGTH AND DOSAGE FORM
TX FOR ATTENTION DEFICIT-HYPERACT(ADHD)/NARCOLEPSY	COTEMPLA XR-ODT	METHYLPHENIDATE	25.9 MG	NEW STRENGTH AND DOSAGE FORM
ANTINEOPLASTIC-ISOCITRATE DEHYDROGENASE INHIBITORS	IDHIFA	ENASIDENIB MESYLATE	50 MG	NEW ENTITY
ANTINEOPLASTIC-ISOCITRATE DEHYDROGENASE INHIBITORS	IDHIFA	ENASIDENIB MESYLATE	100 MG	NEW ENTITY
TISSUE PROTECTIVE TX OF CHEMOTHERAPY EXTRAVASATION	TOTECT	DEXRAZOXANE HCL	500 MG	NEW ENTITY
GLUCOCORTICOIDS, ORALLY INHALED	ARMONAIR RESPICLICK	FLUTICASONE PROPIONATE	55 MCG/ ACTUATION	NEW STRENGTH AND DOSAGE FORM
GLUCOCORTICOIDS, ORALLY INHALED	ARMONAIR RESPICLICK	FLUTICASONE PROPIONATE	113 MCG/ ACTUATION	NEW STRENGTH AND DOSAGE FORM
GLUCOCORTICOIDS, ORALLY INHALED	ARMONAIR RESPICLICK	FLUTICASONE PROPIONATE	232 MCG/ ACTUATION	NEW STRENGTH AND DOSAGE FORM
EMOLLIENTS	NUTRASEB	EMOLLIENT COMBINATION NO.107	CREAM	NEW ENTITY
HEPATITIS C VIRUS- NS5A AND NS3/4A INHIBITOR COMB	MAVYRET	GLECAPREVIR/PIBRENTASVIR	100 MG-40 MG	NEW ENTITY

DESCRIPTION	BRAND NAME	GENERIC NAME	STRENGTH	NOTES
EYE ANTIBIOTIC, GLUCOCORTICOID AND GLUCOCORTICOID COMB	PREDNISOLONE-GATIFLOX-NEPAFENC	GATIFLOXACIN/PREDNISOL/NEPAFEN	0.5 %-1 %-0.1 % DROPS SUSP	NEW COMBINATION NO PRICING
EYE ANTIBIOTIC AND GLUCOCORTICOID COMBINATIONS	PREDNISOLONE-GATIFLOXACIN	GATIFLOXACIN/PREDNISOLONE	0.5 %-1 % DROPS SUSP	NEW COMBINATION NO PRICING
INSULINS	HUMALOG JUNIOR KWIKPEN	INSULIN LISPRO	100 UNIT/ML PEN FOR INJ	NEW DOSAGE FORM
ANTIHYPERLIPIDEMIC - HMG COA REDUCTASE INHIBITORS	FLOLIPID	SIMVASTATIN	20 MG/5 ML (4 MG/ML) ORAL SUSP	NEW STRENGTH AND DOSAGE FORM
ANTIHYPERLIPIDEMIC - HMG COA REDUCTASE INHIBITORS	FLOLIPID	SIMVASTATIN	40 MG/5 ML (8 MG/ML) ORAL SUSP	NEW STRENGTH AND DOSAGE FORM
TOPICAL LOCAL ANESTHETICS	WOUND DEBRIDEMENT-LIDOCAINE	LIDOCAINE/GAUZE/ALGINATE	4% TOPICAL	NEW COMBINATION
TOPICAL LOCAL ANESTHETICS	DOLOTRANZ	LIDOCAINE/PRILOCAINE	4%-2.5%-2.5% CREAM AND GEL KIT	NEW STRENGTH AND DOSAGE FORM

NEW INDICATIONS (EXISTING DRUGS)

Yervoy®

July 24, 2017

PRINCETON, N.J.--(BUSINESS WIRE)--Bristol-Myers Squibb Company (NYSE:BMY) today announced that the U.S. Food and Drug Administration (FDA) has expanded the indication for Yervoy ® (ipilimumab) injection for intravenous use to now include the treatment of unresectable or metastatic melanoma in pediatric patients 12 years of age and older. Yervoy was evaluated in two trials of pediatric patients: a dose-finding study in 33 patients aged two to 21 years with relapsed or refractory solid tumors and an open-label, single-arm trial in 12 adolescents (ages ranging from 12 to 16 years) with previously treated or untreated, unresectable Stage 3 or 4 malignant melanoma. The overall safety profile of Yervoy in children and adolescents was consistent with the safety profile in adults, and similarities in disease between adult and pediatric patients 12 years and older allow for extrapolation of data. Based on a population pharmacokinetic analysis, exposure in adolescents 12 years and older is comparable to that in adults for the approved dose of 3 mg/kg, administered intravenously over 90 minutes every three weeks for a total of four doses.

Source:Bristol-Myers Squibb Company
https://news.bms.com/press-release/corporatefinancial-news/us-food-and-drug-administration-expands-approval-yervoy-ipilim

Benlysta®

July 21, 2017

GSK announced today that the US Food and Drug Administration (FDA) has approved a new subcutaneous formulation of Benlysta (belimumab) for the treatment of adult patients with active, autoantibody positive SLE who are receiving standard therapy. Systemic Lupus Erythematosus (SLE) is the most common form of lupus, a chronic, incurable autoimmune disease producing autoantibodies that can attack almost any system in the body. The approval marks the first subcutaneous self-injection treatment option for patients with SLE.

Source: GSK
http://www.gsk.com/en-gb/media/press-releases/gsk-receives-fda-approval-for-a-new-self-injectable-formulation-of-benlysta-belimumab-for-systemic-lupus-erythematosus/

Abilify Maintena®

July 28, 2017

(TOKYO, Japan & VALBY, Denmark, July 28, 2017) – Otsuka Pharmaceutical Co., Ltd. and H. Lundbeck A/S today announced ABILIFY MAINTENA® (aripiprazole) for extended-release injectable suspension was approved by the U.S. Food and Drug Administration for the maintenance monotherapy treatment of bipolar I disorder (BP I) in adults.

Source: Otsuka Pharmaceutical Co., Ltd. and H. Lundbeck A/S
https://www.otsuka-us.com/discover/articles-1063

Liletta®

August 7, 2017

DUBLIN AND SAN FRANCISCO, Aug. 7, 2017 /PRNewswire/ -- Allergan plc (NYSE: AGN), a leading global pharmaceutical company, and Medicines360, a global nonprofit women's health pharmaceutical company with a mission of expanding access to quality medicines, announced that the U.S. Food and Drug Administration (FDA) approved Medicines360's Supplemental New Drug Application (sNDA) to extend the duration of use of LILETTA® (levonorgestrel-releasing intrauterine system) 52 mg for the prevention of pregnancy for up to four years.

Source: Allergan plc
http://www.prnewswire.com/news-releases/fda-approves-medicines360s-snda-for-liletta-levonorgestrel-releasing-intrauterine-system-52-mg-to-prevent-pregnancy-for-up-to-four-years-300500125.html

Opdivo®

August 1, 2017

PRINCETON, N.J.--(BUSINESS WIRE)--Bristol-Myers Squibb Company (NYSE:BMY) today announced the U.S. Food and Drug Administration (FDA) has approved Opdivo (nivolumab) injection for intravenous use for the treatment of adult and pediatric (12 years and older) patients with microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer (mCRC) that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan. Approval for this indication has been granted under accelerated approval based on overall response rate (ORR) and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. The recommended dose is 240 milligrams administered as an intravenous infusion over 60 minutes every two weeks until disease progression or unacceptable toxicity. In the CheckMate -142 trial, among patients (53/74) who received prior treatment with a fluoropyrimidine, oxaliplatin, and irinotecan, 28% (95% CI: 17-42; 15/53) responded to treatment with Opdivo. The percentage of patients with a complete response was 1.9% (1/53) and the percentage of patients with a partial response was 26% (14/53). Among these responders, the median duration of response was not reached (range: 2.8+-22.1+ months). Among all enrolled patients, 32% (95% CI: 22-44; 24/74) responded to treatment with Opdivo; 2.7% (2/74) experienced a complete response, 30% (22/74) experienced a partial response.

Source: Bristol-Myers Squibb Company
https://news.bms.com/press-release/corporatefinancial-news/bristol-myers-squibb-receives-fda-approval-opdivo-nivolumab-ms

FDA NEWS/BULLETINS/ADVISORIES/SAFETY ALERTS

Cyclobenzaprine HCl and Amantadine HCl by Apace Packaging: Recall – Potential Mislabeling

July 28, 2017

ISSUE: Apace Packaging LLC is voluntarily recalling one lot of Cyclobenzaprine HCl Tablet, USP 5 mg 50ct Unit Dose, NDC# 50268-190-15, Lot Number 16710 and one lot of Amantadine HCl Capsule, USP 100 mg 50ct Unit Dose NDC# 50268-069-15, Lot Number 16710 to the Retail level. These products have been recalled due to a potential mislabeling. A small number of cartons containing Cyclobenzaprine HCl Tablets 5 mg UD Blister Cards may potentially be mislabeled as Amantadine HCl Capsules, USP 100 mg. The unit dose blisters inside the carton are correctly labeled as Cyclobenzaprine HCl Tablet, USP 5 mg.

Unintentional dosing with Cyclobenzaprine HCl may potentially lead to the development of life-threatening serotonin syndrome, which has been reported with Cyclobenzaprine HCI when used in combination with other drugs, such as selective serotonin reuptake inhibitors (SSRIs), serotonin norepinephrine reuptake inhibitors (SNRIs), tricyclic antidepressants (TCAs), tramadol, bupropion, meperidine, verapamil, or MAO inhibitors. The effects of alcohol, barbiturates, and other CNS depressants may be enhanced, and may impair mental and/or physical abilities required for performance of hazardous tasks, such as operating machinery or driving a motor vehicle. Amantadine has a precaution in its prescribing indication about the abrupt discontinuation of the medicine. Missed doses of Amantadine in a few patients with Parkinson's disease have experienced a parkinsonian crisis, i.e., a sudden marked clinical deterioration, when this medication was suddenly stopped.

BACKGROUND: Cyclobenzaprine HCl 5mg 50ct Unit Dose (NDC# 50268-190-15) is used for the relief of muscle spasms and Amantadine HCl 100mg 50ct Unit Dose (NDC# 50268-069- 15) is used for the treatment of Parkinson's and drug-induced extrapyramidal reactions and the treatment of various viral-based conditions. Both products are packaged in 50-count hospital unit dose cartons (10 unit doses per card, 5 cards per carton). The affected lot of Cyclobenzaprine and Amantadine is Lot 16710 with an expiration date of 07/2018. The subject products were fully distributed to R&S Northeast, and then further distributed nationwide.

RECOMMENDATION: Apace Packaging LLC has notified its distributors and customers by email and is arranging for return of all recalled product. Distributors that have any of the subject product which is being recalled should contact Customer Service at AvKARE, Inc. at 931-292-6222 to arrange for the return of the product.

Consumers with questions regarding this recall can contact Apace Packaging by 270-434- 2722 Monday-Friday (8am – 4pm CST). Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using these drug 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)
https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm569056.htm

Compounded Triamicinolone and Moxifloxacin Product for Intravitreal Injection by Guardian Pharmacy Services: Alert to Health Professionals – Serious Adverse Events Reported

July 28, 2017

ISSUE: FDA received adverse event reports on April 5 and June 1, 2017, concerning at least 43 patients who were administered intravitreal (eye) injections of a drug containing triamcinolone (steroid) and moxifloxacin (anti-infective) compounded by Guardian Pharmacy Services in Dallas, Texas. The patients were administered Guardian's product at the end of a cataract surgery procedure at the PRG Dallas

Ambulatory Surgery Center in Dallas, Texas, by physicians affiliated with the Key Whitman Eye Center, and at the Park Central Surgical Center in Dallas, Texas, by physicians affiliated with Tylock-George Eye Care.

According to information received from Park Central, Guardian's product was injected into the vitreous of the eye at the end of the cataract surgery procedure. The purpose of the injection was to provide post-operative prophylaxis for ocular inflammation and endophthalmitis with the expectation that the patient would not need to use post-operative eye drops. Over the course of several months, patients developed various symptoms, including vision impairment (blurred or decreased vision), poor night vision, loss of color perception, photophobia (light sensitivity), glare, halos, flashing lights, ocular discomfort, pain, loss of balance, headaches, and/or nausea. A number of the symptoms were not exhibited until at least one month postoperatively.

During follow-up examinations of the Park Central patients, physicians observed that the patients had diminished visual function involving both visual acuity and visual fields. Optical coherence tomography testing initially showed macular edema (swelling), which was followed in some cases by retinal degeneration. While the symptoms reportedly improved in some patients over the five-month post-operative period, a number of patients remain with a significant reduction in best-corrected visual acuity and visual fields.

BACKGROUND: Compounded drugs are not reviewed by FDA for safety, effectiveness, or quality.

RECOMMENDATION: 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)
https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm569123.htm

0.9% Sodium Chloride Injection by ICU Medical: Recall – Presence of Particulate Matter

July 31, 2017

ISSUE: ICU Medical, Inc. is voluntarily recalling one lot of 0.9% Sodium Chloride Injection, USP 1000 mL to the hospital/user level due to a confirmed customer complaint of particulate matter identified as stainless steel within a single flexible container. Injection of particulate matter could potentially lead to limited adverse events such as allergic reactions, local irritation and inflammation in organs or tissues, or other serious adverse health consequences.

BACKGROUND: 0.9% Sodium Chloride Injection, USP 1000 mL is an intravenous solution indicated for parenteral replenishment of fluid. The affected product lot was manufactured in the U.S. by Hospira, a Pfizer company, on February 1, 2016 and was distributed nationwide to Hospira customers between April 14, 2016 and February 2, 2017. The affected lot is: NDC 0409-7983-09, Lot # 61-841-FW Expires January 01, 2018 - 1000mL Single Dose Flexible Container.

RECOMMENDATION: Prior to administration, healthcare professionals, as instructed in the product labeling, should visually examine the product for particulate matter and discoloration and should discard if a defect is identified.

ICU Medical is notifying its distributors and customers of this recall by letter and is arranging for the return of all recalled products. Hospitals/distributors that have product that is being recalled should stop use/further distribution and return to place of purchase. Customers with questions regarding this recall can call ICU Medical at 1-800-441-4100 Monday through Friday between the hours of 8 a.m. and 5 p.m. Central time. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to using these drug 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)
https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm569225.htm

Man of Steel 1 and Man of Steel 2: Recall – Undeclared Drug Ingredient

July 31, 2017

ISSUE: Man of Steel is voluntarily recalling 175 lots of Man of Steel 1 and Man of Steel 2, 4000mg at the retail level. The products have been found to contained undeclared Sildenafil. The product has/potentially could result in death. The groups affected are men with diabetes, high blood pressure, high cholesterol, or heart disease.

BACKGROUND: The product is marketed as a male enhancement supplement and is packaged in individual blister package. The affected product Man of Steel lots include the following expiration dates: 10-17-18. Man of Steel was distributed throughout local convenience stores in Sacramento, California.

RECOMMENDATION: Man of Steel is notifying its distributors and customers by print media and is arranging for return/replacement etc. of all recalled products. Consumers/distributors/retailers that have Man of Steel which is being recalled should stop using/return to place of purchase/discard/contact their doctor.

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)
https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm569250.htm

Diocto Liquid and Diocto Syrup by Rugby Laboratories: Recall – Possible Product Contamination

August 03, 2017

ISSUE: Rugby Laboratories is voluntarily recalling all lots of Diocto Liquid and Diocto Syrup, (docusate sodium solutions) manufactured by PharmaTech, LLC due to a risk of product contamination with Burkholderia cepacia. FDA informed Rugby that it received several adverse event reports of B. cepacia infections in patients which may be linked to Diocto Liquid or Diocto Syrup manufactured by PharmaTech LLC.
If a product contains B. cepacia, its use 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.
All lots with NDC 0536-0590-85 and NDC 0536-1001-85 are included in this recall.

BACKGROUND: Diocto Liquid and Diocto Syrup are used as stool softeners and are packaged in one pint (473 mL) bottles. Diocto Liquid was distributed nationwide to wholesale and retail facilities including hospitals and pharmacies.

RECOMMENDATION: Rugby Laboratories is notifying its distributors and customers by recall letter and is arranging for return of all recalled products. Consumers, pharmacies, and healthcare facilities that have product which is being recalled should stop using and dispensing the product immediately.

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)
https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm570014.htm

Compounded Curcumin Emulsion Product for Injection by ImprimisRx: FDA Investigation – Serious Adverse Events Associated with Use

August 04, 2017

ISSUE: Two patients administered infusions of curcumin (a component of the spice turmeric) compounded with polyethylene glycol (PEG) 40 castor oil reportedly experienced immediate hypersensitivity reactions. The PEG 40 castor oil was a component of a curcumin emulsion product compounded by a pharmacy, ImprimisRx, located in Irvine, California. Hypersensitivity reactions to intravenous (IV) products containing polyethylene glycol castor oil have been reported in the literature and are the subject of warnings for a number of FDA-approved drugs.

BACKGROUND: On March 10, 2017, the FDA received an adverse event report concerning a 30-year-old female patient who experienced cardiac arrest after IV administration of a curcumin emulsion product compounded by ImprimisRx. The patient reportedly had a history of allergies and was being treated for eczema by a naturopathic doctor. Within minutes of starting the infusion, the patient became pulseless and required CPR. The patient suffered anoxic (depleted oxygen) brain injury and subsequently died. An adverse reaction to infused curcumin solution was identified as a cause of death by the local authorities.

On May 1, 2017, FDA received an adverse event report concerning a 71-year-old male patient who developed a hypersensitivity reaction after IV administration of ImprimisRx's compounded curcumin emulsion product. The patient had a history of allergies and was being treated for thrombocytopenia (a low platelet count) at a holistic health center. According to information FDA received from the center, within minutes of starting the infusion, the patient developed a cough and erythema (skin reddening). Diphenhydramine (an antihistamine) was administered; however, symptoms escalated to include shortness of breath, itching, and hypotension (low blood pressure). The patient was treated with IV epinephrine and transferred to a nearby emergency room where he was treated and then released.

RECOMMENDATION: On June 23, 2017, ImprimisRx recalled all unexpired products containing the ungraded PEG 40 castor oil.

