PERFORMRx℠

Drug Information Update

September 2023

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NEWLY AVAILABLE GENERICS

Generic Name/ Dosage Form	Brand Name	Manufacturer	Indication
Lisdexamfetamine 10 mg, 20 mg, 30 mg, 40 mg, 50 mg, 60 mg, 70 mg oral capsules	Vyvanse	Multiple manufacturers	Treatment of: • Attention Deficit Hyperactivity Disorder (ADHD) • Moderate to Severe Binge Eating Disorder (BED) in adults
Lisdexamfetamine 10 mg, 20 mg, 30 mg, 40 mg, 50 mg, 60 mg chewable tablets	Vyvanse	Sun Pharmaceutical	Treatment of: • Attention Deficit Hyperactivity Disorder (ADHD) • Moderate to Severe Binge Eating Disorder (BED) in adults
Tretinoin microsphere 0.08% topical gel w/pump	Retin-A Micro	Encube Ethicals	• Topical treatment of acne vulgaris
Lopamidol 41%, 61% intrathecal vials	Isovue	Slate Run Pharmaceuticals	• For intrathecal administration in adult neuroradiology including myelography (lumbar, thoracic, cervical, total columnar), and for contrast enhancement of computed tomographic (CECT) cisternography and ventriculography • For thoraco-lumbar myelography in children over the age of two years.

NEW DRUG ENTITIES/STRENGTHS/COMBINATIONS

Drug Name	Generic Name	Description
Airsupra inhalation aerosol 90-80 mcg/act	albuterol-budesonide	First combination ICS/SABA fixed dose inhaler approved for PRN use for asthma.
Veopoz injection solution 400 mg/2 mL	pozelimab-bbfg	First FDA-approved treatment for CHAPLE disease, an ultra-rare disorder.
Eylea HD intravitreal solution 8 mg/ 0.07 mL	aflibercept	High dose aflibercept product for same indications as regular Eylea.
Sohonos oral capsule 1 mg, 1.5 mg, 2.5 mg, 5mg, 10 mg	palovarotene	First and only treatment for fibrodysplasis ossificans progressiva.
Nitrofurantoin oral suspension 50 mg/5mL	nitrofurantoin	New strength. Indicated for UTI.
Pfizer COVID-19 Vac-TriS 6m-4y intramuscular suspension 3 mcg/0.3ml	COVID-19 intramuscular suspension	New formulation, XBB.1.5 variant. Indicated for SARS-CoV-2
Balfaxar intravenous solution reconstituted 500-unit, 1000-unit	prothrombin complex concentrate, human-lans	Indicated for urgent reversal of acquired coagulation factor deficiency induced by vit K antagonist inpatient use
Rykindo intramuscular suspension reconstituted ER 25 mg, 37.5 mg, 50 mg	risperidone	Atypical antipsychotic for schizophrenia and bipolar I disorders. Shorter oral overlap then risperidal consta.
Moderna COVID-19 Vac 6m-11y intramuscular suspension 25 mcg/0.25ml	COVID-19 intramuscular suspension	New formulation, XBB.1.5 variant. Indicated for SARS-CoV-2
Daxxify intramuscular solution Reconstituted 100-unit	daxibotulinumtoxin a-lanm	New botulinum toxin product for the treatment of cervical dystonia in adults.

Drug Name	Generic Name	Description
Lodoco oral tablet 0.5 mg	colchicine	Low-dose colchicine tablets indicated to reduce the risk of myocardial infarction (MI), stroke, coronary revascularization, and cardiovascular death in adult patients with established atherosclerotic disease or with multiple risk factors for cardiovascular disease. First anti-inflammatory atheroprotective cardiovascular medication approved by the FDA to reduce cardiovascular risk.
Comirnaty intramuscular suspension prefilled syringe 30 mcg/0.3ml	COVID-19 intramuscular suspension	New Pfizer formulation, XBB.1.5 variant. Indicated for SARS-CoV-2.
Jesduvroq oral tablet 1 mg, 2 mg, 4 mg, 6 mg, 8 mg	daprodustat	First hypoxia-inducible factor prolyl hydroxylase (HIF PH) inhibitor indicated for the treatment of anemia due to chronic kidney disease in adults who have been receiving dialysis for at least four months.
Cresemba oral capsule 74.5 mg	isavuconazonium sulfate	New strength. Indicated for invasive aspergillosis and invasive mucormycosis.
Akeega oral tablet 50-500 mg, 100-500 mg	niraparib and abiraterone acetate	First single-tablet combination of niraparib, a poly (ADP-ribose) polymerase (PARP) inhibitor, and abiraterone acetate, a CYP17 inhibitor. Indicated with prednisone for the treatment of adult patients with deleterious or suspected deleterious BRCA mutated (BRCAm) metastatic castration-resistant prostate cancer.
Lantidra intravenous suspension	donislecel-jujn	First allogeneic cellular therapy approved for the treatment of T1D in adults who are unable to approach target HbA1c because of repeated episodes of severe hypoglycemia despite intensive diabetes management. Administered as a single infusion into the hepatic portal vein in conjunction with immunosuppressants. Up to two additional infusions may be administered depending on the patient's response.
Spikevax intramuscular suspension prefilled syringe 50 mcg/ml	COVID-19 intramuscular suspension	New Moderna formulation, XBB.1.5 variant. Indicated for SARS-CoV-2.
Breo Ellipta Inhalation Aerosol Powder Breath Activated 50-25 mcg/inh	fluticasone furoate-vilanterol	New strength. Newly expanded indication to age 5 years and up for asthma, previously only indicated in adults.

Drug Name	Generic Name	Description
Ojjaara oral tablet 100 mg, 150 mg, 200 mg	momelotinib	Oral JAK1/JAK2 and activin A receptor type 1 (ACVR1) inhibitor indicated for the treatment of intermediate or high-risk myelofibrosis in adults with anemia. It will compete with Jakafi, which has a broader FDA-approved indication, for patients with myelofibrosis, whereas Ojjaara's label is only for patients with myelofibrosis who are anemic.
Aphexda subcutaneous solution reconstituted 62 mg	motixafortide	To be used in combination with filgrastim to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients with multiple myeloma. After filgrastim has been administered daily for 4 days, Aphexda is to be given as one subcutaneous injection 10 to 14 hours prior to initiation of apheresis. A second dose can be administered 10 to 14 hours prior to a third apheresis. It is not indicated as monotherapy.

NEW INDICATIONS (EXISTING DRUGS)

†**Bolded** items reflect newly approved indication; ~~strikethrough~~ of removed indication/age limit/etc.

Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication†
Reblozyl	luspatercept-aamt 25 mg, 75 mg subcutaneous solution reconstituted	Celgene	• Anemia in adult patients with beta thalassemia who require regular red blood cell (RBC) transfusions • **Anemia without previous erythropoiesis stimulating agent use (ESA-naïve) in adult patients with very low- to intermediate-risk myelodysplastic syndromes (MDS) who may require regular red blood cell (RBC) transfusions** Anemia failing an erythropoiesis stimulating agent and requiring 2 or more RBC units over 8 weeks in adult patients with very low- to intermediate-risk myelodysplastic syndromes with ring sideroblasts (MDS-RS) or with myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis
Tafinlar	dabrafenib 50 mg, 75 mg oral capsules; 10 mg tablets for oral suspension	Novartis Pharmaceuticals	• To be used in combination with trametinib, for the treatment of adult and pediatric patients ~~6~~**1** year~~s~~ of age and older with unresectable or metastatic solid tumors with BRAF V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options This indication is approved under accelerated approval based on overall response rate (ORR) and duration of response (DoR). Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s) *Note: Tafinalr has other approved indications not mentioned here; see full prescribing information for details.* A taxane or irinotecan, and if appropriate, HER2/neu-targeted therapy

Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication†
Mekinist	trametinib 0.5 mg, 2 mg oral tablets; 0.05 mg/ml oral solution	Novartis Pharmaceuticals	• To be used in combination with dabrafenib, for the treatment of adult and pediatric patients ~~6~~**1** year~~s~~ of age and older with unresectable or metastatic solid tumors with BRAF V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options This indication is approved under accelerated approval based on overall response rate (ORR) and duration of response (DoR). Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s) *Note: Mekinist has other approved indications not mentioned here; see full prescribing information for details.*

RECALLS

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Vegetal Vigra, 200mg capsules, 8-count bottle, Manufacturer: Hand-shaking (Int'l) Corp. USA ADD: Hand-shaking Mansion, the 5th Ave., Stanford, USA. UPC 8 931028 556885	Class I	Drugs	All lots, Expires: 01/31/2025	Marketed Without an Approved NDA/ANDA: FDA analysis found the product to be tainted with sildenafil an ingredient found in a FDA approved product for the treatment of male sexual enhancement, making this an unapproved drug.	APG SEVEN, INC
Digoxin Tablets, USP 0.125mg, 100-count bottles, Rx Only, Manufactured for/Distributed by: Marlex Pharmaceuticals, Inc. New Castle, DE NDC# 10135-0747-01	Class I	Drugs	Lot # E3810, expiration date 02/2025	Labeling: Label Mix-Up-Bottles labeled as Digoxin Tablets, USP 0.125 mg contain Digoxin Tablets, USP 0.25mg and bottles labeled as Digoxin Tablets, USP 0.25mg contain Digoxin Tablets, USP 0.125mg.	Marlex Pharmaceuticals, Inc.
SANDIMMUNE Oral Solution (cyclosporine oral solution, USP) 100 mg/mL, 50 mL bottle, Rx Only, Manufactured by: DELPHARM Huningue S.A.S., Huningue, France, Distributed by: Novartis Pharmaceuticals Corporation, East Hanover, New Jersey 07936, NDC 0078-0110-22.	Class I	Drugs	FX001691, Exp. 12/31/2025	Crystallization: bottles of Sandimmune Oral Solution were determined to contain crystals.	Novartis Pharmaceuticals Corp.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Rufinamide Tablets, USP 200 mg, packaged in 120-count bottle, Rx only, Distributed by: Aurobindo Pharma USA, Inc., 279 Princeton-Hightstown Road, East Windsor, NJ 08520, Made in India, NDC 59651-616-08	Class II	Drugs	Lot #: RB2023001A, Exp 02/2025	cGMP deviations: Batch was released prior to approval.	Aurobindo Pharma USA Inc.
Rufinamide Tablets, USP 400 mg, packaged in 120-count bottle, Rx only, Distributed by: Aurobindo Pharma USA, Inc., 279 Princeton-Hightstown Road, East Windsor, NJ 08520, Made in India, NDC 59651-617-08	Class II	Drugs	Lot #: RB4023002A, Exp 02/2025	cGMP deviations: Batch was released prior to approval.	Aurobindo Pharma USA Inc.
Protex Foaming Hand Sanitizer (Benzalkonium Chloride 0.13%), packaged in a) 2 fl oz/60 mL Pump bottles (NDC 30775-040-02) and b)18 fl. oz./550 ml Pump Bottles (NDC 30775-040-18), Parker Laboratories, Inc. 286 Eldridge Road, Fairfield, NJ 07004	Class II	Drugs	Lot #: a) G0323002, Exp. Date 3/1/2025 Lot #: b) G1122001, Exp. Date 11/15/2024	CGMP Deviations	Parker Laboratories, Inc.
Helix Pain Relieving Cream (Menthol 7.4%), packaged in a) 5 gm pouch (NDC 30775-051-01), b) 3 fl. oz. roll-on (NDC 30775-051-03), c) 4 fl. oz. tubes (NDC 30775-051-04), d) 12 fl oz pump bottles (NDC 30775-051-12), e) 32 fl. oz. pump bottles (NDC 30775-051-32), f) 1 U.S. gallon with pump (NDC 30775-051-50), g) Starter Kit (NDC 30775-051-95), Parker Laboratories, Inc. 286 Eldridge Road Fairfield, NJ 07004	Class II	Drugs	a) J0721010, Exp. Date 6/30/2024; J1022017, Exp. Date 10/27/2025; b) A0521002, Exp. Date 4/29/2024; c) A0322006, Exp. Date 3/2/2025, A0323004, Exp. Date 2/24/2026, A0422005, Exp. Date 3/14/2025, A0521001, Exp. Date 4/29/2024, A0822004, Exp. Date 7/27/2025, d)	CGMP Deviations	Parker Laboratories, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			C0222001, Exp. Date 6/30/2023, C0521003, Exp. Date 4/29/2023, C0822005, Exp. Date 7/27/2024, e)C0721019, Exp. Date 6/30/2024, f) C0521001, Exp. Date 4/29/2024, C0721022, Exp. Date 6/30/2024, C0822006, Exp. Date 7/27/2025, g) C0323006, C0821022, C0922006, Exp. Date 4/29/2024, C1221003, Exp. Date 4/09/2024		
Helix Tri-Active Therapy Cream (Camphor 3.2%, Menthol 7.4%, Methyl salicylate 12.5%), packaged in a) 3 fl. oz. roll-on (NDC 30775-052-03) and b) 4 fl. oz. tube (NDC 30775-052-04) Parker Laboratories, Inc. 286 Eldridge Road, Fairfield, NJ 07004	Class II	Drugs	Lot #: a) A1221010, Exp. Date 12/9/2023, b) A1221011, Exp date 12/9/2023	CGMP Deviations	Parker Laboratories, Inc.
Helix CBD Therapy Cream (Menthol 7.4%), packaged in a) 3 g pouch (NDC 30775-053-01), b) 2 fl. oz. tubes (NDC 30775-053-02), c) 4 fl. oz. tubes (NDC 30775-053-04), Parker Laboratories Inc., Fairfield, NJ, 07004	Class II	Drugs	Lot #: a) J1121010, Exp. Date 12/16/2023, b) A0921006, Exp. Date 8/16/2023, c) A0921007, Exp. Date 8/16/2023	CGMP Deviations	Parker Laboratories, Inc.
Helix CBD Clinical Cream (Menthol 7.4%), packaged in a)3 gm pouches (NDC30775-054-	Class II	Drugs	Lot #: a) J1121011, Exp. Date 12/21/2023,	CGMP Deviations	Parker Laboratories, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
01), b)2 fl. oz. tubes (NDC 30775-054-02), and c) 4 fl. oz. tubes (NDC 30775-054-04), Parker Laboratories, Inc. 286 Eldridge Road, Fairfield, NJ 07004			b) A0921009, Exp. Date 8/18/2023, c) A0921008, Exp. Date 8/18/2023		
Blis-To-Sol Liquid (Tolnaftate), 1%, packaged in a) 1 FLUID OZ. (29.5 mL) bottles, UPC 0 11169 20011 8 and b) 1.85 FLUID OZ. (54.5 mL) bottles, UPC 0 11169 20012 5, Distributed by Oakhurst Company, Levittown, NY 11756.	Class II	Drugs	Lot: 9E098A	CGMP Deviations: Products not manufactured under current good manufacturing practices.	Ecometics, Inc.
YAGER'S LINIMENT (Camphor and Turpentine Oil) 3.1% and 8.12% respectively, packaged in a) 4 FL OZ (118 mL) bottles, UPC 0 11169 00004 6, and 8 FL OZ (236 mL) bottles, UPC 0 11169 00008 4, The Oakhurst Co., Dist., Levittown, NY 11756.	Class II	Drugs	Lot: 0E267A	CGMP Deviations: Products not manufactured under current good manufacturing practices.	Ecometics, Inc.
ALCOLADO RELAMPAGO (Menthol and Camphor), 1% and 1.5% respectively, packaged in a 7 FLUID OZ (207 ml) bottles, UPC 7 18864 20102 9 and b) 16 FLUID OZ (472 ml) bottles, UPC 7 18864, 20110 4, Distributed by: The Larkspur Group, Inc., Norwalk, CT 06854.	Class II	Drugs	a) 0E280A, exp 10/23; 0E318A, exp 11/23; 1E109A, exp 3/24; 1E141A, exp 5/24; b) 0E280A, exp 11/23; 1E109A, 1E141A, exp 3/24	CGMP Deviations: Products not manufactured under current good manufacturing practices.	Ecometics, Inc.
Unguentine Ointment, (Camphor 3.0%, Phenol 2.5%, Tannic Acid 2.2%, Zinc Oxide 6.6%), labeled as a) NET WT 1 OZ (28 g) tubes, Improved Formula, UPC 0 11169 10216 0, and b) NET WT 1 OZ (28.3g) tubes, Maximum Strength, UPC 0 11169 11250 3, Distributed by: Oakhurst Company, Levittown, NY 11756.	Class II	Drugs	a) and b) 1E113A, exp 4/24	CGMP Deviations: Products not manufactured under current good manufacturing practices.	Ecometics, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
activator concentrate, Sodium Fluoride 0.96% in Activator Concentrate; 0.08% in diluted Activator Solution, Net 1 FL. OZ., Manufactured for: All USA Direct, LLC, Broadview, IL 60155.	Class II	Drugs	Lot: 1E175B, exp 6/24	CGMP Deviations: Products not manufactured under current good manufacturing practices.	Ecometics, Inc.
AstrinGyn (Ferric Subsulfate) Aqueous, 259 mg/g, 8 gm Single Use Vials, Manufactured for CooperSurgical, Trumbull, CT 06611, NDC 59365-6065-0, Ref 6065.	Class II	Drugs	Lot #: 2E144A, 2E157A, exp: 11/2023; 2E270A, exp: 3/2024; 2E300A, exp: 4/2024	CGMP Deviations: Products not manufactured under current good manufacturing practices.	Ecometics, Inc.
Lugol's (Strong Iodine Solution USP), Each mL contains Iodine 0.05gm and potassium iodide 0.100gm, 8mL Single Use Vials, Rx Only, Manufactured for CooperSurgical, Trumbull, CT 06611, NDC 59365-6064-0, Ref 6064.	Class II	Drugs	Lot #: 2E235A, exp: 2/2024; 2E293A, exp: 3/2024	CGMP Deviations: Products not manufactured under current good manufacturing practices.	Ecometics, Inc.
All Over-The-Counter (OTC) drug products warehoused, salvaged, and sold by Inmar.	Class II	Drugs	Miscellaneous	CGMP Deviations: Potential exposure to rodents and rodent activity in the distribution center. Also, due to unusually hot weather, FDA Recalled Products may have been subjected to temperatures in excess of storage condition instructions on product labeling.	Inmar Supply Chain Solutions, LLC
Semaglutide/Cyanocobalamin 2mg/0.4mg/mL, 1mLvials, Tailor Made Compounding.	Class II	Drugs	Lot#: 07262326A1, BUD: 10/24/2023	Lack of Assurance of Sterility	TMC Acquisitions LLC dba Tailor

