



**June 2017**

Drug Information Update

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## NEWLY AVAILABLE GENERICS

GENERIC DRUG NAME	STRENGTH & DOSAGE FORM	GENERIC MANUFACTURER	BRAND NAME
BUPRENORPHINE	5 MCG/HOUR PATCH	TEVA	BUTRANS
BUPRENORPHINE	10 MCG/HOUR PATCH	TEVA	BUTRANS
BUPRENORPHINE	20 MCG/HOUR PATCH	TEVA	BUTRANS
BUPRENORPHINE	15 MCG/HOUR PATCH	TEVA	BUTRANS
ATOMOXETINE HCL	10 MG CAPSULE	TEVA	STRATTERA
ATOMOXETINE HCL	18 MG CAPSULE	TEVA	STRATTERA
ATOMOXETINE HCL	25 MG CAPSULE	TEVA	STRATTERA
ATOMOXETINE HCL	40 MG CAPSULE	TEVA	STRATTERA
ATOMOXETINE HCL	60 MG CAPSULE	TEVA	STRATTERA
ATOMOXETINE HCL	80 MG CAPSULE	TEVA	STRATTERA
ATOMOXETINE HCL	100 MG CAPSULE	TEVA	STRATTERA
APREPITANT	125 MG CAPSULE	SANDOZ	EMEND
APREPITANT	40 MG CAPSULE	SANDOZ	EMEND

## NEW DRUG ENTITIES/COMBINATIONS/STRENGTHS

DESCRIPTION	BRAND NAME	GENERIC NAME	STRENGTH	NOTES
NARCOTIC ANTAGONISTS	NARCAN	NALOXONE HCL	2 MG/ ACTUATION	NEW STRENGTH AND DOSAGE FORM
ANTIHEMOPHILIC FACTORS	ADYNOVATE	ANTIHEMO.FVIII FULL LENGTH PEG	3,000 (+/-) UNIT RANGE	NEW STRENGTH
GLUCOCORTICOIDS	P-CARE D80	METHLPREDNISOLONE ACETATE	40 MG/ML (2 X 1 ML)	NEW DOSAGE FORM
GLUCOCORTICOIDS	P-CARE D40	METHYLPREDNISOLONE ACETATE	40 MG/ML	NEW DOSAGE FORM
OPHTHALAMIC VEGF-A RECEPTOR ANTAGONIST RCMB MC ANTIBODY	BEVACIZUMAB	BEVACIZUMAB	1 MG/0.04 ML	NEW STRENGTH
OPHTHALAMIC VEGF-A RECEPTOR ANTAGONIST RCMB MC ANTIBODY	BEVACIZUMAB	BEVACIZUMAB	1.25 MG/0.05 ML	NEW STRENGTH
ANTINEOPLASTIC – ANTIANDROGENIC AGENTS	ZYTIGA	ABIRATERONE ACETATE	500 MG	NEW STRENGTH
ANTINEOPLASTIC EGF RECEPTOR BLOCKER MONOCLONAL ANTIBODY	HERCEPTIN	TRASTUZUMAB	150 MG	NEW STRENGTH
ANTINEOPLASTIC COMBINATION – KINASE AND AROMATSE INHIBITOR	KISQUALI AND FEMARA CO-PACK	RIBOCICLIB SUCCINATE/ LETROZOLE	200 MG/ DAY (200 MG X 1) – 2.5 MG	NEW COMBINATION
ANTINEOPLASTIC COMBINATION – KINASE AND AROMATSE INHIBITOR	KISQUALI AND FEMARA CO-PACK	RIBOCICLIB SUCCINATE/ LETROZOLE	400 MG/ DAY (200 MG X 2) – 2.5 MG	NEW COMBINATION
ANTINEOPLASTIC COMBINATION – KINASE AND AROMATSE INHIBITOR	KISQUALI AND FEMARA CO-PACK	RIBOCICLIB SUCCINATE/ LETROZOLE	600 MG/ DAY (200 MG X 3) – 2.5	NEW COMBINATION

DESCRIPTION	BRAND NAME	GENERIC NAME	STRENGTH	NOTES
			MG	
PEDIATRIC VITAMIN PREPARATIONS	QUFLORA FE	PEDIATRIC MULTIVITAMIN 151/IRON/FLUORIDE	9.5 MG IRON – 0.25 MG FLUORIDE PER ML	NEW COMBINATION
BONE FORMATION STIMULATING AGENTS – PTH REL PEPTIDES	TYMLOS	ABALOPARATIDE	80 MCG/DOSE (3, 120 MCG/1.56 ML)	NEW ENTITY
TOPICAL LOCAL ANESTHETICS	LIDOPAC	LIDOCAINE	5%	NEW DOSAGE FORM
ANTINEOPLSATIC SYSTEMIC ENZYME INHIBITORS	RYDAPT	MIDOSTAURIN	25 MG	NEW ENTITY
ANTINEOPLASTIC SYSTEMIC ENZYME INHIBITORS	ANUNBRIG	BRIGATINIB	30 MG	NEW ENTITY
ANTI-PROGRAMMED CELL DEATH LIGAND 1 (PD-L1) MONOCLONAL ANTIBODY	IMFINZI	DURVALUMAB	120 MG/2.4 ML (50 MG/ML)	NEW ENTITY
ANTI-PROGRAMMED CELL DEATH LIGAND 1 (PD-L1) MONOCLONAL ANTIBODY	IMFINZI	DURVALUMAB	500 MG/10 ML (50 MG/ML)	NEW ENTITY
ANALGESICS, NARCOTICS	MORPHABOND ER	MORPHINE SULFATE	15 MG	NEW DOSAGE FORM
ANALGESICS, NARCOTICS	MORPHABOND ER	MORPHINE SULFATE	30 MG	NEW DOSAGE FORM
ANALGESICS, NARCOTICS	MORPHABOND ER	MORPHINE SULFATE	60 MG	NEW DOSAGE FORM
ANALGESICS, NARCOTICS	MORPHABOND ER	MORPHINE SULFATE	100 MG	NEW DOSAGE FORM
SKIN TISSUE REPLACEMENT	KERAMATRIX	TISSUE MATRIX, KERATIN-OVINE	2" X 2" SHEET	NEW ENTITY
SKIN TISSUE REPLACEMENT	KERAMATRIX	TISSUE MATRIX,	4" X 4"	NEW ENTITY

DESCRIPTION	BRAND NAME	GENERIC NAME	STRENGTH	NOTES
		KERATIN-OVINE	SHEET	
TOPICAL HEMOSTATICS	GELFOAM JMI	THROMBIN, BOVINE/GELATIN SPONGE	5,000 UNIT	NEW COMBINATION
TOPICAL LOCAL ANESTHETICS	TRANZAREL	LIDOCAINE HCL	4% GEL	NEW DOSAGE FORM
ANTI-INFLAMMATORY SELECTIVE COSTIMULATORY MODULATING T-CELL INHIBITOR	ORENCIA	ABATACEPT	50 MG/0.4 ML SYRINGE	NEW STRENGTH
ANTI-INFLAMMATORY SELECTIVE COSTIMULATORY MODULATING T-CELL INHIBITOR	ORENCIA	ABATACEPT	87.5 MG/0.7 ML SYRINGE	NEW STRENGTH
METABOLIC DISEASE ENZYME REPLACEMENT, BATTEN DISEASE	BRINEURA	CERLIPONASE ALFA	300 MG/10 ML (150 MG/ 5 ML X 2) VIAL	NEW ENTITY
INTERLEUKIN-6 (IL-6) RECEPTOR INHIBITORS	KEVZARA	SARILUMAB	200 MG/1.14 ML	NEW ENTITY
INTERLEUKIN-6 (IL-6) RECEPTOR INHIBITORS	KEVZARA	SARILUMAB	150 MG/1.14 ML	NEW ENTITY
ANTIPARKINSONISM DRUGS, OTHER	XADAGO	SAFINAMIDE MESYLATE	50 MG	NEW ENTITY
ANTIPARKINSONISM DRUGS, OTHER	XADAGO	SAFINAMIDE MESYLATE	100 MG	NEW ENTITY
AMYOTROPIC LATERAL SCLREOSIS AGENTS	RADICAVA	EDARAVONE	30 MG/100 ML	NEW ENTITY
ANTIHYPERCLYCEMIC, BIGUANIDE TYPE	DM2	METFORMIN/BLOOD SURE DIAGNOSTIC	500 MG CAPSULE	NEW COMBINATION
TOPICAL HEMOSTATICS	GELFOAM JMI	THORMBIN, BOVINE/GELATIN SPONGE	5,000 UNIT	NEW DOSAGE FORM

DESCRIPTION	BRAND NAME	GENERIC NAME	STRENGTH	NOTES
ANTINEOPLASTIC – ANTIMETABOLITES	XATMEP	METHOTREXATE	2.5 MG/ML ORAL SOLUTION	NEW DOSAGE FORM
ANTINEOPLASTIC SYSTEMIC ENZYME INHIBITORS	RUBRACA	RUCAPARIB CAMSYLATE	250 MG TABLET	NEW STRENGTH
OPHTHALMIC ANTIBIOTICS	VANCOMYCIN HCL	VANCOMYCIN/BSS NO.2/PF	2 MG/0.2 MG	NEW STRENGTH
ANTINEOPLASTICS ANTIBODY/ANTIBODY-DRUG COMPLEXES	BLINCYTO	BLINATUMOMAB	35 MCG	NEW DOSAGE FORM
ANTIPSYCHOTICS, ATYPICAL, D2 PARTIAL AGONIST/5HT MIXED	ARISTADA	ARIPIPRAZOLE LAUROXIL	1,064 MG/3.9 ML SYRINGE	NEW STRENGTH
ANTIHEMOPHILIC FACTORS	AFSTYLA	ANTIHEM. FVIII-CHN,B- DM TRU	1,500 (+/-) UNIT RANGE	NEW STRENGTH
ANTIHEMOPHILIC FACTORS	AFSTYLA	ANTIHEM. FVIII-CHN,B- DM TRU	2,500 (+/-) UNIT RANGE	NEW STRENGTH
GLUCOCORTICOIDS	LIDOCIDEX-I	DEXAMETHASONE/ LIDOCAINE HCL	5 MG-10 MG/1.5 ML	NEW COMBINATION

## NEW INDICATIONS (EXISTING DRUGS)

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### Kalydeco®

**May 17, 2017**

BOSTON--(BUSINESS WIRE)-- Vertex Pharmaceuticals Incorporated (Nasdaq: VRTX) today announced that the U.S. Food and Drug Administration (FDA) has approved KALYDECO® (ivacaftor) for use in people with cystic fibrosis (CF) ages 2 and older who have one of 23 residual function mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene. This precision medicine decision is based on analyses of in vitro data and is supported by more than five years of real-world clinical data that demonstrate KALYDECO's strong safety and efficacy profile. More than 900 people ages 2 and older in the U.S. have one of these mutations. Based on this approval, Vertex today increased its guidance for 2017 product revenues of KALYDECO to a range of \$740 million to \$770 million.

Source: Vertex Pharmaceuticals Incorporated  
<http://investors.vrtx.com/releasedetail.cfm?ReleaseID=1026864>

### Keytruda®

**May 10, 2017**

KENILWORTH, N.J.--(BUSINESS WIRE)--Merck (NYSE: MRK), known as MSD outside the United States and Canada, today announced that the U.S. Food and Drug Administration (FDA) has approved KEYTRUDA® (pembrolizumab), the company's anti-PD-1 therapy, in combination with pemetrexed (brand name Alimta®) and carboplatin (pem/carbo), a commonly used chemotherapy regimen, for the first-line treatment of metastatic nonsquamous NSCLC, irrespective of PD-L1 expression. Under the FDA's accelerated approval regulations, this indication is approved based on tumor response rate and progression-free survival (PFS). Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.

Source: Merck  
<http://www.mrknewsroom.com/news-release/prescription-medicine-news/fda-approves-mercks-keytruda-pembrolizumab-first-line-combin>

### Bavencio®

**May 9, 2017**

ROCKLAND, Mass. and NEW YORK, May 9, 2017 /PRNewswire/ -- EMD Serono, the biopharmaceutical business of Merck KGaA, Darmstadt, Germany, in the US and Canada, and Pfizer Inc. (NYSE: PFE) today announced that the US Food and Drug Administration (FDA) has approved BAVENCIO® (avelumab) Injection for the treatment of patients with locally advanced or metastatic urothelial carcinoma (UC) who have disease progression during or following platinum-containing chemotherapy, or who have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy. BAVENCIO was previously granted accelerated approval from the FDA for the treatment of adults and pediatric patients 12 years and older with metastatic Merkel cell carcinoma (MCC). These indications are approved under accelerated approval based on tumor response and duration of response. Continued approval for these indications may be contingent upon verification and description of clinical benefit in confirmatory trials.

Source: EMD Serono Inc.  
<http://media.emdserono.com/2017-05-09-FDA-Grants-BAVENCIO-R-avelumab-Approval-for-a-Common-Type-of-Advanced-Bladder-Cancer>



## Keytruda®

**May 23, 2017**

KENILWORTH, N.J.--(BUSINESS WIRE)--Merck (NYSE:MRK), known as MSD outside the United States and Canada, today announced that the U.S. Food and Drug Administration (FDA) has approved a new indication for KEYTRUDA® (pembrolizumab), the company's anti-PD-1 therapy. KEYTRUDA is now indicated for the treatment of adult and pediatric patients with unresectable or metastatic, microsatellite instability-high (MSI-H) or mismatch repair deficient.

Source: Merck

<http://www.mrknewsroom.com/news-release/prescription-medicine-news/fda-approves-mercks-keytruda-pembrolizumab-first-line-combin>

## Actemra®

**May 22, 2017**

Genentech, a member of the Roche Group (SIX: RO, ROG; OTCQX: RHHBY), announced today that the U.S. Food and Drug Administration (FDA) has approved Actemra® (tocilizumab) subcutaneous injection for the treatment of GCA, a chronic and severe autoimmune condition. Actemra is the first therapy approved by the FDA for the treatment of adult patients with GCA. This is the sixth FDA approval for Actemra since the medicine was launched in 2010.

Source: Genentech

<https://www.gene.com/media/press-releases/14667/2017-05-22/fda-approves-genentechs-actemra-tocilizu>

## Aristada®

**June 6, 2017**

DUBLIN--(BUSINESS WIRE)--Jun. 6, 2017-- Alkermes plc (NASDAQ: ALKS) today announced that the U.S. Food and Drug Administration (FDA) has approved two-month ARISTADA® (aripiprazole lauroxil) extended-release injectable suspension for the treatment of schizophrenia. ARISTADA is now FDA-approved in four doses and three dosing duration options (441 mg, 662 mg or 882 mg once monthly, 882 mg once every six weeks and 1064 mg once every two months) and can be initiated at any dose or interval, offering an unprecedented range of flexibility to patients and healthcare providers. The new two-month dose is expected to be available in mid-June.

Source:Alkermes plc

<http://investor.alkermes.com/phoenix.zhtml?c=92211&p=irol-corporateNewsArticle&ID=2279079>

## Isentress®

**May 30, 2017**

KENILWORTH, N.J.--(BUSINESS WIRE)--Merck (NYSE: MRK), known as MSD outside the United States and Canada, today announced that the U.S. Food and Drug Administration (FDA) has approved ISENTRESS® HD, a new 1200 mg once-daily dose of the company's integrase inhibitor, ISENTRESS® (raltegravir), to be administered orally as two 600 mg filmcoated tablets with or without food, in combination with other antiretroviral agents, for the treatment of HIV-1 infection in adults, and pediatric patients weighing at least 40 kg, who are treatment-naïve or whose virus has been suppressed on an initial regimen of ISENTRESS 400 mg given twice daily.

Source: mrknewsroom.com

<http://www.mrknewsroom.com/news-release/prescription-medicine-news/merck-receives-fda-approval-isentress-hd-raltegravir-new-onc>

## FDA NEWS/BULLETINS/ADVISORIES/SAFETY ALERTS

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### C.O. Truxton, Inc. Issues Voluntary Nationwide Recall of Amitriptyline HCL Tablets, USP 50mg and Phenobarbital Tablets, USP 15mg, 30mg, 60mg, 100mg Due to Potential Label Mix-Up

May 8, 2017

Bellmawr, New Jersey, C.O. Truxton, Inc. is expanding their - 04/21/2017 voluntary recall, as a precaution to include the following C.O. Truxton, Inc. products, registered NDC numbers and corresponding lot numbers, to the consumer/user level. C.O. Truxton has not received any complaints for the products listed below - however, due to the initial recall resulting from a label mix-up error, out of an abundance of caution, we are recalling all products that were repackaged into a Truxton Incorporated label.

<https://www.fda.gov/Safety/Recalls/ucm557260.htm>

### GEC Laxoplex Dietary Supplement Capsules by Genetic Edge Compounds: Recall- Presence of Anabolic Steroids

May 8, 2017

**ISSUE:** Genetic Edge Compounds recalled all lot codes of GEC Laxoplex dietary supplement capsules distributed between February 2, 2015- May 2, 2017 to the retail level and consumer level. FDA analysis found GEC Laxoplex to be tainted with anabolic steroids and steroid like substances. The presence of these anabolic steroids and steroid like substances in GEC Laxoplex renders it an unapproved drug for which safety and efficacy have not been established and therefore subject to recall.

Use or consumption of products containing anabolic steroids may cause acute liver injury, which is known to be a possible harmful effect of using steroid containing products. In addition, abuse of anabolic steroids may cause other serious long-term adverse health consequences in men, women, and children. These include shrinkage of the testes and male infertility, masculinization of women, breast enlargement in males, short stature in children, a higher predilection to misuse other drugs and alcohol, adverse effects on blood lipid levels, and increased risk of heart attack, stroke, and death.

**BACKGROUND:** GEC Laxoplex is marketed as a dietary supplement and sold as a muscle enhancing agent. The product is packaged in a white plastic bottle containing 60 capsules with UPC code 0058049984 and can be identified by GEC Laxoplex. The recall affects all lots of GEC Laxoplex. GEC Laxoplex was distributed Nationwide in the USA through various nutritional supplement retail outlets.

**RECOMMENDATION:** Genetic Edge Compounds is notifying its retailers and customers by a formal recall notification and is arranging for a return of all recalled products. Consumers and retailers that have GEC Laxoplex dietary supplement capsules which are being recalled should stop using them and return to place of purchase.

<https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm557147.htm>

### Canagliflozin (Invokana, Invokamet): Drug Safety Communication – Increased Risk of Leg and Foot Amputations

May 16, 2017

**ISSUE:** Based on new data from two large clinical trials, the FDA has concluded that the type 2 diabetes medicine canagliflozin (Invokana, Invokamet, Invokamet XR) causes an increased risk of leg and foot amputations. FDA is requiring new warnings, including the most prominent Boxed Warning, to be added to the canagliflozin drug labels to describe this risk.

Final results from two clinical trials – the CANVAS (Canagliflozin Cardiovascular Assessment Study) and CANVAS-R (A Study of the Effects of Canagliflozin on Renal Endpoints in Adult Participants With Type 2 Diabetes Mellitus) –

showed that leg and foot amputations occurred about twice as often in patients treated with canagliflozin compared to patients treated with placebo, which is an inactive treatment. Amputations of the toe and middle of the foot were the most common; however, amputations involving the leg, below and above the knee, also occurred. Some patients had more than one amputation, some involving both limbs. See the FDA Drug Safety Communication for additional information, including a data summary.

**BACKGROUND:** This information is an update to the May 18, 2016 MedWatch safety alert. Canagliflozin is a prescription medicine used with diet and exercise to lower blood sugar in adults with type 2 diabetes. It belongs to a class of drugs called sodium-glucose cotransporter-2 (SGLT2) inhibitors. Canagliflozin lowers blood sugar by causing the kidneys to remove sugar from the body through the urine. It is available as a single-ingredient product under the brand name Invokana and also in combination with the diabetes medicine metformin under the brand name Invokamet.

**RECOMMENDATION:** Patients taking canagliflozin should notify your health care professionals right away if you develop new pain or tenderness, sores or ulcers, or infections in your legs or feet. Talk to your health care professional if you have questions or concerns. Do not stop taking your diabetes medicine without first talking to your health care professional.

Health care professionals should, before starting canagliflozin, consider factors that may predispose patients to the need for amputations. These factors include a history of prior amputation, peripheral vascular disease, neuropathy, and diabetic foot ulcers. Monitor patients receiving canagliflozin for the signs and symptoms described above and discontinue canagliflozin if these complications occur.

<https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm558605.htm>

#### **Tri-Ton by Dynamic Technical Formulations, LLC: Recall – Contains Andarine and Ostarine Drug Ingredients May 22, 2017**

**ISSUE:** Dynamic Technical Formulations LLC. is voluntarily recalling all lots of Tri-Ton. This product was sold in 90 count bottles as a dietary supplement and includes all lot number and expiration dates of the product. FDA lab analysis of Tri-Ton was found to contain andarine and ostarine which are selective androgen receptor modulators (SARMs) that are considered unapproved drugs and anabolic steroid-like substances.