FDA's investigation into the adverse events associated with ImprimisRx's curcumin emulsion product for injection highlights some of the risks associated with compounded drugs, particularly those that use non-pharmaceutical grade components and ingredients lacking a USP monograph. The risks illustrated in this case include:

- the absence of a label warning about hypersensitivity reactions associated with the PEG 40 castor oil;
- the use of an ungraded inactive ingredient, i.e., PEG 40 castor oil, that is not suitable for human consumption or therapeutic use and may contain impurities such as DEG; and
- the IV administration of curcumin, despite the fact that its safety profile by this route of administration has not been established, nor has its effectiveness in treating eczema or thrombocytopenia.

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)
https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm570044.htm

Liquid Drug Products Manufactured by PharmTech and Distributed by Rugby Laboratories and Possibly Other Companies: FDA Advisory – Not to Use

August 08, 2017

ISSUE: FDA is advising health care professionals and patients not to use any liquid product manufactured by PharmaTech LLC, Davie, Florida, due to Burkholderia cepacia contamination and the potential for severe patient infection. Rugby Laboratories, Livonia, Michigan, announced a voluntary recall on August 3, 2017, of two such products – Diocto Liquid and Diocto Syrup, both oral liquid docusate products – manufactured by PharmaTech. Additional liquid drug products manufactured by PharmaTech might also be affected. Such products might have been labeled and distributed by Rugby and other companies. Any company that purchased liquid products manufactured by PharmaTech should immediately quarantine material under their control and contact the local FDA pharmaceutical recall coordinator.
Centers for Disease Control and Prevention laboratory testing of PharmaTech's oral liquid docusate detected a strain of B. cepacia, bacteria linked to recent patient infections. Therefore, FDA recommends health care professionals and patients not use PharmaTech's liquid drug products.

BACKGROUND: In 2016, FDA advised health care professionals and patients not to use liquid docusate drug products manufactured at PharmaTech's Davie, Florida, facility after being implicated in CDC's public health investigation. These products were labeled and distributed by multiple companies, including Rugby. An FDA investigation associated with a 2016 multistate outbreak identified B. cepacia in more than 10 lots of oral liquid docusate sodium manufactured by PharmaTech, which was linked to patient infections that required intensive medical treatment. The 2016 investigation also detected B. cepacia in the water system used to manufacture the product.

RECOMMENDATION: Patients, pharmacies, and health care facilities should immediately stop using and dispensing all liquid products manufactured by PharmaTech. It might be difficult to determine the manufacturer because these liquid products are not labeled with a PharmaTech label. FDA advises health care facilities and pharmacies that think they might have liquid PharmaTech drug products, especially oral liquid docusate drug products, to check with their supplier to determine the identity of the manufacturer. Patients who are using liquid drug products and who have concerns should contact their health care professional.

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)
https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm570674.htm

Liquid Products Manufactured by PharmaTech and Distributed by Leader Brand, Major Pharmaceuticals, and Rugby Laboratories: Recall – Possible Product Contamination

August 10, 2017

ISSUE: The distribution firms Leader Brand, Major Pharmaceuticals, and Rugby Laboratories jointly issued a nationwide voluntary recall of all lots within expiry of all liquid products manufactured by PharmaTech LLC at its FDA registered facility in Davie, Fla. due to possible product contamination.

Through recent communication with FDA, the distribution firm Rugby Laboratories learned of a potential issue with a product manufactured by PharmaTech LLC. The FDA informed Rugby Laboratories that it received several adverse event reports of B. cepacia infections in patients, which may be linked to PharmaTech LLC manufactured Diocto Syrup or Diocto Liquid (docusate sodium solutions). In response, Rugby Laboratories issued a voluntary recall on August 3, 2017, of the PharmaTech LLC manufactured Diocto Syrup and Diocto Liquid. As a precautionary measure based on additional information received from the FDA, the three distribution firms are recalling all lots within expiry of all liquid products manufactured by PharmaTech LLC.

See the press release for a list of affected products.

BACKGROUND: The products subject to this recall were distributed nationwide to wholesale and retail facilities, including hospitals and pharmacies.

RECOMMENDATION: The distribution firms are notifying their distributors and customers by recall letter and are arranging for return of all recalled products. Consumers, pharmacies, and healthcare facilities that have product being recalled should stop using and dispensing the product immediately.

Consumers with questions regarding this recall should contact Rugby Laboratories/Major Pharmaceuticals Customer Support at 1-800-645-2158, available Monday through Friday 8 a.m. – 8 p.m. EST or Leader Customer Support at 1-800-200-6313 option #1 Monday through Thursday 8 a.m. – 7p.m. and Friday 8 a.m. – 5 p.m EST. Consumers can contact their physician or healthcare provider if they have additional questions about this product.

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

- Complete and submit the report Online: www.fda.gov/MedWatch/report
- Download form or call 1-800-332-1088 to request a reporting form, 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)
https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm570997.htm

Pravastatin Sodium Tablets by International Laboratories: Recall - Mislabeling

August 10, 2017

ISSUE: International Laboratories, LLC is voluntarily recalling one (1) Lot of Pravastatin Sodium Tablets USP 40 mg packaged in bottles of 30 tablets, to the consumer level due to mislabeling. The product is labeled as Pravastatin Sodium Tablets USP 40 mg but contained Bupropion Hydrochloride XL 300 mg tablets. The affected product is NDC# 54458-925-16; Lot# 115698A

This lot of Pravastatin Sodium Tablets USP 40 mg was recalled when International Laboratories, LLC was informed by a pharmacist that one 30ct bottle of this product was mislabeled and contained Bupropion Hydrochloride XL 300 mg tablets.

If a subject mistakenly takes bupropion, common side effects include: nausea, vomiting, dry mouth, headache, constipation, sweating, sore throat, diarrhea, dizziness, restlessness, blurry vision. These are typically minor and reversible issues. However, individuals with epilepsy are at higher risk of seizure on bupropion due to it lowering the seizure threshold. Also, people on MAOIs can have a risky drug interaction with bupropion (hypertensive crisis). Finally, allergic reactions are also possible and could be life threatening.

BACKGROUND: Pravastatin Sodium Tablets USP 40 mg are an HMG-CoA reductase inhibitor (statin) indicated as an adjunctive therapy to diet when the response to a diet restricted in saturated fat and cholesterol and other non-pharmacologic measures alone has been inadequate. It is used to treat children and adolescent patients ages 8 years and older with heterozygous familial hypercholesterolemia after failing an adequate trial of diet therapy.

Bupropion hydrochloride extended-release tablets (XL) 300 mg are an aminoketone antidepressant, indicated for the treatment of major depressive disorder (MDD) and prevention of seasonal affective disorder (SAD) in children, adolescents, young adults and adults.

RECOMMENDATION: International Laboratories, LLC is notifying its distributors and customer by letter and is arranging for return of all recalled products. Consumers who have purchased this product should not open the package or use the contents. Instead, they should return the product to the location of purchase for a full refund, or call a Customer Complaint phone number at International Laboratories, LLC 727-322-7146 (Monday – Friday 8 AM – 5 PM EST).

Consumers with questions regarding this recall can contact International Laboratories, LLC by phone 727-322-7146 or e-mail address sutka.veselinovic@internationallabs.com on Monday - Friday 8AM – 5PM EST.

Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

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

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

Source: U.S. Food and Drug Administration (FDA)
https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm571066.htm

Sterile Drug Products from Vital Rx, dba Atlantic Pharmacy and Compounding: FDA Alert – Lack of Sterility Assurance

August 10, 2017

ISSUE: FDA is alerting health care professionals and patients not to use drug products intended to be sterile that are produced and distributed nationwide by Vital Rx Inc., dba Atlantic Pharmacy and Compounding, Pompano Beach, Florida, due to lack of sterility assurance. During FDA's recent inspection of Atlantic Pharmacy, investigators observed insanitary conditions, including poor sterile production practices, which raise concerns about Atlantic Pharmacy's ability to assure the sterility of the drug products it produces. Administration of a non-sterile product intended to be sterile may result in serious and potentially life threatening infections or death.

BACKGROUND: On July 31, 2017, FDA recommended that Atlantic Pharmacy cease sterile production until appropriate corrective actions are implemented, and recall all non-expired drug products intended to be sterile. The company has not yet initiated a recall. Therefore, FDA is alerting health care professionals and patients to dispose of and not use drug products intended to be sterile that were produced and distributed by Atlantic Pharmacy.

RECOMMENDATION: Health care professionals and patients should immediately check their medical supplies, quarantine any drug products labeled as sterile from Atlantic Pharmacy, and not administer them to patients. Health care professionals should make alternative arrangements to obtain any medications they administer to patients from reliable sources that adhere to proper quality standards.

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)
https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm570944.htm

STUDIES AND RECENT TOPICS

A Drug Causes Hundreds of Deaths and Millions of ADEs

July 13, 2017

FDA approvals do not necessarily mean that a drug will not later receive additional warnings. Actemra (tocilizumab), a medication for rheumatoid arthritis (RA), has recently been investigated for unlabeled side-effects that have allegedly lead to hundreds of deaths. But when warnings have not been issued yet, how can a pharmacist help?

http://drugtopics.modernmedicine.com/drug-topics/news/drug-causes-hundreds-deaths-and-millions-ades

Controlling asthma in pregnancy may help keep disease from kids

July 15, 2017

Children whose mothers had uncontrolled asthma during pregnancy are at increased risk of developing the disease at a young age, a new study finds.The findings suggest that "maintaining asthma control during pregnancy is an area for possible prevention of asthma in future generations," lead author Xiaoqin Liu said.

https://www.upi.com/Health_News/2017/07/15/Controlling-asthma-in-pregnancy-may-help-keep-disease-from-kids/8411500130494/

Drug combined with care program better at reducing Alzheimer's symptoms than drug alone

July 16, 2017

Combining a specific care management program with a commonly-prescribed drug for Alzheimer's disease multiplies the medication's ability to improve daily function by about 7.5 times, stalling some of the disease's most damaging effects.

These are the findings from a randomized trial developed at NYU Langone Medical Center and presented Sunday July 16 at the Alzheimer's Association International Conference 2017 in London.

https://medicalxpress.com/news/2017-07-drug-combined-alzheimer-symptoms.html

Blood sugar swings tied to depression in elderly with type 2 diabetes

July 18, 2017

Greater ups and downs of hemoglobin A1c (HbA1c), a marker of long-term blood sugar levels, are associated with a higher number of symptoms of depression in elderly individuals with type 2 diabetes, a recent Israeli study finds.

http://www.reuters.com/article/us-health-depression-diabetes-variabilit-idUSKBN1A32E4

Old antibiotic could form new depression treatment

July 19, 2017

An antibiotic used mostly to treat acne has been found to improve the quality of life for people with major depression, in a world-first clinical trial conducted at Deakin University. The trial added a daily dose of minocycline – a broad-spectrum antibiotic that has been prescribed since 1971 – to the usual treatment of 71 people experiencing major depression.

https://medicalxpress.com/news/2017-07-antibiotic-depression-treatment.html

Stopping cholesterol-lowering drugs could be deadly

July 24, 2017

Stopping a cholesterol-lowering drug because of a muscle ache or stomach pain can be dangerous in the long run, suggests a new study. Researchers found that people who stopped taking statins after reporting a side effect were 13 percent more likely to die or have a heart attack or stroke over the next four years than people who kept taking the drugs.

http://www.reuters.com/article/us-health-heart-idUSKBN1A92LP

Prescribing Benzodiazepine with Antidepressants Can Cause Patient Dependence

July 27, 2017

Combining benzodiazepine with an antidepressant treatment regimen can create an addictive habit, according to a recent study from the Northeastern University Bouvé College of Health Sciences.

In a clinical trial, researchers paired a benzodiazepine anxiolytic with an antidepressant for approximately 10% of patients starting medication treatment for major depression in a large US population study. 12.3% of those patients continued the benzodiazepine for longer than 6 months and 2.4% continued it after stopping the antidepressant.

http://www.mdmag.com/medical-news/prescribing-benzodiazepine-with-antidepressants-can-cause-patient-dependence

Steroids Linked to Serious Adverse Events in IgA Nephropathy

August 01, 2017

Corticosteroid treatment in patients with IgA nephropathy, an autoimmune-based kidney disease, was tied to an increased risk for serious adverse events, according to Chinese researchers.

The TESTING (Therapeutic Evaluation of Steroids in IgA Nephropathy Global) trial was halted early after an interim analysis revealed serious adverse events had occurred in 20 patients in the treatment group (14.7%) versus four in the placebo group (3.2%) for a relative risk of 4.63 (95% CI 1.63-13.2, P<0.001). The risk difference was 11.5% (95% CI 4.8%- 18.2%), reported Hong Zhang, PhD, of Peking University in Beijing, and colleagues.

https://www.medpagetoday.com/nephrology/generalnephrology/66990

Less than Half of U.S. Stroke Patients get Rx for Statins

August 02, 2017

Fewer than half of U.S. stroke survivors are prescribed cholesterol-lowering statins, a new study finds.Statins are recommended for patients who have had an ischemic stroke or ministroke (transient ischemic attack) to reduce their risk for a repeat stroke or other cardiovascular events, according to the American Heart Association. Ischemic strokes, the most common kind, are caused by blocked blood flow to the brain.

https://consumer.healthday.com/cardiovascular-health-information-20/statins-news-780/less-than-half-of-u-s-stroke-patients-get-rx-for-statins-725089.html

New injectable antiretroviral treatment proved to be as effective as standard oral therapy

August 03, 2017

Intramuscularly administered antiretroviral therapy (ART) may be as effective for HIV treatment as current oral therapies. This is the main conclusion of a Phase II clinical trial carried out by 50 research centers around the world, including nine in Spain, to which the team of Dr. Daniel Podzamczer of the Bellvitge

University hospital (HUB) has contributed. The results of the trial, published in The Lancet, pave the way to the implantation of allinjectable antiretroviral therapies with a lower frequency of administration, which would imply a significant improvement of the quality of life of HIV patients.

https://medicalxpress.com/news/2017-08-antiretroviral-treatment-effective-standard-oral.html

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 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	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 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	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 package size s	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 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	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 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

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drugs	TORNADO Male Enhancement Herbal Dietary Supplement Capsules, Over 4000 mg value, supplied in 2, 4 and 10 count packages, Made in USA Distributed by American Health Supplements, Chicago, Illinois --- UPC Code 680474228959	Class I	Lot # A25591, Exp. 02/22/2017	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	ZDaily Daily Testosterone and Llibido Booster Herbal Dietary Supplement Capsules, 500 mg, supplied in 2, 4 and 10 count packages, Distributed by Organic Herbal Supply, Roseville, CA --- UPC Code 680474229062	Class I	All lots and package 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	BIGnHARD 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 680474229086	Class I	All lots and package 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	ENHANCEROL 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 680474229086	Class I	All lots and package 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	ZRECT for Women Herbal Dietary Supplement Capsules, 500 mg, supplied in 30 count packages, Distributed by Organic Herbal Supply, Roseville, CA --- UPC Code 680474229055	Class I	All lots and package 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

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drugs	LabidaMAX Herbal Dietary Supplement Capsules, 500 mg, supplied in 30 count packages, Made in Malaysia, Distributed by Organic Herbal Supply, Cheyenne, WY --- UPC Code 680474228904	Class II	All lots and package 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	BRILINTA (ticagrelor) tablets, 90 mg, 8-count Professional Sample bottles, Rx only, Mfd. for: AstraZeneca Pharmaceuticals LP, Wilmington, DE 19850; By: AstraZeneca AB, SE-151 85 Sodertalje, Sweden, NDC 0186-0777-08.	Class I	Lot # JB5047, Exp 10/19	Presence of Foriegn Tablets/Capsules: customer complaint that an 8-count professional sample bottle labeled as BRILINTA 90 mg tablets contained 5 ZURAMPIC 200 mg tablets, in addition to the expected 8 BRILINTA tablets.	AstraZeneca Pharmaceuticals, LP 587 Old Baltimore Pike Newark, DE 19702-1307
Drugs	Paliperidone Extended-Release Tablets, 3 mg, 90 count bottles, Rx only, Manufactured by: Actavis Laboratories FL, Inc., Fort Lauderdale, FL 33314 USA Distributed by: Actavis Pharma, Inc., Parsippany, NJ 07054, USA, NDC: 0591-3693-19	Class I	Lot: 1160682A, EXP. 06/18	Failed Dissolution Specifications: Drug release test result, obtained during routine 9-month stability testing, which was below specification for one tablet. Teva cannot at this time exclude the potential for additional tablets to be below specification.	Teva Pharmaceuticals 425 Pivet Rd Horsham, PA 19044-1220
Drugs	EliquisTablets 5mg, 60 count bottle, Rx Only, Marketed by: Bristol-Meyers Squibb Company Princeton, NJ 08543 USA and Pfizer Inc. New York, NY 10017 USA, NDC 0003-0894-21	Class I	Lot: HN0063, EXP. 09/2019	Labeling: Label Mix-up: One bottle of Eliquis 5 mg tablet was found to contain lower-strength Eliquis 2.5 mg tablets only instead of the labeled 5 mg tablets	Bristol-myers Squibb Company. 1 Squibb Dr New Brunswick, NJ 08901-1588
Drugs	CVS Health Baby Eczema Moisturizing Cream(colloidal oatmeal 1.0%), Net Wt. 7.3 oz (207g) tubes, OTC, Distributed by CVS Pharmacy Inc., Woonsocket, RI --- UPC 050428568033	Class II	lot number 17-01319, exp 01/19	Microbial Contamination of Non Sterile Products; out of specification Total Plate Count	Sigan Industries Inc. 296 Orenda Rd Brampton