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
					Made Compounding
NAD+ 200mg/ml, 10ml vials, Tailor Made Compounding.	Class II	Drugs	Lot#: 07192307A2, BUD: 11/18/2023	Lack of Assurance of Sterility	TMC Acquisitions LLC dba Tailor Made Compounding
CARDIOPLEGIA SOLUTION, 20 mEq K, Maintenance 4:1, Low Potassium, Total Volume = 810 mL, EVA Bag, Rx only, Central Admixture Pharmacy Services, Inc., 2200 South 43rd Avenue, Phoenix, AZ 85043, NDC: 72196-0103-1	Class II	Drugs	Lot# 36-262315, Exp 8/21/2023; 36-262514, Exp 8/25/2023; 36-262993, Exp 8/28/2023.	Lack of Assurance of Sterility: Lack of validation data for sanitization cycles	Central Admixture Pharmacy Services, Inc.
CARDIOPLEGIA SOLUTION, 60 mEq K, Induction 4:1, HIGH POTASSIUM, Total Volume = 830 mL, EVA Bag, RX only, Central Admixture Pharmacy Services, Inc., 2200 South 43rd Avenue, Pheonix, AZ 85043, NDC: 72196-0100-1	Class II	Drugs	Lot# 36-262513, Exp 8/25/2023; 36-262880, Exp 8/27/2023	Lack of Assurance of Sterility: Lack of validation data for sanitization cycles	Central Admixture Pharmacy Services, Inc.
CARDIOPLEGIA SOLUTION, HIGH K, Induction 4:1, Plasmalyte/Tromethamine, High Potassium, EVA Bags, total volume = 500 mL, Rx Only, Central Admixture Pharmacy Services, Inc., 2200 South 43rd Avenue, Pheonix, AZ 85043, NDC: 72196-0111-1	Class II	Drugs	Lot# 36-262515, Exp 8/25/2023.	Lack of Assurance of Sterility: Lack of validation data for sanitization cycles	Central Admixture Pharmacy Services, Inc.
CARDIOPLEGIA SOLUTION, 24 mEq K, Maintenance 8:1, Low Potassium, Total volume = 500 mL, EVA Bag, Rx only, Central Admixture Pharmacy Services, Inc., 2200 South 43rd Avenue, Pheonix, AZ 85043, NDC: 72196-0105-1	Class II	Drugs	Lot# 36-262516, Exp 8/25/2023.	Lack of Assurance of Sterility:Lack of validation data for sanitization cycles	Central Admixture Pharmacy Services, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Cardioplegia Solution, low K, Maintenance 4:1 Plasmalyte, Low Potassium, total volume = 1047 mL, EVA Bag, Rx only, Central Admixture Pharmacy Services, Inc., 2200 South 43rd Avenue, Pheonix, AZ 85043, NDC: 72196-0211-1	Class II	Drugs	Lot# 36-262881, Exp 8/27/2023.	Lack of Assurance of Sterility:Lack of validation data for sanitization cycles	Central Admixture Pharmacy Services, Inc.
Cardioplegia Solution del Nido Formula, Total Volume = 1,052.8 mL, EVA Bag, PLASMA-LYTE A 1000 mL, Mannitol 20% 16.3 mL, Sodium Bicarbonate 8.4% 13 mL, Potassium Chloride 2 mEq/mL 13 mL, Magnesium Sulfate 4.06 mEq/mL 4 mL, Lidocaine 2% 6.5 mL, Rx Only, Central Admixture Pharmacy Services, Inc., 2200 South 43rd Avenue, Phoenix, AZ 85043, NDC: 72196-0202-1	Class II	Drugs	Lot# 36-260068, 36-260062, 36-260070, 36-260063, 36-260064, Exp 8/29/2023; 36-260016, Exp 9/3/2023; 36-262540, 36-262536, 36-262534, Exp 9/9/2023; 36-262990, 36-262992, Exp 9/12/2023.	Lack of Assurance of Sterility:Lack of validation data for sanitization cycles	Central Admixture Pharmacy Services, Inc.
rocuronium 50 mg/5 mL (10 mg/mL), 5 mL Syringes, Rx only, this drug was repackaged by CAPS Inc, 2200 South 43rd Avenue, Pheonix, AZ, NDC 72196-6010-1.	Class II	Drugs	Lot# 36-262729, 36-262982, 36-262981, 36-262732, 36-262731, 36-262730, Exp 10/11/2023	Lack of Assurance of Sterility: Lack of validation data for sanitization cycles	Central Admixture Pharmacy Services, Inc.
Neonatal TPN Starter Bag, Amino Acids (Trophamine) 2.5%/Dextrose 10% with CALCIUM and HEPARIN, total volume = 250mL, EVA Bag, Rx only, Central Admixture Pharmacy Services, Inc., 2200 South 43rd Avenue, Pheonix, AZ 85043, NDC: 72196-0418-1	Class II	Drugs	Lot# 36-260015, Exp 8/19/2023	Lack of Assurance of Sterility: Lack of validation data for sanitization cycles	Central Admixture Pharmacy Services, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Neonatal TPN Starter Bag, Amino Acids (Trophamine) 3% / Dextrose 10%, Total Volume = 250mL, IV Bag, Rx only, Central Admixture Pharmacy Services, Inc., 2200 South 43rd Avenue, Pheonix, AZ 85043, NDC: 72196-0404-1	Class II	Drugs	Lot# 36-262157, Exp 8/21/2023	Lack of Assurance of Sterility: Lack of validation data for sanitization cycles	Central Admixture Pharmacy Services, Inc.
Neonatal TPN Starter Bag, Amino Acids (trophamine) 3.5%/Dextrose 10%, Total Volume = 250mL, IV Bag, Rx only, Central Admixture Pharmacy Services, Inc., 2200 South 43rd Avenue, Pheonix, AZ 85043, NDC: 72196-0406-1	Class II	Drugs	Lot# 36-262872, 36-262873, Exp 8/27/2023	Lack of Assurance of Sterility: Lack of validation data for sanitization cycles	Central Admixture Pharmacy Services, Inc.
Neonatal TPN Starter Bag, Amino Acids (trophamine) 3%/Dextrose 5% with CALCIUM and HEPARIN, IV Bag, total volume = 250mL, Rx only, Central Admixture Pharmacy Services, Inc., 2200 South 43rd Avenue, Pheonix, AZ 85043. NDC: 72196-0419-1	Class II	Drugs	Lot# 36-260022, Exp 8/19/2023	Lack of Assurance of Sterility: Lack of validation data for sanitization cycles	Central Admixture Pharmacy Services, Inc.
Neonatal TPN Starter Bag, Amino Acids (trophamine) 3%/Dextrose 10% with CALCIUM and HEPARIN, IV Bag, total volume = 250mL, Rx only, Central Admixture Pharmacy Services, Inc., 2200 South 43rd Avenue, Pheonix, AZ 85043, NDC: 72196-0420-1	Class II	Drugs	Lot# 36-260019, 36-260023, Exp 8/19/2023	Lack of Assurance of Sterility: Lack of validation data for sanitization cycles	Central Admixture Pharmacy Services, Inc.
Neonatal TPN Starter Bag, Amino Acids (trophamine) 3%/Dextrose 10% with **low calcium** and HEPARIN, IV Bag, total volume = 250mL, Rx only, Central Admixture Pharmacy Services, Inc., 2200 South 43rd Avenue, Pheonix, AZ 85043, NDC: 72196-0428-1	Class II	Drugs	Lot# 36-262160, 36-262146, Exp 8/21/2023	Lack of Assurance of Sterility: Lack of validation data for sanitization cycles	Central Admixture Pharmacy Services, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Neonatal TPN Starter Bag, Amino Acids (trophamine) 3.5% / Dextrose 10% with **low calcium** and HEPARIN, IV Bag, total volume = 250mL, Rx only, Central Admixture Pharmacy Services, Inc., 2200 South 43rd Avenue, Pheonix, AZ 85043, NDC: 72196-0429-1	Class II	Drugs	Lot# 36-260018, Exp 8/19/2023, 36-262155, Exp 8/21/2023	Lack of Assurance of Sterility: Lack of validation data for sanitization cycles	Central Admixture Pharmacy Services, Inc.
Neonatal TPN Starter Bag, Amino Acids (trophamine) 3.5%/Dextrose 10% with HEPARIN, IV Bag, total volume = 250mL, Rx only, Central Admixture Pharmacy Services, Inc., 2200 South 43rd Avenue, Phoenix, AZ 85043, NDC: 72196-0431-1	Class II	Drugs	Lot# 36-262161, Exp 8/21/2023	Lack of Assurance of Sterility: Lack of validation data for sanitization cycles	Central Admixture Pharmacy Services, Inc.
Neonatal TPN Starter Bag, Amino Acids (trophamine) 4%/Dextrose 10% with CALCIUM and HEPARIN, IV Bags, total volume = 250mL, Rx only, Central Admixture Pharmacy Services, Inc., 2200 South 43rd Avenue, Pheonix, AZ 85043, NDC: 72196-0422-1	Class II	Drugs	Lot# 36-260017, Exp 8/19/2023	Lack of Assurance of Sterility: Lack of validation data for sanitization cycles	Central Admixture Pharmacy Services, Inc.
CARDIOPLEGIA SOLUTION, 25 mEq K, SUTTER CARDIOPLEGIA, Total Volume = 572.64 mL, IV Bag, Rx only, Central Admixture Pharmacy Services, Inc., 2200 South 43rd Avenue, Pheonix, AZ 85043, NDC: 72196-0217-1	Class II	Drugs	Lot# 36-262542, Exp 8/25/2023	Lack of Assurance of Sterility: Lack of validation data for sanitization cycles	Central Admixture Pharmacy Services, Inc.
PHENYLephrine 1,000 mcg/10mL, (100mcg/mL) in 0.9% sodium chloride, 10 mL Syringe, Rx Only, CAPS, Inc., 2200 South 43rd Avenue, Phoenix, AZ 85043, NDC: 72196-6009-1	Class II	Drugs	Lot# 36-262312, 36-262314, 36-262311, 36-262313, Exp 10/5/2023; 36-262739, 36-262742, 36-262741, 36-262740, 36-262738,	Lack of Assurance of Sterility: Lack of validation data for sanitization cycles	Central Admixture Pharmacy Services, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			36-262737, Exp 10/11/2023.		
PHENYLephrine, added to 0.9% sodium chloride, 10mg/250ml (40mcg/mL), IV Bag, Rx Only, Central Admixture Pharmacy Services, Inc., 2200 South 43rd Avenue, Phoenix, AZ 85043, NDC: 72196-6058-1.	Class II	Drugs	Lot# 36-260034, 36-260033, Exp 10/3/2023.	Lack of Assurance of Sterility: Lack of validation data for sanitization cycles	Central Admixture Pharmacy Services, Inc.
PHENYLephrine added to 0.9% sodium chloride, 20mg/250ml (80 mcg/mL), IV Bag, Rx Only, Central Admixture Pharmacy Services, Inc., 2200 South 43rd Avenue, Phoenix, AZ 85043, NDC: 72196-7025-1.	Class II	Drugs	Lot# 36-260037, Exp 10/3/2023.	Lack of Assurance of Sterility: Lack of validation data for sanitization cycles	Central Admixture Pharmacy Services, Inc.
PHENYLephrine, added to 0.9% sodium chloride, 40mg/250ml (160mcg/mL), IV Bag, Rx Only, Central Admixture Pharmacy Services, Inc., 2200 South 43rd Avenue, Phoenix, AZ 85043, NDC: 72196-6092-1	Class II	Drugs	Lot# 36-260036, Exp 10/3/2023.	Lack of Assurance of Sterility: Lack of validation data for sanitization cycles	Central Admixture Pharmacy Services, Inc.
PHENYLephrine added to 0.9% sodium chloride 50 mg/250mL (200mcg/mL), IV Bag, Rx Only, Central Admixture Pharmacy Services, Inc., 2200 South 43rd Avenue, Phoenix, AZ 85043. NDC:72196-7039-1	Class II	Drugs	Lot# 36-260038, Exp 10/3/2023.	Lack of Assurance of Sterility: Lack of validation data for sanitization cycles	Central Admixture Pharmacy Services, Inc.
EPINEPHrine, 2 mg added to dextrose 5% 250mL, Concentration = 8 mcg/mL, IV Bag, Rx Only, Central Admixture Pharmacy Services, Inc., 2200 South 43rd Avenue, Phoenix, AZ 85043, NDC: 72196-6030-1.	Class II	Drugs	Lot# 36-260049, Exp 10/3/2023.	Lack of Assurance of Sterility: Lack of validation data for sanitization cycles	Central Admixture Pharmacy Services, Inc.
EPINEPHrine added to 0.9% sodium chloride, 4mg/250mL (16 mcg/mL), IV Bag, RX only, Central Admixture Pharmacy Services, Inc., 2200	Class II	Drugs	Lot# 36-260047, Exp 10/3/2023.	Lack of Assurance of Sterility: Lack of	Central Admixture Pharmacy Services, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
South 43rd Avenue, Phoenix, AZ 85043, NDC: 72196-8093-1.				validation data for sanitization cycles	
EPINEPHrine added to dextrose 5%, 4mg/250ml (16 mcg/mL), IV Bag, Rx Only, Central Admixture Pharmacy Services, Inc., 2200 South 43rd Avenue, Phoenix, AZ 85043, NDC: 72196-7018-1.	Class II	Drugs	Lot# 36-262162, 36-262163, Exp 10/5/2023.	Lack of Assurance of Sterility: Lack of validation data for sanitization cycles	Central Admixture Pharmacy Services, Inc.
oxyTOCIN 30 units added to Lactated Ringer's 500 mL, IV Bag, Rx only, Cental Admixture Pharmacy Services, Inc., 2200 South 43rd Avenue, Phoenix, AZ 85043, NDC: 72196-6039-1	Class II	Drugs	Lot# 36-260043, 36-260039, Exp 9/8/2023; 36-262220, Exp 9/10/2023; 36-262526, 36-262525, 36-262524, Exp 9/14/2023.	Lack of Assurance of Sterility: Lack of validation data for sanitization cycles	Central Admixture Pharmacy Services, Inc.
oxyTOCIN 30 units added to 0.9% sodium chloride 500 mL, IV Bag, Rx only, CAPS, Central Admixture Pharmacy Services, Inc., 2200 South 43rd Avenue, Phoenix, AZ 85043, NDC: 72196-6044-1	Class II	Drugs	Lot# 36-260031, 36-260027, Exp 10/3/2023; 36-262533,36-262532, 36-262531, 36-262530, 36-262529, 36-262528, 36-262527, Exp 10/9/2023.	Lack of Assurance of Sterility: Lack of validation data for sanitization cycles	Central Admixture Pharmacy Services, Inc.
oxyTOCIN, 40 units added to 0.9% sodium chloride 1000 mL, IV Bag, Rx Only, Central Admixture Pharmacy Services, Inc., 2200 South 43rd Avenue, Phoenix, AZ 85043, NDC: 72196-8069-1	Class II	Drugs	Lot# 36-260050, Exp 10/3/2023.	Lack of Assurance of Sterility: Lack of validation data for sanitization cycles	Central Admixture Pharmacy Services, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
heparin added to 0.9% sodium chloride, 2500 units/500mL (5 units/mL), IV Bag, Rx only, Cental Admixture Pharmacy Services, Inc., 2200 South 43rd Avenue, Phoenix, AZ 85043, NDC: 72196-8100-1	Class II	Drugs	Lot# 36-260045, 36-260046, Exp 9/13/2023.	Lack of Assurance of Sterility: Lack of validation data for sanitization cycles	Central Admixture Pharmacy Services, Inc.
vancomycin added to 0.9% Sodium Chloride, 1.25 g/250 mL (5 mg/mL), 250mL Excel Bag, Rx only, Central Admixture Pharmacy Services, Inc., 2200 South 43rd Avenue, Phoenix, AZ 85043, NDC: 72196-6074-1	Class II	Drugs	Lot# 36-262215, 36-262216, Exp 10/5/2023.	Lack of Assurance of Sterility: Lack of validation data for sanitization cycles	Central Admixture Pharmacy Services, Inc.
dilTIAZem 125mg/125mL (1 mg/mL), added to 0.9% sodium chloride, IV Bag, Rx Only, Central Admixture Pharmacy Services, Inc., 2200 South 43rd Avenue, Phoenix, AZ 85043, NDC: 72196-6055-1	Class II	Drugs	Lot# 36-262537, Exp 9/19/2023.	Lack of Assurance of Sterility: Lack of validation data for sanitization cycles	Central Admixture Pharmacy Services, Inc.
dilTIAZem 125mg/125mL (1 mg/mL), added to dextrose 5%, IV Bag, RX only, Central Admixture Pharmacy Services, Inc., 2200 South 43rd Avenue, Phoenix, AZ 85043, NDC: 72196-6054-1	Class II	Drugs	Lot# 36-260048, Exp 9/13/2023; 36-262174, Exp 9/15/2023; 36-262523, Exp 9/19/2023.	Lack of Assurance of Sterility: Lack of validation data for sanitization cycles	Central Admixture Pharmacy Services, Inc.
DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution 1.5% Dextrose, packaged in a) 2000 mL AMBU-FLEX II Container bag, Product Code L5B4825, NDC 0941-0409-06; b) 5000 mL AMBU-FLEX II Container bag, Product Code L5B4826, NDC 0941-0409-07; and c) 6000 mL AMBU-FLEX II Container bag, Product Code L5B9770, NDC 0941-0409-01, Rx Only, Baxter	Class II	Drugs	a) Lots Y403948, Exp 30-Sep-2024; Lot Y406277, Exp 31-Oct-2024. b) Lot 408790, Exp 30-Nov-2024 and c) Lots Y403740, Y403740A, Exp 30-Sep-2024; Lots Y405638, Y405805,	Lack of Assurance of Sterility: Potential presence of leaks originating from the Luer component.	Baxter Healthcare Corporation

