



Drug Information Update

July 2022



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NEWLY AVAILABLE GENERICS

Generic Name/ Dosage Form	Brand Name	Manufacturer	Indication
Daytrana	Methylphenidate 10 mg/9 hr, 15 mg/9 hr, 20 mg/9 hr, 30 mg/9 hr patch	Noven Therapeutics	For the treatment of Attention Deficit Hyperactivity Disorder
Pradaxa	Dabigatran etexilate mesylate 75 mg, 150 mg	Boehringer Ingelheim Pharmaceuticals	<ul style="list-style-type: none"> To reduce the risk of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation For the treatment of deep venous thrombosis (DVT) and pulmonary embolism (PE) in adult patients who have been treated with a parenteral anticoagulant for 5-10 days To reduce the risk of recurrence of DVT and PE in adult patients who have been previously treated For the prophylaxis of DVT and PE in adult patients who have undergone hip replacement surgery For the treatment of venous thromboembolic events (VTE) in pediatric patients 8 to less than 18 years of age who have been treated with a parenteral anticoagulant for at least 5 days To reduce the risk of recurrence of VTE in pediatric patients 8 to less than 18 years of age who have been previously treated
Glyrx-pf	Glycopyrrolate/pf 0.6 mg/3 mL (0.2 mg/mL) IM/IV vial	Exela Pharma Sciences	<ul style="list-style-type: none"> Anesthesia (adult and pediatric patients): <ul style="list-style-type: none"> For reduction of airway or gastric secretions, and volume and acidity of gastric secretions, and blockade of cardiac inhibitory reflexes during induction of anesthesia and intubation, intraoperatively to counteract surgically or drug-induced or vagal reflex-associated arrhythmias, and for protection against peripheral muscarinic effects of cholinergic agents. In peptic ulcer (adults): <ul style="list-style-type: none"> As adjunctive therapy for the treatment of peptic ulcer when rapid anticholinergic effect is desired or oral medication is not tolerated.

Generic Name/ Dosage Form	Brand Name	Manufacturer	Indication
Toviaz	Fesoterodine fumarate 4 mg, 8 mg tablet	Pfizer	<ul style="list-style-type: none"> • For the treatment of overactive bladder (OAB) in adults with symptoms of urge urinary incontinence, urgency, and frequency. • For the treatment of neurogenic detrusor overactivity (NDO) in pediatric patients 6 years of age and older and weighing greater than 25 kg.
Suprep	Sodium, potassium, magnesium sulfates 17.5 gram - 3.13 gram - 1.6 gram	Braintree Laboratories	For cleansing of the colon in preparation for colonoscopy in adult and pediatric patients 12 years of age and older.
Visipaque	Iodixanol 270 mg iodine/mL, 320 mg iodine/mL	GE Healthcare	<ul style="list-style-type: none"> • Intra-arterial procedures in adult and pediatric patients 12 years of age and older (intra-arterial digital subtraction angiography, arteriography) • Intravenous procedures in adult and pediatric patients 12 years of age and older (CT imaging of the head and body, excretory urography, peripheral venography, coronary computed tomography angiography)



NEW DRUG ENTITIES/STRENGTHS/COMBINATIONS

Drug Name	Generic Name	Description	Comments
pemetrexed 100 mg, 500 mg, 1 g intravenous powder for solution	pemetrexed	505(b)(2) drug approval for various uses in NSCLC and mesothelioma	New Dosage Form (lyophilized powder)
levetiracetam 250 mg/50 mL in sodium chloride (iso-osm) IV piggyback	levetiracetam in nacl (iso-os)	Inpatient use product	New Strength
Amvuttra 25 mg/0.5 mL subcutaneous syringe	vutrisiran sodium	Second generation RNA interference (RNAi) therapeutic that offers once-quarterly dosing for hATTR amyloidosis-related polyneuropathy.	New Entity
Skyrizi 60 mg/mL intravenous solution	risankizumab-rzaa	New strength and IV form for newly approved Crohn's disease indication	New Dosage Form and Strength
Skyrizi 360 mg/2.4 mL (150 mg/mL) subcutaneous wearable injector	risankizumab-rzaa	New strength and presentation for newly approved Crohn's disease indication	New Dosage Form and Strength
Ticovac 1.2 mcg/0.25 mL intramuscular syringe	tick-borne encephalitis vaccine	New strength	New Strength
Aspruzyo Sprinkle 500, 1,000 mg granules, extended release in packet	ranolazine	New 505(b)(2) granules dosage form	New Dosage Form
Hyftor 0.2 % topical gel	sirolimus	Topical treatment for facial angiofibromas associated with tuberous sclerosis in ages 6 and older	New Route, Dosage Form and Strength
Moderna COVID-19 Bivalent Booster(PF) 50 mcg/0.5 mL IM susp (Unapp)	COVID-19 vacc, bivalent, mRNA/PF	New not yet approved bivalent booster version of Moderna vaccine that will include original strain and omicron variants of COVID-19	New Formulation; Original Covid-19 and Omicron Strains
Fluad Quad 2022-2023(65yr up)(PF) 60 mcg (15 mcg x 4)/0.5mL IM syringe	Flu vacc qs2022 (65up)/mf59c/pf	Influenza vaccine	2022-2023 vaccine

Drug Name	Generic Name	Description	Comments
Flulaval Quad 2022-2023 (PF) 60 mcg (15 mcg x 4)/0.5 mL IM syringe	Flu vacc qs2022-23(6mos up)/pf	Influenza vaccine	2022-2023 vaccine
Fluarix Quad 2022-2023 (PF) 60 mcg (15 mcg x 4)/0.5 mL IM syringe	Flu vacc qs2022-23(6mos up)/pf	Influenza vaccine	2022-2023 vaccine
Afluria Quad 2022-2023(6mo up) 60 mcg (15 mcg x 4)/0.5 mL IM susp	Flu vacc qs2022-23 (6 mos up)	Influenza vaccine	2022-2023 vaccine
Afluria Quad 2022-23(3yr up)(PF) 60 mcg (15 mcg x 4)/0.5 mL IM syringe	Flu vacc q 2022-23 36mos up/pf	Influenza vaccine	2022-2023 vaccine
Flucelvax Quad 2022-2023 60 mcg (15 mcg x 4)/0.5 mL IM suspension	Flu vac qs2022-23 (6ms up) cell	Influenza vaccine	2022-2023 vaccine
Flucelvax Quad 2022-2023 (PF) 60 mcg (15 mcg x 4)/0.5 mL IM syringe	Flu vac qs2022-23 (6ms up) cel/pf	Influenza vaccine	2022-2023 vaccine
Fluzone Quad 2022-2023 (PF) 60 mcg (15 mcg x 4)/0.5 mL IM syringe	Flu vacc qs2022-23 (6MOS UP)/PF	Influenza vaccine	2022-2023 vaccine
Fluzone Quad 2022-2023 60 mcg (15 mcg x 4)/0.5 mL intramuscular susp.	Flu vacc qs2022-23 (6 MOS UP)	Influenza vaccine	2022-2023 vaccine
Fluzone High-Dose Quad 2022-2023 (PF) 240 mcg/0.7 mL IM syringe	Flu vacc qs2022-23 (65YR UP)/PF	Influenza vaccine	2022-2023 vaccine
Fluzone Quad 2022-2023 (PF) 60 mcg (15 mcg x 4)/0.5 mL IM suspension	Flu vacc qs2022-23 (6MOS UP)/PF	Influenza vaccine	2022-2023 vaccine

Drug Name	Generic Name	Description	Comments
Flublok Quad 2022-2023 (PF) 180 mcg (45 mcg x 4)/0.5 mL IM syringe	Flu vac qv 2022 (18YR UP)RCM/PF	Influenza vaccine	2022-2023 vaccine
Dyanavel XR 5, 10, 15, 20 mg tablet, extended release	amphetamine	New oral dosage form of Dyanavel XR (previously only a suspension). This dosage form has a 60 minute onset of action and lasts up to 13 hours. Adderall XR has a 20 to 60 minute onset and lasts up to 10 hours.	New Dosage Form
Vivjoa 150 mg capsule	oteseconazole	An azole antifungal indicated to reduce the incidence of recurrent vulvovaginal candidiasis (RVVC) in females with a history of RVVC who are NOT of reproductive potential.	New Entity
venlafaxine besylate ER 112.5 mg tablet, extended release 24 hr	Venlafaxine besylate	New salt formulation that underwent the 505(b)(2) pathway (ER tablets and capsules available in HCl salt form).	New Entity
Tauvid 370 MBq (10 mCi) intravenous solution	Flortaucipir f-18	Diagnostic agent used in PET imaging of the brain to estimate the density and distribution of tau neurofibrillary tangles in patients with Alzheimer's disease.	New Entity
Tembexa 10 mg/mL oral suspension	Brincidofovir	Antiviral indicated to treat smallpox. Prodrug that is converted into cidofovir, which itself can be used for other infections like CMV. Distributed through the national stockpile likely in response to monkeypox.	New Entity
Tembexa 100 mg tablet	Brincidofovir	Antiviral indicated to treat smallpox. Prodrug that is converted into cidofovir, which itself can be used for other infections like CMV. Distributed through the national stockpile likely in response to monkeypox.	New Entity
Tpoxx (National Stockpile) 10 mg/mL intravenous solution	Tecovirimat	New IV dosage form (previously only available as oral capsule). Distributed through the national stockpile likely in response to monkeypox.	New Route and Dosage Form

NEW INDICATIONS (EXISTING DRUGS)

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

Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication†
Zulresso	Brexanolone injection, 100 mg/20 mL single-dose vial	Sage Therapeutics	Treatment of postpartum depression in patients 15 years and older adults
Imcivree	Setmelanotide injection, 10 mg/mL in a 1 mL multidose vial	Rhythm Pharmaceuticals	Chronic weight management in adult and pediatric patients 6 years of age and older with monogenic or syndromic obesity due to: <ul style="list-style-type: none"> • Pro-opiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency as determined by an FDA-approved test demonstrating variants in POMC, PCSK1, or LEPR genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance (VUS). • Bardet-Biedl syndrome (BBS)
Skyrizi	risankizumab-rzaa 60 mg/mL intravenous solution; 360 mg/2.4 mL (150 mg/mL) subcutaneous wearable injector; subcutaneous injection, 150 mg/mL in single-dose prefilled pen and syringe, 75 mg/0.83 mL in single-dose syringe	AbbVie	<ul style="list-style-type: none"> • Moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy • Active psoriatic arthritis in adults • Moderately to severely active Crohn's disease in adults
Tafinlar	Dabrafenib capsules, 50 mg, 75 mg	Novartis	<p>In combination with trametinib, for the treatment of adults and pediatric patients 6 years 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</p> <p><i>Note: Tafinlar has many other indications not presented here because there were no changes</i></p>

Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication†
Mekinist	Trametinib tablets, 0.5 mg, 2 mg	Novartis	<p>In combination with dabrafenib for the treatment of adult and pediatric patients 6 years 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</p> <p><i>Note: Mekinist has many other indications not presented here because there were no changes</i></p>
Qsymia	phentermine and topiramate tablets: 3.75 mg/23 mg, 7.5 mg/45 mg, 11.25 mg/69 mg, 15 mg/92 mg	VIVUS, LLC.	<p>Qsymia is a combination of phentermine, a sympathomimetic amine anorectic, and topiramate, indicated as an adjunct to a reduced-caloric diet and increased physical activity for chronic weight management in:</p> <ul style="list-style-type: none"> • Adults with an initial body mass index (BMI) of: <ul style="list-style-type: none"> • 30 kg/m² or greater (obese) or • 27 kg/m² or greater (overweight) in the presence of at least one weight-related comorbidity such as hypertension, type 2 diabetes mellitus, or dyslipidemia • Pediatric patients aged 12 years and older with BMI in the 95th percentile or greater standardized for age and sex
Breyanzi	lisocabtagene maraleucel 50 to 110 x 10 ⁶ CAR-positive viable T cells	Juno Therapeutics, Inc.	<p>Breyanzi is a CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of adult patients with large B-cell lymphoma (LBCL), including diffuse large B-cell lymphoma (DLBCL) not otherwise specified (including DLBCL arising from indolent lymphoma), high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B, who have:</p> <ul style="list-style-type: none"> • refractory disease to first-line chemoimmunotherapy or relapse within 12 months of first-line chemoimmunotherapy; or • refractory disease to first-line chemoimmunotherapy or relapse after first-line chemoimmunotherapy and are not eligible for hematopoietic stem cell transplantation due to comorbidities or age; or • relapsed or refractory disease after two or more lines of systemic therapy
Kyprolis	carfilzomab IV vial: 10, 30, 60 mg	Amgen	<p>Kyprolis is a proteasome inhibitor that is indicated:</p> <ul style="list-style-type: none"> • for the treatment of adult patients with relapsed or refractory multiple myeloma who have received one to three lines of therapy in combination with <ul style="list-style-type: none"> ○ Lenalidomide and dexamethasone; or

Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication†
			<ul style="list-style-type: none"> ○ Dexamethasone; or ○ Daratumumab and dexamethasone; or ○ Daratumumab and hyaluronidase-fihj and dexamethasone; or ○ Isatuximab and dexamethasone <ul style="list-style-type: none"> • as a single agent for the treatment of patients with relapsed or refractory multiple myeloma who have received one or more lines of therapy
Comirnaty	COVID-19 Vaccine, mRNA	Pfizer	<ul style="list-style-type: none"> • Comirnaty is a vaccine indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 12 years of age and older
Xalkori	crizotinib capsules: 200, 250 mg	Pfizer	<p>For the treatment of:</p> <ul style="list-style-type: none"> • patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK) or ROS1-positive as detected by an FDA-approved test • pediatric patients 1 year of age and older and young adults with relapsed or refractory, systemic anaplastic large cell lymphoma (ALCL) that is ALK-positive • adult and pediatric patients 1 year of age and older with unresectable, recurrent, or refractory inflammatory myofibroblastic tumor (IMT) that is ALK-positive
Diacomit	Stiripentol capsules: 250, 500 mg; oral suspension: 250, 500 powder packets	Biocodex	<p>For the treatment of seizures associated with Dravet syndrome in patients taking clobazam who are 2 years of age and older taking clobazam 6 months of age and older and weighing 7 kg or more. There are no clinical data to support the use of Diacomit as monotherapy in Dravet syndrome.</p>
Opzelura	Ruxolitinib 1.5% cream	Incyte	<p>Janus kinase (JAK) inhibitor indicated for:</p> <ul style="list-style-type: none"> • the topical short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immunocompromised adult and pediatric patients 12 years of age and older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. • the topical treatment of nonsegmental vitiligo in adult and pediatric patients 12 years of age and older

RECALLS

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Tegsedi (inotersen) Injection 284 mg/1.5 mL, Rx Only, Sterile solution for Subcutaneous Use, 4 prefilled syringes, each containing 284 mg of inotersen, (equivalent to 300 mg inotersen sodium in 1.5 ml of solution), Distributed by Sobi, Inc. Inc Waltham MA 02451, NDC: 72126-007-01	Class I	Drugs	Lots: 028C21AB, 028C21AC, Exp. 05/2025	Superpotent: High Out of specification (OOS) test result for percent label claim (%LC).	Akcea Therapeutics, Inc.
Allergy Bee Gone for Kids Nasal Swab Remedy 0.33 FL OZ (10 mL) tubes, UPC Code 860002022116	Class I	Drugs	Lot #: 2006491, Exp. Date 08/24	Microbial contamination of non-sterile product: FDA laboratory analysis found product to contain elevated levels of yeast and mold as well as the presence of Bacillus cereus.	Buzzagogo, LLC
SnoreStop NasoSpray, 0.3 FL OZ (9 mL), Green Pharmaceuticals Inc. Camarillo, CA 93012, NDC 61152-199-99, UPC 7 69682 29101 3	Class I	Drugs	Lot #: 2373/21222	Microbial contamination of non-sterile product: FDA laboratory analysis found product to contain microbial contamination identified as Providencia rettgeri.	Green Pharmaceutic als, Inc.
CVS Health Magnesium Citrate SALINE LAXATIVE, Oral Solution, 1.745 g, Lemon Flavor, 10 FL OZ (296 mL), Distributed by: CVS Pharmacy, Inc., One CVS Drive, Woonsocket, RI 02895, UPC 0 50428 30594 2.	Class I	Drugs	Lot: 0556808 Exp. 12/2023	Microbial Contamination of a Non-Sterile Products: Testing of product confirmed the presence of Gluconacetobacter Liquefaciens	Vi-Jon, LLC
Arti King Refozado con Ortiga y Omega 3 Tablets, 100-count bottles, Hecho en Mexico por: "PLANTAS MEDICINALES DE MEXICO", Melchor Ocampo No. 55 Local D, Delegacion	Class I	Drugs	Lot 334 21, Exp: 30 Nov, 2025	Marketed Without An Approved NDA/ANDA: FDA laboratory analysis found the product to	Latin Foods Market

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Xochimilco, C.P. 16800 Mexico, UPC 7 501031 111138				contain undeclared diclofenac and dexamethasone.	
Morphine Sulfate extended-Release Tablets, USP; 30 mg, 100-count bottles, Rx only, manufactured by: Ohm Laboratories Inc., New Brunswick NJ 08901 USA; Relabeled by: Bryant Ranch Prepack, Inc., Burbank, CA, 91504 USA, NDC: 63629-1088-01.	Class I	Drugs	Lot #: 179642, Exp. Date 11/30/2023.	Labeling: Label Mix-up: bottles labeled as Morphine Sulfate 60 mg Extended-Release tablets contain Morphine Sulfate 30 mg Extended-Release tablets and bottles labeled as Morphine Sulfate 30 mg Extended-Release tablets may contain Morphine Sulfate 60 mg Extended-Release tablets.	Bryant Ranch Prepack, Inc.
Morphine Sulfate extended-Release Tablets, USP; 60 mg, 100-count bottles, Rx only, manufactured by: Ohm Laboratories Inc., NJ; Relabeled by: Bryant Ranch Prepack, Inc, CA, NDC 63629-1089-01	Class I	Drugs	Lot #: 179643, Exp. Date 08/31/2023.	Labeling: Label Mix-up: bottles labeled as Morphine Sulfate 60 mg Extended-Release tablets contain Morphine Sulfate 30 mg Extended-Release tablets and bottles labeled as Morphine Sulfate 30 mg Extended-Release tablets may contain Morphine Sulfate 60 mg Extended-Release tablets.	Bryant Ranch Prepack, Inc.
Clonazepam Orally Disintegrating Tablets, USP, 0.125mg, Rx Only, 60 Tablets, Mfd. by: Sun Pharmaceutical Industries Ltd. Mumbai, India, Dist. by: Sun Pharmaceutical Industries In., Cranbury, NJ 08512, NDC 57664-783-68, packaged in bottles.	Class II	Drugs	Lot #: MHC1430A, Exp. Date 09/2023	Failed Tablet/Capsule Specification; oversized tablet found in a bottle	Sun Pharmaceutical Industries Inc
Testosterone Cypionate Injection, USP, 200 mg/mL, 1 mL Single-dose vial per carton, Rx	Class II	Drugs	HAC1974A, HAC1978A, Exp 06/2023	CGMP Deviations: lots made with same active pharmaceutical	Sun Pharmaceutical

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
only, Distributed by: Sun Pharmaceutical Industries, Inc., Cranbury, NJ 08512; Manufactured by: Sun Pharmaceutical Industries Ltd., Halol-Baroda Highway, Halol-389 350, Gujarat, India, NDC 62756-015-40.				ingredient (API) as lots that were rejected due to manufacturing issues that could cause the product to be out of specification for impurities.	al Industries Inc
Testosterone Cypionate Injection, USP, 200 mg/mL, 1 mL Single-dose vial per carton, Rx only, Distributed by: Sun Pharmaceutical Industries, Inc., Cranbury, NJ 08512; Manufactured by: Sun Pharmaceutical Industries Ltd., Halol-Baroda Highway, Halol-389 350, Gujarat, India, NDC 62756-015-40.	Class II	Drugs	Lot: HAC3427A, EXP Date: 08/2023	Lack of Assurance of Sterility: Manufacturing deviation which was reported due to a microbial excursion	Sun Pharmaceutical Industries Inc
Clonidine Transdermal System, USP 0.3 mg/day, 4 Patches (NDC 51862-455-01) per Carton (51862-455-04), Rx only, Manufactured for: Mayne Pharma Greenville, NC 27834	Class II	Drugs	Lot: 41179A Exp. Jan 2023	Defective Delivery System: Out of specification for release liner removal force results at the 3-month CRT stability timepoint.	Mayne Pharma Inc
Tretinoin Capsules, 10 mg, Rx Only, 100 capsules per bottle, Teva Pharmaceuticals USA Inc., North Wales, PA, 19454, NDC 0555-0808-02.	Class II	Drugs	Lot #: 100022971, Exp. 08/2022; 100022972, Exp. 05/2023; 100028920, Exp. 09/2023	Failed Dissolution Specifications; Low Out of Specification (OOS) results for dissolution.	Teva Pharmaceuticals USA Inc
70% ISOPROPYL ALCOHOL First aid antiseptic, 4 FL OZ (118 mL) bottle, Made in US with US and foreign components for Medline Industries, Inc., Mundelein, IL 60060 USA, NDC: 53329-798-04, UPC (01) 10888277362291.	Class II	Drugs	Lots #: 0517418, Exp. 12/2022; 0506632, 0519195, 0522494, Exp. 01/2023; 0525627, 0525629, 0526051, 0526052, 0527664, 0527665, Exp. 03/2023; 0531133, 0531134, Exp. 04/2023; 0533153,	Defective Container: Product may leak when squeezed or when not in an upright position determined to be due to defects in the bottle neck finish and insufficient tightening.	Vi-Jon, LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			0534050, Exp. 05/2023; 0534585, 0534587, 0536089, Exp. 06/2023; 0538694, 0541334, Exp. 07/2023; 0539877, 0542355, Exp. 08/2023; 0545225, 0547054, 0547055, 0547131, Exp. 09/2023; 0547130, 0551014, 0551015, 0552608, Exp. 10/2023; 0552609, 0552610, 0553905, Exp. 11/2023; 0556144, 0557513, Exp. 12/2023; 0559594, 0559602, 0559603, Exp. 01/2024; 0551013, 0559596, 0559604, 0559605, 0561393, 0561395, Exp. 02/2024; 0556143, 0561396, 0561549, Exp. 03/2024; 0565877, Exp. 04/2024		
Losartan Potassium Tablets, USP 25 mg, 90 Tablets bottles, Rx Only Marketed and Packaged By: PD-Rx Pharmaceuticals, Inc. Oklahoma City, OK 73127 Manufactured by: Vivimed Life Sciences Private Limited, Plot No. 101, 102, 107 & 108 SIDCO Pharmaceutical Complex, Alathur,	Class II	Drugs	Lots: D21C18 Exp. 09/30/22; E21A28 Exp. 09/30/22; E21C04 Exp. 09/30/22; E21D59 Exp. 09/30/22; G21B65 Exp. 09/30/22; H21A12 Exp. 09/30/22; H21D42 Exp.	CGMP Deviations- AZIDO Impurity levels observed to be above acceptable limits	PD-Rx Pharmaceuticals, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Kanchipuram-603 110, Tamilnadu, India NDC 72789-163-90 UPC 3 72789 16390 1			09/30/22; K21D19 Exp. 10/31/22; A22A73 Exp. 10/31/22		
Losartan Potassium Tablets, USP 50 mg, 90 Tablets bottles, Rx Only Marketed and Packaged By: PD-Rx Pharmaceuticals, Inc. Oklahoma City, OK 73127 Manufactured by: Vivimed Life Sciences Private Limited, Plot No. 101, 102, 107 & 108 SIDCO Pharmaceutical Complex, Alathur, Kanchipuram-603 110, Tamilnadu, India NDC 72789-164-90 UPC 3 72789 16490 8	Class II	Drugs	Lots: D21D63 Exp. 11/30/22; E21A73 Exp. 11/30/22; E21D35 Exp. 11/30/22; F21A28 Exp. 11/30/22; F21D04 Exp. 09/30/22; G21B03 Exp. 11/30/22; G21E23 Exp. 11/30/22; H21B46 Exp. 11/30/22; H21D46 Exp. 08/31/23; H21D46 Exp. 08/31/23; I21B67 Exp. 01/31/23; J21A26 Exp. 01/31/23; J21C44 Exp. 01/31/23	CGMP Deviations- AZIDO Impurity levels observed to be above acceptable limits	PD-Rx Pharmaceutic als, Inc.
Losartan Potassium Tablets, USP 100 mg, 90 Tablets bottles, Rx Only, Marketed and Packaged By: PD-Rx Pharmaceuticals, Inc. Oklahoma City, OK 73127 Manufactured by: Vivimed Life Sciences Private Limited, Plot No. 101, 102, 107 & 108 SIDCO Pharmaceutical Complex, Alathur, Kanchipuram-603 110, Tamilnadu, India NDC 72789-165-90 UPC 3 72789 16590 5	Class II	Drugs	Lots: G21C26 Exp. 07/31/22; H21B96 Exp. 07/31/22; I21B39 Exp. 07/31/22; I21C44 Exp. 07/31/22; D21F35 Exp. 10/31/22; E21A66 Exp. 10/31/22; E21C72 Exp. 10/31/22; E21F01 Exp. 10/31/22; F21C15 Exp. 10/31/22; F21E19 Exp. 10/31/22; G21B14 Exp. 10/31/22; K21A61 Exp.	CGMP Deviations- AZIDO Impurity levels observed to be above acceptable limits	PD-Rx Pharmaceutic als, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			11/30/22; L21A45 Exp. 11/30/22		
Fluticasone Propionate Nasal Spray, USP, 50 mcg, 16 g net fill weight per amber glass bottle, Rx only, Manufactured by: HI-TECH PHARMACAL CO., INC., Amityville, NY 11701. NDC 50383-700-16	Class II	Drugs	Lot #: 379073, 379079, Exp 9/30/2023	Defective container: defect prevents product from dispensing as intended.	Akorn, Inc.
Losartan potassium & Hydrochlorothiazide Tablets 100 mg/25 mg, 30, 90 & 1000 count NDC # 33342-052-07, NDC #33342-052-10 & NDC # 33342-052-44, Rx Only, MFR: Macleods Pharma USA, Inc. Plainsboro, NJ 08536	Class II	Drugs	Lot # BLM2114A, exp. date 07/2023	CGMP Deviations- AZIDO Impurity levels observed to be above acceptable limits	Macleods Pharma Usa Inc
Desmopressin Acetate Tablets, 0.2 mg, 100-count bottles, Rx Only, Manufactured for: Northstar Rx LLC, Memphis, TN 38141, Manufactured by: Glenmark Pharmaceuticals Ltd., Colvale-Bardez, Goa 403513, India, NDC 16714-884-01	Class II	Drugs	Lot #: 20020121, Exp 01/2024	CGMP Deviations	Glenmark Pharmaceutic als Inc., USA
Calcipotriene Topical Solution, 0.005% (Scalp Solution), Rx only, 60 mL (2 fl. oz.) bottle, Manufactured by: HI-TECH PHARMACAL CO., INC., Amityville, N.Y. 11701. NDC: 50383-732-02	Class II	Drugs	Lot #: 378440, Exp. 07/31/2023	Defective Delivery System: Potential defect that could prevent the product from dispensing as intended.	Akorn, Inc.
Daytrana (methylphenidate transdermal system) Delivers 10 mg over 9 hours (1.1 mg/hr) Contains: 30 Patches, Rx only, Manufactured for Noven Therapeutics, LLC, Miami, FL 33186 By Noven Pharmaceuticals, Inc., Miami, FL 33186. NDC 68968-5552-3	Class II	Drugs	Lot: 91272 Exp. 12/22.	Defective Delivery System: Customer complaints received for ripping patches and tight release/adhesive transfer.	Noven Pharmaceutic als Inc