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drugs	QUELICIN (Succinylcholine Chloride) Injection, USP 20 mg/mL in a) 5 mL vial (NDC 15082-814-67), b) 7mL vial (NDC 15082-814-79), c) 10mL vial (NDC 15082-814-61), Repackaged by Advanced Pharm, 9265 Kirby Dr., Houston, TX 77054 (877) 794-0404	Class II	Lot #: a) 5/15/17 2305 814 67S, BUD 7/29/2017; 5/22/ 17 1000 81467S, BUD 8/5/ 2017; 5/30/17 1549 81467 S,BUD 8/13/2017. b) 5/24/ 17 0307 169-81479S, BUD 7/23/2017; 5/18/17 0220 1 69-81479S, BUD 7/17/2017 ; 5/16/17 0306 169-81479S , BUD 7/15/2017; 6/5/17 0 937 169-81479S, BUD 8/04 /2017; 5/16/17 0314 445-8 1479S, BUD 7/15/2017; 5/1 6/17 0315 493-81479S, BU D 7/15/2017; c) 5/15/17 21 19 81461S, BUD 7/29/2017 ; 5/22/17 0922 81461S, BU D 8/5/2017; 5/30/17 1533 81461S, BUD 8/13/2017; 6/ 12/17 1846 81461S, BUD 8 /26/2017; 6/5/17 0237 157 -81461SB, BUD 8/4/2017	Lack of Assurance of Sterility	Advanced Pharma Inc. 9265 Kirby Dr Houston, TX 77054-2520
Drugs	Potassium Phosphate (USP) QS 0.9% Sodium Chloride (USP) 250 mL 20 mmol in NS 250mL Bag, Advanced Pharma, 9265 Kirby Dr., Houston, TX 77054 (877) 794-0404. NDC15082-926-25	Class II	Lot #: 5/23/17 1404 299-92 625P, BUD: 8/21/2017; 5/2 6/2017 1250 297-92625P, BUD 8/24/2017.	Lack of Assurance of Sterility	Advanced Pharma Inc. 9265 Kirby Dr Houston, TX 77054-2520
Drugs	Potassium PHOSphate added to 250 mL 0.9% Sodium Chloride 10 mMol (14.67 mEq K+) Total Approximate Volume 254 mL, Rx only, SCA Pharmaceuticals, Little Rock, AR 72205, NDC 70004-0840-40	Class II	Lot #: 20170509@2, Exp 6/ 23/2017; 20170524@22, E xp 7/8/2017; 20170602@1 0, Exp 7/17/2017; 2017060 9@27, Exp 7/24/2017	Lack of sterility assurance	SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205-4600
Drugs	Potassium PHOSphate added to 250 mL 0.9% Sodium Chloride 15 mMol (22 mEq K+) Total Approximate Volume 255 mL, Rx only, SCA Pharmaceuticals, Little Rock, AR 72205, NDC 70004-0841-40	Class II	Lot #: 20170509@6, Exp 6/ 23/2017; 20170519@35, E xp 7/3/2017; 20170523@2 2, Exp 7/7/2017; 20170525 @9, Exp 7/9/2017; 201706 05@49, Exp 7/20/2017; 20 170605@9, Exp 7/20/2017	Lack of sterility assurance.	SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205-4600
Drugs	Potassium PHOSphate added to 250 mL 0.9% Sodium Chloride 15 mMol (22 mEq K+) Total Approximate Volume 255 mL, Rx only, SCA Pharmaceuticals, Little Rock, AR 72205, NDC 70004-0841-32	Class II	Lot #: 20170602@29, Ex p 7/17/2017	Lack of sterility assurance	SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205-4600

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drugs	Potassium PHOSphate added to 0.9% Sodium Chloride 250 mL Bag 30 mMol (44 mEq K+) Total Approximate Volume 260 mL, Rx only, SCA Pharmaceuticals, Little Rock, AR 72205, NDC 70004-0843-40	Class II	Lot #: 20170511@58, Exp 6/25/2017	Lack of sterility assurance	SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205-4600
Drugs	5% Dextrose Injection, USP, 100 mL VIAFLEX Plastic Container, Rx only, Baxter Healthcare Corporation, Deerfield IL 60015 USA, Product Code: 2B0089, NDC: 0338-0017-38	Class II	Lot: P361618, Exp 09/30/18;	Lack of Assurance of Sterility: Bags have the potential to leak.	Baxter Healthcare Corporation 1 Baxter Pkwy Deerfield, IL 60015-4625
Drugs	0.9% Sodium Chloride Injection, USP, 100 mL VIAFLEX Container, Rx Only, Baxter Healthcare Corporation, Deerfield IL 60015 USA, Product Code: 2B1309, NDC: 0338-0049-38	Class II	Lots: P361501, P361667, and P361790, Exp 09/30/18	Lack of Assurance of Sterility: Bags have the potential to leak.	Baxter Healthcare Corporation 1 Baxter Pkwy Deerfield, IL 60015-4625
Drugs	0.9% Sodium Chloride Injection USP, 250 mL VIAFLEX Container bag, Rx only, Baxter Healthcare Corporation, Deerfield, IL 60015; Distributed in Canada by Baxter Corporation, Toronto, Ontario, Canada, Product Code: 2B1322, NDC 0338-0049-02.	Class II	Lot: Y229153, Exp 09/30/18	Lack of Assurance of Sterility: Customer complaints for leaking bags.	Baxter Healthcare Corporation 1 Baxter Pkwy Deerfield, IL 60015-4625
Drugs	Potassium Phosphate (USP) QS 0.9% Sodium Chloride (USP) 250 mL 30 mmol in NS 250mL Bag, Advanced Pharma, 9265 Kirby Dr., Houston, TX 77054 (877) 794-0404. NDC15082-924-25	Class II	Lot #: 5/31/17 1416 382-92425P BUD: 8/29/2017.	Lack of Assurance of Sterility	Advanced Pharma Inc. 9265 Kirby Dr Houston, TX 77054-2520
Drugs	Potassium Phosphate (USP) QS 0.9% Sodium Chloride (USP) 250 mL 15 mmol in NS 250mL Bag, Advanced Pharma, 9265 Kirby Dr., Houston, TX 77054 (877) 794-0404. NDC15082-922-25	Class II	Lot #: 6/7/17 1446 515-92225P BUD: 9/5/2017; 6/2/17 1100 515-92225P BUD: 8/31/2017; 5/31/17 1415 382-92225P BUD: 8/29/2017..	Lack of Assurance of Sterility	Advanced Pharma Inc. 9265 Kirby Dr Houston, TX 77054-2520
Drugs	Succinylcholine Chloride Injection (Preserved) 20 mg per mL, 200 mg per 10 mL, 10 mL Total Volume in	Class II	Lots: 171390026D Exp. 08/20/2017; 171370064D Exp. 8/16/2017; 171390027D Ex	Lack of Assurance of Sterility; media fill failure at	PharMedium Services, Llc. 12620 W Airport

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
	BD Syringe, For IV Use, PharMedium Services, LLC, Cleveland, MS --- NDC 61553-364-65		p. 8/20/2017; 171420074D Exp. 8/21/2017; 171430062D Exp. 8/22/2017; 171440058D Exp. 8/23/2017; 171450001D Exp. 8/23/2017; 171450002D Exp. 8/23/2017; 171450056D Exp. 08/24/2017.	manufacturer	Blvd Ste 130 Sugarland, TX 77478-6200
Drugs	Potassium PHOSphate in 0.9% Sodium Chloride Injection, 10 mMol in a) 100 mL in 150 mL Intravia Bag (NDC 61553-288-48) Service Code: 2K5288, and b) 250 mL in 250 mL Intravia Bag (NDC 61553-281-11) Service Code: 2K5281, Rx Only, PharMEDium Services, LLC 12620 W. Airport Blvd #130 Sugar Land, TX 77478 800-523-7749	Class II	Lots: a) 171280006S Exp. 8/6/2017; 171280125S Exp. 8/7/2017; 171290006S Exp. 8/7/2017; 171290028D Exp. 8/8/2017; 171360002S Exp. 8/15/2017; b) 171280011S Exp. 8/7/2017	Lack of Assurance of Sterility; media fill failure at manufacturer.	PharMedium Services, Llc. 12620 W Airport Blvd Ste 130 Sugarland, TX 77478-6200
Drugs	Potassium PHOSphate in 0.9% Sodium Chloride Injection 15 mMol in a) 100 mL in 150 mL Intravia Bag Service Code 2K5295 NDC# 61553-295-48; b) 150 mL in 150 mL Intravia Bag Service Code 2K5292 NDC# 61553-292-01; c) 250 mL in 250 mL Intravia Bag Service Code 2K5282 NDC# 61553-282-11; d) 250 mL in 250 mL Intravia Bag with Additive Cap Service Code 2K5291 NDC# 61553-291-11, Rx Only PharMEDium Services, LLC 12620 W. Airport Blvd #130 Sugar Land, TX 77478 800-523-7749	Class II	Lots: a) 171320006S Exp. 8/13/2017, 171320014D Exp. 8/13/2017,171360020D Exp. 8/15/2017, 171520063D Exp. 8/31/2017; b) 171280054D Exp. 8/7/2017, 171320002D Exp. 8/10/2017, 171370005S Exp. 8/15/2017, 171440016D Exp. 8/23/2017, 171450012D Exp. 8/24/2017, 171510059D Exp. 8/30/2017, 171560027D Exp. 9/4/2017; c) 171170014S Exp. 7/27/2017, 171210127S Exp. 7/31/2017, 171230071D Exp. 8/2/2017, 171240002D Exp. 8/3/2017, 171240004D Exp. 8/3/2017, 171240191S Exp. 8/3/2017, 171280041D Exp. 8/7/2017, 171290077D Exp. 8/8/2017, 171300076D Exp. 8/9/2017, 171310058D Exp. 8/10/2017, 171320059D Exp. 8/13/2017, 171320190S Exp. 8/13/2017, 171360062D Exp. 8/15/2017, 171360068D Exp. 8/15/2017, 171380076D Exp. 8/17/2017, 171390064D Exp. 8/20/2017, 171390065D Exp. 8/20/2017, 171500064D Exp. 8/29/2017, 171530101S Exp. 9/3/2017, 171570058D Exp. 9/5/2017; d) 171210005S Exp. 7/30/2017, 171230008D Exp. 8/2/2017, 171500072D Exp. 8/29/2017, 171560028D Exp. 9/4/20	Lack of Assurance of Sterility; media fill failure at manufacturer	PharMedium Services, Llc. 12620 W Airport Blvd Ste 130 Sugarland, TX 77478-6200

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
			17		
Drugs	Potassium PHOSphate in 0.9% Sodium Chloride Injection 20 mMol in 100 mL in 150 mL Intravia Bag, Rx Only, PharMEDium Services, LLC 12620 W. Airport Blvd #130 Sugar Land, TX 77478 800-523-7749 Service Code 2K5287 NDC# 61553-287-48	Class II	Lot: 171320001D, 8/10/2017	Lack of Assurance of Sterility; media fill failure at manufacturer	PharMedium Services, Llc. 12620 W Airport Blvd Ste 130 Sugarland, TX 77478-6200
Drugs	Potassium PHOSphate in 5% Dextrose Injection, 30 mMol 500 mL in 500 mL Intravia Bag, Rx Only, PharMEDium Services, LLC 12620 W. Airport Blvd #130 Sugar Land, TX 77478 800-523-7749 Service Code 2K5283 NDC# 61553-283-03	Class II	Lot: 171350099S, 8/14/2017	Lack of Assurance of Sterility; media fill failure at manufacturer	PharMedium Services, Llc. 12620 W Airport Blvd Ste 130 Sugarland, TX 77478-6200
Drugs	Potassium PHOSphate in 0.9% Sodium Chloride Injection, 40 mMol in 250 mL in 250 mL Intravia Bag, Rx Only, PharMEDium Services, LLC 12620 W. Airport Blvd #130 Sugar Land, TX 77478 800-523-7749 Service Code 2K5301 NDC# 61553-301-11	Class II	Lots: 171220007S Exp. 7/31/2017, 171280129S Exp. 8/7/2017, 171320112S Exp. 8/13/2017, 171590010S Exp. 9/7/2017	Lack of Assurance of Sterility; media fill failure at manufacturer	PharMedium Services, Llc. 12620 W Airport Blvd Ste 130 Sugarland, TX 77478-6200
Drugs	Potassium PHOSphate in 0.9% Sodium Chloride Injection, 7 mMol in 100 mL in 150 mL Intravia Bag, Rx Only, PharMEDium Services, LLC 12620 W. Airport Blvd #130 Sugar Land, TX 77478 800-523-7749 Service Code 2K5284 NDC# 61553-284-48	Class II	Lots: 171220061D Exp. 8/1/2017, 171250023D Exp. 8/6/2017, 171430008D Exp. 8/22/2017, 171450015D Exp. 8/24/2017, 171510062D Exp. 8/30/2017	Lack of Assurance of Sterility; media fill failure at manufacturer	PharMedium Services, Llc. 12620 W Airport Blvd Ste 130 Sugarland, TX 77478-6200
Drugs	Potassium PHOSphate in 0.9% Sodium Chloride Injection, 7.5 mMol in 100 mL in 150 mL Intravia Bag, Rx Only, PharMEDium Services, LLC 12620 W. Airport Blvd #130 Sugar Land, TX 77478 800-523-7749 Service Code 2K5298 NDC# 61553-298-48NDC# 61553-298-48	Class II	Lots: 171210102S Exp. 7/31/2017, 171320109S Exp. 8/13/2017, 171560012S Exp. 9/4/2017	Lack of Assurance of Sterility; media fill failure at manufacturer	PharMedium Services, Llc. 12620 W Airport Blvd Ste 130 Sugarland, TX 77478-6200
Drugs	Potassium PHOSphate in 5% Dextrose Injection, 7.5 mMol in 100	Class	Lot: 171450017D, 8/24/201	Lack of Assurance of Sterility; media fill failure at manufactur	PharMedium Services, Llc.

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
	mL in 150 mL Intravia Bag, Rx Only, PharMEDium Services, LLC 12620 W. Airport Blvd #130 Sugar Land, TX 77478 800-523-7749 Service Code 2K5299 NDC# 61553-299-48	II	7	er	12620 W Airport Blvd Ste 130 Sugarland, TX 77478-6200
Drugs	Potassium PHOSphate in 0.9% Sodium Chloride Injection, 9 mMol in 100 mL in 150 mL Intravia Bag, Rx Only, PharMEDium Services, LLC 12620 W. Airport Blvd #130 Sugar Land, TX 77478 800-523-7749 Service Code 2K5286 NDC# 61553-286-48	Class II	Lot: 171520062D, 8/31/2017	Lack of Assurance of Sterility; media fill failure at manufacturer	PharMedium Services, Llc. 12620 W Airport Blvd Ste 130 Sugarland, TX 77478-6200
Drugs	Potassium PHOSphate in 5% Dextrose Injection, 9 mMol in 50 mL in 50 mL Intravia Bag, Rx Only, PharMEDium Services, LLC 12620 W. Airport Blvd #130 Sugar Land, TX 77478 800-523-7749 Service Code 2K5310 NDC# 61553-310-41	Class II	Lots: 171160002S Exp. 7/26/2017, 171560007S Exp. 9/4/2017	Lack of Assurance of Sterility; media fill failure at manufacturer	PharMedium Services, Llc. 12620 W Airport Blvd Ste 130 Sugarland, TX 77478-6200
Drugs	Potassium PHOSphate in 0.9% Sodium Chloride Injection, 30 mMol in a) 250 mL in 250 mL Intravia Bag Service Code 2K5290 NDC# 61553-290-11, b) 500 mL in 500 mL Intravia Bag Service Code 2K5285 NDC# 61553-285-03, Rx Only, PharMEDium Services, LLC 12620 W. Airport Blvd #130 Sugar Land, TX 77478 800-523-7749	Class II	Lots: a) 171180027S Exp. 7/29/2017, 171220058D Exp. 8/1/2017, 171230013S Exp. 8/2/2017, 171360008S Exp. 8/14/2017, 171360019D Exp. 8/15/2017, 171380085D Exp. 8/17/2017, 171430069D Exp. 8/22/2017, 171560025D Exp. 9/4/2017; b) 171240007S Exp. 8/3/2017, 171280055D Exp. 8/7/2017, 171320003D Exp. 8/10/2017, 171320008S Exp. 8/13/2017, 171360005S Exp. 8/14/2017, 171370011S Exp. 8/16/2017, 171380086D Exp. 8/17/2017, 171500071D Exp. 8/29/2017	Lack of Assurance of Sterility; media fill failure at manufacturer	PharMedium Services, Llc. 12620 W Airport Blvd Ste 130 Sugarland, TX 77478-6200
Drugs	Potassium PHOSphate in 5% Dextrose Injection, 15 mMol in 250 mL in 250 mL Intravia Bag Service, Rx Only. PharMEDium Services, LLC 12620 W. Airport Blvd #130 Sugar Land, TX 77478 800-523-7749 Service Code 2K5300 NDC# 61553-300-11	Class II	Lot: 171420030D, 8/21/2017	Lack of Assurance of Sterility; media fill failure at manufacturer	PharMedium Services, Llc. 12620 W Airport Blvd Ste 130 Sugarland, TX 77478-6200
Drugs	BUPIVacaine HCl 0.1% PF (From 0.75%) in 0.9% Sodium Chloride,	Class	Lots: 20170429@33 BUD: 7/28/2017, 20170503@23 B	Lack of Assurance of Sterility; product has the potential to leak	SCA Pharmaceuticals.