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Healthcare Corporation, Deerfield, IL 60015 USA.			Y407304, Y407304A Exp 31-Oct-2024; Lots Y407717, Y407717A, Y408554, Exp 30-Nov-2024; Lot Y420075, Exp 30-Apr-2025		
Dianeal PD-2 Peritonial Dialysis Solution with 1.5% Dextrose, 5000 mL AMBU-FLEX ll Container with yellow pull ring, Rx Only, Baxter Healthcare Corporation, Deerfield, IL 60015 USA Product code L5B5193 NDC 0941-0411-07	Class II	Drugs	Lot Y406734, Exp 31-Oct-2024	Lack of Assurance of Sterility: Potential presence of leaks originating from the Luer component.	Baxter Healthcare Corporation
Sodium Fluoride 1.1%, SODIUM FLUORIDE Prescription Dental Toothpaste, 5000 ppm Fluoride Plus Mild Cleaning System Spearmint NET WT. 1.8 OZ. (51g), Rx only, NDC 42291-741-51, Manufactured for: AvKARE Pulaski, TN 38478	Class II	Drugs	Lot # P23025, Exp. 02/24/2025	Cases of Sodium Fluoride 1.1% Prescription Dental Toothpaste may contain cartons labeled as Capsaicin Cream 0.025% but contain correctly labeled tubes of Sodium Fluoride 1.1% Prescription Dental Toothpaste	AVKARE LLC
Capsaicin Cream 0.025%, External Analgesic Cream, Penetrating Pain Relief, NET WT. 2.1 OZ. (60g) NDC 50268-195-60, Manufactured for: AvKARE, Pulaski, TN 38478	Class II	Drugs	Lot # P22078; Exp. 11/30/2024	Product mix-up: Cartons labeled Capsaicin Cream 0.025% may contain tubes of Sodium Fluoride 1.1% Prescription Dental Toothpaste	AVKARE LLC
Digoxin Tablets, USP 0.25mg, 100-count bottles, Rx Only, Manufactured for/Distributed	Class II	Drugs	E3811, expiration date 02/2025	Labeling: Label Mix-Up-Bottles labeled as Digoxin Tablets, USP	Marlex Pharmaceuticals, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
by: Marlex Pharmaceuticals, Inc. New Castle, DE NDC 10135-0748-01				0.125 mg contain Digoxin Tablets, USP 0.25mg and bottles labeled as Digoxin Tablets, USP 0.25mg contain Digoxin Tablets, USP 0.125mg.	
Sucralfate Oral Suspension 1g per 10mL, FOR ORAL ADMINISTRATION ONLY (414 mL bottle), Rx Only, Manufactured and Distributed by: VistaPharm, Inc. Largo, FL 33771, NDC 66689-305-16	Class II	Drugs	Lot #: 921100; Exp. 02/2025	Superpotent/Subpotent single ingredient Drug: Out of Specification Assay results	VistaPharm LLC
Pantoprazole Sodium for Injection 40mg per vial, Single dose vials NDC 71839-122-01 Packaged as (a) 10 Single-dose vials, NDC 71839-122-10; (b) 25 Single-dose vials, NDC 71839-122-25; Rx Only, Mfd. in India for and Distributed by: BE Pharmaceuticals Inc. 203 New Edition Court Cary, NC 27511.	Class II	Drugs	Lots: (a) GSC04002A, GSC04003A, GSC04004A, GSC04006A, Exp Mar-2024; GSC05001A, GSC05006A, GSC05007A, Exp April-2024; GSC10003A, GSC10005A Exp Sep-2024;GSC06004A, GSC06005A, Exp May-2024; GSC07001A, GSC07007A, GSC07008A, GSC07009A, Exp Jun-2024; GSC08001A, Exp Jul-2024; GSC05009A, Exp Apr-2024; (b)	Lack of Assurance of Sterility: Powder discoloration due to small crack in some vials.	BE PHARMACEUTICALS AG