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
<p>Enalapril Maleate Tablets, USP; 2.5 mg; 90 tablets, NDC 60429-183-90; manufactured by Taro Pharmaceutical Industries, Ltd.; packaged by GSMS, Incorporated, CA, USA.</p>	<p>Class II</p>	<p>Drugs</p>	<p>Lots: GS028301, 2.5 mg; 90 tablets, Exp.: 06/2022; Lots: GS029973, GS029974, GS031436, GS031715, GS033191, GS033940, Exp. : 10/2022; Lot: GS034212, Exp.: 12/2022; Lot: GS035315, GS035945, GS036905, GS038038, GS039199, Exp.: 04/2023; Lot: GS039200, GS040149, Exp.: 11/2023. (NDC: 60429-183-90).</p>	<p>CGMP Deviations</p>	<p>Golden State Medical Supply Inc.</p>
<p>Enalapril Maleate Tablets, USP; 5 mg; 90 tablets, NDC 60429-184-90; manufactured by Taro Pharmaceutical Industries, Ltd.; packaged by GSMS, Incorporated, CA.</p>	<p>Class II</p>	<p>Drugs</p>	<p>Lot: GS029041, GS029353, GS02986, 5 mg; 90 tablets, Exp.: 09/2022; Lot: GS030056, GS030869, GS033943, Exp.: 10/2022; Lots: GS034490, GS035197, Exp.:02/2023; Lots: GS035198, Exp.: 03/2023; Lots: GS035596, GS035947, GS036759, GS037400, Exp.: 06/2023; Lots: GS038089, GS038763, GS039559, GS040150, Exp.: 10/2023; Lots: GS040151, GS040708, GS041107,</p>	<p>CGMP Deviations</p>	<p>Golden State Medical Supply Inc.</p>

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
<p>Enalapril Maleate Tablets, USP; 10 mg; 90 tablets, NDC 60429-185-90; manufactured by Taro Pharmaceutical Industries, Ltd.; packaged by GSMS, Incorporated, CA.</p>	<p>Class II</p>	<p>Drugs</p>	<p>Exp.: 12/2023; Lot: GS041654, Exp.: 03/2024. Lots: GS027890, GS028177, GS028488, 10 mg; 90 tablets, Exp.: 04/2022; Lots: GS028847, GS028848, Exp.: 09/2022; GS029627, GS029862, GS030057, GS030481, GS030870, GS031060, GS031437, GS031438, GS033527, GS034231, Exp.: 10/2022; Lots: GS034810, Exp.: 01/2023; Lots: GS035240, GS035598, Exp.: 05/2023; Lots: GS036194, Exp.: 06/2023; Lots: GS036760, GS036981, GS037526, GS038177, GS038728, Exp.: 08/2023; Lots: GS038729, GS041108, Exp.: 09/2023; Lots: GS039412, GS039840, GS041109, Exp.: 12/2023; Lot: GS041655, Exp.: 01/2024; Lot: GS041656, Exp.: 05/2024. (NDC: 60429-185-90).</p>	<p>CGMP Deviations</p>	<p>Golden State Medical Supply Inc.</p>

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Enalapril Maleate Tablets, USP; 20 mg; 90 tablets, NDC 60429-186-90; manufactured by Taro Pharmaceutical Industries, Ltd.; packaged by GSMS, Incorporated, CA.	Class II	Drugs	Lots: GS035031, GS035199, 20 mg; 90 tablets, Exp.: 03/2022; Lots: GS036495, GS036904, Exp.: 05/2022; Lots: GS037401, Exp.: 09/2022; Lots: GS037986, GS038359, GS039560, Exp.: 11/2022; Lot: GS041110, Exp.: 12/2022. (NDC: 60429-186-90).	CGMP Deviations	Golden State Medical Supply Inc.
Bethanechol Chloride 1mg/ml, 80 ml Suspension bottles Banana/Strawberry, Qty:1, Wedgewood Village Pharmacy LLC, 405 Heron Dr. Ste 200, Swedesboro, NJ 08085	Class II	Drugs	Lot #: 000-03715131, Exp Date: 07/19/22	Lack of Processing Controls: Insanitary conditions observed during recent FDA Inspection	Wedgewood Village Pharmacy, LLC
Doxycycline (as Calcium) (equivalent to 50mg/5mL), 10 mg/ml, 60 ml suspension bottles, Peppermint, Qty: 1, Wedgewood Village Pharmacy LLC, 405 Heron Dr, Ste 200, Swedesboro, NJ 08085	Class II	Drugs	Lot#: 000-03852523, Exp Date: 09/01/22; Lot#: 000-03766625, Exp Date:07/10/22; Lot#: 000-03780127, Exp Date: 08/6/22; Lot#: 000-03794760, Exp Date: 08/6/22; Lot#: 000-03892723, Exp Date: 09/1/22; Lot#: 000-03641022, Exp Date: 06/17/22; Lot#: 000-03693714, Exp Date: 06/28/22; Lot#: 000-	Lack of Processing Controls: Insanitary conditions observed during recent FDA Inspection	Wedgewood Village Pharmacy, LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			03770510, Exp Date: 08/6/22; Lot#: 000-03852462, Exp Date: 09/1/22; Lot#: 000-03840601, Exp Date: 09/1/22; Lot#: 000-03706934, Exp Date: 06/28/22; Lot#: 000-03850609, Exp Date: 09/1/22; Lot#: 000-03650269, Exp Date: 06/17/22; Lot#: 000-03870004, Exp Date: 09/1/22; Lot#: 000-03693748, Exp Date: 06/28/22; Lot#: 000-03904403, Exp Date: 09/1/22; Lot#: 000-03799564, Exp Date: 08/06/22; Lot#: 000-03723022, Exp Date: 06/28/22; Lot#: 000-03872892, Exp Date: 09/01/22; Lot#: 000-03885204, Exp Date: 09/01/22; Lot#: 000-03848586, Exp Date: 09/01/22; Lot#: 000-03903599, Exp Date: 09/01/22; Lot#: 000-		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			03812001, Exp Date: 08/06/22;		
Boric Acid 600 mg capsules, 14 capsules per box, Qty: 1, Wedgewood Village Pharmacy LLC, 405 Heron Drive, Ste 200, Swedesboro, NJ 08085	Class II	Drugs	Lot#: 000-03868160, Exp Date: 09/14/22	Lack of Processing Controls: Insanitary conditions observed during recent FDA Inspection	Wedgewood Village Pharmacy, LLC
Boric Acid 600 mg per suppository, 14 Vaginal Suppositories per box, Wedgewood Village Pharmacy LLC, 405 Heron Drive, Ste 200, Swedesboro, NJ 08085	Class II	Drugs	Lot#: 000-03843532 Exp Date: 09/6/22	Lack of Processing Controls: Insanitary conditions observed during recent FDA Inspection	Wedgewood Village Pharmacy, LLC
Estriol 1mg/gm, Vaginal Cream, 30 gm tube, Qty: 1, Wedgewood Village Pharmacy LLC, 405 Heron Drive, Ste 200, Swedesboro, NJ 08085	Class II	Drugs	Lot#: 000-03807142 Exp Date: 08/27/22	Lack of Processing Controls: Insanitary conditions observed during recent FDA Inspection	Wedgewood Village Pharmacy, LLC
Estriol 1mg/gm, Vaginal Cream, 60 gm tube, Qty: 1, Wedgewood Village Pharmacy LLC, 405 Heron Drive, Ste 200, Swedesboro, NJ 08085	Class II	Drugs	Lot#: 000-03866709 Exp Date: 09/18/22	Lack of Processing Controls: Insanitary conditions observed during recent FDA Inspection	Wedgewood Village Pharmacy, LLC
Testosterone Cypionate Injection, USP, 200mg/ml, Rx Only, One Single-dose vial, Distributed by: Sun Pharmaceutical Industries Inc., Cranbury, NJ 08512, Manufactured by: Sun Pharmaceuticals Industries Ltd., Halol-Baroda Highway, Halol-389 350, Gujarat, India, NDC 62756-015-40.	Class II	Drugs	Lots JKX3267A & JKX3686A Exp. Date 08/2022 Lot JKX4700A, Exp Date 10/2022 Lot JKX5727A, Exp date 11/2022	CGMP Deviations: Manufacturing deviations were reported due to an abnormal appearance on parts of machinery.	SUN PHARMACEUTICAL INDUSTRIES INC
Eszopiclone Tablets, USP 1 mg, packaged in 30-count bottles, Rx Only, Manufactured for: Macleods Pharma USA, Inc., Plainsboro, NJ 08536, Manufactured by: Macleods	Class II	Drugs	Lot #: BEK2009A Exp: 11/2023	Shortfill: customer complaints of one to three tablets were reported missing from 30 count bottles.	Macleods Pharma Usa Inc

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Pharmaceuticals Ltd., Baddi, Himachal Pradesh, INDIA, NDC 33342-299-07					
Alpha Lipoic Acid 25mg/mL, 30mL-vial, Refrigerate, Tailor Made Compounding	Class II	Drugs	Batch #: 12082102A2, Exp 3/8/2022; 02212201A1, Exp 5/22/2022.	Lack of Assurance of Sterility	TMC Acquisition LLC dba Tailor Made Compounding
Alprostadil/Papaverine/Phentolamine 60mcg/30mg/3mg/mL, 3mL-vial, Refrigerate, Tailor Made Compounding	Class II	Drugs	Batch #: 01042221A2, Exp 3/5/2022; 02192216A1, Exp 4/20/2022.	Lack of Assurance of Sterility	TMC Acquisition LLC dba Tailor Made Compounding
Anastrozole/Testosterone Cypionate/Propionate 1mg/160mg/40mg/mL, 10 mL-vial, Room Temperature, Tailor Made Compounding	Class II	Drugs	Batch #: 10182113A1, Exp 4/16/2022.	Lack of Assurance of Sterility	TMC Acquisition LLC dba Tailor Made Compounding
Ascorbic Acid 500mg/mL, a) 25 ml-vial, b) 50 ml-vial, Refrigerate, Tailor Made Compounding	Class II	Drugs	Batch #: a) 02282223A1, Exp 8/27/2022; 10112101A2, Exp 4/9/2022; 11032108A1, Exp 4/30/2022; 11222101A2, Exp 5/21/2022; b) 01042234B, Exp 7/3/2022; 01242211A2, Exp 7/23/2022; 02282222A1, Exp 8/27/2022; 10112101A2, Exp 4/9/2022; 10182101A1,	Lack of Assurance of Sterility	TMC Acquisition LLC dba Tailor Made Compounding