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
	250 mL Bag, Preservative Free (Waste From 250 mL Bag), Rx only, SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205 --- NDC# 70004-0060-40	II	UD: 8/1/2017	.	8821 Knoedl Ct Little Rock, AR 72205-4600
Drugs	morphine sulfate 1 mg per mL in 0.9% Sodium Chloride, (Total morphine Dose 100 mg/100 mL), Total Volume 100 mL Single Dose Container bag, Rx Only, SCA Pharmaceuticals, 8821 Knoedl Ct, Little Rock, AR 72205, (877) 550-5059; labeled as a) NDC: 70004-0100-59; b) NDC: 70004-100-58.	Class II	Lots: a) 20170707@34, BUD:10/5/2017; 20170710@21, BUD: 10/8/2017; b) 20170706@44, BUD: 10/4/2017	Lack of Assurance of Sterility: Product made with recalled 0.9 % sodium chloride bags which have the potential to leak	SCA Pharmaceuticals. 8821 Knoedl Ct Little Rock, AR 72205-4600
Drugs	BUPIVacaine HCl 0.125% In 250 mL 0.9% Sodium Chloride Bag, Preservative Free (Total Dose Bupivacaine 312.5 mg per 250 mL), Rx only, SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205 --- NDC# 70004-0062-40	Class II	Lot: 20170502@32 BUD: 7/31/2017	Lack of Assurance of Sterility; product has the potential to leak .	SCA Pharmaceuticals. 8821 Knoedl Ct Little Rock, AR 72205-4600
Drugs	BUPIVacaine HCl 0.2% IN 0.9% Sodium Chloride 250 mL Bag Preservative Free (Total Dose Bupivacaine 500 mg per 250 mL), Rx only, SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205 --- NDC# 70004-0066-40	Class II	Lot: 20170501@69 BUD: 7/30/2017	Lack of Assurance of Sterility; product has the potential to leak .	SCA Pharmaceuticals. 8821 Knoedl Ct Little Rock, AR 72205-4600
Drugs	fentaNYL (as citrate) 5 mcg/mL In 250 mL 0.9% Sodium Chloride Injection Bag (Total fentaNYL Dose 1250 mcg/ 250 mL), Preservative Free, Rx only, SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205 --- NDC# 70004-0201-40	Class II	Lots: 20170428@57 BUD: 7/27/2017; 20170428@58 BUD: 7/27/2017; 20170511@24 BUD: 8/9/2017	Lack of Assurance of Sterility; product has the potential to leak .	SCA Pharmaceuticals. 8821 Knoedl Ct Little Rock, AR 72205-4600
Drugs	fentaNYL (as citrate) 10 mcg per mL in 0.9% Sodium Chloride 250 mL Bag, Rx only, SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205 --- NDC# 70004-0202-40	Class II	Lots: 20170502@18 BUD: 7/31/2017; 20170502@39 BUD: 7/31/2017; 20170502@62 BUD: 7/31/2017; 20170503@22 BUD: 8/1/2017; 20170503@4 BUD: 8/1/2017; 20170503@54 BUD: 8/1/2017; 20170504@10 BUD: 8/2/2017; 20170505@15 BUD: 8/3/2017; 20170506@23 BUD: 8/4/2017	Lack of Assurance of Sterility; product has the potential to leak .	SCA Pharmaceuticals. 8821 Knoedl Ct Little Rock, AR 72205-4600

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drugs	fentaNYL as citrate 5 mcg/mL in 0.9% Sodium Chloride 1 mL in Single Dose syringe, Rx only, SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205 --- NDC# 70004-0225-24	Class II	Lot: 20170510@40 BUD: 8/8/2017	Lack of Assurance of Sterility; product has the potential to leak.	SCA Pharmaceuticals. 8821 Knoedl Ct Little Rock, AR 72205-4600
Drugs	fentaNYL 2 mcg/mL+Bupivacaine 0.0625% PF in 0.9% Sodium Chloride 250 mL, Rx only, SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205 ---- NDC# 70004-0226-40	Class II	Lots: 20170429@29 BUD: 7/28/2017; 20170512@24 BUD: 8/10/2017	Lack of Assurance of Sterility; product has the potential to leak.	SCA Pharmaceuticals. 8821 Knoedl Ct Little Rock, AR 72205-4600
Drugs	fentaNYL 10 mcg/mL PF in NS 1 mL Fill in 3 mL syringe, Rx only, SCA Pharmaceuticals, 8821 Knoedl Ct Little Rock, AR 72205 --- NDC# 70004-0229-05	Class II	Lot: 20170512@19 BUD: 8/10/2017	Lack of Assurance of Sterility; product has the potential to leak.	SCA Pharmaceuticals. 8821 Knoedl Ct Little Rock, AR 72205-4600
Drugs	fentaNYL 10 mcg/mL PF in Sodium Chloride 250 mL (Total Dose=2500 mcg), Rx only, SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205 --- NDC# 70004-0229-40	Class II	Lots: 20170509@20 BUD: 8/7/2017; 20170509@21 BUD: 8/7/2017; 20170509@46 BUD: 8/7/2017; 20170511@33 BUD: 8/9/2017	Lack of Assurance of Sterility; product has the potential to leak.	SCA Pharmaceuticals. 8821 Knoedl Ct Little Rock, AR 72205-4600
Drugs	fentaNYL 2 mcg/mL + BUPIvacaine 0.1% PF in 0.9% NS 250 mL, Rx only, SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205 --- NDC# 70004-0230-40	Class II	Lots: 20170502@47 BUD: 7/31/2017; 20170502@56 BUD: 7/31/2017; 20170505@26 BUD: 8/3/2017; 20170506@25 BUD: 8/4/2017	Lack of Assurance of Sterility; product has the potential to leak.	SCA Pharmaceuticals. 8821 Knoedl Ct Little Rock, AR 72205-4600
Drugs	fentaNYL 2 mcg/mL + BUPIvacaine 0.125% PF in 0.9% Sodium Chloride 250 mL, Rx only, SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205 --- NDC# 70004-0254-40	Class II	Lots: 20170503@75 BUD: 8/1/2017; 20170511@21 BUD: 8/9/2017	Lack of Assurance of Sterility; product has the potential to leak.	SCA Pharmaceuticals. 8821 Knoedl Ct Little Rock, AR 72205-4600
Drugs	fentaNYL 3 mcg/mL + BUPIvacaine 0.1% in 0.9% Sodium Chloride 250 mL, Rx only, SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205 --- NDC# 70004-0290-40	Class II	Lot: 20170506@27 BUD: 8/4/2017	Lack of Assurance of Sterility; product has the potential to leak	SCA Pharmaceuticals. 8821 Knoedl Ct Little Rock, AR 72205-4600
Drugs	Hydromorphone 0.5 mg/mL in 0.9% Sodium Chloride 1 mL Fill in 3 mL BD syringe, Rx only, SCA	Class	Lot: 20170508@75 BUD: 8/	Lack of Assurance of Sterility; product has the potential to leak	SCA Pharmaceuticals. 8821 Knoedl Ct

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
	Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205 --- NDC# 70004-0302-05	II	6/2017	.	Little Rock, AR 72205-4600
Drugs	ePHEDrine Sulfate 5 mg/mL in NS 5 mL Fill in 12 mL Syringe (25 mg), Rx only, SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205 --- NDC# 70004-0600-11	Class II	Lots: 20170503@28 BUD: 7/17/2017; 20170508@60 BUD: 7/22/2017	Lack of Assurance of Sterility; product has the potential to leak	SCA Pharmaceuticals. 8821 Knoedl Ct Little Rock, AR 72205-4600
Drugs	EPINEPHrine HCl 4 mg in 0.9% Sodium Chloride 250 mL, Rx only, SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205 --- NDC# 70004-0613-40		Lots: 20170508@51 BUD: 9/10/2017; 20170503@17 BUD: 9/5/2017	Lack of Assurance of Sterility; product has the potential to leak .	SCA Pharmaceuticals. 8821 Knoedl Ct Little Rock, AR 72205-4600
Drugs	NORepinephrine 4 mg in 0.9% Sodium Chloride 250 mL from Stock, Rx only, SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205 --- NDC# 70004-0771-40		Lots: 20170502@36 BUD: 7/31/2017; 20170512@1 BUD: 8/10/2017; 20170504@13 BUD: 8/2/2017; 20170504@18 BUD: 8/2/2017	Lack of Assurance of Sterility; product has the potential to leak .	SCA Pharmaceuticals. 8821 Knoedl Ct Little Rock, AR 72205-4600
Drugs	NORepinephrine Bitartrate 8 mg in 0.9% Sodium Chloride 250 mL, Rx only, SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205 --- NDC# 70004-0774-40		Lots: 20170502@31 BUD: 7/16/2017; 20170508@34 BUD: 7/22/2017; 20170508@70 BUD: 7/22/2017; 20170512@15 BUD: 7/26/2017	Lack of Assurance of Sterility; product has the potential to leak	SCA Pharmaceuticals. 8821 Knoedl Ct Little Rock, AR 72205-4600
Drugs	NORepinephrine Bitartrate 16 mg in 0.9% Sodium Chloride 250 mL from Stock, Rx only, SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205 --- NDC# 70004-0775-40		Lots: 20170512@8 BUD: 8/10/2017; 20170506@18 BUD: 8/4/2017	Lack of Assurance of Sterility; product has the potential to leak .	SCA Pharmaceuticals. 8821 Knoedl Ct Little Rock, AR 72205-4600
Drugs	PHENYLephrine HCl 60 mg in 0.9% Sodium Chloride 250 mL, Rx only, SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205 --- NDC# 70004-0809-40		Lots: 20170512@20 BUD: 8/10/2017; 20170504@61 BUD: 8/2/2017	Lack of Assurance of Sterility; product has the potential to leak .	SCA Pharmaceuticals. 8821 Knoedl Ct Little Rock, AR 72205-4600
Drugs	PHENYLephrine HCl 10 mg in 0.9% Sodium Chloride 250 mL Bag, Preservative Free, Rx only, SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205 --- NDC# 70004-0811-40		Lots: 20170503@26 BUD: 8/1/2017; 20170510@48 BUD: 8/8/2017	Lack of Assurance of Sterility; product has the potential to leak .	SCA Pharmaceuticals. 8821 Knoedl Ct Little Rock, AR 72205-4600

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drugs	PHENYLephrine 10 mg in 0.9% Sodium Chloride 250 mL bag, Rx only, SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205 ---- NDC# 70004-0811-59		Lots: 20170503@29 BUD: 8/1/2017; 20170512@22 BUD: 8/10/2017; 20170509@64 BUD: 8/7/2017	Lack of Assurance of Sterility; product has the potential to leak .	SCA Pharmaceuticals. 8821 Knoedl Ct Little Rock, AR 72205-4600
Drugs	PHENYLephrine 40 mg in 0.9% Sodium Chloride 250 mL, Rx only, SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205 --- NDC# 70004-0812-40		Lots: 20170429@28 BUD: 7/28/2017; BUD: 20170509@65 BUD: 8/7/2017	Lack of Assurance of Sterility; product has the potential to leak .	SCA Pharmaceuticals. 8821 Knoedl Ct Little Rock, AR 72205-4600
Drugs	PHENYLephrine 100 mg in 0.9% Sodium Chloride 250 mL Bag, Rx only, SCA Pharmaceuticals 882PHENYLephrine 100 mg 1 Knoedl Ct Little Rock, AR 72205 --- NDC# 70004-0813-40	Class II	Lot: 20170503@16 BUD: 8/1/2017	Lack of Assurance of Sterility; product has the potential to leak.	SCA Pharmaceuticals. 8821 Knoedl Ct Little Rock, AR 72205-4600
Drugs	PHENYLephrine 200 mg in 0.9% Sodium Chloride 250 mL, Rx only, SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205 --- NDC# 70004-0815-40	Class II	Lot: 20170511@51 BUD: 8/9/2017	Lack of Assurance of Sterility; product has the potential to leak.	SCA Pharmaceuticals. 8821 Knoedl Ct Little Rock, AR 72205-4600
Drugs	PHENYLephrine 20 mg in 0.9% Sodium Chloride 250 mL Bag, Rx only, SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205 --- NDC# 70004-0816-40	Class II	Lot: 20170503@19 BUD: 8/1/2017	Lack of Assurance of Sterility; product has the potential to leak.	SCA Pharmaceuticals. 8821 Knoedl Ct Little Rock, AR 72205-4600
Drugs	PHENYLephrine 50 mg in 0.9% Sodium Chloride 250 mL, Rx only, SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205 --- NDC# 70004-0820-40	Class II	Lots: 20170512@6 BUD: 8/10/2017; 20170511@56 BUD: 8/9/2017	Lack of Assurance of Sterility; product has the potential to leak	SCA Pharmaceuticals. 8821 Knoedl Ct Little Rock, AR 72205-4600
Drugs	Potassium Chloride 20 meq Added to Sodium Chloride 0.9% 250 mL, Rx only, SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205 --- NDC# 70004-0832-40	Class II	Lots: 20170501@66 BUD: 7/15/2017	Lack of Assurance of Sterility; product has the potential to leak.	SCA Pharmaceuticals. 8821 Knoedl Ct Little Rock, AR 72205-4600
Drugs	Potassium Chloride 40 meq Added to Sodium Chloride 0.9% 250 mL, Rx only, SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205 ----	Class II	Lots: 20170509@10 BUD: 7/23/2017	Lack of Assurance of Sterility; product has the potential to leak.	SCA Pharmaceuticals. 8821 Knoedl Ct Little Rock, AR

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
	NDC# 70004-0833-40				72205-4600
Drugs	fentaNYL 2 mcg/mL + Ropivacaine 0.2% PF in NS 250 mL, Rx only, SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205 --- NDC# 70004-0260-40	Class II	Lots: 20170509@17 BUD: 8/7/2017	Lack of Assurance of Sterility; product has the potential to leak.	SCA Pharmaceuticals. 8821 Knoedl Ct Little Rock, AR 72205-4600
Drugs	fentaNYL (as citrate) 10 mcg per mL in 0.9% Sodium Chloride, (Total fentaNYL Dose 1,000 mcg/100 mL), Total Volume 100 mL Single Dose Container bag, Rx Only, SCA Pharmaceuticals, 8821 Knoedl Ct, Little Rock, AR 72205 (877) 550-5059; NDC: 70004-0202-32.	Class II	Lot: 20170707@27, BUD: 10/5/2017	Lack of Assurance of Sterility: Product made with recalled 0.9% sodium chloride bags which have the potential to leak.	SCA Pharmaceuticals. 8821 Knoedl Ct Little Rock, AR 72205-4600
Drugs	ceFAZolin 3 g added to 100 mL 0.9% Sodium Chloride, Total Approximate Volume 115 mL Single Dose Container bag, Rx Only, SCA Pharmaceuticals, 8821 Knoedl Ct, Little Rock, AR 72205 (877) 550-5059; NDC: 70004-0524-32.	Class II	Lot: 20170707@26, BUD: 8/21/2017	Lack of Assurance of Sterility: Product made with recalled 0.9% sodium chloride bags which have the potential to leak	SCA Pharmaceuticals. 8821 Knoedl Ct Little Rock, AR 72205-4600
Drugs	Diltiazem 125 mg in 0.9% Sodium Chloride, 1 mg per mL, Total Volume 125 mL Single Dose Container bag, Rx Only, SCA Pharmaceuticals, 8821 Knoedl Ct, Little Rock, AR 72205 (877) 550-5059; NDC: 70004-0541-35.	Class II	Lot: 20170707@54, BUD: 10/4/2017	Lack of Assurance of Sterility: Product made with recalled 0.9% sodium chloride bags which have the potential to leak	SCA Pharmaceuticals. 8821 Knoedl Ct Little Rock, AR 72205-4600
Drugs	MAGNESIUM Sulfate 4 g added to 100 mL 0.9% Sodium Chloride, Total Approximate Volume 108 mL (does not include mfg. overfill) Single Dose Container bag, Rx Only, SCA Pharmaceuticals, 8821 Knoedl Ct, Little Rock, AR 72205 (877) 550-5059; NDC: 70004-0737-32.	Class II	Lot: 20170710@54, BUD: 10/8/2017	Lack of Assurance of Sterility: Product made with recalled 0.9% sodium chloride bags which have the potential to leak.	SCA Pharmaceuticals. 8821 Knoedl Ct Little Rock, AR 72205-4600
Drugs	PHENYLephrine HCl 10 mg in 0.9% Sodium Chloride, (Final Concentration = 0.1 mg per mL), Total Volume 100 mL Single Dose Container bag, Rx Only, SCA Pharmaceuticals, 8821 Knoedl Ct, Little Rock, AR 72205 (877) 550-	Class II	Lot: 20170710@3, BUD: 10/8/2017	Lack of Assurance of Sterility: Product made with recalled 0.9% sodium chloride bags which have the potential to leak.	SCA Pharmaceuticals. 8821 Knoedl Ct Little Rock, AR 72205-4600

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
	5059; NDC: 70004-0810-32.				
Drugs	Alka-Seltzer Original (325 mg Aspirin (NSAID), 1916 mg Analgesic, Sodium bicarbonate/Antacid, 1000 mg Anhydrous Citric Acid) Effervescent Tablets, 12-count carton, Made in Germany, Distributed by Bayer HealthCare, LLC Whippany, NJ 07981, UPC 016500040194	Class II	BTAH340; Exp. 02/19 BTAH CP0; Exp. 04/19 BTAHLW0; Exp. 06/19 BTAHLX0; Exp. 0 8/19 BTAHP10; Exp 08/19	Defective Container: Confirmed customer compliant of small holes or cracks in the foil of blister packs.	Bayer HealthCare Pharmaceuticals, Inc. 36 Columbia Rd Morristown, NJ 07960-4526
Drugs	Potassium Phosphates Inj., USP, 45 mM (3 mM P/mL) Also contains: 66 mEq K+ (4.4 mEq/mL) 15 mL, Single-dose, Caution: Must Be Diluted, Rx Only, Mfd by Hospira, Inc. Lake Forest, IL 60045 USA, NDC: 0409-7295-01	Class II	Lot: 74119EV Exp. 02/01/2 019 Lot: 74120EV Exp. 02/0 1/2019 Lot: 74121EV Exp. 0 2/01/2019 Lot: 74307EV Ex p. 02/01/2019 Lot: 75326E V Exp. 03/01/2019 Lot: 753 27EV Exp. 03/01/2019 Lot: 75215EV Exp. 03/01/2019	Lack of Sterility Assurance	Hospira a Pfizer Company 4285 N Wesleyan Blvd Rocky Mount, NC 27804-8612
Drugs	Ibuprofen Tablets, USP 600 mg, 500-count bottle (Capsule Shaped), Rx only, Manufactured for: Time Cap Labs, Inc., 7 Michael Avenue Farmingdale, NJ 11735, USA, Manufactured by: Marksans Pharma Ltd. Plot No. L-82, L-83 Verna Indl. Estate, Verna, Goa-403 722, India, NDC 49483-603-50	Class II	Lot #: HN7003	Presence of foreign tablets/capsules: Ibuprofen Tablets USP, 600 mg bottles were found to contain some Ibuprofen Tablets USP 800 mg	Time-Cap Laboratories, Inc. 7 Michael Ave Farmingdale, NY 11735-3921
Drugs	Amantadine HCl Capsules, USP, 100 mg, Rx Only, 50 Capsules (5x10) Unit Dose Cartons, Manufactured for: AvKARE Inc, Pulaski, TN 38478 --- NDC: 50268-0069-15	Class II	Lot: 16710, exp 07/2018	Labeling; Label Mix up; cartons labeled as Amantadine HCl 100 mg Capsules contain unit dose blister cards of Cyclobenzaprine HCl Tablet, USP 5 mg	Apace KY LLC 12954 Fountain Run Rd Fountain Run, KY 42133-7914
Drugs	8.4% Sodium Bicarbonate Inj., USP 50 mL Single-dose, 50 mEq (1 mEq/mL) 4.2 grams (84 mg/mL), Rx Only, Mfd by Hospira, INC, Lake Forest, IL 60045 USA, NDC: 0409-6625-02	Class II	Lot: 72109EV Exp. 12/01/2 018, Lot: 72110EV Exp. 12/ 01/2018, Lot: 72112EV Exp. 12/01/2018, Lot: 72113EV Exp. 12/01/2018, Lot: 7211 4EV Exp. 12/01/2018, Lot: 73068EV Exp. 01/01/2019, Lot: 73071EV Exp. 01/01/2 019, Lot: 73072EV Exp. 01/ 01/2019, Lot: 73224EV Exp. 01/01/2019, Lot: 73225EV Exp. 01/01/2019, Lot: 7323 0EV Exp. 01/01/2019, Lot: 73231EV Exp. 01/01/2019, Lot: 73232EV Exp. 01/01/2	Lack of Sterility Assurance	Hospira a Pfizer Company 4285 N Wesleyan Blvd Rocky Mount, NC 27804-8612