Use or consumption of products containing SARMs and anabolic steroid-like substances may cause acute liver injury, which is known to be a possible harmful effect of using steroid containing products. In addition, abuse of anabolic steroids may cause other serious long term adverse health consequences in men, women, and children. These include shrinkage of the testes and male infertility, masculinization of women, breast enlargement in males, short stature in children, a higher predilection to misuse other drugs and alcohol, adverse effects on blood lipid levels, and increased risk of heart attack, stroke, and death

**BACKGROUND:** This product was sold in 90 count bottles through retailers nationwide. Shipment of this product was from June 2016 to March 2017

**RECOMMENDATION:** Consumers should stop using the product immediately and throw it away in accordance with your state and local ordinances for disposal of drug products or return the unused portion of product for a refund. Consumers with questions regarding this recall can contact Dynamic Technical Formulations by emailing [customerservice@dtformulations.com](mailto:customerservice@dtformulations.com) or calling 800-331-6723 from 9:00am to 5:00pm EST.

<https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm559907.htm>

### Al-Er-G Capsules by MusclMasster: Recall – Contains Banned Substances Ephedra

May 25, 2017

**ISSUE:** MusclMasster, LLC is recalling all bottles of Al-Er-G Capsules. During a recent FDA inspection, it was discovered that this product contained Ephedra Herb, an FDA banned ingredient. Dietary supplements containing ephedrine alkaloids pose a risk of serious adverse events, including heart attack, stroke, and death, and that these risks are unreasonable in light of any benefits that may result from the use of these products under their labeled conditions of use.

**BACKGROUND:** This item is packed in a white bottle with a white cap. Each bottle contains 60 or 150 capsules, each capsule is 180 mg of ephedra herb in a 650 mg capsule. This product was distributed from Colorado, through the MusclMasster wellness center and retail store and does not contain UPC codes or expiration dates. The company's lot number is 314. Also one bottle each was shipped to WY, SC, and WA between 2016 and 2017. Al-Er-G was not sold on-line. The company has ceased production and distribution of the product and destroyed 100% of the banned product

**RECOMMENDATION:** Consumers who have purchased the product are urged to return them to New Genesis Health, 4565 Kipling Street, Wheat Ridge, CO 80033 for a full refund. Consumers with questions may contact the company at (800) 765-4372 Monday-Friday 9am- 6pm MST.

<https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm560485.htm>

### Brilinta (ticagrelor) 90mg tablets, 8-count Physician Sample Bottles: Recall of Lot #JB5047 – Due to Report of Another Medicine in One Bottle

May 26, 2017

**ISSUE:** AstraZeneca is notifying physicians and consumers that it is voluntarily recalling one lot of professional (physician) sample bottles containing eight tablets of Brilinta (ticagrelor) 90mg tablets as a precautionary measure. This voluntary recall follows a report that a professional sample bottle containing eight tablets of Brilinta 90mg also contained another medicine called Zurampic (lesinurad) 200 mg tablets which is also manufactured by AstraZeneca.

Unintentional dosing with Zurampic has the potential to lead to adverse renal effects including acute renal failure which is more common when Zurampic is given alone as it should be used in combination with a xanthine oxidase inhibitor. Brilinta has a warning in its prescribing information regarding discontinuation of the medicine. Missed doses of Brilinta increase the risk of heart attack and stroke. People who are treated with a stent and miss doses of Brilinta have a higher risk of getting a blood clot in the stent, having a heart attack, or death. Patients should not stop taking Brilinta without talking to their prescribing doctor. To date, AstraZeneca has not received any reports of adverse events related to this recall.

**BACKGROUND:** This is limited to one lot (Brilinta lot #JB5047) of professional sample bottles containing eight tablets of Brilinta 90 mg distributed to physicians in the US between March and April of 2017. Other forms and dosage strengths of Brilinta, including medicine obtained via US retail or mail order pharmacies, are not affected by this voluntary recall. This recall does not affect Zurampic.

Brilinta is indicated to reduce the rate of CV death, heart attack and stroke in patients with acute coronary syndrome (ACS) or a history of heart attack. Brilinta also reduces the rate of stent thrombosis in patients who have been stented for treatment of ACS. Zurampic is a prescription medicine used together with a xanthine oxidase inhibitor such as allopurinol or Uloric in adults with gout who still have a high uric acid level. Brilinta 90 mg tablets are supplied as a round, biconvex, yellow, film-coated tablet, and imprinted with 90 above a T on one side of the pill. Zurampic tablets 200 mg are blue in color and elliptical/oval in shape. They are imprinted with LES200 on one side of the pill.

**RECOMMENDATION:** AstraZeneca is notifying physicians by recall letter and is arranging for return of all recalled products. Consumers that have medicine which is being recalled should contact their physician.

<https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm560786.htm>

#### **Mibela 24 Fe Chewable Tablets by Lupin Pharmaceuticals Inc.: Recall- Out of Sequence Tablets and Missing Expiry/Lot Information**

**May 26, 2017**

**ISSUE:** Lupin Pharmaceuticals Inc. announced a recall of lot L600518, Exp 05/18 of Mibelas 24 Fe (Norethindrone Acetate and Ethinyl Estradiol 1 mg/0.02 mg chewable and ferrous fumarate 75 mg) Tablets at the consumer level. A confirmed market complaint indicated a packaging error, where the blister was rotated 180 degrees within the wallet, reversing the weekly tablet orientation and making the lot number and expiration date no longer visible. The first four days of therapy would have had four non-hormonal placebo tablets as opposed to the active tablets.

As a result of this packaging error, oral contraceptive tablets that are taken out of sequence may place the user at risk for contraceptive failure and unintended pregnancy. The reversing the order may not be apparent to either new users or previous users of the product, increasing the likelihood of taking the tablets out of order. For patients in whom a pregnancy is contraindicated or in whom concomitant medication(s) may have teratogenic effects, an unintended pregnancy may cause significant adverse maternal or fetal health consequences, including death. To date there have been no reports of such adverse events.

**BACKGROUND:** This product is an oral contraceptive indicated for the prevention of pregnancy in women who elect to use oral contraceptives. These products are packaged in blister packs containing 28 tablets: 24 white to off-white tablets of active ingredients debossed with "LU" on one side and "N81" on the other; and 4 tablets of inert ingredients debossed with "LU" on one side and "M22" on the other side. This product was distributed Nationwide in the U.S.A. to wholesalers, clinics and retail pharmacies.

**RECOMMENDATION:** Consumers who have the affected product should notify their physician and return the product to the pharmacy or place of purchase and contact their physician or healthcare provider if they have experienced any problems that may be related to taking this drug product.

<https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm560908.htm>

#### **Eliquis (apixaban) 5 mg tablets: Recall One Lot- Bottle labeled as Eliquis 5 mg was found to contain Eliquis 2.5 mg tablets**

**June 13, 2017**

**ISSUE:** Bristol-Myers Squibb Company is voluntarily recalling one lot (#HN0063) of Eliquis 5 mg tablets to the consumer level. This lot was distributed nationwide in the U.S. to wholesalers and retail pharmacies in February 2017. Bristol-Myers Squibb is taking this precautionary measure based on a customer complaint that a bottle labeled as Eliquis 5 mg was found to contain Eliquis 2.5 mg tablets.

**BACKGROUND:** Eliquis tablets are indicated to reduce the risk of stroke and blood clots in people who have atrial fibrillation; it also treats blood clots in the veins of your legs or lungs as well as reduces the risk of forming a blood clot in the legs and lungs of people who have just had hip or knee replacement surgery.

**RECOMMENDATION:** Patients should not stop taking Eliquis without consulting with their physician. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking this drug product.

<https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm563035.htm>

### Topical Products by Phillips Company: Recall - Due to Concerns of Manufacturing Practices

June 14, 2017

**ISSUE:** Phillips Company is voluntarily recalling all lots of Tetrastem, Diabecline, Tetracycline-ABC, VenomX, Acneen, StaphWash, StringMed, NoPain and LidoMed distributed by Phillips Company, with business offices located in Sun City, Arizona, to the retail level. The products are being recalled after an FDA inspection found significant manufacturing practices that calls into question the safety, identity, strength, quality and purity of unexpired drug products made at the firm during the past three years.

Manufacturing practices that are not in adequate control represent the possibility of risk being introduced into the manufacturing process in decreased quality and consistency of the product. These may have an impact on the safety and efficacy of the product posing a risk to patients. To date, no adverse events have been reported.

**BACKGROUND:** The topical antibiotic products are intended for treatment of minor cuts, scrapes and burns; or as skin cleansers or hair-growth promoters. All products are distributed in 5 mL dropper bottles for topical application. The expiration date is printed on the label on the bottle. Products were distributed nationwide as wholesale products.

**RECOMMENDATION:** Phillips Company is notifying its distributors and customers by issuance of recall letters, and is arranging for return of all recalled products. Consumers/distributors/retailers that have a product which is being recalled should stop using the product and return any unused and unexpired products to the manufacturer. Consumers with questions regarding this recall can contact Phillips Company by e-mail ([hp@valliant.net](mailto:hp@valliant.net)).

<https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm563204.htm>

### Paliperidone Extended-Release Tablets 3mg by Teva Pharmaceuticals: Recall - Dissolution Test Failure

June 15, 2017

**ISSUE:** Teva Pharmaceuticals USA, Inc. (Teva) initiated a voluntary recall to retail-level on 05/31/2017 for one lot of Paliperidone Extended-Release Tablets, 3mg, 90 count bottles, lot 1160682A, expiration 6/2018, NDC 0591-3693-19, that was distributed under the Actavis Pharma Inc. label. In coordination with FDA, Teva is extending this recall to the consumer/user level.

This recall is being carried out due to failing test results for dissolution. Teva cannot at this time exclude the potential for additional tablets to be below specification.

Taking a product for the treatment of schizophrenia and schizoaffective disorders that has failed dissolution could result in less drug being absorbed. If two or more consecutive dosing regimens are with affected product, a failure to maintain therapeutic levels could occur, which could reduce effectiveness in treating a patient's mental and/or mood symptoms, including suicidal thoughts and behavior, self-injurious behavior, mental hospitalizations, assaults, aggressive behavior, as well as vocal and motor tics.

Based on Teva's investigation, the likelihood of consuming two or more consecutive doses with affected product is low. In addition, no post marketing adverse events have been received to date for lack of effectiveness for this recalled lot.

**BACKGROUND:** Paliperidone Extended Release Tablets, 3mg is indicated for the treatment of schizophrenia and schizoaffective disorders and was distributed nationwide in the USA to wholesalers.

**RECOMMENDATION:** Teva has issued an Urgent Drug Recall Letter to its direct accounts. Teva has made arrangements for impacted product to be returned to Inmar. The letter asks these consignees to notify their customers that were shipped the recalled lot informing them of this recall. Anyone with an existing inventory of the recalled lot should stop use and distribution, and follow the instructions in the letter for product returns. Teva does not expect any supply interruptions.

Consumers with questions regarding this recall can contact Teva by 1-888-838-2872, option 3, then option 4, Monday – Friday (excluding holidays), 9 am to 5 pm Eastern Time, or email [druginfo@tevapharm.com](mailto:druginfo@tevapharm.com). Consumers should contact their healthcare provider, physician and/or pharmacist if they have experienced any problems that may be related to this drug product.

<https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm563358.htm>

## STUDIES AND RECENT TOPICS

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### Could adoption of biosimilars be slowed by 'rebate trap'? Yale experts think so

**May 5, 2017**

There is an expectation that biosimilars will reap billions of dollars in saving for U.S. consumers by 2020. But there may be a flaw in that logic tied to the rebates drugmakers offer payers to get expensive biologics on their formularies. The practice could actually raise payers' costs if they offer biosimilars, what two Yale medical experts call the "rebate trap."

<http://www.fiercepharma.com/pharma/could-adoption-biosimilars-be-slowed-by-rebate-trap-yale-experts-think-so>

### Most Docs Make Wrong Choices in Stopping PPIs

**May 7, 2017**

When given the choice of stopping proton pump inhibitors that reduce the risk of gastrointestinal bleeding but have a risk of adverse side effects, doctors tended to make the wrong decision – continuing treatment in patients with the least need for PPIs to prevent bleeding and stopping the treatment in patients most likely to have fatal bleeds, researchers reported here.

<http://www.medpagetoday.com/meetingcoverage/ddw/65101>

### EpiPens should work at least a while past expiration dates

**May 8, 2017**

It's worth a shot to use an expired EpiPen, if that's all you have, a new study suggests. For more than four years past their stamped expiration dates, the handheld injectors retained high-enough concentrations of epinephrine to in all likelihood prevent potentially fatal allergic reactions, the study found.

<http://www.reuters.com/article/us-health-epipens-expiration-idUSKBN1842BW>

### Kisqali Femara Co-Pack Approved by FDA

**May 8, 2017**

The Food and Drug Administration (FDA) has approved Kisqali Femara Co-Pack (Novartis), a co-packaged product indicated as initial endocrine-based therapy for the treatment of postmenopausal women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer.

<http://www.empr.com/news/kisqalie-femera-postmenopausal-breast-cancer/article/655736/>

### Low-Dose Aspirin No Aid Against Cognitive Decline

**May 9, 2017**

Low-dose aspirin does not protect against cognitive decline, according to a review published April 20 in the Journal of the American Geriatrics Society. Nicola Veronese, M.D., from the Italian Research Council in Padova, and colleagues conducted a systematic literature review to identify observational and interventional studies that investigated low-dose aspirin and the incidence of dementia and cognitive impairment.



<http://fortune.com/2017/05/09/fda-new-drug-approvals/>

### **The FDA Has Approved a Crazy Number of New and Groundbreaking Drugs This Year**

**May 9, 2017**

The Food and Drug Administration (FDA) has been on a streak of late. Over the weekend, the agency approved the first new treatment for ALS, or Lou Gehrig's disease, since 1995 (Mitsubishi Tanabe Pharma's Radicava). The brings the total number of new medicine approvals up to 20 so far this year.

<http://fortune.com/2017/05/09/fda-new-drug-approvals/>

### **Nearly 1 In 3 Recent FDA Drug Approvals Followed By Major Safety Actions**

**May 9, 2017**

The Food and Drug Administration is under pressure from the Trump administration to approve drugs faster, but researchers at the Yale School of Medicine found that nearly a third of those approved from 2001 through 2010 had major safety issues years after they were widely available to patients.

<http://khn.org/news/1-in-3-recent-fda-drug-approvals-followed-by-major-safety-actions/>

### **Hormone replacement therapy may increase risk of hearing loss**

**May 10, 2017**

Hearing loss affects tens of millions of people in the United States. New research examines the link between menopausal age, the use of oral hormonal therapy, and hearing loss in the first large-scale study of its kind.

<http://www.medicalnewstoday.com/articles/317387.php>

### **FDA proposes that doctors learn about acupuncture for pain management**

**May 10, 2017**

Chiropractors and acupuncturists who have lobbied for a bigger role in treating pain have won a preliminary endorsement from federal health officials. The Food and Drug Administration released proposed changes Wednesday to its blueprint on educating health care providers about treating pain. The guidelines now recommend that doctors get information about chiropractic care and acupuncture as therapies that might help patients avoid prescription opioids.

<https://www.statnews.com/2017/05/10/pain-acupuncture-chiropractic-fda/>

### **Heroin Epidemic Is Driving A Spike In Hepatitis C Cases, CDC Says**

**May 11, 2017**

The number of new Hepatitis C cases leaped nearly 300 percent from 2010 to 2015, according to a report released Thursday by the Centers for Disease Control and Prevention. And the CDC points to the likely culprit behind the spike in cases of the infectious disease: the use of heroin and other injection drugs.

<http://www.wnyc.org/story/heroin-epidemic-is-driving-a-spike-in-hepatitis-c-cases-cdc-says/>

### [Modern HIV drugs can add 10 years to life expectancy, study says](#)

**May 14, 2017**

The latest treatments for HIV mean that young people living with the virus could live up to a decade longer, a new study says. The paper, published Wednesday, found that 20-year-olds who started with antiretroviral therapy in 2010 are predicted to live up to 10 years longer than those who first underwent similar treatment in 1996 — when it first became widely available.

<http://wtkr.com/2017/05/14/modern-hiv-drugs-can-add-10-years-to-life-expectancy-study-says/>

### [Yelp for drugs? Sermo debuts drug-rating tool for doctors featuring reviews, ratings and comments](#)

**May 15, 2017**

Like consumers who scroll Amazon reviews, doctors looking for opinions on prescription drugs have a new place to turn. The Drug Ratings online database, launched last week by physician social network Sermo, allows doctors to tap into peer reviews, ratings and discussions about drugs.

[http://www.fiercepharma.com/marketing/yelp-for-drugs-sermo-bows-doctor-to-doctor-drug-ratings-tool-med-crowd-sourced-comments?utm\\_medium=nl&utm\\_source=internal&mrkid=696991&mkt\\_tok=eyJpIjoiWm1Rd1pEZ3lZV0V3TjJOaCslInQiOiJTemw1Sm16SUIyQ1VvN1JRc2FCYU5hVDdDOE9](http://www.fiercepharma.com/marketing/yelp-for-drugs-sermo-bows-doctor-to-doctor-drug-ratings-tool-med-crowd-sourced-comments?utm_medium=nl&utm_source=internal&mrkid=696991&mkt_tok=eyJpIjoiWm1Rd1pEZ3lZV0V3TjJOaCslInQiOiJTemw1Sm16SUIyQ1VvN1JRc2FCYU5hVDdDOE9)

### [Diabetes drug metformin shows promise in treating one form of autism](#)

**May 15, 2017**

Metformin has been helping patients with Type 2 diabetes control their blood sugar for more than two decades, but now researchers led by McGill University are investigating a new use for the drug: to treat fragile X syndrome, which causes some forms of autism. Mouse models of fragile X show many of the telltale symptoms of the disease, including a lack of socialization. But within 10 days of being injected with metformin, their brain connections and behaviors were normal, according to a press release from the university. The research was published in the journal Nature Communications.

[http://www.fiercebiotech.com/research/diabetes-drug-metformin-shows-promise-treating-one-form-autism?mkt\\_tok=eyJpIjoiTTJKaVlXTmtZelk1TVRVMCIsInQiOiJyclhrWnQzZ2Q1bkVDS2Z4Q1dEOGM0RTBTBTR0hOYnRXZVBRRDd0d1d0cUI6NE1RREVKKeHNTSU1IVkZLSkdqbERGTmZVVFo1aVVvsSWJHaGFLRnd](http://www.fiercebiotech.com/research/diabetes-drug-metformin-shows-promise-treating-one-form-autism?mkt_tok=eyJpIjoiTTJKaVlXTmtZelk1TVRVMCIsInQiOiJyclhrWnQzZ2Q1bkVDS2Z4Q1dEOGM0RTBTBTR0hOYnRXZVBRRDd0d1d0cUI6NE1RREVKKeHNTSU1IVkZLSkdqbERGTmZVVFo1aVVvsSWJHaGFLRnd)

### [FDA adds Boxed Warning to Janssen's Type 2 Diabetes Drug Label](#)

**May 16, 2017**

Based on new data from two large clinical trials, the US Food and Drug Administration (FDA) on Tuesday concluded that Janssen's type 2 diabetes medicine canagliflozin (brand names include Invokana, Invokamet, Invokamet XR) causes an increased risk of leg and foot amputations.

<http://www.raps.org/Regulatory-Focus/News/2017/05/16/27560/FDA-Adds-Boxed-Warning-to-Janssens-Type-2-Diabetes-Drug-Label/>

### [Hepatitis C infections nearly tripled between 2010 and 2015, CDC says](#)

**May 16, 2017**

New cases of hepatitis C infections nearly tripled from 2010 to 2015, but just three states have laws and Medicaid policies aimed at stemming the spread of the virus and increasing access to treatment, according to a pair of CDC reports published Thursday.

<https://www.advisory.com/daily-briefing/2017/05/16/hep-c-prevalence>

### **HPV vaccine may reduce oral infections by as much as 88 percent**

**May 17, 2017**

With low vaccination rates, impact still modest overall, and low in men. Researchers have found that the human papillomavirus (HPV) vaccine may reduce the rate of oral HPV infections in young adults by as much as 88 percent. However, given the vaccine's low rate of uptake in the U.S. – especially in males – the impact of the vaccine on oral HPV infections remains low.

<https://www.mdanderson.org/newsroom/2017/05/hpv-vaccine-may-reduce-oral-infections-by-as-much-as-88-percent.html>

### **Oral contraceptives associated with worsening lipid profile in PCOS**

**May 18, 2017**

In women with polycystic ovary syndrome, the use of any oral contraceptive was associated with a rise in triglyceride and total cholesterol levels over time, and oral contraceptives containing third-generation progestins did not offer substantial advantages, according to findings from a systematic review and meta-analysis.

<http://www.healio.com/endocrinology/cardiometabolic-disorders/news/in-the-journals/%7Be6d2c806-c47a-4549-8338-62db20af3c7f%7D/oral-contraceptives-associated-with-worsening-lipid-profile-in-pcos>

### **Drugs approved with limited data aren't always well-tested later**

**May 19, 2017**

New medicines that win U.S. marketing approval without conclusive evidence of their effectiveness aren't always proven to work after they go on sale, a recent research review suggests. Researchers focused on medicines approved for sale based on single pivotal trials or based on what's known as "surrogate markers," such as lab tests and signs of risk for disease such as cholesterol levels instead of true clinical outcomes like heart attacks or deaths. Many times no follow-up studies were published after these medicines went on sale, and when studies were published they often continued to rely on surrogate markers to suggest potential effectiveness.