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			Exp 4/16/2022; 11162112A1, Exp 5/15/2022; 12062105A2, Exp 6/4/2022; 12142143A2, Exp 6/12/2022; 12202102A2, Exp 6/18/2022.		
BCAAs (Leucine/Iso-Leucine/Valine) 10mg/10mg/5mg/mL, 30mL-vial, Refrigerate, Tailor Made Compounding	Class II	Drugs	Batch #: 11022106A1, Exp 4/30/2022; 11192106A2, Exp 5/18/2022; 12022105A1, Exp 5/31/2022; 12132108A1, Exp 6/11/2022; 12292117A1, Exp 6/27/2022.	Lack of Assurance of Sterility	TMC Acquisition LLC dba Tailor Made Compounding
Biotin 5mg/mL, 5mL-vial, Refrigerate, Tailor Made Compounding	Class II	Drugs	Batch #: 12032113A2, Exp 6/1/2022; 01102206A1, Exp 7/9/2022.	Lack of Assurance of Sterility	TMC Acquisition LLC dba Tailor Made Compounding
Calcium Chloride Preservative Free, 100mg/mL, a) 5 mL-vial, b) 30 ml-vial, Room Temperature, Tailor Made Compounding	Class II	Drugs	Batch #: a) 12072101A2, Exp 3/7/2022; 01042216A1, Exp 4/4/2022; 02142220A1, Exp 5/15/2022; b)12032129A2, Exp 3/3/2022; 02142220A1, Exp 5/15/2022; 03032213A1, Exp	Lack of Assurance of Sterility	TMC Acquisition LLC dba Tailor Made Compounding

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			6/1/2022; 03102214B, Exp 6/8/2022.		
Dexpanthenol 250mg/mL, 30mL-vial, Room Temperature, Tailor Made Compounding	Class II	Drugs	Batch #: 01032232A1, Exp 7/2/2022; 01242229A2, Exp 7/23/2022.	Lack of Assurance of Sterility	TMC Acquisition LLC dba Tailor Made Compounding
Dexpanthenol Preservative Free 250mg/mL, 2mL-vial, Room Temperature, Tailor Made Compounding	Class II	Drugs	Batch#: 01032234A2, Exp 7/2/2022; 02072212A1, Exp 8/6/2022.	Lack of Assurance of Sterility	TMC Acquisition LLC dba Tailor Made Compounding
Estradiol Cypionate 10mg/mL, a) 1mL-vial, b) 2 mL-vial, Room Temperature, Tailor Made Compounding	Class II	Drugs	Batch #: a) 01052210A1, Exp 4/5/2022; 10202101A1, Exp 4/18/2022; 01052210A1 7/4/2022; b)10202102A1, Exp 4/18/2022; 12022126A1, Exp 5/31/2022; 01052210A1, Exp 7/4/2022.	Lack of Assurance of Sterility	TMC Acquisition LLC dba Tailor Made Compounding
Folic Acid 5mg/mL, 30mL-vial, Refrigerate, Tailor Made Compounding	Class II	Drugs	Batch#: 10132102A2, Exp 3/22/2022; 01062221B, Exp 4/30/2022; 11302103A1, Exp 4/30/2022; 03032227A1, Exp 8/29/2022.	Lack of Assurance of Sterility	TMC Acquisition LLC dba Tailor Made Compounding
GAC (Glutamine/Arginine/L-Carnitine) 25mg/100mg/250mg/mL, 30mL-vial, Refrigerate, Tailor Made Compounding	Class II	Drugs	Batch #: 10122110A2, Exp 3/20/2022; 12062110A2, Exp 4/30/2022;	Lack of Assurance of Sterility	TMC Acquisition LLC dba Tailor

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			02012202A2, 02192207A1, Exp 7/31/2022.		Made Compounding
GOAL (Glutamine/Ornithine/Arginine/Lysine 25mg/75mg/150mg/250mg/ml) 30 ml-vial, Refrigerate, Tailor Made Compounding	Class II	Drugs	Batch #: 10122105A2, Exp 3/20/2022; 01182216A1, Exp 5/31/2022; 02192207A1, Exp 7/31/2022; 03072206A1, Exp 9/3/2022.	Lack of Assurance of Sterility	TMC Acquisition LLC dba Tailor Made Compounding
Glutathione 200mg/mL Preservative Free, Injectable, 30mL-vial, Refrigerate, Tailor Made Compounding	Class II	Drugs	Batch #: 12062113A2, Exp 3/6/2022; 01052209B, Exp 4/5/2022; 01312223A1, Exp 5/1/2022.	Lack of Assurance of Sterility	TMC Acquisition LLC dba Tailor Made Compounding
Glycyrrhizic Acid 8mg/mL, 10mL-vial, Refrigerate, Tailor Made Compounding	Class II	Drugs	Batch #: 12172114A2, Exp 3/17/2022; 01142211A1, Exp 4/14/2022.	Lack of Assurance of Sterility	TMC Acquisition LLC dba Tailor Made Compounding
Gonadorelin 100mcg/mL, 10mL per vial, Refrigerate, Tailor Made Compounding	Class II	Drugs	Batch #: 01062225B, Exp 4/6/2022; 01142207A1, Exp 4/14/2022; 02012228A1, Exp 5/2/2022; 02032203A1, Exp 5/4/2022; 03012211A1, Exp 5/30/2022; 03082240A1, Exp 6/6/2022.	Lack of Assurance of Sterility	TMC Acquisition LLC dba Tailor Made Compounding

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Hydroxocobalamin 25mg/mL, 10mL-vial, Room Temperature, Tailor Made Compounding	Class II	Drugs	Batch#: 12222104A2, Exp 3/22/2022; 01032224A2, Exp 4/3/2022; 01282217A2, Exp 4/28/2022; 02192211A1; Exp 5/20/2022.	Lack of Assurance of Sterility	TMC Acquisition LLC dba Tailor Made Compounding
Hydroxocobalamin Preservative Free 5mg/mL, 1mL-vial, Refrigerate, Tailor Made Compounding	Class II	Drugs	Batch #: 01032236A2, Exp 4/3/2022; 03072232A1, Exp 6/5/2022	Lack of Assurance of Sterility	TMC Acquisition LLC dba Tailor Made Compounding
Inositol/Choline B12 + Carnitine 40mg/40mg/1mg/100mg/mL, 30mL-vial, Refrigerate, Tailor Made Compounding	Class II	Drugs	Batch#: 01212203A2, Exp 4/21/2022; 02232213A1, Exp 5/24/2022.	Lack of Assurance of Sterility	TMC Acquisition LLC dba Tailor Made Compounding
Levocarnitine 500mg/mL, 30mL-vial, Refrigerate, Tailor Made Compounding	Class II	Drugs	Batch #: 12022124A2, Exp 3/2/2022; 03032223A1, Exp 6/1/2022.	Lack of Assurance of Sterility	TMC Acquisition LLC dba Tailor Made Compounding
Melanotan I 200mcg/mL (2mg/ml), a) 1.5mL-vial, b) 5 mL-vial, Refrigerate, Tailor Made Compounding	Class II	Drugs	Batch #: a) 01072212A1, Exp 4/7/2022; 03032220A1, Exp 6/1/2022; b) 12162120A2, Exp 3/16/2022; 01142205A1, Exp 4/14/2022; 02012226A1, Exp 5/2/2022;	Lack of Assurance of Sterility	TMC Acquisition LLC dba Tailor Made Compounding

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			03032220A1, Exp 6/1/2022.		
Methionine/Inositol/Choline B12 + Carnitine 10mg/40mg/40mg/1mg/100mg/mL, a) 4mL-vial, b) 10 mL-vial, c) 30mL- vial, Refrigerate, Tailor Made Compounding	Class II	Drugs	Batch#: a) 01172233A1, Exp 4/17/2022; 01282213A1, Exp 4/28/2022; 02192221A1, Exp 5/20/2022; b)12032118A2, Exp 3/3/2022; 12282120A2, Exp 3/28/2022 01172233A1, Exp 4/17/2022, 01282213A1, Exp 4/28/2022, 02212242A1, Exp 5/22/2022, 03042202A1, Exp 6/2/2022; c) 02192219A1, Exp 5/20/2022; 03062201A1, Exp 6/4/2022.	Lack of Assurance of Sterility	TMC Acquisition LLC dba Tailor Made Compounding
Methionine/Inositol/Choline B12 25mg/50mg/50mg/1mg/mL, a)10 mL-vial, b) 30 mL-vial, Room Temperature, Tailor Made Compounding	Class II	Drugs	Batch#: a) 12092105A2, exp 3/9/2022; 01042219A2, Exp 4/4/2022; 01202210A2, exp 4/20/2022; 01282207A1, exp 4/28/2022; 03032217A1, Exp 6/1/2022; 12092105A2; b) 01282207A1, Exp	Lack of Assurance of Sterility	TMC Acquisition LLC dba Tailor Made Compounding

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			4/28/2022; 03032241A1, Exp 6/1/2022		
Methylcobalamin 10mg/mL, a) 1 mL-vial, b) 10mL-vial, c) 30 mL-vial, Room Temperature, Tailor Made Compounding	Class II	Drugs	Batch#: a)11092114A2, Exp 4/30/2022; 12172113A2, Exp 6/15/2022; 03072227A1, Exp 9/3/2022; b)10122101A2, Exp 4/10/2022; 12022116A1, Exp 5/31/2022; 12292115A1, Exp 6/27/2022; 02222207A1, Exp 8/21/2022; c)10112103A2, Exp 4/9/2022; 11192112A2, Exp 5/18/2022; 12142114A2, Exp 6/12/2022; 12202103A1, Exp 6/18/2022; 12282119A2, Exp 6/26/2022; 01192222A1, Exp 7/18/2022; 02232201A1, Exp 8/22/2022.	Lack of Assurance of Sterility	TMC Acquisition LLC dba Tailor Made Compounding
Methylcobalamin 1mg/mL, a) 10 mL-vial, b) 30 ml-vial, Room Temperature, Tailor Made Compounding	Class II	Drugs	Batch #: a) 10282106A1, Exp 4/26/2022; 11022118A1, Exp 4/30/2022; 12292115A1, Exp 6/27/2022; b)12082113A2, Exp	Lack of Assurance of Sterility	TMC Acquisition LLC dba Tailor Made Compounding

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			6/2/2022; 12292115A1, Exp 6/27/2022; 03072230A1, Exp 9/3/2022.		
Methylcobalamin Preservative Free, 10mg/mL, 1mL-vial, Room Temperature, Tailor Made Compounding	Class II	Drugs	Batch#: 03012234A1, Exp 8/28/2022.	Lack of Assurance of Sterility	TMC Acquisition LLC dba Tailor Made Compounding
Methylene Blue Hypotonic Solution, 10mg/mL, a) 2 mL-vial, b) 10mL-vial, Refrigerate, Tailor Made Compounding	Class II	Drugs	Batch #: a)11032122A2, Exp 4/30/2022; 01142226A1, Exp 7/13/2022; b)10272101A1, Exp 4/25/2022; 11292137A1, Exp 5/28/2022; 12142120A2, Exp 6/12/2022; 01042235B, Exp 7/3/2022; 01142226A1, Exp 7/13/2022; 03012240A1, Exp 8/28/2022; 03042223A1, Exp 8/31/2022.	Lack of Assurance of Sterility	TMC Acquisition LLC dba Tailor Made Compounding
NAD+ 200mg/mL, 10mL-vial, Refrigerate, Tailor Made Compounding	Class II	Drugs	Batch#: 10072110A2, 10142102A2, Exp 3/22/2022; 01112205A1, 11112123A1, Exp 4/30/2022; 11222114A1, 11172107A1,	Lack of Assurance of Sterility	TMC Acquisition LLC dba Tailor Made Compounding