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
			019, Lot: 73233EV Exp. 01/01/2019, Lot: 73234EV Exp. 01/01/2019, Lot: 73235EV Exp. 01/01/2019, Lot: 73236EV Exp. 01/01/2019, Lot: 73298EV Exp. 01/01/2019, Lot: 74058EV Exp. 02/01/2019, Lot: 74104EV Exp. 02/01/2019, Lot: 74105EV Exp. 02/01/2019, Lot: 74106EV Exp. 02/01/2019, Lot; 74107EV Exp. 02/01/2019, Lot: 74197EV Exp. 02/01/2019, Lot: 74198EV Exp. 02/01/2019, Lot: 74199EV Exp. 02/01/2019, Lot: 74200EV Exp. 02/01/2019, Lot: 74201EV Exp. 02/01/2019, Lot: 75171EV Exp. 03/01/2019, Lot: 75172EV Exp. 03/01/2019, Lot: 75173EV Exp. 03/01/2019, Lot: 75174EV Exp. 03/01/2019, Lot: 75175EV Exp. 03/01/2019, Lot: 75176EV Exp. 03/01/2019, Lot: 75177EV Exp. 03/01/2019, Lot: 75178EV Exp. 03/01/2019. Lot: 75293 Exp. 03/01/2019, Lot: 75418EV Exp. 03/01/2019, Lot: 75419EV Exp. 03/01/2019		
Drugs	Succinylcholine Chloride Injection, USP 200 mg (20 mg/mL) Quelicin Multiple-dose vial, 10 mL, For I.V. or I.M. use. a.) one vial (NDC: 0409-6629-02), b.) 25 vial carton (NDC: 0409-6629-25).	Class II	a.) one vial Lot: 74393EV Exp. 05/01/2018 Lot: 75157EV Exp. 06/01/2018 Lot: 75367EV, Exp. 06/01/2018 b.) 25 vial carton Lot: 75158EV ; Exp. 06/01/2018	Lack of Sterility Assurance	Hospira a Pfizer Company 4285 N Wesleyan Blvd Rocky Mount, NC 27804-8612
Drugs	Neut Sodium Bicarbonate 4% (2.4 mEq) Additive Solution 5 mL , a.) Single-dose vial (NDC 0409-6609-02), b.) 25 vial carton (NDC 0409-6609-25), Rx Only, Mfd by Hospira, INC, Lake Forest, IL 60045 USA	Class II	a.) one vial: Lot: 72226EV Exp. 12/01/2018 Lot: 72236EV Exp. 12/01/2018 Lot: 75382EV Exp. 03/01/2019 Lot: 75383EV Exp. 03/01/2019 b.) 25 vial carton: Lot: 7538EV; Exp 03/01/2019	Lack of Sterility Assurance	Hospira a Pfizer Company 4285 N Wesleyan Blvd Rocky Mount, NC 27804-8612
Drugs	Lactulose Solution, USP, 10 g/15 mL, dose cups delivers 15 mL packaged in 50-unit dose cups per case, Manufactured by VistaPharm, Inc., Largo, FL 33771, NDC 66689-038-50	Class II	Lot #: 468300, Exp 09/2018 ; 474400, Exp 11/2018	Microbial contamination of non-sterile product: product failed Total Yeast/Mold Count specification	VistaPharm, Inc. 7265 Ulmerton Rd Largo, FL 33771-4809
Drugs	Lactulose Solution, USP, 20 g/30 mL, dose cups delivers 30 mL packaged	Class	Lot #: 458300, Exp 09/2018 ; 462600, Exp 07/2018; 471	Microbial contamination of non-sterile product: product	VistaPharm, Inc. 7265 Ulmerton

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
	50-unit dose cups per case, Manufactured by VistaPharm, Inc., Largo, FL 33771, NDC 66689-038-01	II	000, Exp 10/2018; 474300, Exp 11/2018	failed Total Yeast/Mold Count specification	Rd Largo, FL 33771-4809
Drugs	Divalproex Sodium Delayed Release Tablets, USP, 125 mg, 100-count bottle Rx only, Manufactured by Cadila Healthcare Ltd, Ahmedabad, India, Distributed by: Zydus Pharmaceuticals, Pennington, NJ 07054, NDC 68382-031-01	Class II	MR6317 Exp.05/17 MR6318 Exp. 05/17 MR6319 Exp. 05/17 MR5361 Exp. 06/17 MR9007 Exp. 08/17 MR10000 Exp. 08/17 MR10923 Exp. 10/17 MR10924 Exp. 10/17 MR10925 Exp. 10/17 MR11554 Exp. 11/17 MR11555 Exp. 11/17 MS1359 Exp. 12/17	Failed Dissolution Specifications	Zydus Pharmaceuticals USA Inc 73 Route 31 N Pennington, NJ 08534-3601
Drugs	Carbamazepine Oral Suspension, USP. 100 mg/5 mL, 5 mL Unit Dose Cups, Rx Only, Pkg: Precision Dose, Inc., S. Beloit, IL 61080, NDC 68094-301-59.	Class II	Lot #: 500326, Exp. 6/30/2018	Labeling Error: Label mix-up. Products' unit dose cups are correctly labeled, but the product carton lists incorrect volume and NDC	Precision Dose Inc. 722 Progressive Ln South Beloit, IL 61080-2616
Drugs	Testosterone Cypionate + Progesterone, 200 mg/ 2.5 mg/mL ,10 mL amber glass vials, Rx Only, Compounded by AXIA Pharmaceutical, Los Angeles, CA 90025	Class II	Lot # 03022017+44906; BUD 08/29/17	CGMP Deviations	Fusion IV Pharmaceuticals, Inc. dba Axia 1990 Westwood Blvd Ste 135 Los Angeles, CA 90025-4650
Drugs	Magnesium Citrate Oral Solution, packaged in a 10 fl. oz. (296 mL) glass bottle, OTC, labeled as: a) GoodSense Magnesium Citrate Oral Solution Saline Laxative Very Low Sodium, UPC# 846036007381, NDC 50804-686-38, Distributed by: Geiss, Desitin &Dunn, Inc., Peachtree City, GA 30269; b) Premier Value Magnesium Citrate Oral Solution salinelaxative very low sodium, UPC# 840986010255, NDC 68016-826-38, Distributed by: Chain Drug Consortium, Boca Raton, FL 33431; c) Swan Very Low Sodium Citroma Magnesium Citrate, UPC# 308690686383, NDC 0869-686-38, Distributed by: Vi-Jon, Smyrna, TN, 37167 ; d) ShopRite Magnesium Citrate Oral Solution Saline Laxative Low Sodium, UPC# 041190211487, NDC 41190-686-38, Distributed by: Wakefern Food Corporation,	Class II	Lot#: a) 0341906, Exp 12/2018; b) 0341906 Exp 12/2018; c) 0341906, Exp 12/2018; 0343709, Exp 1/2019 d) 0343709 Exp 1/2019	Microbial contamination of non-sterile products: product was found to contain mold, identified as Rhinocladiella similis	Vi-Jon, Inc. 1 Swan Dr Smyma, TN 37167-2099

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
	Jamesburg, NJ 08831				
Drugs	Cyclobenzaprine HCl Tablets, USP, 5 mg, 50 Tablets (5x10) Unit Dose Cartons, Rx Only, Manufactured for: AvKARE Inc, Pulaski, TN 38478 --- NDC: 50268-0190-15	Class II	Lot: 16710, exp 07/2018	Labeling; Label Mix up; cartons labeled as Amantadine HCl 100 mg Capsules contain unit dose blister cards of Cyclobenzaprine HCl Tablet, USP 5 mg	Apace KY LLC 12954 Fountain Run Rd Fountain Run, KY 42133-7914
Drugs	Alka-Seltzer Extra Strength (500 mg Aspirin (NSAID), 1985 mg Analgesic Sodium bicarbonate/Antacid, 1000 mg Anhydrous Citric Acid) Effervescent Tablets, 24-count carton, Made in Germany, Distributed by Bayer HealthCare, LLC Whippany, NJ 07981, UPC 016500044048	Class II	BTAHDG0; Exp. 04/19	Defective Container: Confirmed customer compliant of small holes or cracks in the foil of blister packs.	Bayer HealthCare Pharmaceuticals, Inc. 36 Columbia Rd Morristown, NJ 07960-4526
Drugs	Famotidine Tablets USP, 20 mg, 100 count bottles, Rx only, Manufactured For: TEVA PHARMACEUTICALS USA, Sellersville, PA --- NDC 0172-5728-60	Class II	Lot # 3429066, exp 06/2018	Failed Tablet/Capsule Specification; out of specification for tablet weight	Teva Pharmaceuticals USA 1090 Horsham Rd North Wales, PA 19454-1505
Drugs	Famotidine USP 20 mg, 30 tablets bottle, Rx, PKG By; PD Rx Pharmaceuticals Incorporated Oklahoma City, OK 73127 --- NDC 55289-765-30	Class II	Lot: A17F55 Exp. 06/30/2018	Failed Tablet/Capsule Specification: out of specification for tablet weight.	PD-Rx Pharmaceuticals, Inc. 727 N Ann Arbor Ave Oklahoma City, OK 73127-5822
Drugs	Divalproex Sodium Delayed Release Tablets, USP, 250 mg 100-count bottle (NDC 68382-032-01), b.) 500-count bottle (NDC 68382-032-05),Rx only, Manufactured by Cadila Healthcare Ltd, Ahmedabad, India, Distributed by: Zydus Pharmaceuticals, Pennington, NJ 07054	Class II	MR5990 May-17 MR5991 May-17 MR7294 Jun-17 MR7295 Jun-17 MR7296 Jun-17 MR7297 Jun-17 MR7298 Jun-17 MR7603 Jun-17 MR7604 Jun-17 MR7605 Jun-17 MR7606 Jul-17 MR7607 Jul-17 MR8575 Aug-17 MR8576 Aug-17 MR8577 Aug-17 MR8882 Aug-17 MR8883 Aug-17 MR8884 Aug-17 MR8885 Aug-17 MR8886 Aug-17 MR9417 Aug-17 MR9418 Aug-17 MR9419 Aug-17 MR9499 Aug-17 MR9500 Aug-17 MR9501 Sep-17 MR9502 Sep-17 MR9601 Sep-17 MR9602 Sep-17 MR9805 Sep-17 MR9806 Sep-17 MR9	Failed Dissolution Specifications	Zydus Pharmaceuticals USA Inc 73 Route 31 N Pennington, NJ 08534-3601

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
			807 Sep-17 MR9808 Sep-17 MR10536 Oct-17 MR10537 Oct-17 MR10538 Oct-17 MR10539 Oct-17 MR10540 Oct-17 MR10916 Oct-17 MR10918 Oct-17 MR10919 Nov-17 MR10920 Nov-17 MR10921 Nov-17 MR11366 Nov-17 MR11367 Nov-17 MR11368 Nov-17 MR11369 Nov-17 MR11370 Nov-17 MR11671 Nov-17 MR11672 Nov-17 MR11682 Nov-17 MR11682 Nov-17 MS1360 Dec-17 MS1361 Dec-17 MS1362 Dec-17 MS1363 Dec-17 MS1364 Dec-17 M600386 Feb-18 M600387 Feb-18 M600388 Feb-18 M602270 Mar-18 M602272 Apr-18		
Drugs	Divalproex Sodium Delayed Release Tablets, USP, 500 mg, a.) 100-count bottle (NDC 68382-033-01) b.) 500-count bottle (NDC 68382-033-05), Rx only, manufactured by Cadila Healthcare Ltd, Ahmedabad, India, Distributed by: Zydus Pharmaceuticals, Pennington, NJ 07054	Class II	M603084 May-18 M603085 May-18 M603679 May-18 MR10030 Sep-17 MR10040 Sep-17 MR10103 Sep-17 MR10104 Sep-17 MR10259 Sep-17 MR10262 Sep-17 MR10263 Sep-17 MR10413 Sep-17 MR10415 Sep-17 MR10416 Oct-17 MR10695 Oct-17 MR10696 Oct-17 MR10697 Oct-17 MR10698 Oct-17 MR10699 Oct-17 MR10927 Oct-17 MR10929 Oct-17 MR10930 Nov-17 MR11182 Nov-17 MR11184 Nov-17 MR11187 Oct-17 MR11188 Oct-17 MR11189 Nov-17 MR11190 Nov-17 MR11361 Nov-17 MR11362 Nov-17 MR11363 Nov-17 MR11364 Nov-17 MR11365 Nov-17 MR11673 Nov-17 MR11674 Nov-17 MR11675 Nov-17 MR11676 Nov-17 MR11677 Nov-17 MR11872 Nov-17 MR11873 Nov-17 MR11874 Nov-17 MR11875 Nov-17 MR11876 Nov-17 MR11877 Nov-17 MR11878 Nov-17 MR5992 May-17 MR6188 May-17 MR6189 May-17 MR6313 May-17 MR6314 Jun-17 MR6315 Jun-17 MR6316 Jun-17 MR6620 Jun-17 MR6621 Jun-17 MR6622 Jun-17 MR7031 Jun-17 MR7032 Jun-17 MR7033 Jun-17 MR7034 Jun-17 MR7035 Jun-17 MR7299 Jun-17 MR7300 Jun-17 MR7301 Jun-17 MR	Failed Dissolution Specifications	Zydus Pharmaceuticals USA Inc 73 Route 31 N Pennington, NJ 08534-3601

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
			7303 Jun-17 MR7767 Jul-17 MR8223 Jul-17 MR8224 Jul -17 MR8225 Jul-17 MR8248 Jul-17 MR8249 Jul-17 MR8 578 Aug-17 MR8579 Aug-1 7 MR8580 Aug-17 MR8581 Aug-17 MR8888 Aug-17 M R8889 Aug-17 MR8890 Aug -17 MR8891 Aug-17 MR889 4 Aug-17 MR9012 Aug-17 MR9013 Sep-17 MR9015 S ep-17 MR9016 Sep-17 MR9 414 Aug-17 MR9415 Aug-1 7 MR9416 Sep-17 MS1246 Dec-17 MS1247 Dec-17 MS 1248 Dec-17 MS1249 Dec-1 7 MS1250 Dec-17 MS1251 Dec-17 MS1252 Dec-17 MS 1355 Dec-17 MS1356 Dec-1 7 MS1357 Jan-18 MS1358 Dec-17 MS2490 Feb-18 MS 2491 Feb-18 MS2492 Feb-1 8		
Drugs	Alka-Seltzer Gold (1000 mg Anhydrous citric acid, 344 mg Antacid Potassium bicarbonate, 1050 mg Antacid Sodium bicarbonate/Antacid) Effervescent Tablets, 36-count carton, Made in Germany, Distributed by Bayer HealthCare, LLC Whippany, NJ 07981, UPC 016500041085	Class II	BTAHGR0; Exp. 05/19 BTAH GR1; Exp. 05/19 BTAHGR2; Exp. 05/19 BTAJ0K3; Exp. 0 7/19	Defective Container: Confirmed customer compliant of small holes or cracks in the foil of blister packs.	Bayer HealthCare Pharmaceuticals, Inc. 36 Columbia Rd Morristown, NJ 07960-4526
Drugs	Oxygen Refrigerated Liquid USP UN 1073, Rx only, At Home Medical 200 American Road, Morris Plains, NJ 07950,973-538-0485.	Class II	B-06324027 (AHM #E04064 5) Lot #: 051017V1, Exp. Da te: 5/11/17	GMP Deviations: The firm does not include an SOP for testing for out of specifications	AtHome Medical, Inc. 200 The American Rd Morris Plains, NJ 07950-2449
Drugs	Ephedrine Sulfate in 0.9% Sodium Chloride 10 mL, 50 mg/10 mL (5 mg/mL) Single-Dose Syringe, Rx Only, Cantrell Drug Company 7321 Cantrell Rd Little Rock, AR 72207 877-666-5222, NDC 52533-019-12	Class II	Lot #: 9906, 9915 BUD: 7/2 8/2017; 9950, 9984, 10001, 10010, BUD: 8/4/2017; 100 64, BUD: 8/17/2017; 10341 , 10452 BUD: 9/23/2017,	Lack of Sterility Assurance	Cantrell Drug Company 7321 Cantrell Rd Little Rock, AR 72207-4144
Drugs	Nystatin Topical Powder, USP, 100,000 USP units per gram, 15 grams per bottle, Rx only, Vensun, NDC 42543-052-61	Class II	Lot #: 23701.158A, EXP 10/ 31/18	Presence of Foreign Substance: potential presence of plastic particles.	X-Gen Pharmaceuticals Inc. 300 Daniel Zenker Dr Horseheads, NY