<http://www.reuters.com/article/us-health-medicines-approval-idUSKCN18F2JD>

### **Could Cancer Drug Gleevec Help With Severe Asthma?**

**May 20, 2017**

A leukemia drug might also effectively treat severe asthma, a small-scale clinical trial suggests. Gleevec (imatinib) reduced the "twitchiness" of airways, making them less likely to reflexively constrict when exposed to an allergen or asthma trigger, said senior researcher Dr. Elliot Israel.

[http://journalstar.com/lifestyles/health-med-fit/could-cancer-drug-gleevec-help-with-severe-asthma/article\\_0e3e5e4c-566e-5d9c-a806-e0972809cd40.html](http://journalstar.com/lifestyles/health-med-fit/could-cancer-drug-gleevec-help-with-severe-asthma/article_0e3e5e4c-566e-5d9c-a806-e0972809cd40.html)

### **First-Try Antibiotics Now Fail in 1 in 4 Adult Pneumonia Cases**

**May 21, 2017**

The first prescription of an antibiotic that the average U.S. adult with pneumonia receives is now ineffective in about a quarter of cases, a new study finds. In these cases, more or different antibiotics were needed, or the

patient's condition worsened to require ER admission or hospitalization within a month of the antibiotics being taken, the research team said.

<https://consumer.healthday.com/infectious-disease-information-21/pneumonia-news-536/first-try-antibiotics-now-fail-in-1-in-4-adult-pneumonia-cases-722761.html>

### **Checking Patient's Drug History May Help Curb Opioid Abuse**

**May 23, 2017**

Doctors can help stem the U.S. opioid epidemic by checking their patients' drug history before prescribing powerful painkillers, a new study suggests. Addicts frequently "doctor-shop" in an attempt to obtain opioids such as OxyContin (oxycodone), Percocet (oxycodone/acetaminophen) and Vicodin (hydrocodone/acetaminophen).

<https://consumer.healthday.com/bone-and-joint-information-4/opioids-990/checking-patient-s-drug-history-may-help-curb-opioid-abuse-722263.html>

### **Statin Therapy Found to Be of Little Benefit in Older Adults**

**May 23, 2017**

The benefit of pravastatin for primary prevention in older adults with moderate hyperlipidemia and hypertension is questionable, according to a study published online May 22 in JAMA Internal Medicine. Benjamin Han, M.D., M.P.H., an assistant professor of medicine and population health at the New York University School of Medicine in New York City, and colleagues analyzed data from a clinical trial conducted from 1994 to 2002: the Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial-Lipid-Lowering Trial (ALLHAT-LLT). From this study, the researchers drew a sample that included 2,867 adults 65 and older with hypertension, but without baseline atherosclerotic cardiovascular disease. About half of those adults took pravastatin while half received usual care

<http://www.physiciansbriefing.com/Article.asp?AID=722965>

### **Deadly brain infection in German MS patient prompts Roche investigation**

**May 24, 2017**

A person in Germany treated with Roche Holding AG's new multiple sclerosis drug Ocrevus has been diagnosed with an often-deadly brain infection after switching from another medication earlier this year, the Swiss drugmaker said on Wednesday.

<http://www.reuters.com/article/us-roche-pharmaceuticals-idUSKBN18K2SG>

### **Accelerated FDA approval and pricey drugs make a rotten combo, doctors argue**

**May 25, 2017**

Should drugs that win FDA approval on an accelerated path—often without strong evidence of efficacy—command the same high prices as products that undergo the full menu of agency scrutiny? Not necessarily, two doctors contend in a new journal article. And they have some ideas for bringing the costs of those drugs way down, at least until their makers can prove they really work.

<http://www.fiercepharma.com/regulatory/accelerated-fda-approval-and-pricey-drugs-make-a-rotten-combo-doctors-argue>

### **Promising Results for Drug to Fight Arthritis Linked to Psoriasis**

**May 26, 2017**

A new drug might help ease the pain and disability of a form of arthritis often linked to psoriasis. According to Stanford University researchers, psoriatic arthritis is an inflammatory joint disorder tied to an out-of-control immune response. The disease affects about one in every 200 people and is often accompanied by the autoimmune skin disorder psoriasis.

<https://www.mdanderson.org/newsroom/2017/05/hpv-vaccine-may-reduce-oral-infections-by-as-much-as-88-percent.html>

### **New vancomycin kills antibiotic-resistant bacterial superbugs**

**May 29, 2017**

The frightening spread of antibiotic-resistant superbugs threatens to return medicine to the pre-antibiotic era, with the return of deadly infectious diseases long thought vanquished.

<http://www.sandiegouniontribune.com/business/biotech/>

### **In cancer treatment, there's more than one way to measure patient benefit**

**June 1, 2017**

We all want a cure for cancer. But the reality is that advances in cancer treatment rarely come in one big discovery, but rather with the continued step-by-step progress in developing new therapies. Currently, a few cancers—such as childhood leukemia and testicular cancer—can be cured. There are many ways of evaluating cancer therapies, including an improvement in overall survival, stabilizing the disease, and reducing tumor burden and tumor-related symptoms. Over the years, we have discussed with many patients facing serious and life-threatening diseases how to evaluate cancer treatments. The patients have told us there is a need for flexibility in our evaluation process.

<https://blogs.fda.gov/fdavoices/index.php/2017/06/in-cancer-treatment-theres-more-than-one-way-to-measure-patient-benefit/>

### **Are Many A-Fib Patients Getting the Wrong Dose?**

**June 5, 2017**

Nearly one in six Americans who takes newer blood thinners for the heart rhythm problem atrial fibrillation may not receive the proper dose, a new study suggests. A-fib is a common condition, marked by an irregular and often rapid heartbeat. It's associated with a fivefold increased risk of stroke, but blood thinners reduce that risk. Many a-fib patients also have kidney disease and need a lower medication dose than others, the study authors said.

<https://consumer.healthday.com/cardiovascular-health-information-20/atrial-fibrillation-959/are-many-a-fib-patients-getting-the-wrong-dose-723290.html>

### **America is a world leader in health inequality**

**June 5, 2017**

The divide between health outcomes for the richest and poorest Americans is among the largest in the world, according to a new study. Of people in households making less than \$22,500 a year, 38 percent reported being in poor or fair health in a survey taken between 2011 and 2013. That's more than three times the rate of health troubles faced by individuals in households making more than \$47,700 a year, where only 12 percent of people reported being in poor to fair health, according to the findings published in Health Affairs.

[https://www.washingtonpost.com/news/wonk/wp/2017/06/05/america-is-a-world-leader-in-health-inequality/?utm\\_term=.edd23aae9908](https://www.washingtonpost.com/news/wonk/wp/2017/06/05/america-is-a-world-leader-in-health-inequality/?utm_term=.edd23aae9908)

### **Latest Data on Pharmacy Market's Evolution: The Real Story Behind the Retail vs. Mail Battle**

**June 6, 2017**

QuintilesIMS recently released Medicines Use and Spending in the U.S.: A Review of 2016 and Outlook to 2021. The report is an excellent, albeit often misinterpreted, resource for understanding the pharma market.

<http://www.drugchannels.net/2017/06/latest-data-on-pharmacy-markets.html>

### **Standard dosage for one lung cancer treatment may be too high**

**June 6, 2017**

A new study published in the Journal of the National Cancer Institute indicates that the customary pembrolizumab dose for treatment of metastatic non-small cell lung cancer may be higher than is needed for effective treatment. In October 2016, pembrolizumab became the new standard of care for first-line treatment of patients with metastatic non-small cell lung cancer whose tumors express programmed death ligand 1 in at least 50% of cells.

[https://www.eurekalert.org/pub\\_releases/2017-06/oupu-sdf060617.php](https://www.eurekalert.org/pub_releases/2017-06/oupu-sdf060617.php)

### **Drugs for Diabetes: It's No Longer Just About Controlling Blood Sugar**

**June 7, 2017**

Cardiovascular disease is perhaps the most dangerous consequence of diabetes, despite the ravaging impact that neuropathy, nephropathy, and retinopathy can have on people with the disease. About two out of three people ages 65 or older with diabetes die from heart disease, and about one in seven die from stroke. Put another way, adults with diabetes are two to four times more likely to die from heart disease than adults without diabetes.

<https://www.managedcaremag.com/archives/2017/6/drugs-diabetes-it-s-no-longer-just-about-controlling-blood-sugar>

### **Opioids Over-Prescribed After C-Sections: Studies**

**June 8, 2017**

Women are routinely prescribed more opioid painkillers than they need after Cesarean sections, creating a high risk for misuse, a trio of new studies suggests. C-sections are the most common inpatient surgery in the United States, with 1.3 million procedures performed a year, according to the researchers. But there is little data on how much medicine patients actually need to manage their pain. To that end, how many pills are prescribed varies from provider to provider, the researchers added.

<https://consumer.healthday.com/sexual-health-information-32/childbirth-health-news-126/opioids-over-prescribed-after-c-sections-studies-723497.html>

### **FDA Approves Generic Truvada for HIV Treatment and PrEP**

**June 9, 2017**

However, Gilead Sciences, the brand-name manufacturer of Truvada, insists a generic version "will not be immediately available." In a move that has taken HIV advocates by surprise and stewed considerable confusion, the U.S. Food and Drug Administration (FDA) has approved a generic formulation of Gilead Sciences' blockbuster antiretroviral (ARV) Truvada (tenofovir disoproxil fumarate/emtricitabine). This decision could have major implications for the future cost of Truvada, to insurers and consumers alike.

<https://www.poz.com/article/fda-approves-generic-truvada>

### **Study finds no link between PPIs, dementia, Alzheimer's risk**

**June 9, 2017**

Researchers found no association between the use of proton pump inhibitors and the risk for mild cognitive impairment, dementia and Alzheimer's disease in a recent observational, longitudinal study. These findings contrast with those from two recent studies that found significant associations between PPI use and dementia and Alzheimer's disease in older patients.

<https://www.healio.com/gastroenterology/therapeutics-diagnostics/news/online/%7B010be884-13ab-4ec4-88cf-26c382bd2ad3%7D/study-finds-no-link-between-ppis-dementia-alzheimers-risk>

### **Generic drugs see low abandonment rate**

**June 12, 2017**

Prescription abandonment is sharply higher for branded drugs than generic drugs, a new annual report commissioned by the Association for Accessible Medicines (AAM) found. AAM said Monday that abandonment — defined as the failure to pick up a new script — was nearly three times as high for brand-name drugs as for generics last year, according to the “2017 AAM Generic Drug Access & Savings in the U.S.” study.

<http://www.chaindrugreview.com/generic-drugs-see-low-abandonment-rate/>

### **A surprising new link between inflammation and mental illness**

**June 14, 2017**

Up to 75 percent of patients with systemic lupus erythematosus—an incurable autoimmune disease commonly known as lupus—experience neuropsychiatric symptoms. But so far, our understanding of the mechanisms underlying lupus' effects on the brain has remained murky. Now, new research from Boston Children's Hospital has shed light on the mystery and points to a potential new drug for protecting the brain from the neuropsychiatric effects of lupus and other central nervous system (CNS) diseases. The team has published its surprising findings in Nature.

<https://medicalxpress.com/news/2017-06-link-inflammation-mental-illness.html>

## RECALLS

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drugs	LaBri's Body Health Atomic, 60 capsules	Class I	All lot codes, manufacturing codes and expiration dates.	Marketed without an approved NDA/ANDA: Product contains undeclared Sibutramine.	Envy Me 7018 Southhaven Dr Corp Christi, TX 78412-4132
Drugs	Hyland's Baby Teething Tablets [Calcarea Phosphorica 6X HPUS, Chamomilla 6X HPUS, Coffea Cruda 6X HPUS, Belladonna 12X HPUS (0.00000000000003% alkaloids, calculated)] Quick-Dissolving Tablets, packaged in a) 40-count bottles (NDC 54973-3127-3) (UPC 3 54973 31273 9); b) 135-count bottles (NDC 54973-3127-1) (UPCs 3 54973 31271 5, 3 54973 31371 2, 354973 31481 8); and 250-count bottles (NDC 54973-3127-2) (UPCs 3 54973 31272 2, 3 54973 31521 1), Manufactured for: Hyland's, Inc., Los Angeles, CA 90061	Class I	All lots within expiry	Superpotent Drug: FDA analysis found inconsistent amounts of belladonna alkaloids that may differ from the calculated amount on the product labels.	Standard Homeopathic Company 154 W 131st St Los Angeles, CA 90061-1616
Drugs	Hyland's Baby Nighttime Teething Tablets [Belladonna 12X HPUS (0.00000000000003% alkaloids, calculated), Calcarea Phosphorica 6X HPUS, Chamomilla 6X HPUS, Coffea Cruda 6X HPUS, Magnesia Phosphorica 6X HPUS, Rheum 6X HPUS, Silicea 12X HPUS] Quick-Dissolving Tablets, 135-count bottle, Manufactured for: Hyland's, Inc., Los Angeles, CA 90061, NDC 54973-3197-1, UPC 3 54973 31971 4.	Class I	All lots within expiry	Superpotent Drug: FDA analysis found inconsistent amounts of belladonna alkaloids that may differ from the calculated amount on the product labels.	Standard Homeopathic Company 154 W 131st St Los Angeles, CA 90061-1616
Drugs	Infant 25% DEXTROSE Injection, USP, 2.5 g (250 mg/mL), 10 mL Unit of Use Single-dose Syringe per carton, Rx only, Hospira Inc., Lake Forest, IL 60045, NDC 0409-1775-10	Class I	Lot 58382EV*, Exp 10 CT 2017, *lot may be followed by 01 or 02	Presence of Particulate Matter: human hair found within an internal sample syringe.	Hospira Inc. 600 N Field Dr Lake Forest, IL 60045-4835
Drugs	5-MTHF *10ML* MDV 5MG/ML INJ, Injection, 5mg/mL, Rx only, 10mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy	Class II	Lot # t11-21-2016@112, Exp 5/21/2017; 12-15-2016@73, Exp 6/13/2017; 01-13-2017@67, Exp 7/12/2017; t02-14-2017@97, Exp 8/14/2017	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383



Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drugs	5-MTHF 10ML MDV (CALIF) 5MG/ML INJ, Injection, 5mg/mL, Rx only, 10mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy	Class II	Lot # t11-17-2016@86, Exp 5/17/2017; t12-22-2016@103, Exp 7/4/2017; t01-09-2017@111, Exp 7/9/2017; t01-11-2017@118, Exp 7/11/2017; t01-18-2017@89, Exp 7/18/2017; t01-20-2017@83, Exp 7/23/2017.	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383
Drugs	5-MTHF 10ML SDV (CALIF) 5MG/ML INJ, Injection 5mg/mL, Rx only, 10mL Glass /Single Dose vial, Prepared by Key Compounding Pharmacy	Class II	Lot # t12-28-2016@113, Exp 6/27/2017.	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383
Drugs	5-MTHF SDV 5MG/ML INJ, Injection, 5mg/mL, Rx only, packaged in 1 mL, 2 mL, 5 mL, and 10 mL Glass/Single Dose vials, Prepared by Key Compounding Pharmacy	Class II	Lot # t12-05-2016@116, Exp 6/4/2017; t12-15-2016@84, Exp 6/14/2017; t12-23-2016@67, Exp 6/25/2017; t12-28-2016@105, Exp 6/27/2017; t01-30-2017@88, Exp 7/30/2017; t02-06-2017@109, Exp 8/6/2017; t02-14-2017@92, Exp 8/14/2017; t02-20-2017@79, Exp 8/20/2017	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383
Drugs	ATROPINE SULFATE 0.5% OPHTH, Ophthalmic 0.50%, Rx only, 15mL Glass /Multiple Dose vial, Prepared by Key Compounding Pharmacy	Class II	Lot # t01-26-2017@93, Exp 4/27/2017	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383
Drugs	CO-Q-10 OIL 20ML MDV (CALIF) 25MG/ML INJ, Injection, 25mg/mL, Rx only, 20mL Glass /Multiple Dose vial, Prepared by Key Compounding Pharmacy	Class II	Lot # t02-01-2017@119, Exp 5/3/2017.	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drugs	DMPS ACID *5ML* SDV 50MG/ML INJ, Injection, 50mg/ml, Rx only, 5 mL glass/ Single Dose vial, Prepared by Key Compounding Pharmacy	Class II	Lot # t12-16-2016@73, Exp 4/18/2017; t12-27-2016@93, Exp 4/27/2017; t01-09-2017@102, Exp 5/10/2017; t01-10-2017@120, Exp 5/11/2017; 02-01-2017@78, Exp 6/1/2017; t02-08-2017@96, Exp 6/9/2017; t02-20-2017@80, Exp 6/21/2017; t02-21-2017@122, Exp 6/23/2017; t02-23-2017@68, Exp 6/24/2017.	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383
Drugs	DMSO 6.25% OPHTH., 6.25%, Rx only, 15 mL plastic/Multiple Dose bottle, Prepared by Key Compounding Pharmacy	Class II	Lot # 02-23-2017@36, Exp 5/24/2017	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383
Drugs	FERR GLUC/PROCAINE 10ML MDV 60/10MG/ML INJ, Injection, 60mg/10mg/mL, Rx only, 10 mL glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy	Class II	Lot # t01-23-2017@83, Exp 5/24/2017	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383
Drugs	FOLIC ACID 1ML SDV 10MG/ML INJ, Injection, 10mg/mL, Rx only, 1 mL glass/Single Dose vial, Prepared by Key Compounding Pharmacy	Class II	Lot # t01-20-2017@80, Exp 4/23/2017	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383
Drugs	FOLINIC ACID MDV (CALIF) 5MG/ML INJ, Injection, 5mg/mL, Rx only, packaged in 5 mL and 10 mL glass/ Multiple Dose vial, Prepared by Key Compounding Pharmacy	Class II	Lot # t02-09-2017@74, Exp 5/15/2017; t02-17-2017@89, Exp 5/21/2017; t02-20-2017@72, Exp 5/22/2017.	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drugs	FOLINIC ACID MDV INJ, Injection, 10 mg/mL, Rx only, packaged in 2mL and 10 mL glass/Multiple Dose vials, Prepared by Key Compounding Pharmacy	Class II	Lot # t01-31-2017@128, Exp 5/2/2017; 01-31-2017@118, Exp 5/1/2017.	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383
Drugs	HCG *10ML* MDV 500U/ML INJ, Injection, 500u/mL, Rx only, 10 mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy	Class II	Lot # 01-20-2017@74, Exp 4/20/2017; t02-01-2017@123, Exp 5/3/2017; t02-03-2017@47, Exp 5/7/2017; t02-07-2017@70, Exp 5/10/2017; t02-13-2017@100, Exp 5/15/2017	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383
Drugs	HYDROXO-B12 *1ML* SDV 1MG/ML INJ, Injection, 1mg/mL, Rx only, 1 mL Glass/Single Dose vial, Prepared by Key Compounding Pharmacy	Class II	Lot # t01-16-2017@91, Exp 4/17/2017; t02-08-2017@93, Exp 4/30/2017.	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383
Drugs	HYDROXO-B12 1ML SDV 10MG/ML INJ, Injection, 10mg/mL, Rx only, 1 mL glass/ Single Dose vial, Prepared by Key Compounding Pharmacy HYDROXO-B12 2ML SDV 10MG/ML INJ, Injection, 10mg/mL, RX only, 2 mL glass/ Single Dose vial.	Class II	Lot # t01-17-2017@103, Exp 4/18/2017; t01-23-2017@80, Exp 4/24/2017; t02-10-2017@120, Exp 4/30/2017	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383
Drugs	HYDROXO-B12 INH PF GV 5MG/ML SOLN, Inhalation Solution, 5mg/mL, Rx only, 5 mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy	Class II	Lot # 02-01-2017@38, Exp 4/30/2017	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383
Drugs	HYDROXO-B12 10ML PBF MDV 5MG/ML INJ, 5mg/mL, Rx only, 10 mL Glass/ Multiple Dose vial, Prepared by Key Compounding Pharmacy HYDROXO-B12 30ML PBF MDV 5MG/ML INJ, 5mg/mL, RX only, 30 mL Glass/ Multiple Dose vial.	Class II	Lot # t01-20-2017@87, Exp 4/23/2017; t02-08-2017@99, Exp 4/30/2017; t02-21-2017@113, Exp 4/30/2017	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drugs	HYDROXO-B12 5ML PBF MDV 1MG/ML INJ, Injection, 1mg/ml, Rx only, packaged in 5 mL Glass/ Multiple Dose and 30 mL Glass/ Multiple Dose vials, Prepared by Key Compounding Pharmacy	Class II	Lot # t02-06-2017@102, Exp 4/30/2017; t02-16-2017@106, Exp 4/30/2017.	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383
Drugs	HYDROXO-B12 PBF MDV 10MG/ML INJ, Injection, 10mg/mL, Rx only, packaged in a 5 mL and 30 mL Glass/ Multiple Dose vials, Prepared by Key Compounding Pharmacy	Class II	Lot # t01-16-2017@93, Exp 4/17/2017; t01-20-2017@81, Exp 4/23/2017	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383
Drugs	HYDROXO-B12 5ML PBF MDV (CALIF) 10MG/ML INJ, Injection, 10mg/mL, RX only, 5mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy	Class II	Lot # t02-15-2017@111, Exp 4/30/2017.	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383
Drugs	PAPAVERINE/PHEMT 5ML MDV 30/0.5MG/ML INJ, Injection, 30/0.5mg/mL, Rx only, 5mL glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy	Class II	Lot # t11-28-2016@111, Exp 5/28/2017; 02-10-2017@1, Exp 8/9/2017.	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383
Drugs	PAPAVERINE/PHEMT 5ML MDV 30/1MG/ML INJ, Injection, 30mg/1mg/mL, Rx only, 5mL glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy	Class II	Lot # t12-21-2016@110, Exp 6/20/2017; t12-27-2016@84, Exp 6/26/2017; t12-30-2016@74, Exp 7/2/2017.	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383
Drugs	PGE1 MDV 20MCG/ML INJ, Injection, 20mcg/mL, Rx only, packaged in a 5 mL, 10mL, and 15 mL Glass/Multiple Dose vials, Prepared by Key Compounding Pharmacy	Class II	Lot # t01-05-2017@102, Exp 7/5/2017; t02-02-2017@105, Exp 8/2/2017; t02-10-2017@121, Exp 8/2/2017.	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drugs	PGE1 5ML MDV INJ, Injection, 40mcg/mL, Rx only, 5mL glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy	Class II	Lot # t01-06-2017@92, Exp 7/5/2017	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383
Drugs	PGE1/CPZ 5ML MDV 20MCG/1MG/ML INJ, Injection, 20mcg/1mg/mL, Rx only, 5 mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy	Class II	Lot # t01-25-2017@112, Exp 7/5/2017	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383
Drugs	PGE1/PAP 10/30 5ML MDV MCG/MG/ML INJ, Injection, 10mg/30mg/mL, Rx only, 5mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy	Class II	Lot # t11-16-2016@90, Exp 4/19/2017	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383
Drugs	TRI MIX 10/15/1 5ML MDV MCG/MG/MG/ML INJ, Injection, 10mcg/15mg/1mg/mL, Rx only, 5 mL Glass/ Multiple Dose vial, Prepared by Key Compounding Pharmacy	Class II	Lot # t12-22-2016@102, Exp 6/18/2017	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383
Drugs	TRI MIX 10/15/2.5 5ML MDV MCG/MG/MG/ML INJ, Injection, 10mcg/15mg/2.5mg/mL, Rx only, 5 mL Glass/ Multiple Dose vial, Prepared by Key Compounding Pharmacy	Class II	Lot # t12-19-2016@69, Exp 5/22/2017	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383
Drugs	TRI MIX 10/30/0.5 *5ML* MDV MCG/MG/MG/ML INJ, Injection, 10mcg/30mg/0.5mg/mL, Rx only, 5 mL Glass/ Multiple Dose vial, Prepared by Key Compounding Pharmacy	Class II	Lot # 11-18-2016@70, Exp 4/19/2017; 11-23-2016@84, Exp 5/22/2017; t12-14-2016@99, Exp 5/22/2017; t01-03-2017@94, Exp 6/18/2017; 01-13-2017@71, Exp 7/5/2017; 01-25-2017@103, Exp 7/5/2017; 02-06-2017@94, Exp	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
			p 7/5/2017; t02-17-2017@87, Exp 8/2/2017.		
Drugs	TRI MIX 10/30/1 5ML MDV MCG/MG/MG/ML INJ, Injection, 10mcg/30mg/1mg/mL, Rx only, 5 mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy	Class II	Lot # t11-21-2016@125, Exp 4/19/2017; t01-09-2017@105, Exp 6/18/2017; t01-18-2017@90, Exp 7/5/2017	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383
Drugs	TRI MIX 11.8/17.6/0.59 5ML MDV MCG/MG/MG/ML INJ, Injection, 11.8mcg/17.6mg/0.59mg/mL, Rx only, 5mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy	Class II	Lot # t12-12-2016@84, Exp 5/22/2017	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383
Drugs	TRI MIX 13/30/0.8 5ML MDV MCG/MG/MG/ML INJ, Injection, 13mcg/30mg/0.8mg/mL, RX only, 5 mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy	Class II	Lot # t01-31-2017@127, Exp 7/5/2017	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383
Drugs	TRI MIX 16.7/4/0.27 5ML MDV MCG/MG/MG/ML INJ, Injection, 16.7mcg/4mg/0.27mg/ml, Rx only, 5mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy	Class II	Lot # t01-31-2017@120, Exp 7/5/2017	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383
Drugs	TRI MIX 20/20/1 5ML MDV MCG/MG/MG/ML INJ, Injection, 20mcg/20mg/1mg/mL, Rx only, 5 mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy	Class II	Lot # t01-10-2017@115, Exp 7/5/2017.	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383
Drugs	TRI MIX 20/30/0.5 5ML MDV MCG/MG/MG/ML INJ, Injection, 20mcg/30mg/0.5mg/mL, Rx only, 5 mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy	Class II	Lot # t11-23-2016@110, Exp 5/22/2017	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
					98003-6383
Drugs	TRI MIX 20/30/1 5ML MDV MCG/MG/MG/ML INJ, Injection, 20mcg/30mg/1mg/mL, Rx only, 5 mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy	Class II	Lot # t12-01-2016@9 3, Exp 5/22/2017; t02 -02-2017@100, Exp 8/ 2/2017.	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383
Drugs	TRI MIX 20/30/2 5ML MDV MCG/MG/MG/1ML INJ, Injection, 20mcg/30mg/2mg/mL, Rx only, 5 mL Glass/Multiple Dose vial , Prepared by Key Compounding Pharmacy	Class II	Lot # t12-07-2016@9 7, Exp 5/22/2017; t12 -12-2016@88, Exp 5/2 2/2017; t12-20-2016 @109, Exp 5/22/2017 ; t12-20-2016@119, E xp 6/18/2017; t12-23- 2016@63, Exp 6/18/2 017; t12-30-2016@84 , Exp 6/18/2017; t01- 09-2017@97, Exp 6/1 8/2017; t12-22-2016 @120, Exp 6/18/2017 ; t02-07-2017@72, Ex p 8/2/2017	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383
Drugs	TRI MIX 30/30/1 5ML MDV MCG/MG/MG/ML INJ, Injection, 30mcg/30mg/1mg/mL, Rx only, 5 mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy	Class II	Lot # t12-13-2016@9 5, Exp 5/22/2017	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383
Drugs	TRI MIX 40/30/2 5ML MDV MCG/MG/MG/ML INJ, Injection, 40mcg/30mg/2mg/mL, Rx only, 5 mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy	Class II	Lot # t02-02-2017 @93, Exp 8/2/2017	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383
Drugs	TRI MIX 40/30/4 5ML MDV MCG/MG/MG/ML INJ, Injection, 40mcg/30mg/4mg/mL, Rx only, 5 mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy	Class II	Lot # t12-30-2016 @73, Exp 6/18/201 7	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drugs	TRI MIX 45.45/27.27/0.45 5ML MDV MCG/MG/MG/ML INJ, Injection, 45.45mcg/27.27mg/0.45mg/mL, Rx only, 5 mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy	Class II	Lot # t12-12-2016@87, Exp 5/22/2017	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383
Drugs	TRI MIX 5.88/17.65/0.588 5ML MDV MCG/MG/MG/ML INJ, , Injection, 5.88mcg/17.65mg/0.588mg/mL, Rx only, 5 mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy	Class II	Lot # t12-02-2016@100, Exp 5/22/2017; t12-28-2016@104, Exp 6/18/2017.	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383
Drugs	TRI MIX 5.95/17.8572/0.6 5ML MDV MCG/MG/MG/ML INJ, Injection, 5.95mcg/17.85mg/0.6mg/mL, Rx only, 5 mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy	Class II	Lot # t12-12-2016@93, Exp 5/22/2017; t02-22-2017@93, Exp 8/2/2017	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383
Drugs	TRI MIX 5/30/0.5 5ML MDV MCG/MG/MG/ML INJ, Injection, 5mcg/30mg/0.5mg/mL, Rx only, 5 mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy	Class II	Lot # t02-01-2017@127, Exp 7/5/2017	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383
Drugs	TRI MIX 6/18/0.6 5ML MDV MCG/MG/MG/ML INJ, Injection, 6mcg/18mg/0.6mg/mL, Rx only, 5 mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy	Class II	Lot # t12-13-2016@98, Exp 5/22/2017	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383
Drugs	QUAD MIX 1/30/0.5/0.1 5ML MDV MCG/MG/MG/MG/ML INJ, Injection, 1mcg/30mg/0.5mg/0.15mg/mL, Rx only, 5 mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy	Class II	Lot # t01-05-2017@110, Exp 6/17/2017	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383



Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drugs	QUAD MIX 50/30/1/0.2 5ML MDV (CALIF) MCG/MG/MG/MG/ML INJ, Injection, 50mcg/30mg/1mg/0.2mg/mL, Rx only, 5 mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy	Class II	Lot # t02-02-2017@102, Exp 7/26/2017	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383
Drugs	PGE1/PROCAINE 5ML MDV 20MCG/ML/0.1% INJ, Injection, 20mcg/ml 0.1%, Rx only, 5 mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy	Class II	Lot # t12-12-2016@92, Exp 5/22/2017; t02-14-2017@103, Exp 8/2/2017	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383
Drugs	PGE1/PROCAINE 5ML MDV 40MCG/ML/0.1% INJ, Injection, 40mcg/mL, 0.1%, Rx only, 5 mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy	Class II	Lot # t11-28-2016@86, Exp 5/22/2017; t12-19-2016@73, Exp 5/22/2017	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383
Drugs	ALPHA LIPOIC ACID 25ML MDV 25MG/ML INJ, Injection, 25mg/mL, Rx only, 25 mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy	Class II	Lot # t02-22-2017@96, Exp 5/24/2017	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383
Drugs	VIT C/GSH 1.25%-1.25% OPHTH, Ophthalmic, 1.25%, Rx only, 15 mL Plastic/Multiple Dose bottle, Prepared by Key Compounding Pharmacy	Class II	Lot # 02-23-2017@35, Exp 4/24/2017	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383
Drugs	CHOL/IN/ME(L)/B6 10ML MDV 50/50/25/0.1MG/ML INJ, Injection, 50mg/50mg/25mg/0.1mg/mL, Rx only, 10mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy	Class II	Lot # t02-06-2017@107, Exp 4/30/2017 Lot t02-06-2017@107, Expiry date 4/30/2017	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drugs	CYANOCOBALAMIN 10ML MDV 1MG/ML INJ, Injection, 1mg/mL, Rx only, 10mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy	Class II	Lot # t02-13-2017@99, Exp 5/15/2017	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383
Drugs	CYCLOSPORIN (VET) *CORN OIL* 1% OPHTH, Ophthalmic, 1%, Rx only, 15mL Plastic/Multiple Dose vial, Prepared by Key Compounding Pharmacy	Class II	Lot # 01-30-2017@2, Exp 4/30/2017	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383
Drugs	FERR GLUC MDV 60MG/ML INJ, Injection, 60mg/mL, Rx only, Packaged in 5mL and 10mL Glass /Multiple Dose vial, Prepared by Key Compounding Pharmacy	Class II	Lot # t02-13-2017@98, Exp 5/15/2017; t02-14-2017@98, Exp 5/16/2017; t02-15-2017@120, Exp 5/17/2017	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383
Drugs	IRON SPECIAL 5ML MDV 60/10MG/5MCG/ML INJ, Injection, 60mg/1mg/5mcg/mL, Rx only, 5mL Glass /Multiple Dose vial, Prepared by Key Compounding Pharmacy	Class II	Lot # t02-16-2017@108, Exp 5/18/2017	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383
Drugs	GLUTATHIONE INH *PV* 200MG/ML SOLN, Inhalation Solution, 200mg/mL, Rx only, 4mL Plastic/Multiple Dose vial, Prepared by Key Compounding Pharmacy	Class II	Lot # 02-20-2017@8, Exp 4/21/2017	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383
Drugs	GSH/NAC INH 2ML PV 60/100MG/ML SOLN, Inhalation Solution, 60mg/100mg/mL, Rx only, 5mL Plastic/Single Dose vial, Prepared by Key Compounding Pharmacy	Class II	Lot # t02-20-2017@75, Exp 4/22/2017.	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drugs	GSH/NAC INH PV 150/50MG/ML SOLN, Inhalation Solution, 150mg/50mg/mL, Rx only, 4mL Plastic/Multiple Dose vial, Prepared by Key Compounding Pharmacy	Class II	Lot # t02-21-2017@111, Exp 4/23/2017	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383
Drugs	MAGNESIUM SO4 10ML MDV 50% INJ, Injection, 50%, Rx only, 10 mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy	Class II	Lot # t02-06-2017@106, Exp 5/8/2017; 02-13-2017@75, Exp 5/14/2017	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383
Drugs	METHYL-B12 5ML MDV (CALIF) 1MG/ML INJ, Injection, 1mg/mL, Rx only, 5 mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy	Class II	Lot # t02-17-2017@101, Exp 4/21/2017; t02-17-2017@88, Exp 4/21/2017.	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383
Drugs	METHYL-B12 *10ML* MDV 5MG/ML INJ, Injection, 5mg/mL, Rx only, 10 mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy	Class II	Lot # t02-17-2017@86, Exp 4/21/2017	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383
Drugs	PROCAINE HCL 50ML MDV (CALIF) 1% INJ, Injection, 1%, Rx only, 50mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy	Class II	Lot # t01-18-2017@94, Exp 4/19/2017; t01-25-2017@115, Exp 4/26/2017	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383
Drugs	PROCAINE HCL *5ML* SDV SULFITE FREE 1% INJ, Injection, 1%, RXonly, 5mL Glass/Single Dose vials, Prepared by Key Compounding Pharmacy	Class II	Lot # t01-13-2017@84, Exp 4/18/2017; 02-02-2017@97, Exp 5/3/2017	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drugs	PROCAINE HCL SDV 1% INJ, Injection, 1%, Rx only, packaged in 5mL and 50 mL Glass/Single Dose vials, Prepared by Key Compounding Pharmacy	Class II	Lot # t11-21-2016@115, Exp 5/21/2017; t11-23-2016@109, Exp 5/27/2017; t12-13-2016@94, Exp 6/12/2017; t01-19-2017@85, Exp 7/22/2017; 02/01/2017@116, Exp 7/31/2017	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383
Drugs	PROCAINE HCL SDV 2% INJ, Injection, 2%, Rx only, packaged in 10mL and 50 mL Glass/Single Dose vials, Prepared by Key Compounding Pharmacy	Class II	Lot # t01-25-2017@122, Exp 4/26/2017; t12-12-2016@98, Exp 6/11/2017; t01-10-2017@119, Exp 7/10/2017	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383
Drugs	PROGESTERONE SESAME OIL 10ML MDV 100MG/ML INJ, Injection, 100mg/mL, Rx only, 10mL Glass; Multiple Dose vial, Prepared by Key Compounding Pharmacy	Class II	Lot t# 02-14-2017@102, Exp 5/1/2017	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383
Drugs	PYRIDOXAL-5-PHOS 10ML MDV 100MG/ML INJ, Injection, 100mg/mL, Rx only, 10mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy	Class II	Lot # t01-31-2017@132, Exp 5/2/2017	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383
Drugs	PYRIDOXAL-5-PHOS 5ML MDV 50MG/ML INJ, 50mg/mL, Rx only, 5mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy	Class II	Lot # t02-20-2017@74, Exp 5/22/2017	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383
Drugs	SODIUM BICARB 50ML MDV 8.4% (2 MOSMOL/ML) INJ, Injection, 8.40%, Rx only, 5mL Glass/Multiple Dose via, Prepared by Key Compounding Pharmacy	Class II	Lot # t01-26-2017@94, Exp 4/27/2017	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drugs	SODIUM CARBOXYM-CELL PF 0.5% OPHTH, ophthalmic, 0.50%, Rx only, 10mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy	Class II	Lot # t02-17-2017@85, Exp 5/21/2017	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383
Drugs	SODIUM CHLORIDE INH PF GV 0.9% SOLN, Inhalation Solution, 0.90%, Rx only, 5mL Glass/Single Dose vial, Prepared by Key Compounding Pharmacy	Class II	Lot # 11-29-2016@27, Exp 5/20/2017; 01-25-2017@25, Exp 7/24/2017	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383
Drugs	SOD PHENYL BUTYRATE SDV 30ML (CALIF or NEZ-CALIF) 200MG/ML INJ, Injection, 200mg/mL, Rx only, 30 mL Glass/Single Dose vial, Prepared by Key Compounding Pharmacy	Class II	Lot # t12-19-2016@76, Exp 4/27/2017; t11-28-2016@114, Exp 5/28/2017; t11-29-2016@102, Exp 5/29/2017; t12-06-2016@98, Exp 6/6/2017; t12-22-2016@118, Exp 6/21/2017; t12-22-2016@119, Exp 6/21/2017; t02-06-2017@98, Exp 8/6/2017; t02-07-2017@60, Exp 8/7/2017; t02-21-2017@109, Exp 08/21/2017	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383
Drugs	TESTOST CYP SESAME OIL 5ML MDV 100MG/ML INJ, Injection, 100mg/mL, Rx only, 5 mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy	Class II	Lot # t01-16-2017@9, Exp 4/17/2017; t01-19-2017@89, Exp 4/20/2017.	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383
Drugs	TESTOST AQ MDV 50MG/ML INJ, Injection, 50mg/mL, Rx only, packaged in 5mL and 10mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy	Class II	Lot # t02-09-2017@79, Exp 5/14/2017; t02-22-2017@91, Exp 5/24/2017	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drugs	VITAMIN B COMPLEX 1ML SDV NA INJ, Injection, 100mg/2mg/2mg/2mg/100mg/mL, Rx only, 1mL Glass; Single Dose, Prepared by Key Compounding Pharmacy	Class II	Lot # t02-03-2017@37, Exp 5/7/2017	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383
Drugs	VITAMIN D3 IN OLIVE OIL SDV 100,000U/ML INJ, Injection, 100,000u/mL, Rx only, packaged in 1 mL Glass/Single Dose vial, Prepared by Key Compounding Pharmacy	Class II	Lot # t02-10-2017@122, Exp 5/14/2017	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383
Drugs	VITAMIN D3 IN OLIVE OIL SDV 100,000U/ML INJ, Injection, 150,000u/mL, Rx only, packaged in 2mL Glass/Single Dose vial, Prepared by Key Compounding Pharmacy	Class II	Lot # t01-31-2017@119, Exp 5/2/2017; t02-01-2017@130, Exp 5/4/2017	Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.	Key Pharmacy and Compounding Center 530 S 336th St Federal Way, WA 98003-6383
Drugs	Fluconazole Injection, USP, 200 mg/100 mL (2mg/mL), 100 mL Single-Dose Intravia Container bag, Rx only, Baxter Healthcare Corporation, Deerfield, IL 60015 USA, Product Code 2J1446, NDC 0338-6046-48	Class II	Lot #: P344028/P344028A, Exp 12/31/17; P352377, Exp 8/31/18; P3348136, Exp 4/30/18	Lack of assurance of sterility: customer complaints received for the presence of leaks.	Baxter Healthcare Corporation 1 Baxter Pkwy Deerfield, IL 60015-4625
Drugs	Milrinone Lactate in 5% Dextrose Injection, 20 mg/100 mL, 100 mL Single-Dose Intravia Container bag, Rx only, Baxter Healthcare Corporation, Deerfield, IL 60015, NDC 0338-6010-48	Class II	Lot #: P342485, Exp 11/30/17; P344408, Exp 12/31/17	Lack of assurance of sterility: customer complaints received for the presence of leaks.	Baxter Healthcare Corporation 1 Baxter Pkwy Deerfield, IL 60015-4625
Drugs	Optic Splash (naphazoline hydrochloride) Eye Drops, packaged in 0.5 FL OZ (15mL) bottles, Manufactured by SATO Pharmaceuticals CO., LTD. 1-5-27 Motoakasaka Minato-Ku Tokyo, Japan, NDC 49873-501-01.	Class II	Lot #: XXWC, Exp. August 2018	Lack of Assurance of Sterility: Firm failed to establish an adequate system for monitoring environmental conditions in aseptic processing areas.	Sato Pharmaceutical Co., Ltd. 1468 Hazama-Machi Hachioji
Drugs	SATO CLEAR (naphazoline hydrochloride) Redness Reliever Eye Drops, packaged in 0.5 FL OZ (15mL) bottles, Manufactured by SATO Pharmaceuticals CO., LTD. 1-5-27 Motoakasaka Minato-Ku Tokyo, Japan, NDC	Class II	Lot #: WXWZ, Exp. March 2019; WXTS, Exp. October 201	Lack of Assurance of Sterility: Firm failed to establish an adequate system for monitoring environmental conditions in	Sato Pharmaceutical Co., Ltd. 1468 Hazama-Machi