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			11182120A2, Exp 5/7/2022; 01102207A1, 01122211A1, Exp 5/11/2022; 12162119A1, 12162121A1, Exp 5/24/2022; 02022223A2, Exp 6/30/2022; 03012204A1, Exp 8/23/2022; 03082249B, Exp 9/4/2022; 03092226B, 03092236B, Exp 9/5/2022.		
Nandrolone Decanoate 200mg/mL, a) 5 mL-vial, b) 10mL-vial, Refrigerate, Tailor Made Compounding	Class II	Drugs	Batch#: a) 10272107A1, Exp 4/25/2022; 12072130A1, Exp 6/5/2022; b) 01032230A1, Exp 7/2/2022.	Lack of Assurance of Sterility	TMC Acquisition LLC dba Tailor Made Compounding
Pentosan Polysulfate Sodium 250mg/mL, 5mL-vial, Room Temperature, Tailor Made Compounding	Class II	Drugs	Batch#: 11292109A2, Exp 5/28/2022, 01242202A1, Exp 6/18/2022; 03022214A1, Exp 8/29/2022.	Lack of Assurance of Sterility	TMC Acquisition LLC dba Tailor Made Compounding
Procaine HCL 2% (20mg/mL), 30 mL-vial, Refrigerate, Tailor Made Compounding	Class II	Drugs	Batch#: 10112102A2, Exp 4/9/2022; 11302101A1, Exp 5/29/2022; 01242201A1, Exp 5/31/2022.	Lack of Assurance of Sterility	TMC Acquisition LLC dba Tailor Made Compounding
PT-141 10mg/mL a) 1mL-vial, b) 2 mL-vial, Refrigerate, Tailor Made Compounding	Class II	Drugs	Batch#: a) 01042226A2, Exp 4/4/2022; 01242228A2, Exp 4/24/2022; 02212208A1,	Lack of Assurance of Sterility	TMC Acquisition LLC dba Tailor

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			Exp 5/22/2022; b) 01192230A2, Exp 4/19/2022; 02212217A1, Exp 5/22/2022.		Made Compounding
Semaglutide/Cyanocobalamin 2mg/0.4mg/ml, 1mL-vial, Refrigerate, Tailor Made Compounding	Class II	Drugs	Batch#: 12032123A2, Exp 3/3/2022; 12102101A2, Exp 3/10/2022; 12202105A2, Exp 3/20/2022; 12292106A2, Exp 3/29/2022; 01062218B, Exp 4/6/2022; 01192228A2, Exp 4/19/2022; 01312214A2, Exp 5/1/2022; 02012211A1, Exp 5/2/2022; 02182201A1, 02182203A1, Exp 5/19/2022; 02242205A1, 02242206A1, Exp 5/25/2022; 03072209A1, Exp 6/5/2022; 03092203A1, 03092206A1, Exp 6/7/2022.	Lack of Assurance of Sterility	TMC Acquisition LLC dba Tailor Made Compounding
Semaglutide/Cyanocobalamin 5mg/0.2mg/ml, 2ml-vial, Refrigerate, Tailor Made Compounding	Class II	Drugs	Batch#: 12092115A2, Exp 3/9/2022; 12162116A2, Exp 3/16/2022; 12212106A2, Exp 3/21/2022; 01062219B, Exp 4/6/2022;	Lack of Assurance of Sterility	TMC Acquisition LLC dba Tailor Made Compounding

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			01072205A1, 01072208A1, Exp 4/7/2022; 01102203A1, Exp 4/10/2022; 01132207A1, Exp 4/13/2022; 01192216A1, Exp 4/19/2022; 01202204A2, Exp 4/20/2022; 01272223A2, Exp 4/27/2022; 01312219A2, Exp 5/1/2022; 02032204A2, Exp 5/4/2022; 02072203A1, Exp 5/8/2022; 02182216A1, 02182224A1, Exp 5/19/2022; 02232202A1, 02232210A1, Exp 5/24/2022; 02242202A1, 02242203A1, 02242235A1, 02242238A1, Exp 5/25/2022; 03072217A1, 03072223A1, Exp 6/5/2022; 03082223A1, 03082229A1, Exp 6/6/2022; 03092207A1, 03092219A1, Exp 6/7/2022.		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Sermorelin 2000mcg/mL, 7.5mL-vial, Refrigerate, Tailor Made Compounding	Class II	Drugs	Batch#: 10122103A2, Exp 3/22/2022; 11092108A2, Exp 4/30/2022; 11192115A2, Exp 5/7/2022; 12022107A2, Exp 5/22/2022; 12132107A2, Exp 5/24/2022; 01182201A2, Exp 6/30/2022; 02142212A1, Exp 8/13/2022; 03022217A1, Exp 8/29/2022.	Lack of Assurance of Sterility	TMC Acquisition LLC dba Tailor Made Compounding
Sermorelin/Glycine 2000mcg/5mg/mL, 4mL-vial, Refrigerate, Tailor Made Compounding	Class II	Drugs	Batch#: 11102107A2, Exp 4/9/2022; 11232104A1, Exp 5/7/2022; 02212229A1, 11292103A2, Exp 5/22/2022; 12132105A2, Exp 5/24/2022; 02282207A1, Exp 5/29/2022; 03082209A1, Exp 6/6/2022; 03112231B, Exp 6/9/2022; 01042212A1, Exp 6/27/2022.	Lack of Assurance of Sterility	TMC Acquisition LLC dba Tailor Made Compounding
Sermorelin/Glycine 2000mcg/5mg/mL, 7.5mL-vial, Refrigerate, Tailor Made Compounding	Class II	Drugs	Batch #: 10122102A2, Exp 3/22/2022; 10252101A2, Exp 3/24/2022; 11092106A2, Exp 4/8/2022; 11232102A1, Exp 5/7/2022;	Lack of Assurance of Sterility	TMC Acquisition LLC dba Tailor Made Compounding

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			11162106A1, Exp 5/15/2022; 12032114A1, 02212224A1, Exp 5/22/2022; 12142111A1, 12202109A2, Exp 5/24/2022; 03032244A1, Exp 6/1/2022; 03082209A1, Exp 6/6/2022; 12292116A2, Exp 6/27/2022; 01182204A1, 01262232A1, 01262233A1, Exp 6/30/2022.		
Teriparatide 226mcg/ml Injectable, 4 Pre-filled Syringes, 0.25 mL-Syringe, Refrigerate, Tailor Made Compounding	Class II	Drugs	Batch#: 01132208A1, Exp 4/13/2022; 02252205A1, Exp 5/26/2022.	Lack of Assurance of Sterility	TMC Acquisition LLC dba Tailor Made Compounding
Testosterone Cypionate (GSO) 100mg/ml a)1mL-vial , b) 2mL-vial, Room temperature, Tailor Made Compounding	Class II	Drugs	Batch#: a) 12212109A2, Exp 6/19/2022; 01312217A1, Exp 7/30/2022; b) 10202108A1, Exp 4/18/2022; 12012125A, Exp 5/30/2022 ;02182230A1, Exp 8/17/2022; 10202108A1; 03022222A1, Exp 8/29/2022.	Lack of Assurance of Sterility	TMC Acquisition LLC dba Tailor Made Compounding

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
<p>Testosterone Cypionate (GSO) 200mg/ml a) 2 mL-vial, b) 4 mL-vial, c) 5 mL-vial, d) 10 mL-vial, Room temperature, Tailor Made Compounding</p>	<p>Class II</p>	<p>Drugs</p>	<p>Batch#: a)12212105A2, Exp 6/19/2022; 02182229A1, Exp 8/17/2022; b) 12012121A2, Exp 5/30/2022; 12212104A2, Exp 6/19/2022; 01242216A2, Exp 7/23/2022; 02182236A1, Exp 8/17/2022; c) 12072133A1, Exp 6/5/2022; 01192225A1, Exp 7/18/2022; 02182228A1, Exp 8/17/2022; d)10142105A, Exp 4/12/2022; 10272105A1, Exp 4/25/2022; 11102101A1, 11032120A2, Exp 4/30/2022; 11222116A2, Exp 5/21/2022; 12012121A2, Exp 5/30/2022; 12072132A1, Exp 6/5/2022; 12152110A1, Exp 6/13/2022; 12162118A1, Exp 6/14/2022; 12212103A2, Exp 6/19/2022; 01052206A1, Exp 7/4/2022;</p>	<p>Lack of Assurance of Sterility</p>	<p>TMC Acquisition LLC dba Tailor Made Compounding</p>

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			01142229A1, Exp 7/13/2022; 01212207A2 Exp, 7/20/2022; 02042201A1, Exp 8/3/2022; 02182226A1, Exp 8/17/2022; 02252224A1, 02252226A1, Exp 8/24/2022.		
Testosterone Cypionate/Anastrozole 200mg/0.5mg/mL, 10mL-vial, Room temperature, Tailor Made Compounding	Class II	Drugs	Batch#: 11232117A1, Exp 5/22/2022; 01312215A1, Exp 7/30/2022	Lack of Assurance of Sterility	TMC Acquisition LLC dba Tailor Made Compounding
Testosterone Cypionate/Anastrozole 200mg/1mg/mL, a) 4 mL-vial, b)10mL-vial, Room temperature, Tailor Made Compounding	Class II	Drugs	Batch#: a)10142123A2, Exp 4/12/2022, 02042202A1, Exp 8/3/2022; b) 10142121A2, Exp 4/12/2022; 10202105A1, Exp 4/18/2022; 11102102A1, Exp 4/30/2022; 02042202A1, Exp 8/3/2022.	Lack of Assurance of Sterility	TMC Acquisition LLC dba Tailor Made Compounding
Testosterone Cypionate/Enanthate 100/100mg/ml, a) 2 mL-vial, b) 4 mL-vial c) 10 mL-vial, Room temperature, Tailor Made Compounding	Class II	Drugs	Batch#: Expiry: a) 01142227A1, Exp 7/13/2022; b) 12012126A2, Exp 5/30/2022; 02042203A1, Exp 8/3/2022; c)	Lack of Assurance of Sterility	TMC Acquisition LLC dba Tailor Made Compounding

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			01052207A1, Exp 7/4/2022.		
Testosterone Cypionate/Enanthate/Propionate 80/80/40mg, a) 5 mL-vial, b) 10 mL-vial, Room temperature, Tailor Made Compounding	Class II	Drugs	Batch#: a) 10202107A1, Exp 4/18/2022; b) 10142120A2, Exp 4/12/2022; 10272102A1, Exp 4/25/2022 ; 11032117A2, 11102104A2, Exp 4/30/2022; 01252212A2 , Exp 7/24/2022; 02182227A1, Exp 8/17/2022 .	Lack of Assurance of Sterility	TMC Acquisition LLC dba Tailor Made Compounding
Testosterone Cypionate/Propionate 180/20mg/ml, a) 5 mL-vial, b) 10 mL-vial, Room temperature, Tailor Made Compounding	Class II	Drugs	Batch#: a)11042102A1, Exp 4/30/2022; 12072135A1, Exp 6/5/2022, 01142228A1, Exp 7/13/2022; 02182231A1, Exp 8/17/2022; b)11042102A1, Exp 4/30/2022; 01142228A1, Exp 7/13/2022.	Lack of Assurance of Sterility	TMC Acquisition LLC dba Tailor Made Compounding
Testosterone Enanthate (GSO) 100mg/ml, 2 mL-vial, Room temperature, Tailor Made Compounding	Class II	Drugs	Batch#: 11102106A1, Exp 4/30/2022; 01142230A1, Exp 7/13/2022.	Lack of Assurance of Sterility	TMC Acquisition LLC dba Tailor Made Compounding

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Testosterone Enanthate (GSO) 200mg/ml, a) 5 mL-vial, b) 10 mL-vial, Room temperature, Tailor Made Compounding	Class II	Drugs	Batch#: a)10142117A2, Exp 4/12/2022; 10272108A1, Exp 4/25/2022; 11302113A2, Exp 5/29/2022; 02252220A1, Exp 8/24/2022; b)10142108A2, Exp 4/12/2022; 12072134A1, Exp 6/5/2022.	Lack of Assurance of Sterility	TMC Acquisition LLC dba Tailor Made Compounding
Testosterone Propionate 100mg/ml, 10mL-vial, Room temperature, Tailor Made Compounding	Class II	Drugs	Batch#: 12012123A2, Exp 5/30/2022; 01312212A1, Exp 7/30/2022.	Lack of Assurance of Sterility	TMC Acquisition LLC dba Tailor Made Compounding
Vitamin B-Complex, a) 10 mL-vial, b) 30 mL-vial, Refrigerate, Tailor Made Compounding	Class II	Drugs	Batch#: a) 01252201A2, Exp 3/26/2022; b) 01252201A2, Exp 3/26/2022; 02032213A2, Exp 4/4/2022; 03042209A1, Exp 5/3/2022.	Lack of Assurance of Sterility	TMC Acquisition LLC dba Tailor Made Compounding
Vitamin B-Complex Preservative Free, 3mL-vial, Refrigerate, Tailor Made Compounding	Class II	Drugs	Batch#: 03112233B, Exp 5/10/2022	Lack of Assurance of Sterility	TMC Acquisition LLC dba Tailor Made Compounding
Vitamin D3 50,000IU/mL, 10mL-vial, Room Temperature, Tailor Made Compounding	Class II	Drugs	Batch#: 02252201A1, Exp 4/15/2022.	Lack of Assurance of Sterility	TMC Acquisition LLC dba Tailor