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			GSC04005A, Exp Mar-2024; GSC06003A, Exp May-2024; GSC10001A, Exp Sep-2024; GSC07006A,Exp Jun-2024; GSC08002A, Exp Jul-2024; GSD02012A, Exp Jan-2025; GSD03005A, GSD03008A, Exp Feb-2025;		
BD ChloraPrep Clear, 2% w/v chlorhexidine gluconate (CHG) and 70% v/v isopropyl alcohol (IPA) Sterile Solution, 0.03mL (1 ml) each, 60 applicators in carton, applicator is sterile if package is intact. CareFusion 213, LLC, El Paso, TX 79912, subsidiary of Becton, Dickinson and Co., NDC 54365-400-31 REF 930480 Product is packaged in the following manner: There is one (1) sterile applicator (sponge) per pouch. Each inner carton contains sixty (60) pouches. There are four (4) inner cartons per shipping case (total of 240 pouches per case).	Class II	Drugs	Lot # 2272350, Exp. Date 09/30/2025 and Lot # 2301939, Exp. Date 09/30/2025	Stability data does not support expiry: Shelf-life of the impacted lots of BD ChloraPrep" Clear 1 mL Applicator cannot be substantiated beyond 12-months although labeled with 36-month expiry. Stability studies indicate that the impacted lots, if stored at 30¿C/75% relative humidity continuously beyond 12 months, may exhibit growth of Aspergillus penicillioides.	CareFusion 213, LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Rasagiline Tablets 0.5mg, 30-count bottle, Rx only, Mylan Pharmaceuticals Inc. Morgantown, WV 26505 U.S.A., NDC 0378-1270-93	Class II	Drugs	Lot #: 3112444, Exp 8/2023	Failed dissolution specifications - results obtained were below spec average.	Aurobindo Pharma USA Inc.
Humanrace Suncare, Ozone Face Protection Daily Moisturizer, Broad Spectrum Sunscreen SPF 30, packaged as a 53mL (1.8 fl oz.) bottle, 100% mineral, Active Ingredient: Zinc oxide 15%, Snow Mushroom, Dist. By: @Humanrace 2022 Beverly Hills, CA 90210, USA, NDC 82779-01	Class II	Drugs	Lot #: 1732A, 1732B, 1742A, 1742B, 1742C, 1742D; Exp. 06/2024.	Subpotent Drug: Product does not contain SPF that is declared on the label.	HUMANRACE
Humanrace Suncare, Ozone Body Protection Cream, Broad Spectrum Sunscreen SPF 30, packaged as a 148mL (5 fl oz.) bottle, PA ++++, 100% mineral, Active Ingredient: Zinc oxide 15%, Snow Mushroom, Squalene, Aloe, Dist. By: @Humanrace 2022 Beverly Hills, CA 90210, USA, NDC 82779-002	Class II	Drugs	Lot #: 1752A, 1752B, 1782E, 1782G, 1782C, 1752C, 1782B; Exp. 06/2024.	Subpotent Drug: Product does not contain SPF that is declared on the label.	HUMANRACE
TRP Natural Eyes, Aging Eye Relief, Sterile Eye Drops, Homeopathic 0.33 FL OZ (10 mL), Manufactured in Jordan, exclusively for TRP Company, Inc., 1575 Delucchi Lane, Reno, NV 89502 NDC: 17312-027-15.	Class II	Drugs	Lot#:DB001 EXP: 06/24	Lack of Assurance of Sterility	AMMAN PHARMACEUTICAL INDUSTRIES
TRP Natural Eyes, Allergy Eyes Relief, Sterile Eye Drops, Homeopathic 0.33 FL OZ (10 mL), Manufactured in Jordan, exclusively for TRP	Class II	Drugs	Lot: IY001; EXP 07/24	Lack of Assurance of Sterility	AMMAN PHARMACEUTICAL INDUSTRIES