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
	49873-044-01		9	aseptic processing areas.	Hachioji
Drugs	DORAMA-NEO (naphazoline hydrochloride) Eye wash, packaged in 0.5 FL OZ (15mL) bottles, Manufactured by SATO Pharmaceuticals CO., LTD. 1-5-27 Motoakasaka Minato-Ku Tokyo, Japan, NDC 49873-020-01	Class II	Lot #: WXTZ, Exp. Sep 2019	Lack of Assurance of Sterility: Firm failed to establish an adequate system for monitoring environmental conditions in aseptic processing areas.	Sato Pharmaceutical Co., Ltd. 1468 Hazama-Machi Hachioji
Drugs	Alprazolam Extended-release Tablets, USP, 1 mg, 60-count bottle, Rx Only, Manufactured and Distributed by: Mylan Pharmaceuticals Inc., Morgantown, WV 26505 U.S.A., NDC 0378-5022-91	Class II	Code: 0378-5022-91 Lot: 3065878; Exp. 04/17	Failed Dissolution Specifications	Mylan Pharmaceuticals Inc. 781 Chestnut Ridge Rd Morgantown, WV 26505-2730
Drugs	Ventolin HFA (albuterol sulfate) Inhalation, 90 mcg per actuation, 200 Metered Inhalations, Net Wt. 18 g inhalers, Rx only, GlaxoSmithKline, Research Triangle Park, NC 27709, NDC 0173-0682-20.	Class II	Lot#: 7ZP0634, 7ZP0810, 7ZP0990, Exp. 5/18	Defective Delivery System: Elevated number of units with out of specification results for leak rate	GlaxoSmithKline, LLC 1011 N Arendell Ave Zebulon, NC 27597-2309
Drugs	Shield and Protect Moisture Barrier Cream, 1.1% Clotrimazole, Net Weight 4 oz - 115 g Anti-Fungal, Gentell, Inc., Bristol, PA NDC 61554-232-40	Class II	Product Code GEN-23240	GMP Deviations; product may not meet cGMP requirements	Gentell, Inc 2701 Bartram Rd Bristol, PA 19007-6810
Drugs	Estriol, For Prescription Compounding, packaged in a) 1 G bottle (NDC: 51552-1392-1), b) 5 G bottle (NDC: 51552-1392-2), c) 25 G bottle (NDC: 51552-1392-3), d) 100 G bottle (NDC: 51552-1392-5), RX only, Distributed by Fagron, Inc. 2400 Pilot Knob Rd, St. Paul, MN 55120 Tel. 1-(800) 423-6967 Also packaged as: Estriol USP Micronized, For prescription compounding, packaged in a 100 G bottle (NDC 52372-9292-01), Rx only, Distributed by FREEDOM, 801 W. New Orleans St. Broken Arrow, OK 74011	Class II	Lot #, Expiration Date: a) 1 G bottle: 16D08-U02-030005, Exp. 3/6/2018; 16F23-U05-033657, Exp. 5/26/2018; 17C02-U02-035889, Exp. 1/19/2019. b) 5 G bottle: 16D08-U02-030004, 16D08-U02-032486, Exp. 3/6/2018; 16F23-U05-033656, 16F23-U05-035093, Exp. 5/26/2018; 17C02-U02-035890, Exp. 1/19/2019. c) 25 G bottle: 16D08-U02-030003, 16D08-U02-032475, Exp. 3/6/2018; 16F23-U05-033655, 16F23-U05-035092, Exp. 5/26/2018; 17C02-U02-035887, Exp. 1/19/2019. d) 100 G bottle: 16D08-U02-030002, 16D08-U02	cGMP Deviations: lack of quality assurance at the API manufacturer.	Fagron, Inc 2400 Pilot Knob Rd Saint Paul, MN 55120-1118

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
			-032474, Exp. 3/6/2018; 16F23-U05-031158, 16F23-U05-033654, 16F23-U05-035091, 16G18-F002, Exp. 5/26/2018; 17C02-U02-035888, Exp. 1/19/2019.		
Drugs	Estrone, For Prescription Compounding, packaged in a) 1 G bottle (NDC: 51552-0445-1), b) 5 G bottle (NDC 51552-0445-2), c) 25 G bottle (NDC: 51552-0445-4), d) 100 G bottle (NDC: 51552-0445-5), RX only, Distributed by Fagron, Inc. 2400 Pilot Knob Rd, St. Paul, MN 55120 Tel. 1-(800) 423-6967 Also packaged as: Estrone USP, For Prescription Compounding, packaged in a) 1 G bottle (NDC 52372-9494-01), b) 5 G bottle (NDC 52372-9494-05), c) 25 G bottle (NDC 52372-9494-03), d) 100 G bottle ( NDC 52372-9494-02), Rx only, Distributed by FREEDOM 801 W. New Orleans St. Broken Arrow, OK 74011 Tel. (877) 839-8547	Class II	Lot #, Expiration Date: a) 16J05-U01-032346, 16G18-F003A, Exp. 5/17/2018; 16J25-U05-033898, Exp. 5/18/2018. b) 16F23-U04-031011, 16J05-U02-032345, 16G18-F003A, Exp. 5/17/2018; 16J25-U05-033897, 16J25-U05-034708, 16J25-U05-035527, Exp. 5/18/2018; c) 16F23-U04-031024, 16K16-U337-033665, 16G18-F003; 16G18-F003A, Exp. 5/17/2018. d) 16K16-U337-033664, 16G18-F003, Exp. 5/17/2018; 16J25-U05-034707, Exp. 5/18/2018.	cGMP Deviations: lack of quality assurance at the API manufacturer.	Fagron, Inc 2400 Pilot Knob Rd Saint Paul, MN 55120-1118
Drugs	Refresh Tears (Carboxymethylcellulose Sodium Solution) 0.5%, Lubricant Eye Drops, Sterile packaged as 1) two 15 mL bottles, USPC Code 784190442214, 2) 4x15 mL and one 5 mL bonus bottles, USPC Code 069886941746, Distributed by Cell Distributors, Union, NJ	Class II	all lots Expiration date August 2019	Labeling: Not elsewhere classified; product labeling lacks a NDC number, net weight information and does not contain the Drug Facts Panel.	Cell Distributors 675 Rahway Ave Union, NJ 07083-6683
Drugs	Bupivacaine HCl in 0.9% Sodium Chloride all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054	Class II	all lots	Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.	Advanced Pharma Inc. 9265 Kirby Dr Houston, TX 77054-2520
Drugs	Ropivacaine HCl in 0.9% Sodium Chloride all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054	Class II	all lots	Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.	Advanced Pharma Inc. 9265 Kirby Dr Houston, TX 77054-2520
Drugs	Lidocaine all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston,	Class II	all lots	Labeling: Not Elsewhere Classified: Products may contain synthetic latex	Advanced Pharma Inc. 9265 Kirby Dr Houston, TX



Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
	Houston, TX 77054			and/or natural latex.	77054-2520
Drugs	Nalbuphine all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054	Class II	all lots	Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.	Advanced Pharma Inc. 9265 Kirby Dr Houston, TX 77054-2520
Drugs	RECK PeriCapsular injection all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054	Class II	all lots	Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.	Advanced Pharma Inc. 9265 Kirby Dr Houston, TX 77054-2520
Drugs	NOVA PeriCapsular injection all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054	Class II	all lots	Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.	Advanced Pharma Inc. 9265 Kirby Dr Houston, TX 77054-2520
Drugs	Ofirmev (Acetaminophen) injection all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054	Class II	all lots	Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.	Advanced Pharma Inc. 9265 Kirby Dr Houston, TX 77054-2520
Drugs	Ropi/ Epi/ Clon PeriCapsular injection all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054	Class II	all lots	Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.	Advanced Pharma Inc. 9265 Kirby Dr Houston, TX 77054-2520
Drugs	NICU STARTER TPN all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054	Class II	all lots	Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.	Advanced Pharma Inc. 9265 Kirby Dr Houston, TX 77054-2520
Drugs	TPN Neonatal all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054	Class II	all lots	Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.	Advanced Pharma Inc. 9265 Kirby Dr Houston, TX 77054-2520
Drugs	Standard Starter TPN all strengths, all dosage forms and all packaging, Rx Only,	Class II	all lots	Labeling: Not Elsewhere Classified: Products may contain synthetic latex	Advanced Pharma Inc. 9265 Kirby Dr Houston, TX

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
	Avella of Houston, Houston, TX 77054			and/or natural latex.	77054-2520
Drugs	Early TPN (Neonatal) all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054	Class II	all lots	Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.	Advanced Pharma Inc. 9265 Kirby Dr Houston, TX 77054-2520
Drugs	Early Baby TPN (Neonatal) all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054	Class II	all lots	Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.	Advanced Pharma Inc. 9265 Kirby Dr Houston, TX 77054-2520
Drugs	ADD HEPARIN PF 50 Units ONLY TO TPN all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054	Class II	all lots	Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.	Advanced Pharma Inc. 9265 Kirby Dr Houston, TX 77054-2520
Drugs	Sufentanil Citrate all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054	Class II	all lots	Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.	Advanced Pharma Inc. 9265 Kirby Dr Houston, TX 77054-2520
Drugs	Fentanyl Citrate all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054	Class II	all lots	Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.	Advanced Pharma Inc. 9265 Kirby Dr Houston, TX 77054-2520
Drugs	Hydromorphone HCl all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054	Class II	all lots	Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.	Advanced Pharma Inc. 9265 Kirby Dr Houston, TX 77054-2520
Drugs	Meperidine HCl all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054	Class II	all lots	Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.	Advanced Pharma Inc. 9265 Kirby Dr Houston, TX 77054-2520
Drugs	Morphine Sulfate all strengths, all dosage forms and all packaging, Rx Only, Avella of	Class II	all lots	Labeling: Not Elsewhere Classified: Products may contain synthetic latex	Advanced Pharma Inc. 9265 Kirby Dr Houston, TX

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
	Houston, Houston, TX 77054			and/or natural latex.	77054-2520
Drugs	Ketamine HCl all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054	Class II	all lots	Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.	Advanced Pharma Inc. 9265 Kirby Dr Houston, TX 77054-2520
Drugs	Midazolam HCl all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054	Class II	all lots	Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.	Advanced Pharma Inc. 9265 Kirby Dr Houston, TX 77054-2520
Drugs	Lorazepam HCl all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054	Class II	all lots	Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.	Advanced Pharma Inc. 9265 Kirby Dr Houston, TX 77054-2520
Drugs	Methohexital Sodium all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054	Class II	all lots	Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.	Advanced Pharma Inc. 9265 Kirby Dr Houston, TX 77054-2520
Drugs	Cefazolin all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054	Class II	all lots	Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.	Advanced Pharma Inc. 9265 Kirby Dr Houston, TX 77054-2520
Drugs	Vancomycin HCl all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054	Class II	all lots	Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.	Advanced Pharma Inc. 9265 Kirby Dr Houston, TX 77054-2520
Drugs	Penicillin G Potassium all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054	Class II	all lots within expiry.	Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.	Advanced Pharma Inc. 9265 Kirby Dr Houston, TX 77054-2520
Drugs	Gentamicin Sulfate all strengths, all dosage forms and all packaging, Rx Only, Avella of	Class II	all lots within expiry.	Labeling: Not Elsewhere Classified: Products may contain synthetic latex	Advanced Pharma Inc. 9265 Kirby Dr Houston, TX

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
	Houston, Houston, TX 77054			and/or natural latex.	77054-2520
Drugs	Oxytocin all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054	Class II	all lots within expiry.	Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.	Advanced Pharma Inc. 9265 Kirby Dr Houston, TX 77054-2520
Drugs	Heparin sodium all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054	Class II	all lots within expiry.	Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.	Advanced Pharma Inc. 9265 Kirby Dr Houston, TX 77054-2520
Drugs	0.9% Sodium Chloride Slip Tip all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054	Class II	all lots within expiry.	Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.	Advanced Pharma Inc. 9265 Kirby Dr Houston, TX 77054-2520
Drugs	Diltiazem HCl all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054	Class II	all lots within expiry.	Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.	Advanced Pharma Inc. 9265 Kirby Dr Houston, TX 77054-2520
Drugs	Phenylephrine HCl all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054	Class II	all lots within expiry.	Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.	Advanced Pharma Inc. 9265 Kirby Dr Houston, TX 77054-2520
Drugs	Ephedrine Sulfate all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054	Class II	all lots within expiry.	Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.	Advanced Pharma Inc. 9265 Kirby Dr Houston, TX 77054-2520
Drugs	Norepinephrine Bitartrate all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054	Class II	all lots within expiry.	Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.	Advanced Pharma Inc. 9265 Kirby Dr Houston, TX 77054-2520
Drugs	Epinephrine HCl all strengths, all dosage forms and all packaging, Rx Only, Avella of	Class II	all lots within expiry.	Labeling: Not Elsewhere Classified: Products may contain synthetic latex	Advanced Pharma Inc. 9265 Kirby Dr Houston, TX

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
	Houston, Houston, TX 77054			and/or natural latex.	77054-2520
Drugs	Calcium Gluconate all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054	Class II	all lots within expiry.	Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.	Advanced Pharma Inc. 9265 Kirby Dr Houston, TX 77054-2520
Drugs	Amiodarone all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054	Class II	all lots within expiry.	Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.	Advanced Pharma Inc. 9265 Kirby Dr Houston, TX 77054-2520
Drugs	Succinylcholine Chloride all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054	Class II	all lots within expiry.	Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.	Advanced Pharma Inc. 9265 Kirby Dr Houston, TX 77054-2520
Drugs	Adenosine all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054	Class II	all lots within expiry.	Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.	Advanced Pharma Inc. 9265 Kirby Dr Houston, TX 77054-2520
Drugs	Nicardipine HCl all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054	Class II	all lots within expiry.	Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.	Advanced Pharma Inc. 9265 Kirby Dr Houston, TX 77054-2520
Drugs	Rocuronium Bromide all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054	Class II	all lots within expiry.	Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.	Advanced Pharma Inc. 9265 Kirby Dr Houston, TX 77054-2520
Drugs	Labetalol HCl all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054	Class II	all lots within expiry.	Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.	Advanced Pharma Inc. 9265 Kirby Dr Houston, TX 77054-2520
Drugs	Esmolol HCl all strengths, all dosage forms and all packaging, Rx Only, Avella of	Class II	all lots within expiry.	Labeling: Not Elsewhere Classified: Products may contain synthetic latex	Advanced Pharma Inc. 9265 Kirby Dr Houston, TX

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
	Houston, Houston, TX 77054			and/or natural latex.	77054-2520
Drugs	Glycopyrrolate all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054	Class II	all lots within expiry.	Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.	Advanced Pharma Inc. 9265 Kirby Dr Houston, TX 77054-2520
Drugs	Neostigmine Methylsulfate all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054	Class II	all lots within expiry.	Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.	Advanced Pharma Inc. 9265 Kirby Dr Houston, TX 77054-2520
Drugs	Atropine Sulfate all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054	Class II	all lots within expiry.	Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.	Advanced Pharma Inc. 9265 Kirby Dr Houston, TX 77054-2520
Drugs	Betamethasone Sodium Phosphate & Betamethasone Acetate all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054	Class II	all lots within expiry.	Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.	Advanced Pharma Inc. 9265 Kirby Dr Houston, TX 77054-2520
Drugs	Famotidine HCl all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054	Class II	all lots within expiry.	Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.	Advanced Pharma Inc. 9265 Kirby Dr Houston, TX 77054-2520
Drugs	Ondansetron HCl all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054	Class II	all lots within expiry.	Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.	Advanced Pharma Inc. 9265 Kirby Dr Houston, TX 77054-2520
Drugs	Bumetadine all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054	Class II	all lots within expiry.	Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.	Advanced Pharma Inc. 9265 Kirby Dr Houston, TX 77054-2520
Drugs	Dexamethasone Sodium Phosphate all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston,	Class II	all lots within expiry.	Labeling: Not Elsewhere Classified: Products may contain synthetic latex	Advanced Pharma Inc. 9265 Kirby Dr Houston, TX

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
	Houston, TX 77054			and/or natural latex.	77054-2520
Drugs	Dexmedetomidine HCl all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054	Class II	all lots within expiry.	Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.	Advanced Pharma Inc. 9265 Kirby Dr Houston, TX 77054-2520
Drugs	Cardioplegic Solution Maintenance all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054	Class II	all lots within expiry.	Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.	Advanced Pharma Inc. 9265 Kirby Dr Houston, TX 77054-2520
Drugs	Magnesium Sulfate all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054	Class II	all lots within expiry.	Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.	Advanced Pharma Inc. 9265 Kirby Dr Houston, TX 77054-2520
Drugs	Potassium Phosphate all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054	Class II	all lots within expiry.	Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.	Advanced Pharma Inc. 9265 Kirby Dr Houston, TX 77054-2520
Drugs	Sodium Phosphate all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054	Class II	all lots within expiry.	Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.	Advanced Pharma Inc. 9265 Kirby Dr Houston, TX 77054-2520
Drugs	Sodium Citrate all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054	Class II	all lots within expiry.	Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.	Advanced Pharma Inc. 9265 Kirby Dr Houston, TX 77054-2520
Drugs	Fentanyl Citrate with Ropivacaine HCl all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston, Houston, TX 77054	Class II	all lots within expiry.	Labeling: Not Elsewhere Classified: Products may contain synthetic latex and/or natural latex.	Advanced Pharma Inc. 9265 Kirby Dr Houston, TX 77054-2520
Drugs	Fentanyl Citrate and Bupivacaine HCl all strengths, all dosage forms and all packaging, Rx Only, Avella of Houston,	Class II	all lots within expiry.	Labeling: Not Elsewhere Classified: Products may contain synthetic latex	Advanced Pharma Inc. 9265 Kirby Dr Houston, TX

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
	Houston, TX 77054			and/or natural latex.	77054-2520
Drugs	morphine sulfate in 0.9% Sodium Chloride injectable, 1 mg per mL, Total Volume 100 mL, Single Dose Container bag, (Total morphine Dose 100 mg/ 100mL), Preservative Free (Contains Sulfites), Rx only, SCA Pharmaceuticals, 8821 Knoedl Ct, Little Rock, AR 72205, NDC 70004-0100-32.	Class II	LOT # 20170508@57, Use By: 08/06/17	Lack of assurance of sterility: Product bags leaking at seam.	SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205-4600
Drugs	morphine sulfate in 0.9% Sodium Chloride injectable, 1 mg per mL, Total Volume 100 mL, Single Dose Container bag, (Total morphine Dose 100 mg/ 100 mL), Preservative Free (Contains Sulfites), Rx only, SCA Pharmaceuticals, 8821 Knoedl Ct, Little Rock, AR 72205, NDC 70004-0100-55	Class II	LOT # 20170508@48, Use By: 08/06/17; 20170505@19, Use By: 08/03/17	Lack of assurance of sterility: Product bags leaking at seam.	SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205-4600
Drugs	fentaNYL (as citrate) in 0.9% Sodium Chloride injectable, 10 mcg per mL, Total Volume 100 mL, Single Dose Container bag, (Total fentanyl Dose 1,000 mcg/100 mL) Preservative Free, Rx Only, SCA Pharmaceuticals, 8821 Knoedl Ct. Little Rock, AR 72205, NDC 70004-0229-32	Class II	LOT # 20170505@14, Use By: 08/03/17; 20170510@2, Use By: 08/08/17	Lack of assurance of sterility: Product bags leaking at seam.	SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205-4600
Drugs	fentaNYL (as citrate) in 0.9% Sodium Chloride injectable, 10 mcg per mL, Total Volume 100 mL, Single Dose Container bag, (Total fentanyl Dose 1,000 mcg/100 mL) Preservative Free, Rx Only, SCA Pharmaceuticals, 8821 Knoedl Ct. Little Rock, AR 72205, NDC 70004-0202-32	Class II	LOT # 20170506@14, Use By: 08/04/17	Lack of assurance of sterility: Product bags leaking at seam.	SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205-4600
Drugs	fentaNYL (as citrate) in 100mL 0.9% Sodium Chloride injectable, 20 mcg per mL, Single Dose Container bag, (Total fentanyl Dose 2,000 mcg/100 mL) Preservative Free, Rx Only, SCA Pharmaceuticals, 8821 Knoedl Ct. Little Rock, AR 72205, NDC 70004-203-32	Class II	LOT # 20170508@59, Use By: 08/06/17	Lack of assurance of sterility: Product bags leaking at seam.	SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205-4600
Drugs	HYDROMORPHONE HCL in 0.9% Sodium Chloride injectable, 0.2 mg per mL, Total Volume 100mL, Single Dose Container bag, (Total HYDROMORPHONE Dose 20 mg per 100 mL) Preservative Free, Rx Only, SCA Pharmaceuticals, 8821 Knoedl Ct. Little Rock, AR 72205, NDC 70004-0300-55	Class II	LOT # 20170505@23, 20170505@28, Use By: 08/03/17	Lack of assurance of sterility: Product bags leaking at seam.	SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205-4600
Drugs	ceFAZolin sodium added to 100 mL 0.9%	Class	LOT # 20170510@12,	Lack of assurance of	SCA



Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
	Sodium Chloride injectable, 2g, Total Approximate Volume 100 mL, Single Dose Container bag, Preservative Free, Rx Only, SCA Pharmaceuticals, 8821 Knoedl Ct. Little Rock, AR 72205, NDC 70004-0522-32	II	Use By: 06-24-17	sterility: Product bags leaking at seam.	Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205-4600
Drugs	ceFAZolin sodium added to 100 mL 0.9% Sodium Chloride injectable, 3g, Total Approximate Volume 115 mL, Single Dose Container bag, Preservative Free, Rx Only, SCA Pharmaceuticals, 8821 Knoedl Ct. Little Rock, AR 72205, NDC 70004-0524-32	Class II	LOT # 20170508@15, Use By: 06/22/17	Lack of assurance of sterility: Product bags leaking at seam.	SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205-4600
Drugs	MAGNESIUM Sulfate added to 100 mL 0.9% Sodium Chloride injectable, 4g, Total Approximate Volume 108 mL (does not include mfg. overfill) Single Dose Container bag, Preservative Free, Rx Only, SCA Pharmaceuticals, 8821 Knoedl Ct. Little Rock, AR 72205, NDC: 70004-0737-32	Class II	LOT # 20170509@29, Use By: 08/07/17	Lack of assurance of sterility: Product bags leaking at seam.	SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205-4600
Drugs	PHENylephrine HCL in 0.9% Sodium Chloride injectable, 10 mg (Final Concentration = 0.1 mg per mL) Total Volume 100 mL, Single Dose Container bag, Preservative Free (Contains Sulfites), Rx Only, SCA Pharmaceuticals, 8821 Knoedl Ct. Little Rock, AR 72205, NDC: 70004-0810-32	Class II	LOT # 20170511@17, Use By: 08/09/17	Lack of assurance of sterility: Product bags leaking at seam.	SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205-4600
Drugs	Saphris 10 mg (asenapine) sublingual tablets, 6x10 count blister packs, Rx only, Black Cherry Flavor, Manufactured by: Catalent UK Swindon, Zydis Ltd, Blagrove, Swindon, Wilshire SN5 BRU, UK Distributed by Forest Pharmaceuticals, Inc. subsidiary of Forest Laboratories, LLC, Cincinnati OH 45209 USA --- NDC 0456-2410-60; Shellpack containing 1 blister card --- NDC 0456-2410-06	Class II	Lots W00733 and W00946, exp Apr 2019	Labeling; Label Mixup; blister lidding foil and shell-pack labeled as 10 mg but package actually contains 5 mg tablets	Forest Laboratories, LLC Harborside Financial Center Plaza V- Suite 1900 Jersey City, NJ 07311
Drugs	Zenatane (isotretinoin) Capsules, USP, 10 mg, 30-count (3 x 10 Prescription Packs) per carton, Rx Only, Manufactured By: Cipla Limited, Kurkumbh Village, Pune 413802 India, Manufactured For: Dr. Reddy's Laboratories, Bachupally 500 090 India, NDC 55111-135-81	Class II	Lot #: KB50471, Exp 06/17; KB50710, KB50710A, Exp 08/17; KB60198, Exp 02/18	Failed Dissolution Specifications: out of specification results observed for low dissolution.	Dr. Reddy's Laboratories, Inc. 107 College Rd E Princeton, NJ 08540-6623
Drugs	Zenatane (isotretinoin) Capsules, USP, 20 mg, 30-count (3 x 10 Prescription Packs) per carton, Rx Only, Manufactured By: Cipla Limited, Kurkumbh Village, Pune 413802	Class II	Lot #: KB50361, KB50362, Exp 05/17; KB50540, Exp 07/17; KB50638, KB50639, Exp 08	Failed Dissolution Specifications: out of specification results observed for low	Dr. Reddy's Laboratories, Inc. 107 College Rd E Princeton, NJ

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
	India, Manufactured For: Dr. Reddy's Laboratories, Bachupally 500 090 India, NDC 55111-136-81		/17; KB50725, KB50726, KB50755, KB50756, Exp 09/17; 01KB60255, 79KB60252, 79KB60253, 79KB60254, Exp 03/18; 01KB60347, 01KB60348, 01KB60349, 01KB60350, 79KB60351, Exp 05/18; 01KB60421, 01KB60422, 01KB60423, 79KB60419, 79KB60420, Exp 06/18	dissolution.	08540-6623
Drugs	Zenatane (isotretinoin) Capsules, USP, 30 mg, 30-count (3 x 10 Prescription Packs) per carton, Rx Only, Manufactured By: Cipla Limited, Kurkumbh Village, Pune 413802 India, Manufactured For: Dr. Reddy's Laboratories, Bachupally 500 090 India, NDC 55111-113-81	Class II	Lot #: KB50414, KB50456, Exp 05/17; KB50457, KB50458, KB50459, KB50460, Exp 06/17; KB50580, KB50581, KB50582, KB50583, KB50599, KB50600, Exp 07/17; KB50646, KB50647, KB50721, KB50722, KB50723, KB50724, Exp 09/17; KB50833, KB50834, KB50835, KB50836, KB50837, Exp 10/17; KB50902, KB50903, KB50904, Exp 11/17; KB60037, KB60038, KB60039, KB60040, KB60041, Exp 12/17; KB60109, KB60110, KB60111, KB60112, KB60113, Exp 01/18; 01KB60249, 01KB60266, 01KB60268, 01KB60269, 01KB60284, Exp 03/18; 01KB60369, 01KB60372, 79KB60368, 79KB60371, Exp 05/18; 79KB60507, 79KB60508, 79KB60509, 79KB60510, 79KB60511, 79KB60512, 79KB60513, 79KB60514, 79KB60515, 79KB60516, Exp 07/18; 79KB60570, 79KB60571, 79KB60585, 79KB60586, Exp 08/18	Failed Dissolution Specifications: out of specification results observed for low dissolution.	Dr. Reddy's Laboratories, Inc. 107 College Rd E Princeton, NJ 08540-6623
Drugs	Zenatane (isotretinoin) Capsules, USP, 40 mg, 30-count (3 x 10 Prescription Packs) per carton, Rx Only, Manufactured By: Cipla Limited, Kurkumbh Village, Pune 413802 India, Manufactured For: Dr. Reddy's Laboratories, Bachupally 500 090 India, NDC	Class II	Lot #: KB50363, KB50364, KB50365, KB50366, KB50367, KB50368, KB50369, KB50370, KB50371, Exp 05/17; 01KB50598, KB50541, KB50542, KB50543, KB50544, KB50545, KB	Failed Dissolution Specifications: out of specification results observed for low dissolution.	Dr. Reddy's Laboratories, Inc. 107 College Rd E Princeton, NJ 08540-6623

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
	55111-137-81		50546, KB50547, KB50548, KB50549, KB50550, KB50551, Exp 07/17; 01KB50643, 01KB50644, KB50640, KB50641, KB50642, KB50645, Exp 08/17; KB50715, KB50716, KB50717, KB50718, KB50719, KB50720, KB50757, KB50758, KB50759, KB50760, KB50761, Exp 09/17; KB50872, KB50874, KB50875, KB50876, KB50916, KB50938, KB50943, Exp 11/17; 01KB60062, 01KB60063, 01KB60064, 01KB60065, 01KB60066, 01KB60101, KB60025, KB60026, KB60027, KB60028, KB60029, KB60030, KB60031, KB60032, KB60059, KB60060, KB60061, Exp 12/17; 01KB60100, 01KB60161, Exp 01/18; 01KB60256, 01KB60257, 01KB60258, 01KB60259, 01KB60260, Exp 03/18; 01KB60292, 01KB60293, 01KB60294, 01KB60314, 01KB60321, 01KB60333, 01KB60334, 79KB60295, 79KB60296, 79KB60332, 79KB60335, 79KB60346, Exp 04/18; 01KB60393, 01KB60394, 79KB60390, 79KB60391, 79KB60392, Exp 05/18; 01KB60505, 01KB60506, 01KB60538, 79KB60502, 79KB60503, 79KB60504, 79KB60535, 79KB60536, 79KB60537, 79KB60539, 79KB60542, Exp 07/18; 01KB60589, 79KB60566, 79KB60567, 79KB60568, 79KB60569, 79KB60587, 79KB60588, Exp 08/18		
Drugs	Option 2, Levonorgestrel Tablet, 1.5 mg, Emergency Contraceptive, 1 Tablet per box, Distributed By Perrigo, Allegan, MI 49010. NDC 0113-2003-12	Class II	Lot #: 6LV1114, 6LV1115, 6LV1116, 6MV0976, 6MV0977, Exp.04/18; 7AV1173, 7AV1175, 7AV1176, Exp.07/18.	Defective Container: Carton is missing the tablet blister strip and tablet.	L. Perrigo Company 515 Eastern Ave Allegan, MI 49010-9070

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drugs	methylcobalamin 1mg/1mL, vial for injection, Rx only, MedPark Pharmacy 2002 Medical Pkwy. # 170 Annapolis, MD 21401	Class II	Lot #: 20170323-01, Exp.09/18/2017	Lack of Assurance of Sterility	MedPark Pharmacy, LLC 2002 Medical Pkwy Ste 170 Annapolis, MD 21401-3276
Drugs	Estradiol 25 mg pellet 99.5% Estradiol USP, .5% Stearic Acid NF, in 1 count, 12 count, and 30 count bottles, Sterile Office Use Only, For Subcutaneous Use Only. Rx Only ,Manufactured by: Qualgen 14844 Bristol Park Blvd Edmond, OK 73013 NDC 69761-025-01,	Class II	Lot # C031; Exp. 03/2/18 Lot # B077; Exp. 08/10/17 Lot # B040; Exp. 05/16/17	CGMP deviations- Lack of Quality Assurance	Qualgen 14844 Bristol Park Blvd Edmond, OK 73013-1891
Drugs	Estradiol 22 mg pellet 99.5% Estradiol USP, .5% Stearic Acid NF, in 1 count, 12 count, and 30 count bottles, Sterile Office Use Only, For Subcutaneous Use Only Rx Only, Manufactured by: Qualgen 14844 Bristol Park Blvd Edmond, OK 73013 NDC 69761-022-01	Class II	Lot # B128; Exp. 11/1/17 Lot # B075; Exp. 08/3/17	CGMP deviations- Lack of Quality Assurance	Qualgen 14844 Bristol Park Blvd Edmond, OK 73013-1891
Drugs	Estradiol 20 mg pellet 99.5% Estradiol USP, .5% Stearic Acid NF in 1 count and 12 count bottles, Sterile Office Use Only, For Subcutaneous Use Only Rx Only, Manufactured by Qualgen 14844 Bristol Park Blvd Edmond, OK 73013 NDC: 69761-020-01	Class II	Lot# C022; Exp. 08/21/17 Lot# B143; Exp. 1/22/17 Lot# B104; Exp. 09/27/17 Lot# B073 ; Exp. 08/1/17 Lot# B052; Exp. 06/13/17	CGMP deviations- Lack of Quality Assurance	Qualgen 14844 Bristol Park Blvd Edmond, OK 73013-1891
Drugs	Estradiol 18 mg pellet , 99.5% Estradiol USP, .5% Stearic Acid NF in 1 count, 12 count, and 30 count bottles, Sterile Office Use Only, Subcutaneous Use Only, Rx Only, Manufactured by: Qualgen 14844 Bristol Park Blvd Edmond, OK 73013 NDC: 69761-018-01.	Class II	Lot# C018; Exp. 08/2/17 Lot# B151; Exp. 12/7/17 Lot# B108; Exp. 10/3/17 Lot# B095; Exp. 09/12/17 Lot# B062; Exp. 07/6/17 Lot# B035; Exp. 05/2/17 Lot# B133; Exp. 11/4/17	CGMP deviations- Lack of Quality Assurance	Qualgen 14844 Bristol Park Blvd Edmond, OK 73013-1891
Drugs	Estradiol 15 mg pellet 99.5% Estradiol USP, .5% Stearic Acid NF in 1 count, 12 count, and 30 count bottles. Sterile Office Use Only, For Subcutaneous Use Only, Rx Only, Manufactured by: Qualgen 14844 Bristol Park Blvd Edmond, OK 73013, NDC: 69761-015-01	Class II	Lot# C028; Exp. 02/28/18 Lot# C005; Exp. 07/11/17 Lot# B142; Exp. 11/21/17 Lot# B114 ; Exp. 10/10/17 Lot# B099; Exp. 09/16/17 Lot# B069; Exp. 07/12/17 Lot# B048; Exp. 06/	CGMP deviations- Lack of Quality Assurance	Qualgen 14844 Bristol Park Blvd Edmond, OK 73013-1891

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
			6/17		
Drugs	Estradiol 12.5 mg pellet 99.5% Estradiol USP, .5% Stearic Acid NF in 1 count, 12 count, and 30 count bottles, Sterile Office Use Only, For Subcutaneous Use Only, Rx Only, Manufactured by: Qualgen 14844 Bristol Park Blvd Edmond, OK 73013, NDC: 69761-012-01	Class II	Lot# C044; Exp. 03/14/18 Lot# C013; Exp. 07/23/17 Lot# B150; Exp. 12/6/17 Lot# B119; Exp. 10/18/17 Lot# B097; Exp. 09/14/17 Lot# B061; Exp. 07/5/17	CGMP deviations- Lack of Quality Assurance	Qualgen 14844 Bristol Park Blvd Edmond, OK 73013-1891
Drugs	Estradiol 10 mg pellet 99.5% Estradiol USP, .5% Stearic Acid NF in 1 count, 12 count, and 30 count bottles, Sterile Office Use Only, For Subcutaneous Use Only Rx Only, Manufactured by: Qualgen 14844 Bristol Park Blvd Edmond, OK 73013 NDC: 69761-010-01	Class II	Lot# C021; Exp. 08/20/17 Lot# B160, Exp. 12/29/17 Lot# B140; Exp. 11/15/17 Lot# B107; Exp. 09/29/17 Lot# B079; Exp. 08/15/17 Lot# B046; Exp. 06/01/17	CGMP deviations- Lack of Quality Assurance	Qualgen 14844 Bristol Park Blvd Edmond, OK 73013-1891
Drugs	Estradiol 6 mg pellet 99.5% Estradiol USP, .5% Stearic Acid NF in 1 count, 12 count, and 30 count bottles, Sterile Office Use Only, For Subcutaneous Use Only Rx Only, Manufactured by: Qualgen 14844 Bristol Park Blvd. Edmond, OK 73013 NDC: 69761-006-01.	Class II	Lot# C046; Exp. 03/15/18 Lot# C025; Exp. 08/23/17 Lot# B159; Exp. 12/28/17 Lot# B121; Exp. 10/10/17 Lot# B118; Exp. 10/17/17 Lot# B086; Exp. 08/29/17 Lot# B068; Exp. 07/11/17 Lot# B053; Exp. 06/14/17 Lot# B034; Exp. 04/26/17	CGMP deviations- Lack of Quality Assurance	Qualgen 14844 Bristol Park Blvd Edmond, OK 73013-1891
Drugs	Estradiol (17-B-Estradiol; Estra-1,3,5(10)-triene-3, 17B-diol; Oestradiol) Plant Base, Micronized, U.S.P active pharmaceutical ingredient, packaged in 1g, 5g, 25g, 6 x 25g, and 100g containers, Rx only, Spectrum Chemical Mfg. Corp, Gardena, CA 90248, New Brunswick, NJ 08901, Product code E1435.	Class II	Lot #: 2FH0257, Exp 09/30/2017; 2GA0254, Exp 03/24/2018	CGMP Deviations: these repackaged and redistributed products are being recalled due to a recall notice from the active pharmaceutical ingredient manufacturer for deviations from current Good Manufacturing Practices that were found during a recent FDA inspection.	Spectrum Laboratory Products, Inc. 755 and 769 Jersey Ave New Brunswick, NJ 08901-3605
Drugs	Levonorgestrel, U.S.P. active pharmaceutical ingredient, packaged in 1 kg container, Rx only, Spectrum Chemical Mfg. Corp, Gardena, CA 90248, New Brunswick, NJ 08901, Product code L1229.	Class II	Lot #: 2FD0376, Exp 02/21/21	CGMP Deviations: these repackaged and redistributed products are being recalled due to a recall notice from the active pharmaceutical ingredient manufacturer for deviations from current Good Manufacturing Practices that were found during a	Spectrum Laboratory Products, Inc. 755 and 769 Jersey Ave New Brunswick, NJ 08901-3605

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
				recent FDA inspection.	
Drugs	Fluocinonide Cream UPS, 0.05% (Emulsified Base), packaged in 60 g tube, Rx only, Mfd. by: Taro Pharmaceuticals Inc., Brampton, Ontario, Canada, Dist. by Taro Pharmaceuticals U.S.A., Inc., Hawthorne, NY 10532, NDC 51672-1254-3	Class III	Lot #: D301311473, D 301411473, Exp 3/2017	Cross contamination with other products: Certain lots of Fluocinonide Cream were found to be contaminated with a small quantity of hydrocortisone-17-valerate.	Taro Pharmaceuticals U.S.A., Inc. 3 Skyline Dr Hawthorne, NY 10532-2174
Drugs	Desoximetasone Ointment USP, 0.25%, 15 g tubes, Rx Only, Teligent Pharma, Inc. Buena. New Jersey 08310 NDC 52565-030-15	Class III	Lot #: 5760, Exp. 5/31/2018	Superpotent Drug	Teligent, Inc. 105 Lincoln Avenue Buena, NJ 08310
Drugs	HYDROCORTISONE LOTION, USP, 2.5%, 2 FL OZ (59 mL) bottle, Rx only, Manufactured for: QUALITEST PHARMACEUTICALS, HUNTSVILLE, AL 35811, NDC 0603-7785-52.	Class III	Lot #: 0000004961, Exp. 05/17; 0000005197, 0000005198, 0000005199, Exp. 07/17; 0000005201, 0000005202, 0000005203, 0000005204, Exp. 09/17; 0000005200, 0000007998, 0000007999, 0000007022, Exp. 12/17; 0000009176, Exp. 04/18; 0000012281, 0000012282, Exp. 12/18	Superpotent Drug: above specification for the assay.	Vintage Pharmaceuticals LLC, DBA Qualitest Pharmaceuticals 150 Vintage Dr NE Huntsville, AL 35811-8216
Drugs	Children's Cetirizine Hydrochloride Chewable Tablets, 5 mg, 30-count bottle, Manufactured by: Sun Pharmaceutical Ind. Ltd., Halol-Baroda Highway, Halol - 389 350, Gujarat, India; Distributed by: Sun Pharmaceutical Industries, Inc., Cranbury, NJ 08512, NDC 47335-343-83.	Class III	Lot #: JKR5135A, Exp 11/17	Failed Tablet/Capsule Specifications: out of specification results for increased tablet hardness.	Sun Pharmaceutical Industries, Inc. 270 Prospect Plains Rd Cranbury, NJ 08512-3605
Drugs	Benzonatate capsules, 200 mg, 100-count bottle, Rx only, Manufactured by: Strides Shasun Limited Bangaluru -560076 India, Distributed by Strides Pharma Inc East Brunswick, NJ 08816, NDC 64380-713-06	Class III	Lot #: 7225075, 7225076, 7225077, 7225078, 7225079, 7225080 Exp 7/2017; 7225180, 7225181, 7225322, 7225323, Exp 8/2017; 7225649A, 7225650A, 7225651A, 7225652A, 7225653A, 7225654A, Exp 9/2017	Failed Stability Specifications: Out of Specification results obtained for preservative Methylparaben content.	Strides Pharma INC 2 Tower Center Blvd Ste 1102 East Brunswick, NJ 08816-1100
Drugs	Tarina Fe 1/20 (Norethindrone Acetate and Ethinyl Estradiol Tablets, USP and Ferrous Fumarate Tablets), 1 blister pack containing 28 tablets (NDC 50102-128-01), packaged in 3 pouches, each pouch contains one blister	Class III	Lot #: 6327A006, Exp 02/18	Chemical Contamination: out of specification results for impurities were found to be the result of contamination of product	Mylan Pharmaceuticals Inc. 781 Chestnut Ridge Rd

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
	pack of 28 tablets (NDC 50102-128-03), Rx only, Manufactured for: Afaxys, Inc., Charleston, SC 29403, USA, Product of India.			from vapors associated with paint thinner used in repair of the manufacturing room.	Morgantown, WV 26505-2730
Drugs	Norethindrone Acetate and Ethinyl Estradiol Tablets, USP, 1 mg/0.02 mg, 1 blister pack containing 21 tablets (NDC 0378-7280-85), packaged in 3 pouches, each contains one blister pack of 21 tablets (NDC 0378-7280-53), Rx only, Manufactured for: Mylan Pharmaceuticals Inc., Morgantown, WV 26505 U.S.A., Made in India.	Class III	Lot #: 6327A006, Exp 02/18	Chemical Contamination: out of specification results for impurities were found to be the result of contamination of product from vapors associated with paint thinner used in repair of the manufacturing room.	Mylan Pharmaceuticals Inc. 781 Chestnut Ridge Rd Morgantown, WV 26505-2730
Drugs	Amoxicillin and Clavulanate Potassium Tablets, USP, 500 mg/125 mg, in 20 count bottles, Rx Only, Manufactured in Austria by Sandoz Gmbh for Sandoz Inc. Princeton NJ NDC 0781-1831-20	Class III	Lot FP8735, 8/2017	Subpotent Drug; Clavulanic Acid	Sandoz Inc 100 College Rd W Princeton, NJ 08540-6604
Drugs	Nystatin Oral Suspension, USP, 100,000 units/mL, packaged in a) 2 fl.oz. (60mL) bottles (NDC 66689-008-02), and 500,000 units/5mL individual unit dose cup (NDC 66689-037-01) packaged in b) 50 count unit dose cups/case (NDC 66689-037-50) and c) 100 count unit dose cups/case (NDC 66689-037-99) Rx only, Manufactured by: VistaPharm, Largo, FL 33771.	Class III	a) Lot #: 431300, Exp. 01/2018; b) Lot #: 434000, 432500, Exp. 07/2017; 462200, Exp. 02/2018 c) Lot #: 443800, 445500, Exp. 09/2017; 460500, 461500, Exp. 01/2018.	Failed Impurities/Degradation Specifications: Presence of an impurity peak that exceeds approved specification.	VistaPharm, Inc. 7265 Ulmertown Rd Largo, FL 33771-4809

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

# CURRENT DRUG SHORTAGES

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## Scopolamine Transdermal System

**May 16, 2017**

### Reason for the Shortage

- Baxter has Transderm Scop in 10 count and 24 count available.
- Sandoz has Transderm Scop on shortage due to increased demand. Sandoz changed their NDC number in late 2016.