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
					Made Compounding
Glutathione 200mg/ml, a) 10ml-vial, b) 30ml-vial, Refrigerate, Tailor Made Compounding	Class II	Drugs	Batch#: a) 01122204A1, Exp 4/12/2022; 02192214A1, Exp 5/20/2022; b) 12142122A2, Exp. 3/14/2022; 12282118A2, Exp 3/28/2022; 01112203A1, Exp 4/11/2022; 01122208A1, Exp 4/12/2022; 01202211A2, Exp 4/20/2022; 02032205A1, Exp 5/4/2022; 02192212A1, Exp 5/20/2022; 03042201A1, Exp 6/2/2022.	Lack of Assurance of Sterility	TMC Acquisition LLC dba Tailor Made Compounding
Testosterone Cypionate Injection, USP, 200mg/mL, CIII, Rx only, 1mL Single-dose vial, Distributed by: Sun Pharmaceutical Industries, Inc., Cranbury, NJ 08512, Manufactured by: Sun Pharmaceuticals Industries Ltd., Halol- Baroda Highway, Halol-Baroda, Highway, Halol- 389 350, Gujarat, India, NDC 62756-015-40.	Class II	Drugs	HAC4337A	cGMP - Water leakage	SUN PHARMACEUTICAL INDUSTRIES INC
Draximage MAA (Kit for the preparation of Technetium Tc 99m Albumin Aggregate) 2.5 mg per vial, 30 glass vials per carton, Rx	Class II	Drugs	Lot # 1H005, exp. date Nov 30, 2023	Lack of Assurance of Sterility: Out-of-specification test results obtained for Endotoxin testing.	Jubilant Draximage Inc

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Only, Manufactured for Jubilant Draximage Inc. Kirkland, Canada, NDC 65174-270-30.					
Hydrogen Peroxide Topical Solution, USP, 32 fl. oz. (1 QT) 946 mL, Distributed by: CVS Pharmacy, Inc. One CVS Drive Woonsocket, RI 02895, NDC 59779-871-45, UPC 0-50428-40950-3	Class II	Drugs	Lot: 0562272, Exp 02/2025	Labeling: Label Mix-Up-The primary label on the front of the bottles have Hydrogen Peroxide affixed to the front and back of the containers. However, the product inside the bottle is 70% Isopropyl Alcohol.	Vi-Jon, LLC
Amino Acid Injection 50 g/1000 mL (50 mg/mL) bags, Rx Only, Nephron 503B outsourcing facility, 4500 12th Extension, West Columbia, SC 29172, NDC: 69374-988-10	Class II	Drugs	Lots: AA2012A, Exp. 07/04/2022	Lack of Assurance of Sterility	Nephron Sterile Compounding Center LLC
Atropine Sulfate Injection, USP 1.2 mg/3 mL (0.4 mg/mL) syringe, packaged in 5 x 3 mL Pre-Filled Syringes per carton, 6 x 5 Syringe Carton per case, Rx Only, Nephron 503B outsourcing facility 4500 12th Street Extension, West Columbia, SC 29172, NDC: 69374-935-03	Class II	Drugs	Lots: AS2001A, Exp. 8/2/2022; AS2002A, Exp. 8/17/2022; AS2003A, Exp. 9/3/2022.	Lack of Assurance of Sterility	Nephron Sterile Compounding Center LLC
0.125% Bupivacaine HCl Injection, USP, 62.5 mg/50 mL (1.25 mg/mL) syringes, packaged in 5 x 50 mL Pre-Filled Syringes per carton, 6 x 5 Syringe Carton per case, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Ext., West Columbia, SC 29172, NDC: 69374-970-50	Class II	Drugs	Lots: BH2001A, Exp. 7/15/2022; BH2002A, Exp. 8/7/2022; BH2004A, Exp. 8/22/2022; BH2005A, Exp. 9/2/2022; BH2006A, Exp. 9/14/2022; BH2007A, Exp. 9/29/2022; BH2008A, Exp. 10/3/2022; BH2010A, Exp. 10/19/2022	Lack of Assurance of Sterility	Nephron Sterile Compounding Center LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
0.9% Buffered Lidocaine HCl (buffered in 8.4% Sodium Bicarbonate), 45 mg/5 mL (9 mg/mL) syringes, packaged in 5 x 5 mL Prefilled Syringes per carton, 6 x 5 Syringe Carton per case, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-947-50	Class II	Drugs	Lots: BL2007A, Exp. 7/3/2022	Lack of Assurance of Sterility	Nephron Sterile Compounding Center LLC
Bupivacaine HCl 150 mg (3.0 mg/mL), Ketorolac Tromethamine 60 mg (1.2 mg/mL), Ketamine HCl 60 mg (1.2 mg/mL) Injection, 50 mL syringes, packaged in 5 x 50 mL Pre-Filled Syringes per carton, 6 x 5 Syringe Carton per case, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-514-50	Class II	Drugs	Lots: BP2001A, Exp. 7/6/2022; BP2002A, Exp. 7/27/2022; BP2007A, Exp. 7/3/2022	Lack of Assurance of Sterility	Nephron Sterile Compounding Center LLC
EPINEPHrine Injection, USP, 0.1 mg/10 mL (10 mcg/mL) syringes, 5 x 10 mL Pre-Filled Syringes per carton, 6 x 5 Syringe Carton per case, Rx Only, Nephron 503B outsourcing facility, 4500 12th Street Extension, West Columbia SC 29172, NDC: 69374-544-10	Class II	Drugs	Lots: EN2001A, Exp. 7/9/2022; EN2003A, Exp. 7/18/2022; EN2004A, Exp. 8/1/2022; EN2012A, Exp. 9/1/2022	Lack of Assurance of Sterility	Nephron Sterile Compounding Center LLC
EPINEPHrine Injection, USP, 1 mg/10 mL (100 mcg/mL) syringe, packaged in 5 x 10 mL Pre-Filled Syringes per carton, 6 x 5 Syringe Carton per case, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-925-10	Class II	Drugs	Lots: EN2007A, Exp. 7/31/2022; EN2008A, Exp. 8/18/2022; EN2013A, Exp. 9/11/2022; EN2014A, Exp. 10/2/2022	Lack of Assurance of Sterility	Nephron Sterile Compounding Center LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Fentanyl Citrate in 0.9% Sodium Chloride Injection, USP, 2500 mcg/250 mL (10 mcg/mL*) bags, packaged as 10 x 1 IV bag per case, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-523-21	Class II	Drugs	Lots: FN2001A, Exp. 7/8/2022; FN2001B, Exp. 7/8/2022; FN2002A, Exp. 7/19/2022; FN2002B, Exp. 7/19/2022; FN2003A, Exp. 8/24/2022; FN2003B, Exp. 8/24/2022	Lack of Assurance of Sterility	Nephron Sterile Compounding Center LLC
Glycopyrrolate Injection, USP, 1 mg/5 mL (0.2 mg/mL) syringes, packaged in 5 x 5 mL Pre-Filled Syringes per carton, 6 x 5 Syringe Carton per case, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-903-05	Class II	Drugs	Lots: GL2001A, Exp. 7/15/2022	Lack of Assurance of Sterility	Nephron Sterile Compounding Center LLC
Glycopyrrolate Injection, USP, 0.6 mg/3 mL (0.2 mg/mL) syringes, packaged in 5 x 3 mL Pre-Filled Syringes per carton, 6 x 5 Syringe Carton per case, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-903-30	Class II	Drugs	Lot: GL2004A, Exp. 8/26/2022	Lack of Assurance of Sterility	Nephron Sterile Compounding Center LLC
HYDROmorphone HCl Injection, USP, 10 mg/50 mL (0.2 mg/mL) syringes, 5 x 50 mL Pre-Filled Syringes per carton, 6 x 5 Syringe Carton per case, Rx Only, Nephron 503B outsourcing facility, 4500 12th Street Extension, West Columbia SC 29172, NDC: 69374-529-50	Class II	Drugs	Lots: HH2002A, Exp. 7/7/2022; HH2004A, Exp. 8/28/2022; HH2005A, Exp. 8/11/2022; HH2007A, Exp. 9/2/2022; HH2009A, Exp. 9/10/2022; HH2011A, Exp. 10/17/2022	Lack of Assurance of Sterility	Nephron Sterile Compounding Center LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
HYDROmorphone HCl Injection, USP, 6 mg/30 mL (0.2 mg/mL) syringes, 5 x 30 mL Pre-Filled Syringes per carton, 6 x 5 Syringe Carton per case, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-529-30	Class II	Drugs	Lots: HH2003A, Exp. 7/26/2022; HH2006A, Exp. 8/22/2022	Lack of Assurance of Sterility	Nephron Sterile Compounding Center LLC
HYDROmorphone HCl Injection, USP 30 mg/30 mL (1 mg/mL) syringe, 5 x 30 mL Pre-Filled Syringes per carton, 6 x 5 Syringe Carton per case, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-559-30	Class II	Drugs	Lots: HN2001A, Exp. 7/23/2022; HN2003A, Exp. 8/19/2022; HN2004A, Exp. 9/9/2022	Lack of Assurance of Sterility	Nephron Sterile Compounding Center LLC
HYDROmorphone HCl Injection, USP, 50 mg/50 mL (1 mg/mL) syringes, packaged in 5 x 50 mL Pre-Filled Syringes per carton, 6 x 5 Syringe Carton per case, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-559-50	Class II	Drugs	Lot: HN2002A, Exp. 7/26/2022	Lack of Assurance of Sterility	Nephron Sterile Compounding Center LLC
Ketamine HCl Injection, USP, 50 mg/5 mL (10 mg/mL*) syringes, packaged in 5 x 5 mL Pre-Filled Syringes per carton, 6 x 5 Syringe Carton per case, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-982-55	Class II	Drugs	Lots: KH2006A, Exp. 7/20/2022; KH2006B, Exp. 7/20/2022; KH2012B, Exp. 8/23/2022	Lack of Assurance of Sterility	Nephron Sterile Compounding Center LLC
Ketamine HCl Injection, USP 30 mg/3 mL (10 mg/mL*) syringes, packaged in 5 x 3 mL Pre-	Class II	Drugs	Lots: KH2002A, Exp. 7/5/2022	Lack of Assurance of Sterility	Nephron Sterile