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
					14845-1014
Drugs	Hydromorphone Hydrochloride Injection, USP, 500 mg/50 mL (10 mg/mL), 50 mL Single Dose Vial. Mfd For: Teva Parenteral Medicines, Inc., Irvine, CA 92618 USA. NDC: 0703-0018-01	Class II	Lot #: 560053F, Exp. 01AUG2017	Presence of Particulate Matter: Silicone oil	Hospira Inc, Lake Forest 275 North Forest Drive Lake Forest, IL 60045
Drugs	Ephedrine Sulfate in 0.9% Sodium Chloride 5 mL, 25 mg/5 mL (5 mg/mL) Single-Dose Syringe, Rx Only, Cantrell Drug Company 7321 Cantrell Rd Little Rock, AR 72207 877-666-5222, NDC 52533-019-15	Class II	Lot #: 9910, 9928, BUD: 7/28/2017; 9962, 9993, BUD: 8/4/2017; 10333, 10481, 10538, BUD: 9/23/2017	Lack of Sterility Assurance	Cantrell Drug Company 7321 Cantrell Rd Little Rock, AR 72207-4144
Drugs	Ephedrine Sulfate Injection Solution 1 mL, 50 mg/1 mL (50 mg/mL) Single-Dose Syringe, Rx Only, Cantrell Drug Company 7321 Cantrell Rd Little Rock, AR 72207 877-666-5222, NDC 52533-258-45		Lot #: 10099, BUD: 7/27/2017; 10127, BUD: 8/1/2017; 10208, BUD: 8/10/2017; 10254, BUD: 8/15/2017; 10278, BUD: 8/17/2017; 10303, BUD: 8/21/2017; 10371, BUD: 9/3/2017; 10457, BUD: 9/17/2017	Lack of Sterility Assurance.	Cantrell Drug Company 7321 Cantrell Rd Little Rock, AR 72207-4144
Drugs	Ephedrine Sulfate in 0.9% Sodium Chloride 5 mL, 50 mg/5 mL (10 mg/mL) Single-Dose Syringe, Rx Only, Cantrell Drug Company 7321 Cantrell Rd Little Rock, AR 72207 877-666-5222, NDC 52533-118-15		Lot #: 9904, 9914, 9939, BUD: 7/28/2017; 9952, 9969, 10004, BUD: 8/4/2017; 10043, 10088, 10115, BUD: 8/17/2017; 10269, BUD: 9/8/2017;10431, BUD: 9/23/2017; 10554, BUD: 10/27/2017	Lack of Sterility Assurance	Cantrell Drug Company 7321 Cantrell Rd Little Rock, AR 72207-4144
Drugs	Glycopyrrolate Injection Solution, 5 mL 1 mg/5 mL (0.2 mg/mL) Single-Dose Syringe, Rx Only, Cantrell Drug Company 7321 Cantrell Rd Little Rock, AR 72207 877-666-5222; NDC 52533-028-15	Class II	Lot #: 9783, BUD: 7/27/2017; 9801, BUD: 7/29/2017; 9807, BUD: 7/30/2017; 9847, BUD: 8/4/2017; 9954, BUD: 8/20/2017; 10022, BUD: 9/1/2017; 10052, BUD: 9/6/2017; 10063, BUD: 9/7/2017; 10086, BUD: 9/9/2017; 10108, BUD: 9/13/2017; 10156, BUD: 9/20/2017; 10180, BUD: 9/22/2017; 10245, BUD: 9/29/2017; 10264, BUD: 9/30/2017; 10322, BUD: 10/8/2017; 10339, BUD: 10/13/2017;10368, BUD: 10/18/2017; 10406, BUD: 10/25/2017; 10419, BUD: 10/26/2017; 10435, BUD: 10/28/2017; 10455, BUD: 11/1/2017; 10489, BUD: 11/5/20	Lack of Sterility Assurance	Cantrell Drug Company 7321 Cantrell Rd Little Rock, AR 72207-4144

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
			17; 10497, BUD: 11/6/2017 ; 10516, BUD: 11/9/2017; 1 0527, BUD: 11/10/2017; 10 577, BUD: 11/19/2017		
Drugs	Glycopyrrolate Injection Solution, 2 mL 0.4 mg/2 mL (0.2 mg/mL) Single-Dose Syringe, Rx Only, Cantrell Drug Company 7321 Cantrell Rd Little Rock, AR 72207 877-666-5222; NDC 52533-028-16	Class II	Lot #: 9781, BUD: 7/26/201 7; 9784, BUD: 7/27/2017; 9 822, BUD: 8/2/2017; 9852, BUD: 8/5/2017; 10061, BU D: 9/7/2017; 10105, BUD: 9 /13/2017; 10150, BUD: 9/1 7/2017; 10178, BUD: 9/22/ 2017; 10185, BUD: 9/23/20 17; 10501, BUD: 11/8/2017	Lack of Sterility Assurance	Cantrell Drug Company 7321 Cantrell Rd Little Rock, AR 72207-4144
Drugs	Glycopyrrolate Injection Solution, 1 mL 0.2 mg/1 mL (0.2 mg/mL) Single-Dose Syringe, Rx Only, Cantrell Drug Company 7321 Cantrell Rd Little Rock, AR 72207 877-666-5222; NDC 52533-028-45	Class II	Lot #: 9868, BUD: 8/9/2017 ; 9872, BUD: 8/10/2017; 10 318, BUD: 10/7/2017	Lack of Sterility Assurance	Cantrell Drug Company 7321 Cantrell Rd Little Rock, AR 72207-4144
Drugs	Succinylcholine Chloride Injection Solution 10 mL, 200 mg/10 mL (20 mg/mL) Single-Dose Syringe, Rx Only, Cantrell Drug Company 7321 Cantrell Rd. Little Rock, AR 72207 877-666-5222, NDC 52533-067-12	Class II	Lot #: 10078, BUD: 7/24/20 17; 10111, BUD: 7/27/2017 ; 10125, BUD: 7/31/2017; 1 0143, BUD: 8/2/2017; 1016 6, BUD: 8/6/2017; 10191, B UD: 8/2/2017; 10195, BUD: 7/31/2017; 10221, BUD: 8/ 13/2017; 10297, BUD: 8/20 /2017; 10376, BUD: 9/3/20 17; 10398, BUD: 9/6/2017; 10432, BUD: 9/12/2017; 10 447,10472, BUD: 9/14/201 7; 10547, BUD: 9/27/2017; 10571, BUD: 10/3/2017	Lack of Sterility Assurance	Cantrell Drug Company 7321 Cantrell Rd Little Rock, AR 72207-4144
Drugs	Succinylcholine Chloride Injection Solution 5 mL, 100 mg/5 mL (20 mg/mL) Single-Dose Syringe, Rx Only, Cantrell Drug Company 7321 Cantrell Rd. Little Rock, AR 72207 877-666-5222, NDC 52533-067-15	Class II	Lot #: 10076, BUD: 7/24/20 17; 10106, BUD: 7/27/2017 ; 10145, BUD: 8/2/2017; 10 220, BUD: 8/13/2017; 1029 8, BUD: 8/20/2017; 10400, BUD: 9/6/2017; 10446, BU D: 9/14/2017; 10548, BUD: 9/27/2017	Lack of Sterility Assurance	Cantrell Drug Company 7321 Cantrell Rd Little Rock, AR 72207-4144
Drugs	Norepinephrine Bitartrate 8 mg Added to 0.9% Sodium Chloride 250 mL (32 mcg per mL) Single-Dose Bag, Rx Only, Cantrell Drug Company 7321 Cantrell Rd. Little Rock, AR 72207 877-666-5222, NDC	Class II	Lot #: 10095, BUD: 7/27/20 17; 10119, BUD: 7/31/2017 ; 10135, BUD: 8/2/2017; 10 162, BUD: 8/6/2017; 10168 , BUD: 8/7/2017; 10186, B UD: 8/9/2017; 10247, BUD: 8/15/2017; 10301, BUD: 8/	Lack of Sterility Assurance	Cantrell Drug Company 7321 Cantrell Rd Little Rock, AR 72207-4144

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
	52533-217-18		21/2017; 10325, BUD: 8/24 /2017; 10390, BUD: 9/5/20 17; 10465, BUD: 9/18/2017 ; 10487, BUD: 9/20/2017; 1 0542, BUD: 9/27/2017		
Drugs	Norepinephrine Bitartrate 4 mg Added to 0.9% Sodium Chloride 250 mL (16 mcg per mL) Single-Dose Bag, Rx Only, Cantrell Drug Company 7321 Cantrell Rd. Little Rock, AR 72207 877-666-5222, NDC 52533-134-18	Class II	Lot #: 10069, BUD: 7/24/20 17; 10090, BUD: 7/26/2017 ; 10121, BUD: 7/31/2017; 1 0142, BUD: 8/3/2017; 1018 3, BUD: 8/8/2017; 10360, B UD: 8/31/2017; 10443, BU D: 9/14/2017	Lack of Sterility Assurance	Cantrell Drug Company 7321 Cantrell Rd Little Rock, AR 72207-4144
Drugs	Norepinephrine Bitartrate 16 mg Added to 0.9% Sodium Chloride 250 mL (64 mcg per mL) Single-Dose Bag, Rx Only, Cantrell Drug Company 7321 Cantrell Rd. Little Rock, AR 72207 877-666-5222, NDC 52533-288-18	Class II	Lot 3:: 10374, BUD: 8/4/20 17; 10429, BUD: 8/13/2017 ; 10532, BUD: 8/27/2017	Lack of Sterility Assurance	Cantrell Drug Company 7321 Cantrell Rd Little Rock, AR 72207-4144
Drugs	Diltiazem HCl 125 mg in 5% Dextrose 125 mL Single-Dose- Bag, Rx Only, Cantrell Drug Company 7321 Cantrell Rd. Little Rock, AR 72207 877-666-5222; NDC 52533-103-13	Class II	Lot #: 10084, BUD: 7/25/20 17; 10137, BUD: 8/2/2017; 10252, BUD: 8/15/2017; 10 271, BUD: 8/17/2017; 1035 0, BUD: 8/30/2017; 10491, BUD: 9/21/2017	Lack of Sterility Assurance	Cantrell Drug Company 7321 Cantrell Rd Little Rock, AR 72207-4144
Drugs	Phenylephrine HCL in 0.9% Sodium Chloride 10 mL, 1 mg/10 mL (100 mcg/mL) Single-Dose Syringe, Rx Only, Cantrell Drug Company 7321 Cantrell Rd. Little Rock, AR 72207 877-666-5222, NDC 52533-171-12	Class II	Lot #: 9556, BUD: 7/26/201 7; 9566, BUD: 7/30/2017; 9 584, BUD; 8/1/2017; 9613, BUD: 8/6/2017; 9656, BUD: 8/14/2017; 9798, BUD: 9/1 1/2017; 9812, BUD: 8/31/2 017; 9819, BUD: 9/16/2017 ; 9836, BUD: 9/17/2017; 99 44, BUD: 10/3/2017; 10158 , 10493, 10565, BUD: 10/30 /2017	Lack of Sterility Assurance	Cantrell Drug Company 7321 Cantrell Rd Little Rock, AR 72207-4144
Drugs	Sodium Bicarbonate 8.4% Injection Solution 50 mL, 50 mEq (1mEq/mL) Single-Dose Syringe, Rx Only, Cantrell Drug Company 7321 Cantrell Rd. Little Rock, AR 72207 877-666-5222	Class II	Lot#: 10349, BUD: 7/30/20 17; 10356, BUD: 7/31/2017 ; 10377, BUD: 8/4/2017; 10 386, BUD: 8/5/2017; 10394 , BUD: 8/6/2017; 10404, B UD: 8/8/2017; 10423 BUD: 8/12/2017; 10468, BUD: 8/ 18/2017; 10473, BUD: 8/19 /2017; 10482, BUD: 8/20/2 017; 10514, BUD: 8/25/201 7; 10524, BUD: 8/26/2017;	Lack of Sterility Assurance	Cantrell Drug Company 7321 Cantrell Rd Little Rock, AR 72207-4144

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
			10569, BUD: 9/3/2017		
Drugs	Adenosine in 0.9% Sodium Chloride 30mL, 90 mg/30 mL (3 mg/mL) Single-Dose Syringe, Rx Only, Cantrell Drug Company 7321 Cantrell Rd. Little Rock, AR 72207 877-666-5222; NDC 52533-236-03	Class II	Lot #: 9814, 9831 BUD: 9/12/2017; 10059, BUD: 10/18/2017	Lack of Sterility Assurance	Cantrell Drug Company 7321 Cantrell Rd Little Rock, AR 72207-4144
Drugs	Neostigmine Methylsulfate Injection Solution 5 mL, 5 mg/5 mL (1 mg/mL) Single-Dose Syringe, Rx Only, Cantrell Drug Company 7321 Cantrell Rd. Little Rock, AR 72207 877-666-5222, NDC 52533-046-15	Class II	Lot #: 10081, BUD: 7/25/2017; 10096, BUD: 7/27/2017; 10112, BUD: 7/30/2017; 10117, BUD: 7/31/2017; 10152, BUD: 8/3/2017; 10159, BUD: 8/6/2017; 10170, BUD: 8/7/2017; 10174, BUD: 8/8/2017; 10193, BUD: 8/9/2017; 10202, BUD: 8/10/2017; 10212, BUD: 8/13/2017; 10242, BUD: 8/15/2017; 10276, BUD: 8/17/2017; 10294, BUD: 8/20/2017; 10320, BUD: 8/23/2017; 10328, BUD: 8/24/2017;10334, BUD: 8/28/2017; 10342, BUD: 8/29/2017; 10364, BUD: 9/3/2017; 10392, BUD: 9/6/2017; 10420, BUD: 9/11/2017; 10427, BUD: 9/12/2017; 10440, BUD: 9/14/2017; 10463, BUD: 9/18/2017; 10495, BUD: 9/22/2017; 10499, BUD: 9/24/2017; 10512, BUD: 9/25/2017; 10556, BUD: 10/1/2017; 10567, BUD: 10/3/2017; 10583, BUD: 10/6/2017	Lack of Sterility Assurance	Cantrell Drug Company 7321 Cantrell Rd Little Rock, AR 72207-4144
Drugs	Rocuronium Bromide Injection Solution 5 mL, 50 mg/5 mL (10 mg/mL) Single-Dose Syringe, Rx Only, Cantrell Drug Company 7321 Cantrell Rd. Little Rock, AR 72207 877-666-5222, NDC 52533-064-15	Class II	Lot #: 9598, BUD: 8/2/2017; 9609, BUD: 8/5/2017; 9621, BUD: 8/7/2017; 9681, BUD: 8/19/2017; 9765, BUD: 9/5/2017; 10102, BUD: 10/24/2017; 10347, BUD: 11/26/2017; 10357, BUD: 11/26/2017; 10387, BUD: 12/3/2017; 10478, 10505, 10585, BUD: 12/16/2017	Lack of Sterility Assurance	Cantrell Drug Company 7321 Cantrell Rd Little Rock, AR 72207-4144
Drugs	Hydromorphone Hydrochloride Injection, USP, 500 mg/50 mL (10 mg/mL), 50 mL Single Dose Vial per Carton, 100 vials per case. Hospira, Inc., Lake Forest, IL 60045 USA,	Class II	Lot #: 56260DD, Exp. 01AUG2017	Presence of Particulate Matter: Silicone oil	Hospira Inc, Lake Forest 275 North Forest Drive Lake Forest, IL

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
	NDC: 0409-2634-50				60045
Drugs	Hydromorphone Hydrochloride Injection, USP, 50 mg/5 mL (10 mg/mL), 5 mL Single Dose Vial.(10 vials per carton NDC 0703-0113-01) and 180 vials per case (NDC 0703-0113-03) Mfd By: Hospira, Inc., Lake Forest, IL 60045 USA, Mfd For: Teva Parenteral Medicines, Inc., Irvine, CA 92618 USA.	Class II	Lot #: 560103F, Exp. 01AUG2017	Presence of Particulate Matter: Silicone oil	Hospira Inc, Lake Forest 275 North Forest Drive Lake Forest, IL 60045
Drugs	Paroxetine Extended-Release Tablets USP, 12.5 mg, 30 count bottle, Rx only, Manufactured for: Lupin Pharmaceuticals, Inc. Baltimore, Maryland, 21202, Manufactured by: Lupin Limited, Pithampur (M.P.) 454 775, India, NDC: 68180-647-06	Class III	Lots: H605712, H605711, H605710, EXP November 2018; H702255, H702202 EXP March 2019	Failed Dissolution Specifications: out of specification observed in dissolution testing at 3 month long term stability study..	Lupin Pharmaceuticals Inc. 111 S Calvert St Fl 21st Baltimore, MD 21202-6174
Drugs	Mefenamic Acid, 250mg capsules, packaged in 30-count bottles, Rx Only, Distributed by: Prasco Laboratories Mason, OH 45040 USA, Manufactured by: Halo Pharmaceutical Inc. Whippany, NJ 07981, NDC 66993-070-30	Class III	Lot #: 5H66200103G, Exp. June 2018; 7H66200103G, Exp. Dec 2019	Labeling: Not Elsewhere Classified: Incorrect volume printed on the product label.	Shionogi Inc. 5770 Shiloh Rd Alpharetta, GA 30005-8408
Drugs	Obagi-C Rx System C-Therapy Night Cream, Net wt. 2 oz. (57g) bottle, Rx only, Distributed by OMP, Inc., Long Beach, CA Made in USA, NDC 62032-222-02	Class III	Lot #: 2578400, 0Exp 8/2019	Labeling: Incorrect or Missing Package Insert - Obagi-C Rx System C-Therapy Night Cream is being recalled due to incomplete packaging/labeling. The bottle is missing the product insert and outer carton which contain the complete instruction for use and safety information..	Valeant Pharmaceuticals North America LLC 400 Somerset Corporate Blvd Bridgewater, NJ 08807-2867
Drugs	PONSTEL (Mefanamic Acid) USP, 250 mg capsules, 30-count bottles, Rx Only, Manufactured for: Shionogi Inc. Florham Park, NJ 07932 Manufactured by: Halo Pharmaceutical Inc. Whippany, NJ 07981	Class III	Lot #: 5H66200103, Exp. June 2018	Failed Dissolution Specifications: Low dissolution results were obtained during stability testing.	Shionogi Inc. 5770 Shiloh Rd Alpharetta, GA 30005-8408