### Estimated Resupply Dates

- Sandoz has Transderm Scop in 4 count on back order and the company cannot estimate a release date.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=837>

## Multiple Vitamins for Infusion

**May 16, 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 5mL Dual vials on back order and the company estimates a release date of June 2017
- Pfizer has M.V.I. pediatric 5mL vials on back order and the company estimates a release date of early 4<sup>th</sup> quarter 2017.

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

## Hepatitis B Vaccine Recombinant

**May 16, 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 does not anticipate these products will be available in 2017.
- Merck has Recombivax HB pediatric/adolescent formulation syringes on intermittent back order and the company estimates this will continue through 3<sup>rd</sup> quarter 2017.

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

## Fluconazole Injection

**May 16, 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 200mg/100mL and 400mg/200mL in 0.9% sodium chloride premixed bags on back order and the company cannot estimate a release date.
- Claris Lifesciences has fluconazole injection 100mg/50mL in 0.9% sodium chloride premixed bag 6 count presentation on back order and the company cannot estimate a release date. Fluconazole injection 200mg/100mL and 400mg/200mL in 5% dextrose premixed bag 6 count presentations are on back order and the company cannot estimate a release date.
- Pfizer has fluconazole injection 200mg/100mL in 0.9% sodium chloride premixed bags on back order and the company estimates a release date of June 2017.
- West-Ward has all presentations on back order and the company cannot estimate a release date.

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

### Procainamide Hydrochloride Injection

**May 18, 2017**

#### Reason for the Shortage

- Pfizer did not provide a reason for the shortage

#### Estimated Resupply Dates

- Pfizer procainamide 500mg/mL 2mL vials on back order and the company estimates a release date of 3<sup>rd</sup> quarter 2017.

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

### Hydroxyzine Hydrochloride Injection

**May 18, 2017**

#### Reason for the Shortage

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

#### Estimated Resupply Dates

- American Regent has hydroxyzine 50mg/mL 10mL vials on back order and the company cannot estimate a release date

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

### Haloperidol Lactate Injection

**May 18, 2017**

#### Reason for the Shortage

- Mylan Institutional has haloperidol lactate injection available.
- Patriot Pharmaceuticals has haloperidol lactate available.
- Sagent has haloperidol lactate on shortage due to manufacturing delays.
- Teva is not currently marketing haloperidol lactate.
- West-Ward is not actively marketing haloperidol lactate at this time.

- Janssen has Haldol injection available.

#### Estimated Resupply Dates

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

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=527>

#### Indocyanine Green

**May 19, 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 25mg kits on back order and the company estimates a release date of mid-July 2017.

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

#### Ceftazidime Injection

**May 19, 2017**

#### Reason for the Shortage

- Pfizer has Tazicef on shortage due to increased demand.
- 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 1 gram, 2 gram, and 6 gram vials on allocation.
- Teligent has Fortaz 1 gram, 2 gram, and 6 gram vials on back order and the company estimates a release date of June 2017 for the 1 gram vials and cannot estimate a release date for the 2 gram and 6 gram vials.
- WG Critical Care has ceftazidime 1 gram, 2 gram, and 6 gram vials on back order and the company estimates a release date of June 2017 for the 2 gram vials and July 2017 for the 1 gram and 6 gram vials.
- Pfizer has Tazicef 1 gram and 2 gram ADD-Vantage vials on back order and the company estimates a release date of mid-June 2017 for the 1 gram vials and late-June 2017 for the 2 gram vials.

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

#### Topotecan Capsules

**May 22, 2017**

#### Reason for the Shortage

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

#### Estimated Resupply Dates

- Novartis has Hycamtin 0.25 mg capsules available with an expiration date of December 2017.

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

## Tetanus and Diphtheria Toxoids Adsorbed

May 22, 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 of late-June to July 2017.

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

## Reteplase Injection

May 22, 2017

### Reason for the Shortage

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

### Estimated Resupply Dates

- Chiesi USA has Retavase on long-term back order and the company cannot estimate a release date.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=569>

## Lidocaine Hydrochloride Oral Topical Solution (Viscous) 2%

May 22, 2017

### Reason for the Shortage

- Akorn has viscous lidocaine available.
- West-Ward did not provide a reason for the viscous lidocaine shortage

### Estimated Resupply Dates

- West-Ward has viscous lidocaine 100 mL bottles on 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=1171>

### Erythromycin Lactobionate Injection

**May 22, 2017**

#### Reason for the Shortage

- Pfizer has Erythrocin on shortage due to manufacturing delays.

#### Estimated Resupply Dates

- Pfizer has Erythrocin 500 mg ADD-Vantage vials on back order and the company estimates a release date of 4<sup>th</sup> quarter 2017.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=546>

### Levocarnitine Oral Tablets and Solution

**May 25, 2017**

#### Reason for the Shortage

- Akorn has levocarnitine tablets available.
- Sigma-Tau has Carnitor presentations on shortage due to increased demand.
- Rising Pharmaceuticals discontinued levocarnitine tablets in January 2017

#### Estimated Resupply Dates

- Sigma-Tau has Carnitor 100 mg/mL oral solution and Carnitor SF 100 mg/mL Sugar-Free oral solution on allocation

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1254>

### Leucovorin Calcium Injection

**May 25, 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

- Sagent has leucovorin 50mg and 100mg vials on allocation.
- Teva has leucovorin 100mg and 350mg vials on allocation.
- West-Ward has leucovorin 350mg vials on allocation.

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

### Trace Elements Injection

**May 30, 2017**

#### Reason for the Shortage

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

#### Estimated Resupply Dates

- American Regent has the Multitrac-4 10 mL vials, Multitrac-4 Concentrate 10 mL vials, and trace elements-4 pediatric vials on back order and the company cannot estimate a release date.

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

### **Selenium Injection**

**May 30, 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.

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

### **Papaverine Injection**

**May 30, 2017**

Reason for the Shortage

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

Estimated Resupply Dates

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

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

### **Nitroglycerin Injection**

**May 30, 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 available

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

### **Fentanyl Citrate Injection**

**May 30, 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 2 mL ampules and 5 mL ampules in 25 count on back order and the company estimates a release date of mid-July 2017. Fentanyl 5mL ampules in 10 count and 25 count are on back order and the company estimates a release date of late-June 2017.
- Pfizer has fentanyl 5 mL vials on back order and the company estimates a release date of late-June 2017. The fentanyl 2mL vials and 2mL Carpuject syringes are on allocation.

- West-Ward has fentanyl 2 mL vials, 20 mL vials, and 50 mL vials on allocation. Fentanyl 2 mL ampules, 5 mL ampules, 20 mL ampules, and 5 mL vials are on back order and the company estimates a release date in 3rd quarter 2017.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1273>

### **Dextrose (25%) Injection**

**May 30, 2017**

Reason for the Shortage

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

Estimated Resupply Dates

- Pfizer has 25% dextrose 10mL Ansyr syringes 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=1011>

### **Caffeine and Sodium Benzoate Injection**

**May 30, 2017**

Reason for the Shortage

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

Estimated Resupply Dates

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

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=817>

### **Talc, Sterile**

**June 2, 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 4gm/50mL vials and September 2017 for the 2 gram/50mL and 3 gram/10mL vials.

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

### **Sodium Chloride 0.9% Injection Bags**

**June 2, 2017**

Reason for the Shortage

- Baxter discontinued 0.9% sodium chloride 250 mL and 500 mL AVIVA bags. The other presentations are available.

- BBraun has 0.9% sodium chloride on allocation.
- Pfizer cited increased demand as the reason for the shortage. Fresenius Kabi is no longer importing product.
- Baxter has received FDA approval for 0.9% sodium chloride in Viaflo containers manufactured in an FDA-approved facility in Spain.

#### Estimated Resupply Dates

- BBraun has 0.9% sodium chloride in 250 mL, 500 mL, and 1000 mL PVC/DEHP-free bags on allocation.
- Baxter has 0.9% sodium chloride in 1000mL 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=993>

### Potassium Chloride Injection

**June 2, 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/50 mL and 20 mEq/50 mL vials on back order and company cannot estimate a release date. They have potassium chloride 20 mEq/500 mL in 5% dextrose and 0.2% sodium chloride, potassium chloride 20 mEq/500 mL in 5% dextrose and 0.45% sodium chloride, potassium chloride 20 mEq/1000 mL in 5% dextrose and lactated ringers, potassium chloride 20 mEq/1000 mL in 5% dextrose, potassium chloride 20 mEq/1000 mL in 5% dextrose and 0.2% sodium chloride, potassium chloride 20 mEq/1000 mL in 5% dextrose and 0.9% sodium chloride, potassium chloride 20 mEq/1000 mL in 0.9% sodium chloride, potassium chloride 30 mEq/1000 mL in 5% dextrose and 0.45% sodium chloride, potassium chloride 40 mEq/1000 mL in 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.
- Pfizer has potassium chloride 20 mEq/1000 mL in 0.9% sodium chloride on back order and the company estimates a release date of mid-June 2017. Potassium chloride 2 mEq/10 mL vials are on backorder and the company estimates a release date of July 2017. Pfizer has potassium chloride 2 mEq/mL 250 mL vials and 10 mEq/500 mL in 5% dextrose and 0.225% sodium chloride on back order and the company cannot estimate a release date.

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

### Mupirocin Calcium 2% Nasal Ointment

**June 2, 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

June 2, 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>

### Penicillin G Procaine Injection

June 5, 2017

#### Reason for the Shortage

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

#### Estimated Resupply Dates

- Pfizer has penicillin G procaine 6000,000 unit/mL 1mL and 2mL vials on back order and the company estimates a release date of 4<sup>th</sup> quarter 2017.

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

### Penicillin G Benzathine/Penicillin G Procaine

June 5, 2017

#### Reason for the Shortage

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

#### Estimated Resupply Dates

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

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

### Penicillin G Benzathine

June 5, 2017

#### Reason for the Shortage

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

#### Estimated Resupply Dates

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

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



### **Ketorolac Tromethamine Injection**

**June 5, 2017**

#### Reason for the Shortage

- BD Rx has ketorolac injection available. 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.
- Fresenius Kabi has ketorolac 30mg/mL 1 mL vials on back order and the company estimates a release date of mid-to-late-June 2017
- Pfizer has ketorolac 30mg/mL 2mL carpject syringes for intramuscular use on back order and the company estimates a release date of July 2017.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=593>

### **Dobutamine Injection**

**June 5, 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 dobutamine 1 mg/mL 250 mL 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 12.5mg/mL 20mL regular vials in single count are on back order and the company estimates a release date of late-June 2017.
- Pfizer has dobutamine 1 mg/mL, 2 mg/mL, and 4 mg/mL in 250 mL bags 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=929>

### **Disopyramide Phosphate Controlled-release Capsules**

**June 5, 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 100mg capsules in 500 count and 150mg capsules in 100 count and 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>

### **Dexmedetomidine Hydrochloride in 0.9% Sodium Chloride Injection**

**June 5, 2017**

#### Reason for the Shortage

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

#### Estimated Resupply Dates

- Pfizer has Precedex 4 mcg/mL premixed bottles available

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

### **Ammonium Molybdate Injection**

**June 5, 2017**

#### Reason for the Shortage

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

#### Estimated Resupply Dates

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

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1003>

### **Acetylcysteine Oral and Inhalation Solution**

**June 5, 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 had acetylcysteine oral and inhalation solution on shortage due to manufacturing delays
- Roxane Labs discontinued acetylcysteine oral and inhalation solution in April 2024.

#### Estimated Resupply Dates

- American Regent has acetylcysteine solution 100mg/mL 10mL vials, and 200mg/mL 10mL and 30mL vials on back order and the company cannot estimate a release date.

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

## Tetracaine Hydrochloride Ophthalmic Drops

June 6, 2017

### Reason for the Shortage

- Altaire did not provide a reason for the shortage.
- Novartis has tetracaine ophthalmic drops available.
- Ocusoft has Tetravisc and Tetravisc Forte available.
- Valeant has tetracaine ophthalmic drops available.

### Estimated Resupply Dates

- Altaire has Altacaine on back order and the company estimates a release date in mid-June 2017.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1242>

## Rocuronium Injection

June 6, 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 will be launching rocuronium with an estimated launch date of June 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 3rd quarter 2017.
- Pfizer has rocuronium 10 mg/mL 5 mL and 10 mL vials on back order and the company estimates a release date of 3rd quarter 2017.
- Sagent has rocuronium 10 mg/mL 5 mL and 10 mL vials on back order and the company estimates a release date of September 2017 for the 5 mL vials and cannot estimate a release date for the 10 mL vials.
- Sandoz has rocuronium 10 mg/mL 10mL vials on back order and the company estimates a release date of mid-to-late June 2017.
- X-Gen has rocuronium 10 mg/mL 5 mL vials and 10mL vials on back order and the company estimates a release date of mid-June 2017 for the 5mL vials and early-to-mid June 2017 for the 10mL vials.

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

## Oxacillin Sodium Injection

June 6, 2017

### Reason for the Shortage

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

### Estimated Resupply Dates

- AuroMedics has oxacillin 10 gram vials on intermittent back order and the company is releasing supplies as they become available.

- Sagent has oxacillin 1 gram, 2 gram, and 10 gram vials on back order and the company cannot estimate a release date.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1121>

### **Olanzapine Injection**

**June 6, 2017**

#### Reason for the Shortage

- Sandoz did not provide a reason for the shortage

#### Estimated Resupply Dates

- Sandoz has olanzapine 10 mg vials on back order and the company estimates a release date of mid-June 2017.

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

### **Liotrix Tablets**

**June 6, 2017**

#### Reason for the Shortage

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

#### Estimated Resupply Dates

- Actavis (formerly Forest) has all Thyrolar presentations on long-term back order and the company cannot estimate a release date.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=24>

### **Indigo Carmine Injection**

**June 6, 2017**

#### Reason for the Shortage

- American Regent has indigo carmine on back order due to manufacturing delays.1
- Akorn has discontinued production of indigo carmine due to shortage of raw material.2

#### Estimated Resupply Dates

- American Regent has indigo carmine 8 mg/mL 5 mL ampules on back order and the company cannot estimate a release date.1

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

### **Diazepam Injection**

**June 6, 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 mid-June 2017.

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

### **Dextrose (50%) Injection**

**June 6, 2017**

#### Reason for the Shortage

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

#### Estimated Resupply Dates

- Amphastar has 50% dextrose 50 mL syringes on allocation and is regularly releasing product.
- Pfizer has 50% dextrose 50 mL LifeShield syringes and 50 mL Ansyf syringes on back order and the company estimate a release date of June 2017. The 50 mL vials are on back order and the company estimates a release date of late-June 2017.

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

### **Clindamycin Injection**

**June 6, 2017**

#### Reason for the Shortage

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

#### Estimated Resupply Dates

- Alvogen has clindamycin 150 mg/mL 60 mL bulk vials available but with short-dating.
- Fresenius Kabi has clindamycin 150 mg/mL 2 mL vials available with short expiration dating of <1 month. The 6 mL vials and 60 mL bulk vials are on back order and the company cannot estimate a release date.
- Sagent has clindamycin 150 mg/mL 2 mL vials available with an expiration date of October 2017.

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

### **Bupivacaine with epinephrine Injection**

**June 6, 2017**

#### Reason for the Shortage

- Fresenius Kabi has bupivacaine and epinephrine on shortage due to increased demand and manufacturing delays.
- Pfizer has bupivacaine with epinephrine on shortage due to manufacturing delays.

#### Estimated Resupply Dates

- Fresenius Kabi has 0.25% Sensorcaine-MPF with epinephrine 10 mL and 30 mL vials on back order and the company estimates a release date of mid-July 2017 for the 10 mL vials and mid-June 2017 for the 30 mL vials. The 0.25% Sensorcaine with epinephrine 50 mL vials are on back order and the company estimates a release date of early-June 2017. The 0.5% Sensorcaine-MPF with epinephrine 10 mL vials are on back order and the company estimates a release date of early-July 2017. The 0.5% Sensorcaine-MPF with epinephrine 30 mL vials are on back order and the company estimates a release date of early-June 2017. The 0.5% Sensorcaine-MPF with epinephrine 30 mL vials sterile packs are on back order and the company

estimates a release date of early-June 2017. The 0.5% Sensorcaine with epinephrine 50 mL vials are on back order and the company estimates a release date of early-June 2017.

- 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-June 2017 for the 10 mL vials and October 2017 for the 30 mL vials. 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 mid-June 2017 for the 10 mL vials and early-August 2017 for the 30 mL vials. The 0.5% bupivacaine with epinephrine 50 mL vials are on back order and the company estimates a release date of 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 mid-July 2017 for the 10 mL vials and early-June 2017 for the 30 mL vials. 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 mid-June 2017.

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

### **Belatacept Injection**

**June 6, 2017**

#### Reason for the Shortage

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

#### Estimated Resupply Dates

- Bristol-Myers Squibb has limited the distribution of Nulojix. They have product only for existing patients available through the US Nulojix Distribution Program. They have no estimated recovery date, but do not expect full recovery before the end of 2017. Nulojix is distributed by McKesson Plasma Biologics.

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

### **Ampicillin Sulbactam**

**June 6, 2017**

#### Reason for the Shortage

- Mylan Institutional discontinued ampicillin sulbactam 1.5 gram and 3 gram vials.
- Pfizer has discontinued generic ampicillin sulbactam.
- Sandoz cannot provide a reason for the shortage.
- Sagent has ampicillin sulbactam vials on allocation due to 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, 3 gram, and 15 gram vials on allocation.
- Sandoz has ampicillin sulbactam 1.5 gram, 3 gram, and 15 gram vials temporarily unavailable and the company cannot estimate a release date.
- West-Ward has ampicillin sulbactam 1.5 gram, 3 gram, and 15 gram vials on back order and the company cannot estimate a release date.

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

## Indomethacin Capsules

June 8, 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.
- 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 50 mg capsules in 100 count on back order and the company estimates a release date of mid-June 2017.
- 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>

## Dexamethasone Sodium Phosphate

June 8, 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 5 mL and 30 mL vials on intermittent back order.
- Mylan has dexamethasone sodium phosphate 4 mg/mL 30 mL vials on back order and the company estimates a release date of late-June 2017.

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

## Atropine Sulfate Injection

June 8, 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 available in limited supply.
- Pfizer has atropine 0.05 mg/mL 5 mL Ansyr syringes on back order and the company estimates a release date of mid-June 2017. The 0.1 mg/mL 10 mL LifeShield syringes are on back order and the company

estimates a release date of June 2017. The 0.1 mg/mL 5 mL LifeShield syringes are on back order and the company estimates a release date of early-August 2017. The 0.1 mg/mL 10 mL Ansyf syringes are on back order and the company estimates a release date of June 2017.

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

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

**June 8, 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
- ICU Medical has 5% dextrose 250 mL PVC/DEHP-free bags 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=1269>

### 5% Dextrose Injection

**June 8, 2017**

#### Reason for the Shortage

- Pfizer states the shortage was due to increased demand and manufacturing delays.
- Baxter did not provide a reason for the shortage.
- 5% dextrose 1,000-mL bags are not affected at this time.

#### Estimated Resupply Dates

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

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

### Vancomycin Hydrochloride Injection

**June 9, 2017**

#### Reason for the Shortage

- Pfizer has vancomycin bulk vials on back order due to manufacturing delays. All other presentations are available.
- Fresenius Kabi has vancomycin injection on shortage due to increased demand.
- Mylan Institutional has vancomycin injection available.
- Baxter has vancomycin injection available.
- Sagent has vancomycin injection on shortage due to manufacturing delays.

#### Estimated Resupply Date



- Fresenius Kabi has vancomycin 500 mg and 10 gram vials on intermittent back order with regular releases.<sup>2</sup>
- Sagent has vancomycin 10 gram vials on back order and the company estimates a release date of June 2017. The 5 gram vials are on allocation.<sup>5</sup>
- Pfizer has vancomycin lyophilized powder 5 gram vials on back order and the company estimates a release date of mid-June 2017. The 500 mg vials are also on back order and the company estimates a release date of June 2017.

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

### Sodium Bicarbonate Injection

June 9, 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 related to obtaining glass syringe components.