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Company, Inc., 1575 Delucchi Lane, Reno, NV 89502, NDC: 17312-032-15.					
TRP Natural Eyes, Allergy Relief PF, Sterile Eye Drops, Homeopathic 0.33 FL OZ (10 mL), Manufactured in Jordan, exclusively for TRP Company, Inc., 1575 Delucchi Lane, Reno, NV 89502, NDC: 17312-097-19.	Class II	Drugs	Lot: FT001; EXP: 07/24	Lack of Assurance of Sterility	AMMAN PHARMACEUTICAL INDUSTRIES
TRP Natural Eyes, Blur Relief, Sterile Eye Drops, Homeopathic 0.5 FL OZ (15 mL), Manufactured in Jordan, exclusively for TRP Company, Inc., 1575 Delucchi Lane, Reno, NV 89502, NDC: 17312-002-11.	Class II	Drugs	Lot: DC001 EXP: 06/24	Lack of Assurance of Sterility	AMMAN PHARMACEUTICAL INDUSTRIES
TRP Natural Eyes, Dryness Relief, Sterile Eye Drops, Homeopathic 0.33 FL OZ (10 mL), Manufactured in Jordan, exclusively for TRP Company, Inc., 1575 Delucchi Lane, Reno, NV 89502, NDC:17312-178-15.	Class II	Drugs	Lot: IX001 EXP: 07/24; Lot: IX002 EXP: 12/24	Lack of Assurance of Sterility	AMMAN PHARMACEUTICAL INDUSTRIES
TRP Natural Eyes, Dryness Relief PF, Sterile Eye Drops, Homeopathic 0.33 FL OZ (10 mL), Manufactured in Jordan, exclusively for TRP Company, Inc., 1575 Delucchi Lane, Reno, NV 89502, NDC: 17312-096-19.	Class II	Drugs	Lot: FR001 EXP: 07/24; Lot: FR004 EXP: 04/25; Lot:FR005 EXP: 04/25; Lot:FR006 EXP: 04/25; Lot: FR007 Exp: 04/25	Lack of Assurance of Sterility	AMMAN PHARMACEUTICAL INDUSTRIES