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drugs	Argatroban Injection, 250 mg/2.5 mL (100 mg/mL), 5 mL Single-use vial, Rx Only, Sterile, Manufactured by: Gland Pharma Limited, Hyderabad, India, Manufactured for: Hospira, Inc, Lake Forest, IL 60045 --- NDC 0409-1140-01	Class III	Lot: DP601, exp 10/2018	Failed Impurities/Degradation Specifications; out of specification result for denitroquinoline-related impurity during three month time point.	Hospita Inc., A Pfizer Company 275 N Field Dr Lake Forest, IL 60045-2579
Drugs	Buprenorphine and Naloxone Sublingual Tablets, 2 mg/0.5 mg 30 tablets per bottle, Rx only, Distributed by: Teva Pharmaceuticals USA, Inc., North Wales, PA 19454, NDC 0093-5720-56	Class III	Lot #: 30227613A, 30227614A, 30227615A, EXP 6/2017; 30228559A, 30228560A, EXP 9/2017; 3000123, EXP 7/2018	Failed Impurities/Degradation Specifications: out of specification test results for related compounds largest unknown impurity.	Teva Pharmaceuticals USA 1090 Horsham Rd North Wales, PA 19454-1505
Drugs	Pravastatin Sodium Tablets, USP, 10 mg, packaged in a) 90-count bottles (NDC 55111-229-90) and b) 500-count bottles (NDC 55111-229-05), Rx only, Manufactured by: Dr. Reddy's Laboratories Limited, Bachupally - 500 090 INDIA; Distributed by: Dr. Reddy's Laboratories Inc., Princeton, NJ 08540 USA.	Class III	Lot #: a) C700220, Exp 06/18; b) C700220, Exp 06/18	Failed Impurities/Degradation Specifications: high out of specification results for related impurity for lot C700220.	Dr. Reddy's Laboratories, Inc. 107 College Rd E Princeton, NJ 08540-6623
Drugs	Albuterol Sulfate Inhalation Solution, 0.021% (0.63 mg/3mL), packaged in 5 pouches of 5 x 3mL Sterile Unit-Dose Vials For Inhalation per carton, Rx only, Mfd. for: Watson Laboratories, Inc., Corona, CA 92880; Mfd. by: Cipla Ltd., Verna, Goa INDIA, NDC 0591-3467-53.	Class III	Lot #s: GA60206, GA60207, Exp 08/17; GA60283, GA60284, Exp 09/17; GA60378, GA60379, GA60478, Exp 10/17; GA60491, Exp 11/17; GA60615, GA60616, Exp 12/17; GA60719, GA60720, GA60721, GA60749, GA60750, GA60751, Exp 01/18; GA70001, GA70031, GA70046, GA70047, GA70074, GA70075, Exp 06/18	Failed Impurities/Degradation Specifications: high out of specification results for related compound D.	Teva Pharmaceuticals USA 1090 Horsham Rd North Wales, PA 19454-1505
Drugs	Glipizide Extended-Release Tablets (anti-diabetic agent), 5 mg, packaged in 30-unit dose blister pack per carton, Rx only, Mfd for: Watson Laboratories, Inc., Corona, CA 92880, Mfd by: Patheon Pharmaceuticals, Inc., Cincinnati, OH 43215, NDC 0591-0844-15	Class III	Lot # 3138405A, Exp 8/2017	Failed Moisture Limits: out of specification test results for water content obtained during stability testing	Teva Pharmaceuticals USA 1090 Horsham Rd North Wales, PA 19454-1505

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

CURRENT DRUG SHORTAGES

Leuprolide Acetate 14-Day Kit

July 18, 2017

Reason for the Shortage

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

Estimated Resupply Dates

- Teva has leuprolide acetate injection on 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=737

Indigo Carmine Injection

July 18, 2017

Reason for the Shortage

- American Regent launched indo 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

Tetanus and Diphtheria Toxoids Adsorbed

July 21, 2017

Reason for the Shortage

- Grifols has tetanus and diphtheria toxoids adsorbed (Td) available.
- Sanofi Pasteur has Tenivac on shortage due to manufacturing delays.
- Adult tetanus toxoid, reduced diphtheria toxoid and acellular pertussis (Tdap) vaccines are not affected by this shortage.
- Pediatric diphtheria and tetanus toxoids adsorbed (DT) and diphtheria and tetanus toxoids and acellular pertussis vaccines (DTaP) are not affected by this shortage.

Estimated Resupply Dates

- Sanofi Pasteur has Tenivac on back order and the company estimates a release date in the second half of 2017.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1260

Lidocaine Topical 4% Solution

July 21, 2017

Reason for the Shortage

- Amphastar has Laryng-O-Jet syringes available.
- Teligent did not provide a reason for the shortage.
- West-Ward has lidocaine 4% topical solution available.

Estimated Resupply Dates

- Teligent has lidocaine topical 4% solution in 50 mL bottles on allocation.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1128

Hepatitis B Vaccine Recombinant

July 21, 2017

Reason for the Shortage

- Merck did not provide a reason for the shortage.

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

70% Dextrose Injection Large Volume Bags

July 21, 2017

Reason for the Shortage

- Baxter has 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 are 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 on intermittent back order with regular releases.
- 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

Sodium Phosphate Injection

July 25, 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 was 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.
- Pfizer has sodium phosphate 3 mmol/mL 15 mL vials on back order and the compay estimates a release date of August 2017.

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

Diazepam Injection

July 25, 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 September 2017.

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

Dexpanthenol Injection

July 25, 2017

Reason for the Shortage

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

Estimated Resupply Dates

- American Regent has dexpanthenol injection on long-term back order and the company cannot estimate a release date.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1103

Atropine Sulfate Injection

July 25, 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 0.05 mg/mL 5 mL Ansyr syringes on allocation. The 0.1 mg/mL 10 mL Ansyr syringes are on allocation. 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 late-August 2017.

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

Sincalide Injection

July 28, 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

Mupirocin Calcium 2% Nasal Ointment

July 28, 2017

Reason for the Shortage

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

Estimated Resupply Dates

- GlaxoSmithKline has Bactroban Nasal 2% Ointment in 1 gram tubes on long-term back order and the company cannot estimate a release date.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1094

Mupirocin Calcium 2% Cream

July 28, 2017

Reason for the Shortage

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

Estimated Resupply Dates

- GlaxoSmithKline has Bactroban 2% cream in 15 gram and 30 gram sizes on long-term back order and the company cannot estimate a release date.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1206

Ketorolac Tromethamine Injectio

July 28, 2017

Reason for the Shortage

- BD RX is now part of Fresenius Kabi.
- Fresenius Kabi has ketorolac injection available.
- 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

- 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 and 30 mg/mL 1 mL iSecure syringes on back order and the company estimates a release date of October 2017. The 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

5% Dextrose Injection (PVC-free and DEHP-free)

July 28, 2017

Reason for the Shortage

- ICU Medical states the shortage is due to increased demand and manufacturing delays. ICU Medical discontinued the 500 mL VisIV bags in 2011 due to leaking around the administration and medications ports.
- ICU Medical is now the IV fluid business of Pfizer after the acquisition of Hospira.
- Baxter did not provide a reason for the shortage.
- BBraun has 250 mL, 500 mL, and 1,000 mL PVC/DEHP-free bags on allocation. The company is not adding any new allocations at this time.

Estimated Resupply Dates

- BBraun has 5% dextrose 250 mL, 500 mL, and 1,000 mL PVC/DEHP-free bags on allocation.
- Baxter has 5% dextrose 250 mL and 500 mL PVC/DEHP-free bags on back order and the company cannot estimate a release date.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1269

5% Dextrose Injection

July 28, 2017

Reason for the Shortage

- ICU Medical states the shortage was due to increased demand and manufacturing delays.
- Baxter currently has product available.
- 5% dextrose 1,000-mL bags are not affected at this time.

Estimated Resupply Dates

- Baxter has 5% dextrose 250 mL and 500 mL bags available in limited supply.

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

Pantoprazole Injection

July 30, 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 25 count packs on back order and the company estimates a release date of August 2017. The 10 packs are 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

Tobramycin Injection

July 31, 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.
- Mylan Institutional has tobramycin 40 mg/mL 2 mL vials on back order and the company estimates a release date of early-August 2017.
- Pfizer has tobramycin 40 mg/mL 2 mL vials on back order and the company estimates a release of early-August 2017.
- X-Gen has tobramycin 1.2 gram preservative-free powder 50 mL vials in 1 count and 6 count on back order and the company estimates a release date of mid-September 2017 for the 1 count and early-August 2017 for the 6 count.

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

Metoclopramide Injection

July 31, 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

- Pfizer has metoclopramide 5 mg/mL 2 mL vials on back order and the company estimates a release date of late-August 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

Mepivacaine Injection

July 31, 2017

Reason for the Shortage

- Pfizer said the reason for the back order is manufacturing delays.
- Fresenius Kabi did not provide a reason for the back order.

Estimated Resupply Dates

- Pfizer has call Cabocaine presentations on back order. Carbocaine 1% in 50 mL multiple-dose vials are on back order and the company estimates a release date of early-September 2017. Carbocaine 1% 30 mL preservative-fee 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 early August 2017.
- Fresenius Kabi has Polocaine-MPF 1% 30 mL preservative-free vials, 1.5% 30 mL preservative-free vials, and 2% 20 mL preservative-free vials on back order and the company estimates a release date of mid-September 2017 for the 1% 30 mL vials and early-August 2017 for the 1.5% 30 mL vials and 2% 20 mL vials.

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

Levetiracetam Injection

July 31, 2017

Reason for the Shortage

- American Regent has product available.
- AuroMedics did not provide a reason for the shortage.
- Caraco will not provide availability information on levetiracetam.
- Fresenius Kabi had levetiracetam injection on shortage due to manufacturing delays.
- Mylan has product available.
- Pfizer has product available.
- Sagent has levetiracetam injection on shortage due to manufacturing delays.
- UCB has product available.
- West-Ward has product available.
- X-Gen has product available.

Estimated Resupply Dates

- AuroMedics has levetiracetam 100 mg/mL 5 mL vials and 15 mg/mL 100 mL premixed bags on intermittent back order and the company is releasing product as it becomes available.
- Sagent has levetiracetam 100 mg/mL 5 mL vials on back orde and the company estimates a release date of August 2017.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1183

Hydroxyzine Hydrochloride Injection

July 31, 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

Fludarabine Injection

July 31, 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 early-August 2017.

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

Dexmedetomidine Hydrochloride in 0.9% Sodium Chloride Injection

July 31, 2017

Reason for the Shortage

- Pfizer had Precedex premixed bottles on shortage due to manufacturing delays.
- Dexmedetomidine 100 mcg/mL vials are not affected by this shortage.

Estimated Resupply Dates

- Pfizer has Precedex 4mcg/mL 50 mL premixed bottles available in limited supply.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1263

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

July 31, 2017

Reason for the Shortage

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

Estimated Resupply Dates

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

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1259

Potassium Phosphate Injection

August 1, 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 has potassium phosphate injection on shortage due to manufacturing delays.

Estimated Resupply Dates

- Fresenius Kabi has potassium phosphate 3 mmol/mL 15 mL and 50 mL vials on back order and the company estimates a release date of mid-August 2017.
- Pfizer has potassium phosphate 3 mmol/mL 15 mL vials available in limited supply.

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

Hyoscyamine Sulfate Injection

August 1, 2017

Reason for the Shortage

- Mylan did not provide a reason for the shortage.

Estimated Resupply Dates

- Mylan has Levsin 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=1277

Dexamethasone Sodium Phosphate

August 1, 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.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=751

Cisplatin Injection

August 1, 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-August 2017.
- Mylan Institutional has cisplatin 50 mL and 100 mL vials temporarily unavailable and the company cannot estimate a release date.
- Teva has cisplatin 100 mL vials on allocation.

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

Indocyanine Green

August 2, 2017

Reason for the Shortage

- Akorn has IC-Green on shortage due to manufacturing delays.
- Hub has indocyanine green available.

Estimated Resupply Dates

- Akorn has IC-Green 25 mg kits on back order and the company estimates a release date of early-September 2017.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1107

Hydromorphone Hydrochloride Injection

August 2, 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

- Pfizer has hydromorphone 0.5 mg/0.5 mL iSecure syringes on back order and the company estimates a release date of mid-August 2017. The 1 mg/mL iSecure syringes are available in limited supply. The 2 mg/mL 1 mL vials are on back order and the company estimates a release date of early-September 2017. Hydromorphone 2 mg/mL 1 mL ampules are on back order and the company estimates a releases date of late-September 2017. The 1 mg/mL 1 mL Carpuject syringes are on back order and the company estimates a release date of early-September 2017.
- Tevas has hydromorphone 10 mg/mL 1 mL and 5 mL vials on allocation. The 10 mg/mL 50 mL vials are on intermittent back order and are being allocated upon release.

- West-Ward has hydromorphone 2 mg/mL 1 mL vials on allocation.

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

Famotidine Injection

August 2, 2017

Reason for the Shortage

- Ben Venue stopped production in its plant in Bedford, Ohio and closed in July 2014.
- West-Ward stated the shortage was due to manufacturing delays.
- Oral famotidine products are not affected by this shortage.
- Pfizer launched famotidine injections in March 2012.
- Mylan Institutional acquired famotidine injections from Pfizer on December 6, 2013.
- Baxter has famotidine premixed bags available.
- Fresenius Kabi has famotidine vials available.

Estimated Resupply Dates

- Mylan Institutional has famotidine 10 mg/mL 4 mL and 20 mL vials on back order and the company estimates a release date of early-September 2017.
- West-Ward has famotidine 10 mg/mL 2 mL vials on allocation.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=810

Ceftazidime Injection

August 2, 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

- Sagent has ceftazidime 2 gram vials on allocation. The 1 gram vials are on back order and the company estimates a release date of August 2017.
- 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

Olanzapine Injection

August 4, 2017

Reason for the Shortage

- Sandoz did not provide a reason for the shortage of olanzapine intramuscular injection.

Estimated Resupply Dates

- All marketed presentations are available.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1093

Indomethacin Capsules

August 4, 2017

Reason for the Shortage

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

Estimated Resupply Dates

- Glenmark has indomethacin 25 mg capsules in 100 count on back order and the company cannot estimate a release date.
- Heritage has indomethacin 50 mg capsules in 100 count and 500 count on back order and the company cannot estimate a release date. Heritage has short-dated indomethacin 25 mg capsules in 100 count and 1000 count available.
- Mylan has indomethacin 25 mg capsules in 100 count and 50 mg capsules in 100 count on back order and the company estimates a release date of early-September 2017. The 50 mg capsules in 500 count are available with an expiration date of June 2018. The 50 mg capsules in 100 count unit-dose presentations are available with an expiration date of May 2018. The 50 mg capsules in 300 count unit-dose presentations are on back order and the company cannot estimate a release date.
- Teva has all indomethacin presentations temporarily unavailable and the company cannot estimate a release date.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1236

Fluconazole Injection

August 4, 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 August to September 2017.

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

Epinephrine Injection

August 4, 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 mid-August 2017.

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

Dobutamine Injection

August 4, 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 mid-August 2017.
- Pfizer has dobutamine 1 mg/mL in 250 mL bags on back order and the company estimates a release date of mid-August 2017.

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

Cefoxitin Sodium Injection

August 4, 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

- Fresenius Kabi has cefoxitin 1 gram vials and 2 gram vials on back order and the company estimates a release date of early- to mid-August 2017. The 10 gram vials are available with an expiration date of < 8 months.
- Sagent has cefoxitin 10 gram vials on back order and the company estimates a release date of August 2017. The 2 gram vials are on back order and the company cannot estimate a release date. The 1 gram vials are on allocation.
- West-Ward has cefoxitin 10 gram vials on back order and the company cannot estimate a release date. The 2 gram vials are on allocation.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1256

Cefepime Injection

August 4, 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 late-August 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

Atenolol Tablets

August 4, 2017

Reason for the Shortage

- Mylan, Sandoz, and Teva did not provide a reason for the back order.
- Zydus states increased demand as the reason for the back order.
- Ranbaxy refuses to provide us with any information regarding drug availability.

Estimated Resupply Dates

- Major has atenolol 25 mg tablets on back order and the company cannot estimate a release date.
- Mylan has all atenolol in bottles on back order and the company cannot estimate a release date.
- Sandoz has all atenolol tablets temporarily unavailable and the company cannot estimate a release date.
- Teva has all presentations of atenolol 50 mg and 100 mg tablets on back order and the company cannot estimate a release date.
- Zydus has all presentations of atenolol 25 mg, 50 mg, and 100 mg tablets on allocation.
- Almatica has Tenormin 100 mg tablets on back order and the company cannot estimate a release date. The 25 mg and 50 mg tablets are on allocation.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1127

23.4% Sodium Chloride Injection

August 4, 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 early-September 2017.
- Pfizer has 23.4% sodium chloride 200 mL vials available in limited supply.

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

August 4, 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 in early-September 2017.

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

Promethazine Injection

August 7, 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 25 mg/mL 1 mL vials and ampules on a weekly allocation. The 50 mg/mL 1 mL vials and ampules are on a weekly allocation.
- West-Ward has Phenergan 25 mg/mL 1 mL vials on back order and the company estimates a release date of August or September 2017. Phenergan 50 mg/mL 1 mL vials are on a weekly allocation.
- X-Gen has promethazine 25 mg/mL 1 mL ampules on back order and the company estimates a release date of late-August 2017.

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

Norepinephrine Bitartrate Injection

August 7, 2017

Reason for the Shortage

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

Estimated Resupply Dates

- Pfizer has Levophed 1 mg/mL 4 mL vials on allocation.
- Teva has norepinephrine 1 mg/mL 4 mL vials on allocation.

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

Erythromycin Lactobionate Injection

August 7, 2017

Reason for the Shortage

- Pfizer has Erythrocin on shortage due to manufacturing delays.

Estimated Resupply Dates

- Pfizer has Eryhrocin 500 mg ADD-Vantage vials and regular 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=546

Disopyramide Phosphate Controlled-Release Capsules

August 7, 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 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

Calcium Gluconate Injection

August 7, 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 early-September 2017. Check wholesalers for inventory.

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

Bumetanide Injection

August 7, 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 October 2017.
- West-Ward has bumetanide 0.25 mg/mL 4 mL vials on a weekly allocation. The 10 mL vials are on back order and the company estimates a release date of August to September 2017.

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

5% Lidocaine and 7.5% Dextrose Injection

August 7, 2017

Reason for the Shortage

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

Estimated Resupply Dates

- Pfizer has 5% lidocaine and 7.5% dextrose 2 mL ampules on long-term back order and the company estimates a release date of 2nd quarter 2018.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1245

Multiple Vitamins for Infusion

August 8, 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 5 mL vials in 10 count and 50 mL Dual vials on back order and the company estimates a release date of August 2017 for the 5 mL vials in 10 count and September 2017 for the 50 mL vials.
- 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

Furosemide Tablets

August 8, 2017

Reason for the Shortage

- Major, 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 and 1000 count bottles on back order and the company estimates a release date of early-August 2017. Furosemide 20 mg tablets in 300 count bottles are on back order and the company cannot estimate a release date.
- 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 100 count unit-dose blister packs on back order and the company cannot estimate a release date. Furosemide 80 mg in 100 count bottles is on allocation.

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

Dexrazoxane Injection

August 8, 2017

Reason for the Shortage

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

Estimated Resupply Dates

- Pfizer has Zinecard 250 mg and 500 mg vials on back order and the company estimates a release date of October-November 2017 for the 250 mg vials and 3rd quarter 2018 for the 500 mg vials.

- Mylan has dexrazoxane 500 mg vials on back order and the company estimates a release date of early-September 2017.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=415

Ciprofloxacin Oral Suspension

August 8, 2017

Reason for the Shortage

- Lupin did not provide a reason for the shortage.
- Bayer has Cipro oral suspension available.