#### Estimated Resupply Dates

- Amphastar has 8.4 % sodium bicarbonate 50 mL syringes on allocation.
- Pfizer has 8.4 % sodium bicarbonate 50 mL syringes on allocation. The 8.4 % sodium bicarbonate 50 mL vials are on back order and the company estimates a release date of September 2017. The 8.4% sodium bicarbonate 10 mL syringes are on back order and the company estimates a release date of early-August 2017. The 4.2% sodium bicarbonate 10 mL syringes are on back order and the company estimates a release date of late-June 2017. The 7.5% sodium bicarbonate 50 mL syringes are on back order and the company estimates a release date of October 2017.
- To help alleviate the shortage, FDA is granting Athenex Pharmaceutical Division (APD) the ability to import 10 mL vials of sodium bicarbonate from Phebra, an Australian company. Supplies are limited and only available via direct orders. Orders may be placed by contacting customer service at 855-273-0154 or [apddorders@dlss.com](mailto:apddorders@dlss.com).

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

### Sodium Acetate Injection

June 9, 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 mid- to late-June 2017.
- Pfizer has sodium acetate 2 meq/mL 20 mL vials available in limited supply. The 2 meq/mL 50 mL and 100 mL vials are on back order and the company estimates a release date of June 2017 for the 50 mL vials and mid-June 2017 for the 100 mL vials.

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

## Promethazine Injection

June 9, 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 on a weekly allocation. The 50 mg/mL 1 mL ampules are on a weekly allocation. The 50 mg/mL 1 mL vials on back order and the company estimates a release date of June 2017.
- West-Ward has Phenergan 25 mg/mL 1 mL vials on back order and the company estimates a release date of June 2017. Phenergan 25 mg/mL 1 mL ampules are on a weekly allocation. The 50 mg/mL 1 mL vials are on back order and the company estimates a release date of June 2017.
- X-Gen has promethazine 25 mg/mL 1 mL ampules on back order and the company estimates a release date of mid-June 2017.

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

## Morphine Injections

June 9, 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.
- 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 morphine 0.5 mg/mL 10 mL preservative-free vials and 1 mg/mL 10 mL preservative-free vials on back order and the company estimates a release date of mid-July 2017. The 2 mg/mL 2 mL Carpuject syringes are on back order and the company estimates a release date of mid-June 2017. The 25 mg/mL 1 mL preservative-free vials are on back order and the company estimates a release date of late-June 2017.
- West-Ward has Infumorph 10 mg/mL 20 mL preservative-free vials on back order and the company cannot estimate a release date.

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

## Methotrexate Injection

June 9, 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 estimates a release date of late-June 2017.
- Fresenius Kabi has methotrexate 1 gram powder on back order and the company estimates a release date of mid-to late-June 2017. The 25 mg/mL 10 mL vials are on allocation.
- Mylan Institutional has methotrexate injection temporarily unavailable and the company cannot estimate a release date.
- Pfizer has methotrexate 25 mg/mL 2 mL vials and 40 mL vials on allocation.
- Teva has methotrexate 25 mg/mL 2 mL, 10 mL, and 40 mL vials on allocation. Please check wholesaler for inventory.

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

#### Mepivacaine Injection

**June 9, 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 all Carbocaine presentations on back order. Carbocaine 1% in 50 mL multiple-dose vials is available in limited quantities. Carbocaine 1% in 30 mL preservative-free vials, Carbocaine 1.5% in 30 mL preservative-free vials, and Carbocaine 2% in 20 mL preservative-free vials are all on back order with expected release dates sometime in the 4th quarter of 2017. Carbocaine 2% in 50 mL multiple-dose vials is on back order and the company expects a release date in mid-July 2017.
- Fresenius Kabi has Polocaine-MPF 1% and 1.5% preservative-free vials on back order and the company expects a release date of late-July 2017 for the 1% vials and mid-June 2017 for the 1.5% vials.

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

#### Lorazepam Injection

**June 9, 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

- Akorn has lorazepam 2 mg/mL 1 mL vials on intermittent back order and is releasing product as it becomes available.
- Pfizer has lorazepam 2 mg/mL 1 mL Carpuject syringes on back order and the company estimates a release date of mid-June 2017. The 2 mg/mL 1 mL vials are on back order and the company estimates a release date of 4th quarter 2017. The 4 mg/mL 1 mL vials are on back order and the company estimates a release date of 3rd quarter 2017.
- West-Ward has lorazepam 4 mg/mL 1 mL vials on back order and the company estimates a release date of June or July 2017.

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

## Lidocaine Injection

June 9, 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 2 mL and 5 mL vials on intermittent back order and the company is releasing product as it becomes available. AuroMedics has 2% lidocaine 2 mL and 5 mL vials on intermittent back order and the company is releasing product as it becomes available.
- Fresenius Kabi has 1% Xylocaine 20 mL and 50 mL vials on back order and the company estimates a release date of mid-June 2017 for the 20 mL vials and mid- to late-June 2017 for the 50 mL vials. The 2% Xylocaine 20 mL vials are on back order and the company estimates a release date of mid-June 2017.
- Pfizer has 1% lidocaine 5 mL preservative-free ampules on back order and the company estimates a release date of June 2017. The 2% lidocaine 5 mL Ansyr syringes and 5 mL LifeShield syringes are on back order and the company estimates a release date of June 2017.

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

## Labetalol Injection

June 9, 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 vials on back order and the company estimates a release date of mid-June 2017. The 40 mL vials are on back order and the company estimates a release date of late-June 2017. The 5 mg/mL 4 mL syringes are on back order and the company estimates a release date of mid-June 2017.
- West-Ward has labetalol 5 mg/mL 20 mL vials on allocation.

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

## Cefuroxime Sodium Injection

June 9, 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 7.5 gram vials on back order and the company cannot estimate a release date.
- Teligent has Zinacef 1.5 gram vials on back order and the company estimates a release date of late-June 2017. Zinacef 1.5 gram ADD-Vantage vials are on back order and the company cannot estimate a release date. The 750 mg ADD-Vantage vials and 7.5 gram vials are 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>

### Ceftriaxone Sodium Injection

**June 9, 2017**

#### Reason for the Shortage

- Fresenius Kabi states the reason for the shortage is increased demand.
- Pfizer states the reason for the shortage is manufacturing delay.
- Sagent states the reason for the shortage is manufacturing delay.
- Sandoz has 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.

#### Estimated Resupply Dates

- Apotex has ceftriaxone 2 gram vials on back order and the company estimates a release date of late-June 2017.
- Fresenius Kabi has ceftriaxone 500 mg vials on back order and the company cannot estimate a release date.
- Lupin has all ceftriaxone presentations on allocation.
- Pfizer has ceftriaxone 2 gram ADD-Vantage vials on back order and the company estimates a release date of July 2017.
- Sagent has ceftriaxone 1 gram vials on allocation.
- West-Ward has ceftriaxone 250 mg and 2 gram vials on back order and the company estimates a release date of July or August 2017. The 1 gram vials are on allocation..
- WG Critical Care has ceftriaxone 10 gram vials on back order and the company estimates a release date of late-June 2017.
- Wockhardt has ceftriaxone 250 mg and 2 gram vials on back order and the company estimates a release date of early to mid-July 2017 for the 250 mg vials and late-June 2017 for the 2 gram vials.

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

### Bupivacaine Injection

**June 9, 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.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=864>

### Bumetanide Injection

June 9, 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 vials on back order and the company estimates a release date of mid-June 2017. The 10 mL vials are on back order and the company estimates a release date of 2018.
- West-Ward has bumetanide 0.25 mg/mL 4 mL vials on a weekly allocation.

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

### Alcohol Dehydrated Injection (Ethanol)

June 9, 2017

#### Reason for the Shortage

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

#### Estimated Resupply Dates

- American Regent has dehydrated alcohol 1 mL ampules on back order and the company cannot estimate a release date.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=778>

### Vecuronium Bromide Injection

June 12, 2017

#### Reason for the Shortage

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

#### Estimated Resupply Dates

- Pfizer has vecuronium 10 mg and 20 mg vials 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=490>

### Sodium Phosphate Injection

June 12, 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.
- Fresenius Kabi has sodium phosphate 3 mmol/mL 5 mL vials on back order and the company estimates a release date of late-June 2017.
- Pfizer has sodium phosphate 3 mmol/mL 15 mL vials on allocation.

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

### **Sodium Nitroprusside Injection**

**June 12, 2017**

#### Reason for the Shortage

- Valeant has Nitropress available but short-dated.
- Sagent launched sodium nitroprusside 25 mg/mL 2 mL vials in late 2016. They have product available.
- Exela launched Nipride RTU 0.5 mg/mL 100 mL vials in March 2017.

#### Estimated Resupply Dates

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

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

### **Rabies Vaccine**

**June 12, 2017**

#### Reason for the Shortage

- GlaxoSmithKline Vaccines has RabAvert currently available.
- Sanofi Pasteur has Imovax available.

#### Estimated Resupply Dates

- GlaxoSmithKline Vaccines has RabAvert on back order and the company estimates a release date in May 2017. Emergency stock is available if a patient has been exposed.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=959>

### **Potassium Phosphate Injection**

**June 12, 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 5 mL, 15 mL, and 50 mL vials on back order and the company estimates a release date of mid-June 2017.
- Pfizer has potassium phosphate 3 mmol/mL 15 mL vials on back order and the company estimates a release date of late-July 2017.

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

## Piperacillin Tazobactam Injection

June 12, 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.
- Baxter has Zosyn frozen premixes on allocation due to increased demand.
- Fresenius Kabi has piperacillin/tazobactam on shortage due to increased demand.
- Mylan Institutional launched piperacillin/tazobactam 3.375 gram and 4.5 gram vials in early-June 2016.
- Pfizer has Zosyn on shortage due to manufacturing delays.
- Sagent has piperacillin/tazobactam on shortage due to increased demand.
- Sandoz 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.
- X-Gen recently launched piperacillin/tazobactam injection.

### 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-June 2017.
- AuroMedics has piperacillin/tazobactam on intermittent back order and the company is releasing product as it becomes available. Check wholesalers for inventory.
- Baxter has all frozen piperacillin/tazobactam presentations available in limited supply.
- Fresenius Kabi has piperacillin/tazobactam 40.5 gram vials on back order and the company estimates a release date of mid-June 2017.
- 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.
- WG Critical Care has piperacillin/tazobactam 2.25 gram vials on back order and the company estimates a release date in late-June 2017. Piperacillin/Tazobactam 3.375 gram, 4.5 gram, and 40.5 gram 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=1075>

## Pantoprazole Injection

June 12, 2017

### Reason for the Shortage

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

### Estimated Resupply Dates

- Pfizer has Protonix 40 mg vials in 10 count and 25 count packs on back order and the company estimates a release date of mid-July 2017 for the 10 count presentation and mid-June 2017 for the 25 count presentation.
- 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>



### Metronidazole Hydrochloride Injection

June 12, 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

- Baxter has metronidazole injection available in limited quantities.
- Braun has metronidazole injection on back order and the company estimates a release date of mid-June 2017. They will be allocating product upon release.
- Claris has metronidazole injection on long-term back order and the company cannot estimate a release date.
- Pfizer has metronidazole injection in 24 count and 80 count on back order and the company estimates a release date of August 2017 for the 24 count size and June 2017 for the 80 count size.

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

### Methylphenidate Transdermal

June 12, 2017

#### Reason for the Shortage

- Noven has Daytrana patches on shortage due to packaging problems.

#### Estimated Resupply Dates

- Noven has all Daytrana presentations on intermittent back order and the company is releasing supplies as they become available. Noven estimates a full recovery in June 2017.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1216>

### Methylene Blue Injection

June 12, 2017

#### Reason for the Shortage

- Akorn has methylene blue on shortage due to manufacturing delays.<sup>1</sup>
- American Regent has recently launched an FDA approved presentation, ProvayBlue and product is available

#### Estimated Resupply Dates

- Akorn has methylene blue 10 mg/mL 1 mL and 10 mL vials on back order and the company estimates a release date of mid-July 2017.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=27>

### Magnesium Sulfate Injection

June 12, 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 on back order and the company estimates a release date of early-July 2017.
- Pfizer has magnesium sulfate 500 mg/mL 10 mL syringes and 20 mL vials on back order and the company estimates a release date of June 2017 for the 10 mL syringes and 1st quarter 2018 for the 20 mL vials. The 40 mg/mL 1000 mL premixed bags are on back order and the company estimates a release date of late-June 2017. The 80 mg/mL 50 mL premixed bags are on back order and the company estimates a release date of late-July 2017.

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

#### Lidocaine with Epinephrine Injection

**June 12, 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 and 50 mL vials on back order and the company estimates a release date of mid-June 2017. The 1% lidocaine with epinephrine (1:100,000) 30 mL vials are on back order and the company estimates a release date of mid-July 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 October 2017. 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-July 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.
- Fresenius Kabi has 0.5% Xylocaine with epinephrine (1:200,000) 50 mL vials on back order and the company estimates a release date of late-June 2017. The 1% Xylocaine with epinephrine (1:200,000) 10 mL, 20 mL, and 50 mL vials are on back order and the company estimates a release date of late-July 2017 for the 10 mL vials and mid-to late-June 2017 for the 20 mL vials, and mid-June 2017 for the 50 mL vials. The 1% Xylocaine-MPF with epinephrine (1:200,000) 30 mL vials are on back order and the company estimates a release date of mid-June 2017. The 1% Xylocaine-MPF with epinephrine (1:200,000) 30 mL vials in sterile packs are on back order and the company estimates a release date of mid-August 2017. The 1.5% Xylocaine-MPF with epinephrine (1:200,000) 30 mL vials in sterile packs are on back order and the company estimates a release date of mid-June 2017. There are short-dated 1.5% Xylocaine-MPF with epinephrine (1:200,000) 30 mL vials available. 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 mid-June 2017 for the 20 mL vials and early-July 2017 for the 50 mL vials. The 2% Xylocaine-MPF with epinephrine (1:200,000) 10 mL and 20 mL vials are on back order and the company estimates a release date of late-June 2017 for the 10 mL vials and mid-June 2017 for the 20 mL vials. The 2% Xylocaine-MPF with epinephrine (1:200,000) 20 mL vials in sterile packs are on back order and the company estimates a release date of mid-June 2017..

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

#### loversol Injection

**June 12, 2017**

#### Reason for the Shortage

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

#### Estimated Resupply Dates

- Guerbet had most Optiray products on allocation. However, the company did not provide updated availability information.

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1253>

#### Hydromorphone Hydrochloride Injection

**June 12, 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.

#### Estimated Resupply Dates

- Pfizer has hydromorphone 0.5 mg/0.5 mL 0.5 mL iSecure syringes on allocation. The 1 mg/mL 1 mL iSecure syringes are on back order and the company estimates a release date of mid-June 2017. Hydromorphone 2 mg/mL 1 mL ampules are on back order and the company estimates a release date of early-July 2017. The 2 mg/mL 1 mL vials are on back order and the company estimates a release date of mid-June 2017.
- Teva has hydromorphone 10 mg/mL 50 mL vials on allocation.

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

#### Furosemide Injection

**June 12, 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

- Fresenius Kabi has furosemide 10 mg/mL 4 mL vials on back order with an estimated release date of late-June 2017.
- Pfizer has furosemide 0 mg/mL 10 mL syringes on back order and the company estimates a release date of late-June 2017. The 10 mg/mL 4 mL and 10 mL vials are available in limited supply

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

#### Etoposide Injection

**June 12, 2017**

#### Reason for the Shortage

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

#### Estimated Resupply Dates

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

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

### **Diltiazem Hydrochloride Injection**

**June 12, 2017**

#### Reason for the Shortage

- Akorn states the reason for the shortage is 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

- Akorn has diltiazem 5 mg/mL 5 mL vials on back order and the company cannot estimate a release date. The diltiazem 25 mL vials in 1 count and 25 count are available in limited supply.
- Pfizer has 100 mg ADD-Vantage vials on back order and the company estimates a release date of mid-June 2017. 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>

### **Dihydroergotamine Mesylate Injection**

**June 12, 2017**

#### Reason for the Shortage

- Perrigo has dihydroergotamine injection available.
- Valeant did not provide a reason for the shortage.

#### Estimated Resupply Dates

- Valeant has D.H.E. 45 1 mg/mL 1 mL ampules on back order and the company estimates a release date of late-June 2017

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1050>

### **Cisplatin Injection**

**June 12, 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 available.
- WG Critical Care did not provide a reason for the shortage.

#### Estimated Resupply Dates

- Fresenius Kabi has cisplatin 100 mL vials on back order and the company estimates a release date of mid-June 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.
- WG Critical Care has cisplatin 50 mL and 100 mL vials on back order and the company estimates a release date of July 2017.

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

### **Asparaginase Erwinia chrysanthemi**

**June 12, 2017**

#### Reason for the Shortage

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

#### Estimated Resupply Dates

- Jazz Pharmaceuticals has Erwinaze available. The company requests that Erwinaze only be ordered for patients who are currently undergoing treatment or initiating treatment.

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

### **Albendazole Tablets**

**June 12, 2017**

#### Reason for the Shortage

- Impax did not provide a reason for the shortage.

#### 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>

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

**June 12, 2017**

#### Reason for the Shortage

- Fresenius Kabi did not provide a reason for the shortage.
- Pfizer did not provide a reason for the shortage.

#### Estimated Resupply Dates

- Fresenius Kabi has 0.9% sodium chloride 10 mL single dose vials on back order and the company estimates a release date in late-June 2017. The 20 mL single dose vials are available with short expiration dating (< 5 months). The company estimates the 20 mL vials with regular dating will be released in late-June 2017.
- Pfizer has 0.9% sodium chloride 10 mL Life-Shield vials on back order and the company estimates a release date of mid-June 2017.

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

### **Theophylline Extended-Release Tablets**

**June 14, 2017**

#### Reason for the Shortage

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

#### Estimated Resupply Dates

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

<https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortage-Detail.aspx?id=1221>

### **Sincalide Injection**

**June 14, 2017**

#### Reason for the Shortage

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

#### Estimated Resupply Dates

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

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

### **Octreotide Injection**

**June 14, 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 and 500 mcg/mL 1 mL vials on back order and the company estimates a release date of July for the 50 mcg/mL vials and June 2017 for the 500 mcg/mL 1 mL vials.

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

### **Multiple Vitamins for Infusion**

**June 14, 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 and 50 mL Dual vials on back order and the company estimates a release date of August 2017 for the 5 mL vials and mid-July 2017 for the 50 mL vials.
- Pfizer has M.V.I. pediatric 5 mL vials on back order and the company cannot estimate a release date.

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

### **Gentamicin injection**

**June 14, 2017**

#### Reason for the Shortage

- Pfizer has discontinued all premixed bags.

- Baxter did not provide a reason for the shortage.

#### Estimated Resupply Dates

- Pfizer has gentamicin 40 mg/mL 2 mL vials available in limited supply.

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

### Epinephrine Injection

**June 14, 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 early-July 2017.

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

### Dopamine Hydrochloride Injection

**June 14, 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/250 mL premixed bags are on back order and the company estimates a release date of mid-June 2017. The dopamine 800 mg/500 mL premixed bags are on back order and the company estimates a release date of mid-July 2017. The dopamine 800 mg/250 mL premixed bags are 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=1243>

### Ceftazidime Injection

**June 14, 2017**

#### Reason for the Shortage

- Pfizer has Tazicef on shortage due to increased demand.
- 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 1 gram, 2 gram, and 6 gram vials on allocation.
- Teligent has Fortaz 1 gram, 2 gram, and 6 gram vials on back order and the company estimates a release date of June 2017 for the 1 gram vials and cannot estimate a release date for the 2 gram and 6 gram vials.
- WG Critical Care has ceftazidime 1 gram and 6 gram vials on back order and the company estimates a release date of late-June 2017 for the 1 gram vials and mid-July 2017 for the 6 gram vials.
- Pfizer has Tazicef 2 gram ADD-Vantage vials on back order and the company estimates a release date of late-June 2017. The 6 gram vials are available in limited supply.

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

#### Cefoxitin Sodium Injection

**June 14, 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 mid-July 2017 for the 1 gram vials and late-July 2017 for the 2 gram vials.
- Sagent has cefoxitin 1 gram and 10 gram vials on back order and the company estimates a release date of June 2017. The 2 gram vials are on back order and the company cannot estimate a release date.
- West-Ward has cefoxitin 1 gram, 2 gram, and 10 gram vials on back order and the company estimates a release date of June or July 2017 for the 1 gram and 2 gram vials and cannot estimate a release date for the 10 gram vials.

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

#### Cefepime Injection

**June 14, 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

- Apotex has cefepime 1 gram vials in 1 count on back order and the company cannot estimate a release date. The 1 gram vials in 10 count and 2 gram vials in 10 count are available in limited supply.
- BBraun has cefepime 1 gram premixed bags on back order and the company cannot estimate a release date.
- Fresenius Kabi has cefepime 1 gram vials on back order and the company estimates a release date of mid-to late-June 2017.



- Pfizer has Maxipime 1 gram ADD-Vantage vials on back order and the company estimates a release date of July 2017. The 2 gram ADD-Vantage vials are on back order and the company estimates a release date of August 2017.
- Sagent has cefepime 1 gram and 2 gram vials on back order and the company estimates a release date of June 2017.

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

### **Amino Acid Products**

**June 14, 2017**

#### Reason for the Shortage

- Baxter has all amino acid products available.
- BBraun has all amino acid products available.
- Pfizer has Aminosyn on back order due to an ingredient shortage which has caused a supply disruption. Pfizer has obtained the ingredient, but does not yet have an estimated date as to when manufacturing will resume.

#### Estimated Resupply Dates

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

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