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Filled Syringes per carton, 6 x 5 Syringe Carton per case, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-982-33					Compounding Center LLC
Ketamine HCl Injection, USP, 50 mg/1 mL (50 mg/mL*) syringe, packaged in 5 x 1 mL Pre-Filled Syringes per carton, 6 x 5 Syringe Carton per case, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-511-01	Class II	Drugs	Lots: KH2009A, Exp. 8/16/2022; KH2011A, Exp. 8/24/2022; KH2013A, Exp. 8/28/2022; KH2014A, Exp. 9/9/2022; KH2018A, Exp. 10/7/2022; KH2020A, Exp. 10/18/2022	Lack of Assurance of Sterility	Nephron Sterile Compounding Center LLC
Labetalol HCl Injection, USP, 20 mg/4 mL (5 mg/mL) syringe, packaged in 5 x 4 mL Pre-Filled Syringes per carton, 6 x 5 Syringe Carton per case, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-946-04	Class II	Drugs	Lots: LB2002A, Exp. 7/12/2022; LB2004A, Exp. 8/21/2022; LB2006A, Exp. 9/3/2022; LB2008A, Exp. 10/6/2022	Lack of Assurance of Sterility	Nephron Sterile Compounding Center LLC
Lidocaine HCl Injection, USP 2%, 100 mg/5 mL (20 mg/mL) syringe, packaged in 5 x 5 mL Pre-Filled Syringes per carton, 6 x 5 Syringe Carton per case, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-949-05	Class II	Drugs	Lots: LI2007A, Exp. 9/24/2022	Lack of Assurance of Sterility	Nephron Sterile Compounding Center LLC
Lidocaine HCl Injection, USP 1%, 50 mg/5 mL (10 mg/mL) syringe, packaged in 5 x 5 mL Pre-Filled Syringes per carton, 6 x 5 Syringe Carton per case, Rx Only, Nephron 503B	Class II	Drugs	Lots: LI2004A, Exp. 8/6/2022; LI2005A, Exp. 8/31/2022; LI2006A, Exp.	Lack of Assurance of Sterility	Nephron Sterile Compounding Center LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-985-05			9.21.2022; LI2008A, Exp. 10/11/2022		
Morphine Sulfate Injection, USP, 50 mg/50 mL (1 mg/mL) syringe, packaged in 5 x 50 mL Pre-Filled Syringes per carton, 6 x 5 Syringe Carton per case, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-979-50	Class II	Drugs	Lots: MS2002A, Exp. 7/2/2022; MS2003A, Exp. 7/30/2022; MS2005A, Exp. 7/31/2022; MS2008A, Exp. 8/23/2022; MS2013A, Exp. 9/9/2022; MS2015A, Exp. 9/26/2022; MS2019A, Exp. 10/14/2022	Lack of Assurance of Sterility	Nephron Sterile Compounding Center LLC
Morphine Sulfate Injection, USP, 30 mg/30 mL (1 mg/mL) syringe, packaged in 5 x 30 mL Pre-Filled Syringes per carton, 6 x 5 Syringe Carton per case, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-979-30	Class II	Drugs	Lots: MS2004A, Exp. 7/30/2022; MS2007A, Exp. 8/23/2022; MS2012A, Exp. 9/6/2022; MS2014A, Exp. 9/10/2022; MS2016A, Exp. 9/29/2022; MS2018A, Exp. 10/12/2022	Lack of Assurance of Sterility	Nephron Sterile Compounding Center LLC
Morphine Sulfate Injection, USP, 2 mg/2 mL (1 mg/mL) syringe, packaged in 5 x 2 mL Pre-Filled Syringes per carton, 6 x 5 Syringe Carton per case, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-979-02	Class II	Drugs	Lots: MS2001A, Exp. 7/2/2022; MS2006A, Exp. 8/9/2022; MS2009A, Exp. 8/25/2022; MS2011A, Exp. 9/3/2022; MS2017A, Exp. 10/2/2022	Lack of Assurance of Sterility	Nephron Sterile Compounding Center LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Morphine Sulfate Injection, USP, 1 mg/mL syringe, packaged in 5 x 1 mL Pre-Filled Syringes per carton, 6 x 5 Syringe Carton per case, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-979-01	Class II	Drugs	Lot: MS2010A, Exp. 8/26/2022	Lack of Assurance of Sterility	Nephron Sterile Compounding Center LLC
del Nido Cardioplegia Solution 1000 mL (1000 mL) Single-Dose Container IV bag, 4 x 1 IV Bag per case, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-984-10	Class II	Drugs	Lots: NC2031A, Exp. 7/7/2022; NC2033A, Exp. 7/12/2022; NC2034A, Exp. 7/18/2022; NC2035A, Exp. 7/19/2022	Lack of Assurance of Sterility	Nephron Sterile Compounding Center LLC
Neostigmine Methylsulfate Injection, USP, 3 mg/3 mL (1 mg/mL) syringe, packaged in 5 x 3 mL Pre-Filled Syringes per carton, 6 x 5 Syringe Carton per case, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-932-03	Class II	Drugs	Lots: NE2002A, Exp. 7/14/2022; NE2003A, Exp. 7/24/2022; NE2006A, Exp. 8/1/2022; NE2007A, Exp. 8/9/2022; NE2008A, Exp. 8/18/2022; NE2009A, Exp. 8/27/2022; NE2012D, Exp. 10/3/2022	Lack of Assurance of Sterility	Nephron Sterile Compounding Center LLC
Neostigmine Methylsulfate Injection, USP, 4 mg/4 mL (1 mg/mL) syringe, packaged in 5 x 4 mL Pre-Filled Syringes per carton, 6 x 5 Syringe Carton per case, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-942-04	Class II	Drugs	Lots: NE2004A, Exp. 7/26/2022; NE2010A, Exp. 9/5/2022; NE2013A, Exp. 10/20/2022	Lack of Assurance of Sterility	Nephron Sterile Compounding Center LLC
Neostigmine Methylsulfate Injection, USP, 5 mg/5 mL (1 mg/mL) syringe, packaged in 5 x 5 mL Pre-Filled Syringes per carton, 6 x 5	Class II	Drugs	Lots: NE2005A, Exp. 7/23/2022; NE2012A, Exp. 10/3/2022; NE2012B, Exp.	Lack of Assurance of Sterility	Nephron Sterile

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Syringe Carton per case, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-902-05			10/3/2022; NE2012C, Exp. 10/3/2022		Compounding Center LLC
Oxytocin 30 Units/500 mL (0.06 Units/mL) in 0.9% Sodium Chloride Injection, USP IV bag, packaged in 10 x 1 IV Bag per case, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-543-50	Class II	Drugs	Lots: OX2013C, Exp. 7/9/2022; OX2013E, Exp. 7/9/2022	Lack of Assurance of Sterility	Nephron Sterile Compounding Center LLC
Phenylephrine HCl Injection, USP, 0.4 mg/10 mL (40 mcg/mL) syringe, packaged in 5 x 10 mL Pre-Filled Syringes per carton, 6 x 5 Syringe Carton per case, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-955-10	Class II	Drugs	Lots: PE2001A, Exp. 7/1/2022; PE2003A, Exp. 7/12/2022; PE2013A, Exp. 8/29/2022; PE2014A, Exp. 10/5/2022	Lack of Assurance of Sterility	Nephron Sterile Compounding Center LLC
Phenylephrine HCl Injection, USP, 0.8 mg/10 mL (80 mcg/mL) syringe, packaged in 5 x 10 mL Pre-Filled Syringes per carton, 6 x 5 Syringe Carton per case, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-956-10	Class II	Drugs	Lots: PE2018A, Exp. 10/3/2022	Lack of Assurance of Sterility	Nephron Sterile Compounding Center LLC
Phenylephrine HCl Injection, USP, 1 mg/10 mL (100 mcg/mL) syringe, packaged in 5 x 10 mL Pre-Filled Syringes per carton, 6 x 5 Syringe Carton per case, Rx Only, Nephron 503B outsourcing facility, 4500 12th St.	Class II	Drugs	Lots: PE2004A, Exp. 7/11/2022; PE2008A, Exp. 7/22/2022; PE2008B, Exp. 7/22/2022; PE2008C, Exp. 7/22/2022; PE2009A, Exp. 8/5/2022; PE2009B, Exp.	Lack of Assurance of Sterility	Nephron Sterile Compounding Center LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Extension, West Columbia, SC 29172, NDC: 69374-957-10			8/5/2022; PE2009C, Exp. 8/5/2022; PE2011B, Exp. 8/22/2022; PE2017C, Exp. 9/14/2022; PE2019B, Exp. 4/11/2023; PE2019C, Exp. 4/11/2023		
Rocuronium Bromide Injection, 50 mg/5 mL (10 mg/mL) syringe, packaged in 5 x 5 mL Pre-Filled Syringes per carton, 6 x 5 Syringe Carton per case, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-924-05	Class II	Drugs	Lot: RC2003B, Exp. 8/28/2022	Lack of Assurance of Sterility	Nephron Sterile Compounding Center LLC
Ropivacaine HCl 123 mg (2.46 mg/mL), Clonidine HCl 0.04 mg (0.0008 mg/mL), Ketorolac Tromethamine 15 mg (0.3 mg/mL) Injection, 50 mL syringe, packaged in 5 x 50 mL Pre-Filled Syringes per carton, 6 x 5 Syringe Carton per case, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-515-50	Class II	Drugs	Lots: RP2003A, Exp. 7/20/2022; RP2003B, Exp. 7/20/2022	Lack of Assurance of Sterility	Nephron Sterile Compounding Center LLC
8.4% Sodium Bicarbonate Injection, USP, 4.2 g/50 mL (84 mg/mL) 1 mEq/mL syringe, packaged in 1 x 50 mL Pre-Filled Syringe per carton, 30 x 1 syringe carton per case, Rx Only Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-214-50	Class II	Drugs	Lots: SB2001B, Exp. 1/2/2023; SB2001C, Exp. 1/2/2023; SB2003A, Exp. 2/14/2023; SB2003B, Exp. 2/14/2023; SB2003C, Exp. 2/14/2023; SB2004A, Exp. 3/1/2023; SB2004B, Exp. 3/1/2023; SB2004C, Exp.	Lack of Assurance of Sterility	Nephron Sterile Compounding Center LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			3/1/2023; SB2005A, Exp. 3/8/2023; SB2007A, Exp. 3/22/2023; SB2007B, Exp. 3/22/2023; SB2008A, Exp. 3/29/2023; SB2008B, Exp. 3/29/2023; SB2009A, Exp. 4/5/2023; SB2009B, Exp. 4/5/2023		
Anticoagulant Sodium Citrate Solution, USP 4%, 200 mg/5 mL (40 mg/mL) syringe, packaged in 5 x 5 mL Pre-Filled Syringes per carton, 6 x 5 Syringe Carton per case, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-906-05	Class II	Drugs	Lots: SC2002A, Exp. 7/9/2022; SC2004A, Exp. 7/17/2022; SC2005A, Exp. 8/2/2022; SC2006A, Exp. 8/16/2022; SC2007A, Exp. 8/27/2022; SC2008A, Exp. 9/7/2022; SC2009A, Exp. 9/14/2022; SC2010A, Exp. 9/20/2022; SC2011A, Exp. 10/10/2022	Lack of Assurance of Sterility	Nephron Sterile Compounding Center LLC
Succinylcholine Chloride Injection, USP, 200 mg/10 mL (20 mg/mL) syringe, packaged in 5 x 10 mL Pre-Filled Syringes per carton, 6 x 5 Syringe Carton per case, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-919-10	Class II	Drugs	Lot: SU2014A, Exp. 7/2/2022	Lack of Assurance of Sterility	Nephron Sterile Compounding Center LLC
Hydrogen Peroxide Topical Solution USP, 3%, 16 FL OZ (1 PT) 473 mL bottle, packaged as a) Signature Care NDC 21130-871-43 UPC 3 21130-78060 1 Distributed By Better Living Brands LLC P.O. Box 99, Pleasanton, CA	Class II	Drugs	Lots: 0555123 Exp. 11/2023 ; 0556347 Exp. 01/2024 ; 0559888 Exp. 03/2024 ; 0546090 Exp. 09/2023 ; 0546364 Exp.	Cross Contamination With Other Products: Product is cross contaminated with low levels of isopropyl alcohol.	Vi-Jon, LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
<p>94566-0009; b) Solimo UPC 8 42379 14781 4 Distributed By: Amazon.com Services, Inc. Seattle, WA 98109; c) QC Quality Choice UPC 6 35515 99466 9 Distributed by C.D.M.A., Inc. 43157 W 9 Mile Rd, Novi, MI; d) CVS Health UPC 0 50428 37591 4 Distributed by: CVS Pharmacy, Inc. One CVS Drive, Woonsocket, RI 02895; e) Careone UPC 3 41520 31311 0 Distributed By: Foodhold U.S.A., LLC Landover, MD 20785; f) Market Basket UPC 0 49705 75280 7 Distributed By Demoulas Super Markets, Inc. 875 East Street, Tewksbury, MA 01876; g) Rexall UPC 0 72785 13848 3 Distributed By Old East Main Co. 100 Mission Ridge, Goodlettsville, TN 37072; h) HEB UPC 9 41220 25111 7 Distributed By: HEB San Antonio, TX 78204; i) Core Values UPC 0 79068 00707 8 Distributed by Liberty Procurement Co., Inc. Union, NJ 07083; j) Swan NDC 0869-0871-43 UPC 3 08694 70610 0 Distributed by Vi-Jon One Swan Drive, Smyrna, TN 37167; k) Cariba Care UPC 6 46702 05602 2 Distributed by: Cariba International P.O. Box 1208. Safety Harbor, Florida 34695; l) Kroger UPC 0 11110 79460 4 Distributed By The Kroger Co., Cincinnati, Ohio 45202; m) CVP Health UPC 7 61706 16314 6 Distributed By Salado Sales, Inc. Temple, TX 76503; n) Medline NDC 53329-981-06 UPC 0 80196</p>			<p>08/2023 ; 0554099 Exp. 11/2023 ; 0535281 Exp. 05/2023 ; 0538263 Exp. 07/2023 ; 0542015 Exp. 07/2023 ; 0550161 Exp. 10/2023 ; 0550164 Exp. 11/2023 ; 0556345 Exp. 01/2024 ; 0557214 Exp. 12/2023 ; 0557366 Exp. 01/2024 ; 0568635 Exp. 05/2024 ; 0556328 Exp. 11/2023 ; 0557465 Exp. 03/2024 ; 0566639 Exp. 03/2024 ; 0566835 Exp. 03/2024 ; 0538261 Exp. 06/2023 ; 0538264 Exp. 07/2023 ; 0541465 Exp. 07/2023 ; 0556809 Exp. 11/2023 ; 0566640 Exp. 03/2024 ; 0556351 Exp. 01/2024 ; 0563077 Exp. 02/2024 ; 0564653 Exp. 03/2024 ; 0565511 Exp. 04/2024 ; 0566646 Exp. 03/2024 ; 0532595 Exp. 04/2023</p>		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
<p>74870 2 Made in US with US and foreign components for Medline Industries, Inc., Northfield, IL 60093; o) Exchange Select UPC 6 14299 39968 6 Manufactured For Your Military Exchanges By: Vi-Jon 8515 Page Avenue, St. Louis, MO 63114; p) Premier Value UPC 8 40986 01021 7 Distributed by: Pharmacy Value Alliance LLC 407 East Lancaster Avenue Wayne, PA 19087; q) Publix UPC 0 41415 00973 8 Distributed By Publix Super Markets, Inc. 3300 Publix Corporate Parkway Lakeland, FL 33811; r) Being Well UPC 0 51933 13950 3 Distributed By: Moran Foods, LLC St. Ann, MO 63074; s) Medicare NPN 80016265 UPC 8 39748 00017 7 Manufactured by/Fabrique par: Vi-Jon Inc., Smyrna, TN 37167; t) Swan NPN 80035214 UPC 0 72785 11239 1 Manufactured By: Vi-Jon, Inc. St. Louis, MO 63114; u) Equate NPN 80036214 UPC 6 28915 16613 3 Manufactured By: Vi-Jon, Inc. St. Louis, MO 63114; v) Iris UPC 61504-871-43 UPC 0 41512 12940 7 Distributed By: Amerifoods Trading Co. P.O. Box 512377, Los Angeles, CA 90051-0377; w) Equaline NDC 41163-871-43 UPC 0 41163 25134 2 Distributed by Supervalu Inc. Eden Prairie, MN 55344 USA; x) TopCare health UPC 0 36800 26711 4 Distributed By TopCo Associates LLC Elk Grove Village, IL 60007; y)</p>					