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
TRP Natural Eyes, Eye Lid Relief PF, Sterile Eye Drops, Homeopathic 0.33 FL OZ (10 mL), Manufactured in Jordan, exclusively for TRP Company, Inc., 1575 Delucchi Lane, Reno, NV 89502, NDC: 17312-417-19.	Class II	Drugs	Lot: FV005 EXP:03/25	Lack of Assurance of Sterility	AMMAN PHARMACEUTICAL INDUSTRIES
TRP Natural Eyes, Eye Lid Relief, Sterile Eye ointment, Homeopathic 0.14 oz (4 grams), Manufactured in Jordan, exclusively for TRP Company, Inc., 1575 Delucchi Lane, Reno, NV 89502, NDC: 17312-165-13.	Class II	Drugs	Lot: 180001 EXP: 01/25	Lack of Assurance of Sterility	AMMAN PHARMACEUTICAL INDUSTRIES
TRP Natural Eyes, Floaters Relief, Sterile Eye drops, Homeopathic 0.33 FL OZ (10 mL), Manufactured in Jordan, exclusively for TRP Company, Inc., 1575 Delucchi Lane, Reno, NV 89502, NDC: 17312-098-15.	Class II	Drugs	Lot: DA001 EXP: 06/24; Lot: DA002 EXP: 11/24	Lack of Assurance of Sterility	AMMAN PHARMACEUTICAL INDUSTRIES
MAJOR LubriFresh P.M. Nighttime Ointment, Lubricant Eye Ointment, Sterile, 0.125 OZ (3.5g), Distributed by: MAJOR PHARMACEUTICALS, Indianapolis, IN 46268, Made in Jordan, NDC: 0904-6488-38.	Class II	Drugs	Lot: 184001 EXP: 11/24; 184002 EXP: 11/24; 184003 EXP: 11/24; Lot: 184004 EXP: 12/24; Lot: 184005 EXP: 12/24; Lot:184006 EXP:12/24;	Lack of Assurance of Sterility	AMMAN PHARMACEUTICAL INDUSTRIES
TRP Natural Eyes, Pink Eye Relief, Sterile Eye drops, Homeopathic 0.33 FL OZ (10 mL), Manufactured in Jordan, exclusively for TRP	Class II	Drugs	Lot: IV001 EXP:06/25; Lot:IV002 EXP: 11/24; Lot:IV004 EXP:01/25	Lack of Assurance of Sterility	AMMAN PHARMACEUTICAL INDUSTRIES

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Company, Inc., 1575 Delucchi Lane, Reno, NV 89502 NDC: 17312-013-15.					
TRP Natural Eyes, Pink Eye Relief PF, Sterile Eye drops, Homeopathic 0.33 FL OZ (10 mL), Manufactured in Jordan, exclusively for TRP Company, Inc., 1575 Delucchi Lane, Reno, NV 89502 NDC: 17312-094-19.	Class II	Drugs	Lot: FP001 EXP:07/24	Lack of Assurance of Sterility	AMMAN PHARMACEUTICAL INDUSTRIES
TRP Natural Eyes, Red Eye Relief, Sterile Eye drops, Homeopathic 0.33 FL OZ (10 mL), Manufactured in Jordan, exclusively for TRP Company, Inc., 1575 Delucchi Lane, Reno, NV 89502, NDC: 17312-058-15.	Class II	Drugs	Lot: FQ001 EXP:07/24	Lack of Assurance of Sterility	AMMAN PHARMACEUTICAL INDUSTRIES
TRP Natural Eyes, Red Eye Relief PF, Sterile Eye drops, Homeopathic 0.33 FL OZ (10 mL), Manufactured in Jordan, exclusively for TRP Company, Inc., 1575 Delucchi Lane, Reno, NV 89502 NDC: 17312-095-19.	Class II	Drugs	Lot: IW001 EXP:07/24; Lot: IW002 EXP: 12/24	Lack of Assurance of Sterility	AMMAN PHARMACEUTICAL INDUSTRIES
TRP Natural Eyes, Stye Relief, Sterile Eye Ointment, Homeopathic 0.14 oz (4 grams), Manufactured in Jordan, exclusively for TRP Company, Inc., 1575 Delucchi Lane, Reno, NV 89502, NDC: 17312-014-13.	Class II	Drugs	Lot:182002 EXP: 11/24; Lot:182003 EXP: 11/24; Lot:182004 EXP: 12/24; Lot:182005 EXP:02/25; Lot:182006 EXP:02/25; Lot:182007EXP:02/25;	Lack of Assurance of Sterility	AMMAN PHARMACEUTICAL INDUSTRIES

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			Lot:182008 EXP:02/25; Lot:182009 EXP:02/25; Lot:182010 EXP:03/25: Lot:182011 EXP:03/25;		
TRP Natural Eyes, Twitching Relief, Sterile Eye Ointment, Homeopathic 0.33 FL OZ (10 mL), Manufactured in Jordan, exclusively for TRP Company, Inc., 1575 Delucchi Lane, Reno, NV 89502, NDC: 17312-099-15.	Class II	Drugs	Lot:DD001 EXP: 07/24;		AMMAN PHARMACEUTICAL INDUSTRIES
octiq Lubricating Eye Drops, Dextran 70.01%, Hypromellose 0.3%, 0.5 FL OZ Each (2X 15 mL Bottles), Manufactured for Innovus Pharmaceuticals, Inc., Englewood, CO 80112, Made in Jordan, NDC:57483-610-15.	Class II	Drugs	Lot: YM308 EXP:10/24;		AMMAN PHARMACEUTICAL INDUSTRIES
Moxifloxacin - Bromfenac Sterile Ophthalmic Solution 0.5% / 0.075%, 5mL bottle, Imprimis NJOF, LLC. 1705 Route 46 West, Unit 6B, Ledgewood, NJ 07852 (844)-446-6979, NDC: 71384-311-05.	Class III	Drugs	Lot #s: 22DEC047 exp 9/16/23, 23FEB057 exp 11/24/23.	Subpotent Drug; sub-potent Bromfenac levels, below the 90.0-110.0% specification range.	Imprimis NJOF, LLC
Trandolapril and Verapamil Hydrochloride Extended-Release Tablets 2 mg / 180 mg, 100-count Bottle, Rx only, Manufactured by: Glenmark Pharmaceuticals Ltd. Colvale -Bardez,	Class III	Drugs	Batch # 19224744	Subpotent: Out of Specification for Assay Test at the 3-month time point.	Glenmark Pharmaceuticals Inc., USA

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Goa 403513, India, Manufactured for Glenmark Pharmaceuticals Inc., USA, Mahwah, NJ 07430, NDC 68462-295-01					
Bendamustine HCl Injection, 100mg/4mL (25mg/mL), One 4 mL Multiple-Dose Vial, Rx only, Manufactured for Baxter Healthcare Corporation, Deerfield, IL 60015, NDC 10019-079-01.	Class III	Drugs	Lots: 3A004A, 3A004B, Exp 12/31/2024; 3B005A, Exp 1/31/2025	Labeling: Missing Label; customer complaint received that labels were partially or completely peeled off injection vial.	Baxter Healthcare Corporation
Sabril (vigabatrin) for Oral Solution, 500 mg, 50 Packets, Rx only, Manufactured by: Patheon, Cincinnati, OH 45237, NDC 67386-211-65	Class III	Drugs	Lot#: 3207333A, 3207334A, Exp 03/2027; 3214707A, 3214709A, 3214710A, Exp 02/2028 .	Cross contamination with other products	Lundbeck LLC
Clindamycin Phosphate Topical Solution USP, 1%, 60 mL bottle, Rx only, Manufactured by: Contract Pharmaceuticals Limited Canada, Mississauga, Ontario, Canada, Manufactured for: Glasshouse Pharmaceuticals Limited Canada, Mississauga, Ontario, Canada, NDC# 71428-003-60	Class III	Drugs	Lot # 118920, exp. January 2024.	Defective Container: slow leakage under the cap	Contract Pharmaceuticals Limited Canada