Estimated Resupply Dates

- Lupin has ciprofloxacin oral suspension 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=1247

Ampicillin Sulbactam

August 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, 3 gram, and 15 gram vials on intermittent back order and the company is releasing product as it becomes available.
- Fresenius Kabi has ampicillin sulbactam 1.5 gram, 3 gram, and 15 gram vials on long-term back order and the company cannot estimate a release date.
- Sagent has ampicillin sulbactam 1.5 gram and 3 gram vials on allocation. The 15 gram vials are on back order and the company estimates a release date of August 2017.
- Sandoz has ampicillin sulbactam 1.5 gram, 3 gram, and 15 gram vials temporarily unavailable and the company cannot estimate a release date.
- WG Critical Care has ampicillin sulbactam 15 gram vials on back order and the company estimates a release date of mid-August 2017.

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

Carboplatin Solution for Injection

August 9, 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

- Fresenius Kabi has carboplatin 10 mg/mL 45 mL vials available with an expiration date of < 1 month.
- Mylan Institutional has all carboplatin injection on back order and the company cannot estimate a release date.
- Sagent has all carboplatin injection on back order and the company cannot estimate a release date.
- Teva has carboplatin 10 mg/mL 60 mL vials on allocation. Please check wholesaler for inventory.

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

Octreotide Injection

August 10, 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.
- Sagent has octreotide 50 mcg/mL 1 mL vials on back order and the company estimates a release date of August 2017.

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

Calcium Chloride Injection

August 10, 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 LifeShielf syringes are on back order and the company estimates a release date of late-August 2017.

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

Morphine Injections

August 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

- Pfizer has morphien 0.5 mg/mL 10 mL preservative-free vials on back order and the company estimates a release date of late-Septmber 2017. The 1 mg/mL 10 mL preservative-free vials are on back order and the company estimates a release date of late-August 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 are on back order and the company estimates a release date of 2nd quarter 2018.
- West-Ward has Infumorph 10 mg/mL 20 mL preservative-free ampules on back order and the company estimates a release date of August 2017. 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 August 2017.

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

Magnesium Sulfate Injection

August 11, 2017

Reason for the Shortage

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

Estimated Resupply Dates

- Fresenius Kabi has magnesium sulfate 40 mg/mL 50 mL premixed bags and 80 mg/mL 50 mL premixed on back order and the company estimates a release date of mid-August 2017.

- 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

Lorazepam Injection

August 11, 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 late-August 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 3rd quarter 2017. The 4 mg/mL 1 mL Carpuject syringes are 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=1270

Diltiazem Hydrochloride Injection

August 11, 2017

Reason for the Shortage

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

Estimated Resupply Dates

- Pfizer has 100 mg ADD-Vantage vials on intermittent back order and the company is releasing product as it becomes available. The 5 mg/mL 5 mL and 10 mL vials are on back order and the company estimates a release date of 3rd quarter 2017 for the 5 mL vials and 2018 for the 10 mL vials.
- West-Ward has diltiazem 5 mg/mL 25 mL vials on a weekly allocation.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1271

Dextrose (50%) Injection

August 11, 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 vials and 50 mL Ansyr II syringes on back order and the company estimates a release date of August 2017 for the 50 mL vials and late-September 2017 for the 50 mL Ansyr II syringes. The 50% dextrose 50 mL LifeShield syringes are available in limited supply.

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

Trace Elements Injection

August 13, 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 on back order and the company cannot estimate a release date. The Multitrace-5 Concentrate 10 mL vials, Multitrace-4 Pediatric 3 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

Selenium Injection

August 13, 2017

Reason for the Shortage

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

Estimated Resupply Dates

- American Regent has selenium 40 mcg/mL 10 mL vials available in limited supply.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=784

Nitroglycerin Injection

August 13, 2017

Reason for the Shortage

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

Estimated Resupply Dates

- American Regent has nitroglycerin 50 mg/mL 10 mL vials in limited quantities.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=786

Leucovorin Calcium Injection

August 13, 2017

Reason for the Shortage

- Fresenius Kabi has leucovorin available.
- Sagent has leucovorin on shortage due to manufacturing delay.
- Teva had leucovorin on allocation due to increased demand.
- 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 late-August to early-September 2017.
- Sagent has leucovorin 50 mg, 100 mg, and 350 mg vials on back order and the company estimates a release date of August 2017. The 200 mg vials are on back order and the company cannot estimate a release date.
- Teva has leucovorin 100 mg and 350 mg vials on allocation.
- West-Ward has leucovorin 350 mg vials on allocation.

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

Cefuroxime Sodium Injection

August 13, 2017

Reason for the Shortage

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

Estimated Resupply Dates

- Sagent has cefuroxime 1.5 gram and 7.5 gram vials on back order and the company cannot estimate a release date.
- Teligent has Zinacef 750 mg vials, 750 mg ADD-Vantage vials, 1.5 gram vials, and 7.5 gram vials on long-term back order and the company cannot estimate a release date.
- West-Ward has cefuroxime 750 mg vials available with an expiration date of March 2018. The cefuroxime 7.5 gram vials are available with an expiration date of < March 2018.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=990

Talc, Sterile

August 15, 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 release dates in late-August to 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 late-August 2017 for the 4 gm/50 mL vials and 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

Sodium Bicarbonate Injection

August 15, 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 4.2% sodium bicarbonate 5 mL vials and 8.4% bicarbonate 50 mL vials on back order with an estimated release date of early-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 mid-August 2017 for the syringes and late-August 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-August 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.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=788

Sodium Acetate Injection

August 15, 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 early-August 2017.
- Pfizer has sodium acetate 2 meq/mL 20 mL vials on back order and the company estimates a release date of mid-August 2017. The 50 mL and 100 mL vials are on intermittent back order and the company is releasing supplies as they become available.

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

Procainamide Hydrochloride Injection

August 15, 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 and the company estimates a release date of December 2017. The 500 mg/mL 2 mL vials are on allocation.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=868

Potassium Chloride Injection

August 15, 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-September 2017.
- Pfizer has potassium chloride 20 mEq/50 mL in sterile water on back order and the company estimates resupply in late-August 2017. Potassium chloride 20 mEq/100 mL in sterile water is on back order and the company estimates a release date in mid-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

Piperacillin Tazobactam Injection

August 15, 2017

Reason for the Shortage

- Apotex has piperacillin/tazobactam on shortage due to regulatory delays.
- AuroMedics and Sandoz could not provide a reason for the shortage.
- Fresenius Kabi has piperacillin/tazobactam on shortage due to increased demand.
- Mylan Institutional launched piperacillin/tazobactam 3.375 gram and 4.5 gram vials in early-June 2016.
- Pfizer has Zosyn single dose vials and piperacillin/tazobactam on shortage due to manufacturing delays.
- Sagent has piperacillin/tazobactam on shortage due to increased demand.
- Sandoz has piperacillin/tazobactam available for contracted customers.
- WG Critical Care states the reason for the shortage is increased demand.
- FDA in conjunction with SteriMax was allowing temporary importation of piperacillin/tazobactam 3.375 gram, 4.5 gram, and 40.5 gram vials from Canada. This was being distributed through X-Gen Pharmaceuticals. These are no longer being imported with the launch of the products from X-Gen. The product codes on these items will not be recognized by U.S. systems so institutions will need to implement alternative plans to assure the dose is being given correctly. More information can be found here on the FDA site.
- Wockhardt has piperacillin/tazobactam injection available.
- X-Gen has piperacillin/tazobactam injection available.

Estimated Resupply Dates

- Apotex has piperacillin/tazobactam 2.25 gram, 3.375 gram, 4.5 gram, and 40.5 gram vials on back order and the company estimates a release date of late-August 2017.
- AuroMedics has piperacillin/tazobactam on intermittent back order and the company is releasing product as it becomes available. Check wholesalers for inventory.
- Pfizer has Zosyn 2.25 gram vials, 3.375 gram vials, 4.5 gram vials, and 40.5 gram vials on back order and the company estimates a release date of January 2018.
- Sagent has piperacillin/tazobactam 4.5 gram vials on allocation.

- Sandoz has piperacillin/tazobactam 2.25 gram (NDC 00781-3110-85) on back order and the company cannot estimate a release date. The 4.5 gram vials are on back order and the company estimates a release date of late-August 2017 for NDC 00781-3367-95 and early-September 2017 for NDC 00781-3114-95.
- WG Critical Care has piperacillin/tazobactam 3.375 gram and 4.5 gram vials on back order and the company estimates a release date of August 2017.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1075

Metronidazole Hydrochloride Injection

August 15, 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 injection on intermittent back order and the company cannot estimate a release date.
- Claris has metronidazole injection on long-term back order and the company cannot estimate a release date.
- Pfizer has metornidaozle injection in 24 count and 80 count on back order and the company estimates a release date of late-August 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

Hepatitis A Virus Vaccine Inactivated

August 15, 2017

Reason for the Shortage

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

Estimated Resupply Dates

- Merck has Vaqta pediatric/adolescent formulation 25 U/0.5 mL prefilled syringes in 10 count on back order and the company estimates a release date of 3rd quarter 2017.
- Merck has Vaqta adult formulation 50 U/1 mL vials in 1 count on back order and the company estimates product will not be available in 2017. Vaqta 50 U/1 mL prefilled syringes are on back order and the company estimates a release date of 3rd quarter 2017.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=180

Etomidate Injection

August 15, 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

Doxorubicin Injection

August 15, 2017

Reason for the Shortage

- West-Ward has Adriamycin available.
- Teva has doxorubicin solution for injection available.
- Fresenius Kabi has doxorubicin solution for injection available.
- Caraco has discontinued doxorubicin solution for injection 25 mL and 100 mL vials.
- Pfizer has doxorubicin solution for injection available.
- Sagent has doxorubicin solution for injection on back order due to manufacturing delays.
- Mylan Institutional has doxorubicin lyophilized powder for injection available.
- Actavis has doxorubicin on shortage due to increased demand.

Estimated Resupply Dates

- Actavis has doxorubicin 2 mg/mL 100 mL vials on allocation.
- Sagent has doxorubicin 2 mg/mL 5 mL, 25 mL, and 100 mL vials on back order and the company cannot estimate a release date.
- West-Ward has Adriamycin 2 mg/mL 5 mL, 10 mL and 25 mL vials available with short-expiration dating (July 2018).

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=464

Clindamycin Injection

August 15, 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 in August 2017.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1029

Ceftriaxone Sodium Injection

August 15, 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 expects to relaunch the product in 2018.
- 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.
- West-Ward has ceftriaxone 1 gram and 2 gram vials on allocation. Ceftriaxone 250 mg vials are on back order and the company estimates a release date in September 2017.

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

Albendazole Tablets

August 15, 2017

Reason for the Shortage

- Impax has Albenza available.

Estimated Resupply Dates

- Impax has Albenza on intermittent back order and the company is releasing supplies as they become available.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1274

Acetylcysteine Oral and Inhalation Solution

August 15, 2017

Reason for the Shortage

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

Estimated Resupply Dates

- American Regent has acetylcysteine solution 100 mg/mL 10 mL vials, and 200 mg/mL 10 mL and 30 mL vials on back order and the company cannot estimate a release date. Acetylcysteine 200 m/mL 4 mL in 25 count is available in limited quantities.
- Pfizer has acetylcysteine solution 200 mg/mL 30 mL vials on back order and the company estimates a release date in December 2017.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=932

Vancomycin Hydrochloride Injection

August 16, 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.
- Pfizer has vancomycin lyophilized powder 500 mg, 750 mg, and 1 gram vials on back order and the company estimates a release date of late-August 2-17/ The 5 gram and 10 gram vials are on back order and the company estimates a release date of mid-August 2017. The 500 mg, 750 mg, and 1 gram ADD-vantage vials are on allocation.
- Sagent has vancomycin 5 gram and 10 gram vials on back order and the company estimates a release date of August 2017.

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

Succinylcholine Injection

August 16, 2017

Reason for the Shortage

- Pfizer has Quelicin on shortage due to manufacturing delays.

Estimated Resupply Dates

- Pfizer has Quelicin 20 mg/mL 10 mL vials available in limited supply.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1267

Rocuronium Injection

August 16, 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 5 mL and 10 mL vials on back order and the company estimates a release date of late-August to early-September 2017 for the 5 mL vials and 3rd quarter 2017 for the 10 mL vials.
- 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 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 September 2017. The 10 mL vials are on back order and the company cannot estimate a release date.

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

Mannitol Injection

August 16, 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 mid- to late-September 2017.
- Pfizer has mannitol 250 mg/mL 50 mL vials on back order and the company estimates a release date of late-August 2017.

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

Flurbiprofen Sodium Ophthalmic Solution

August 16, 2017

Reason for the Shortage

- Allergan discontinued Ocufen ophthalmic solution in February 2017.
- Valeant has flurbiprofen sodium on shortage due to manufacturing delay.

Estimated Resupply Dates

- Valeant has flurbiprofen sodium on back order and the company estimates a release in November 2017.

https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1283

C1-Esterase Inhibitor (Human) Injection

August 16, 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

Vecuronium Bromide Injection

August 17, 2017

Reason for the Shortage

- Pfizer has vecuronium on shortage due to manufacturing delays.
- Teva has vecuronium available.
- Pfizer sold vecuronium injection to Mylan Institutional in December 2013.
- Ben Venue has stopped production in its plant in Bedford, Ohio and closed in 2014.
- Sun Pharma refuses to provide information on availability of any of their products.
- Sagent is not marketing vecuronium 10 mg and 20 mg vials.
- Fresenius Kabi has vecuronium on shortage due to manufacturing delays.

Estimated Resupply Dates

- Mylan Institutional has vecuronium 10 mg vials on back order with an estimated release date of early-December 2017.
- Pfizer has vecuronium 10 mg and 20 mg vials on back order and the company estimates a release date of 1st quarter 2018.
- Fresenius Kabi has vecuronium 10 mg and 20 mg 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=490

Methotrexate Injection

August 17, 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 on back order and the company estimates a release date of early-September 2017.
- 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

Lidocaine with Epinephrine Injection

August 17, 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-August 2017. The 1% lidocaine with epinephrine (1:100,000) 50 mL vials are on back order and the company estimates a release date of late-August 2017.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 mid-August 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 mid-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 mid-August 2017 for the 10 mL and 50 mL vials and late-August 2017 for the 20 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-August 2017. The 1.5% 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 with epinephrine (1:200,000) 20 mL and 50 mL vials are on back order and the company estimates a release date of late-August 2017 for the 20 mL vials and early-September 2017 for the 50 mL vials. 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-August 2017. The 2% Xylocaine-MPF with epinephrine (1:200,000) 10 mL vials and 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

Lidocaine Injection

August 17, 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 20 mL and 50 mL vials on back order and the company estimates a release date of late-August 2017 for the 20 mL vials and mid-August 2017 for the 50 mL vials. The 1% lidocaine 2 mL vials are available with an expiration date of < 5 months. The 1% Xylocaine-MPF 30 mL vial sterile packs are on back order and the company estimates a release date of mid- to late-September 2017. The 2% Xylocaine 20 mL and 50 mL vials are on back order and the company estimates a release date of late-August 2017 for the 20 mL vials and mid-September 2017 for the 50 mL vials. The 2% Xyclocaine-MPF 10 mL ampules are on back order and the company estimates a release date of late-August to early-September 2017.
- Pfizer has 1% lidocaine 5 mL preservative-free ampules on back order and the company estimates a release date of late-August 2017. The 1% lidocaine 50 mL vials are available in limited supply. The 2% lidocaine 10 mL ampules and 2% lidocaine 5 mL LifeShield syringes are available in limited supply. The 2% lidocaine 5 mL Ansyr syringes are on back order and the company estimates a release date of late-August 2017.

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

Labetalol Injection

August 17, 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 late-August 2017.

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

Furosemide Injection

August 17, 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 2 mL vials on back order with an estimated release date of late-August to early-September 2017.
- Pfizer has furosemide 10 mg/mL 10 mL syringes on back order and the company estimates a release date of late-August 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

August 17, 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 estimates a release date of late-August 2017.
- Pfizer has fentanyl 50 mcg/mL 5 mL ampules on back order and the company estimates a release date of early-October 2017. The 20 mL ampules are on back order and the company estimates a release date of early-October 2017. The 2 mL Carpuject syringes are on back order and the company estimates a release date of 2nd quarter 2018. The 5 mL vials are on back order and the company estimates a release date of early-September 2017. The 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 2 mL and 50 mL vials on allocation. The 5 mL and 20 mL vials are on back order and the company estimates a release date of September to October 2017. 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

Dopamine Hydrochloride Injection

August 17, 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.

Estimated Resupply Dates

- American Regent has all dopamine presentations on back order and the company cannot estimate a release date.
- Pfizer has dopamine 40 mg/mL 10 mL vials on back order and the company estimates a release date of 2018. The dopamine 200 mg/250 mL and 400 mg/500 mL premixed bags are on back order and the company cannot estimate a release date. The 400 mg/250 mL, 800 mg/250 mL, and 800 mg/500 mL premixed bags are on back order and the company estimates a release date of late-August 2017.

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

Bupivacaine Injection

August 17, 2017

Reason for the Shortage

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

Estimated Resupply Dates

- Fresenius Kabi has 0.25% Sensorcaine preservative-free 30 mL vials in sterile packs on intermittent back order and the company is releasing product as it becomes available.
- Pfizer has 0.5% Marcaine 10 mL preservative-free vials on back order and the company estimates a release date of 2nd quarter 2018. The 0.25% bupivacaine 10 mL vials are on back order and the company estimates a release date of mid-September 2017. The 0.5% bupivacaine 10 mL vials are 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=864

Bupivacaine with epinephrine Injection

August 18, 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 on back order and the company estimates a release date of late-August 2017. The 30 mL vials are on intermittent back order and the company is releasing product as it is available. The 0.25% Sensorcaine with epinephrine 50 mL vials are on back order and the company estimates a relase date of early-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-August

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-August 2017. The 0.5% Sensorcaine with epinephrine 50 mL vials are on back order and the company estimates a release date of late-August 2017. The 0.75% Sensorcarine 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 mid-September 2017 for the 10 mL vials and October 2017 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 October 2017. 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 October 2017. The 0.5% bupivacaine with epinephrine 50 mL vials are on back order and the company estimates a release date of October 2017.
- 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

*Please refer to ASHP website for more information at:
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