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Best Choice UPC 0 70038 20055 0 Distributed By: Valu Merchandisers, Co. 6000 Kansas Ave. Kansas City, KS 66106; z) Walgreens NDC 0363-0871-43 UPC 3 11917 20771 1 Distributed By: Walgreen Co. 200 Wilmot Rd., Deerfield, IL 60015; aa) Equate NDC 49035-871-43 UPC 6 81131 11871 2 Distributed By: Walmart, Inc., Bentonville, AR 72716					
Aripiprazole Tablets, USP 20 mg, packaged in a) 1,000-count bottle (NDC 60505-2676-8, UPC 3 60505 26768 2), b) 30-count bottle (NDC 60505-2676-3, UPC 3 60505 26763 7), Rx only, Manufactured by: Apotex, Inc. Toronto, Ontario Canada M9L 1T9 Manufactured for: Apotex Corp. Weston, Florida 33326	Class II	Drugs	Lots: a) TD9591 Exp. 04/2023; b) TD9592 Exp. 04/2023	Failed dissolution specifications: OOS for dissolution at the 12- month stability time point.	Apotex Corp.
Difluprednate Ophthalmic Emulsion, 0.05%, 5ml bottles, Rx only, Mfd. by: Cipla Ltd., India At M/S Indoco Remedies Limited., L- 32, 33, 34, Verna Industrial area, Verna - Goa, 403722, India; Mfd. for: Cipla USA, Inc., 10 Independence Boulevard, Suite 300, Warren, NJ 07059, NDC 69097-341-35.	Class II	Drugs	Batch# DEG4LC2, exp. date 05/2023	Lack of Assurance of Sterility: customer complaint for defective container where breakage of the protective cap exposes tip of eye drop which could compromise sterility.	CIPLA
Olopatadine HCl, Ophthalmic Solution, USP, 0.2%, 2.5 mL per dropper bottle, Rx Only, Manufactured by: Akorn, Inc., Lake Forest, IL 60045, NDC 17478-305-12	Class III	Drugs	Lot#: 1D90A, 1D92A, Exp 3/2023; 1E30A, Exp 4/2023	Failed impurity/degradation specifications: Out of specification for 2-HMP (a product leachable) measured in retention samples	Akorn, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Mometasone Furoate, Topical Solution USP, 0.1 % Lotion, a) 30 ml-bottle (NDC 68462-385-37), b) 60 ml-bottle (NDC 68462-385-02), Rx only, Manufactured by: Glenmark Pharmaceuticals Limited, Baddi Himachal Pradesh 173205, Manufactured for: Glenmark Pharmaceuticals Inc., USA Mahwah NJ 07430.	Class III	Drugs	Lot # a) 05201358, Exp 06/2022; 05210287, 05210288, Exp 01/2023; 05211446, Exp 07/2023; 05211704, 05211714, Exp 08/2023; 05212217, Exp 10/2023: b) 05201358, Exp 06/2022; 05210287, 05210288, 05210424, Exp 01/2023; 05210425, 05210435, Exp 02/2023; 05211427, 05211439, 05211445, Exp 07/2023; 05211723, 05211731, 05211850, 05211864, Exp 08/2023; 05212226, 05212250, 05212261, Exp 10/2023.	Defective Container	Glenmark Pharmaceutic als Inc., USA
Aspirin and Extended-Release Dipyridamole Capsules, 25mg/200 mg, 60-count bottle, Rx Only, Manufactured for: Glenmark Pharmaceuticals Inc., USA, Mahwah, NJ 07430, Product of India, NDC 68462-405-60.	Class III	Drugs	Lot#: 17201639, Exp 08/2022; 17201759, Exp 09/2022; 17202067, Exp 10/2022; 17210696, Exp 02/2023; 17210092, Exp 11/2022; 17210145, Exp 12/2022; 17210732, Exp 02/2023; 17211062, Exp 04/2023; 17211441, Exp 05/2023; 17211670, Exp 06/2023; 17211810, Exp 07/2023; 17211862,	Failed Tablet/Capsule Specification : Capsule breakage	Glenmark Pharmaceutic als Inc., USA



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			17212020, 17212068, Exp 08/2023; 17212438, Exp 10/2023; 17220172, 17220251, Exp 12/2023.		

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

FDA DRUG SAFETY COMMUNICATIONS

[6/30/2022] FDA warns about possible increased risk of death and serious side effects with cancer drug Copiktra (duvelisib)

Consider risks and benefits of continued use versus other treatments

The U.S. Food and Drug Administration (FDA) is warning that results from a clinical trial show a possible increased risk of death with Copiktra (duvelisib) compared to another medicine to treat a chronic blood cancer called leukemia and a lymphoma, a cancer found in the lymph nodes. The trial also found Copiktra was associated with a higher risk of serious side effects, including infections, diarrhea, inflammation of the intestines and lungs, skin reactions, and high liver enzyme levels in the blood.

We are notifying the public of these risks and are continuing to evaluate the safety of Copiktra. We plan to hold a future public meeting to discuss the findings from the clinical trial and whether Copiktra should continue to be prescribed for patients. We will update the public when we have more information.

Copiktra was approved in 2018 to treat adults with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) who have received at least two prior therapies that did not work or stopped working. CLL is a type of cancer that begins in the white blood cells, and SLL is a type of cancer that begins mostly in the lymph nodes. With the approval in 2018, the information on survival or risk of death was limited, and the FDA required longer follow-up from the clinical trial to gain more information. Copiktra works by blocking key signals that cause cancer cells to multiply, which may help reduce or stop the growth of certain types of cancer. Copiktra is in a class of medicines called PI3 kinase inhibitors and available as a capsule that is swallowed.

Health care professionals should consider the risks and benefits of continuing Copiktra in the context of other available treatments. Advise patients receiving Copiktra of the possible increased risk of death and higher risk of serious adverse events.

Patients should talk to your health care professional about the risks and benefits of receiving Copiktra for you. Discuss any questions or concerns you may have, including about possible alternative treatments.

To help FDA track safety issues with medicines, we urge patients and health care professionals to report side effects involving Copiktra or other medicines to the FDA MedWatch program, using the information in the “Contact FDA” box at the bottom of the page.

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

Amifostine Injection
Amino Acids
Amoxapine Tablets
Amphetamine Oral Suspension, Extended Release
Atropine Sulfate Injection
Azacitidine for Injection
Azithromycin (Azasite) Ophthalmic Solution 1%
Bacteriostatic 0.9% Sodium Chloride Injection
Bacteriostatic Water for Injection
Belatacept (Nulojix) Lyophilized Powder for Injection
Bumetanide Injection
Bupivacaine Hydrochloride and Epinephrine Injection
Bupivacaine Hydrochloride Injection
Calcium Disodium Versenate Injection
Calcium Gluconate Injection
Cefazolin Injection
Cefixime Oral Capsules
Cefotaxime Sodium Injection
Cefotetan Disodium Injection
Chlordiazepoxide Hydrochloride Capsules
Chloroprocaine Hydrochloride Injection
Conivaptan Hydrochloride (Vaprisol) in 5% Dextrose Plastic Container
Continuous Renal Replacement Therapy (CRRT) Solutions
Cortisone Acetate Tablets
Cyclopentolate Ophthalmic Solution
Cytarabine Injection
Dacarbazine Injection
Desmopressin Acetate Nasal Spray
Dexamethasone Sodium Phosphate Injection
Dexmedetomidine Injection
Dextrose 10% Injection
Dextrose 25% Injection
Dextrose 5% Injection
Dextrose 50% Injection
Diazepam Rectal Gel
Diflunisal Tablets
Digoxin Injection
Diltiazem Hydrochloride Injection



Disopyramide Phosphate (Norpace) Capsules
Dobutamine Hydrochloride Injection
Dopamine Hydrochloride Injection
Echthiophate Iodide (Phospholine Iodide) Ophthalmic Solution
Enalaprilat Injection
Epinephrine Injection, 0.1 mg/mL
Epinephrine Injection, Auto-Injector
Erythromycin Ophthalmic Ointment
Fentanyl Citrate (Sublimaze) Injection
Floxadine for Injection
Fludarabine Phosphate Injection
Fluorescein Injection
Fluvoxamine ER Capsules
Furosemide Injection
Gentamicin Sulfate Injection
Guanfacine Hydrochloride Tablets
Heparin Sodium and Sodium Chloride 0.9% Injection
Hydromorphone Hydrochloride Injection
Hydroxypropyl (Lacrisert) Cellulose Ophthalmic Insert
Ibutilide Fumarate Injection
Iodixanol Injection
Iohexol Injection
Iopromide injection
Iopromide (Ultravist) Injection
Isoniazid Injection
Ketamine Injection
Ketoprofen Capsules
Ketorolac Tromethamine Injection
Leucovorin Calcium Lyophilized Powder for Injection
Leuprolide Acetate Injection
Lidocaine Hydrochloride (Xylocaine) and Dextrose Injection Solution-Premix Bags
Lidocaine Hydrochloride (Xylocaine) Injection
Lidocaine Hydrochloride (Xylocaine) Injection with Epinephrine
Lipid Injection
Lithium Oral Solution
Lorazepam Injection
Lutetium Lu 177 Dotatate (LUTATHERA) Injection
Mannitol Injection
Mepivacaine Hydrochloride Injection
Methyldopa Tablets
Methylprednisolone Acetate Injection
Metronidazole Injection
Midazolam Injection
Morphine Sulfate Injection
Multi-Vitamin Infusion (Adult and Pediatric)
Nizatidine Capsules



Paclitaxel Injection (protein-bound particles)
Pantoprazole Sodium for Injection
Parathyroid Hormone (Natpara) Injection
Pentostatin Injection
Physostigmine Salicylate Injection
Potassium Acetate Injection
Potassium Chloride Concentrate Injection
Promethazine (Phenergan) Injection
Propofol Injectable Emulsion
Protamine Sulfate Injection
Remifentanil Injection
Rifampin Capsules
Rifampin Injection
Rifapentine Tablets
Ropivacaine Hydrochloride Injection
Semaglutide (WEGOVY®) Injection
Sincalide (Kinevac) Lyophilized Powder for Injection
Sodium Acetate Injection
Sodium Bicarbonate Injection
Sodium Chloride 0.9% Injection Bags
Sodium Chloride 14.6% Injection
Sodium Chloride 23.4% Injection
Sodium Chloride Injection USP, 0.9% Vials and Syringes
Sodium Phosphates Injection
Sterile Water for Injection
Streptozocin (Zanosar) Sterile Powder
Streptozocin Powder for Injection
Sufentanil Citrate Injection
Sulfasalazine Tablets
Technetium TC-99M Mebrofenin Injection
Technetium Tc99m Succimer Injection (DMSA)
Teprotumumab-trbw
Thiothixene Capsules
Triamcinolone Acetonide Injectable Suspension
Triamcinolone Hexacetonide Injectable suspension
Trimethobenzamide Hydrochloride Capsules
Valproate Sodium Injection
Vandetanib Tablets
Vecuronium Bromide for Injection