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Fosfomycin Tromethamine Granules for Oral Solution, 3 g single- dose sachet, Rx only, Manufactured by: Alkem Laboratories Ltd., INDIA, Distributed by: Ascend Laboratories, LLC, Parsippany, NJ 07054, NDC# 67877-749-57	Class III	Drugs	Lot #22121970, 22122158, 22121971, 22122189, 22122190, 22122277, 22122278, Exp June 2024; 22122521, 22122522, 22122523, Exp July 2024; 22123328, 22123329, 22123330, Exp September 2024.	Failed Impurities/Degradation Specifications: Out-of-specification results observed for the organic impurities test at 6 months, RT Stability.	Ascend Laboratories, LLC
Nexlizet (bempedoic acid and ezetimibe), 180ng/18mg, 30 tablets, Rx only, Manufactured for: Esperion Therapeutics, Inc, Ann Arbor, MI 48108, NDC 72426-818-03	Class III	Drugs	Lot# 1904872, Exp 1/31/2025; 1950377, Exp 6/30/2025	Failed dissolution specifications: below specification results at stability 12-month	Esperion
Milrinone Lactate Injection, USP 20mg/20 mL (1mg/mL), packaged in 10 x 20 mL vials per carton, NDC 72485-502-01 (single vial), Rx only, Distributed by: Armas Pharmaceuticals, Inc. Freehold, NJ 07728(USA) Manufactured by: Caplin Steriles Limited, India, NDC 72485-502-10	Class III	Drugs	Lot #: 90000228	Failed Impurities/Degradation Specifications	Caplin Steriles Limited

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Cequa (cyclosporine ophthalmic solution) 0.09%, 60 Single-Use Vials (6 pouches x 10 single-use vials (0.25 mL each)), Rx only, Manufactured for Sun Pharma Global FZE by: Laboratoire Unither, Coutances, France NDC 47335-506-96	Class III	Drugs	Lot# 10026, Lot 10027, Exp. 09/2023.	Subpotent: Out of Specification result observed for low assay	SUN PHARMACEUTICAL INDUSTRIES INC

*Please refer to FDA website for further information at: http://www.fda.gov/Safety/Recalls

CURRENT DRUG SHORTAGES

Below is the list of drugs listed by the FDA as currently in shortage. Please refer to the FDA website for more information at: https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm

Generic Name or Active Ingredient

Albuterol Sulfate Solution
Alprostadil Suppository
Amifostine Injection, Powder, Lyophilized, For Solution
Amino Acid Injection
Amoxapine Tablet
Amoxicillin Powder, For Suspension
Amphetamine Aspartate Monohydrate, Amphetamine Sulfate, Dextroamphetamine Saccharate, Dextroamphetamine Sulfate Tablet
Atropa Belladonna, Opium Suppository
Atropine Sulfate Injection
Azacitidine Injection, Powder, Lyophilized, For Solution
Bazedoxifene Acetate, Estrogens, Conjugated Tablet, Film Coated
Bumetanide Injection
Bupivacaine Hydrochloride Injection
Bupivacaine Hydrochloride, Epinephrine Bitartrate Injection, Solution
Capecitabine Tablet
Carboplatin Injection, Solution
Cefixime Capsule
Cefotaxime Sodium Injection
Cefotetan Disodium Injection
Cefotetan Disodium Injection, Powder, For Solution
Chloramphenicol Sodium Succinate Injection, Powder, Lyophilized, For Solution
Chloroprocaine Hydrochloride Injection, Solution
Cisplatin Injection
Clindamycin Phosphate Injection, Solution
Clindaymycin Phosphate Injection
Clonazepam Tablet
Collagenase Clostridium Histolyticum Ointment
Conivaptan Hydrochloride Injection, Solution
Cyclopentolate Hydrochloride Ophthalmic Solution
Cyclopentolate Hydrochloride, Phenylephrine Hydrochloride Ophthalmic Solution
Cytarabine Injection, Solution
Dacarbazine Injection, Powder, For Solution
Desmopressin Acetate Spray
Dexamethasone Sodium Phosphate Injection
Dexmedetomidine Hydrochloride Injection
Dextrose Monohydrate Injection, Solution
Dextrose Monohydrate, Lidocaine Hydrochloride Anhydrous Injection, Solution

Diazepam Gel
Difluprednate Emulsion
Digoxin Injection, Solution
Diltiazem Hydrochloride Injection
Dimercaprol Injection
Disopyramide Phosphate Capsule
Dobutamine Hydrochloride Injection
Dopamine Hydrochloride Injection, Solution
Dulaglutide Injection, Solution
Echothiophate Iodide Ophthalmic Solution
Edetate Calcium Disodium Injection
Enalaprilat Injection
Epinephrine Bitartrate, Lidocaine Hydrochloride Injection
Epinephrine Injection
Erythromycin Ointment
Etomidate Injection
Fentanyl Citrate Injection
Fluconazole Injection
Fludarabine Phosphate Injection
Fluorescein Sodium Injection
Flurazepam Hydrochloride Capsule
Furosemide Injection
Gentamicin Sulfate Injection
Guanfacine Hydrochloride Tablet
Heparin Sodium Injection
Heparin Sodium Injection, Solution
Hydrocortisone Sodium Succinate Injection, Powder, For Solution
Hydromorphone Hydrochloride Injection, Solution
Hydroxypropyl Cellulose (1600000 Wamw) Insert
I.V. Fat Emulsion
Indigotindisulfonate Sodium Injection
Isoniazid Tablet
Ketamine Hydrochloride Injection
Ketorolac Tromethamine Injection
Ketorolac Tromethamine Tablet, Film Coated
Leucovorin Calcium Injection
Lidocaine Hydrochloride Injection
Lidocaine Hydrochloride Injection, Solution
Lidocaine Hydrochloride Solution
Liraglutide Injection, Solution
LISDEXAMFETAMINE DIMESYLATE CAPSULE
Lisdexamfetamine Dimesylate Tablet, Chewable
Lorazepam Injection
Lutetium Lu-177 Vipivotide Tetraxetan Injection, Solution
Mannitol Injection, Solution
Mepivacaine Hydrochloride Injection, Solution

Methamphetamine Hydrochloride Tablet
Methotrexate Sodium Injection
Methotrexate Sodium Injection, Solution
Methotrexate Sodium Tablet
Methyldopa Tablet, Film Coated
Methylphenidate Hydrochloride Tablet
Methylphenidate Hydrochloride Tablet, Extended Release
Methylprednisolone Acetate Injection, Suspension
Metronidazole Injection
Midazolam Hydrochloride Injection
Midazolam Hydrochloride Injection, Solution
Morphine Sulfate Injection
Multi-Vitamin Infusion (Adult and Pediatric) Injection
Neomycin Sulfate Tablet
Nizatidine Capsule
Oxybutynin Chloride Syrup
Palifermin Injection, Powder, Lyophilized, For Solution
Parathyroid Hormone Injection
Penicillin G Benzathine Injection, Suspension
Physostigmine Salicylate Injection
Potassium Acetate Injection, Solution, Concentrate
Potassium Chloride Injection, Solution
Quinapril Hydrochloride Tablet
Quinapril/Hydrochlorothiazide Tablet
Remifentanil Hydrochloride Injection
Remifentanil Hydrochloride Injection, Powder, Lyophilized, For Solution
Rifampin Capsule
Rifampin Injection, Powder, Lyophilized, For Solution
Rifapentine Tablet, Film Coated
Rocuronium Bromide Injection
Rocuronium Bromide Injection, Solution
Rocuronium Bromide Solution
Ropivacaine Hydrochloride Injection
Ropivacaine Hydrochloride Injection, Solution
Semaglutide Injection, Solution
Sodium Acetate Injection
Sodium Bicarbonate Injection
Sodium Chloride 0.9% Injection
Sodium Chloride 23.4% Injection
Sodium Chloride Injection
Sodium Chloride Irrigant
Sodium Phosphate, Dibasic, Anhydrous, Sodium Phosphate, Monobasic, Monohydrate Injection, Solution
Somatropin Injection
Somatropin Injection, Solution
Streptozocin Powder, For Solution

Sucralfate Tablet
Sufentanil Citrate Injection
Sulfasalazine Tablet
Tirzepatide Injection, Solution
Triamcinolone Acetonide Injection, Suspension
Triamcinolone Hexacetonide Injection, Suspension
Trimethobenzamide Hydrochloride Capsule
Valproate Sodium Injection
Vecuronium Bromide Injection, Powder, Lyophilized, For Solution
Vinblastine Sulfate Injection
Water Injection
Water Irrigant