PERFORMRx℠

Drug Information Update

May 2023

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NEWLY AVAILABLE GENERICS

Generic Name/ Dosage Form	Brand Name	Manufacturer	Indication
Ephedrine sulfate 25 mg/5 mL IV syringe	Akovaz	Exela Pharma Sciences	Treatment of clinically important hypotension occurring in the setting of anesthesia
Ephedrine sulfate 25 mg/5 mL IV syringe	Emerphed	Nexus Pharmaceuticals	Treatment of clinically important hypotension occurring in the setting of anesthesia
Gefitinib 250 mg oral tablet	Iressa	AstraZeneca	First-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test
Methsuximide 300 mg oral capsule	Celontin	Parke-Davis/Pfizer	For the control of absence (petit mal) seizures that are refractory to other drugs
Nitisonone 20 mg oral capsule	Orfadin	Swedish Orphan Biovitrum AB	Treatment of adult and pediatric patients with hereditary tyrosinemia type 1 (HT-1) in combination with dietary restriction of tyrosine and phenylalanine

NEW DRUG ENTITIES/STRENGTHS/COMBINATIONS

Drug Name	Generic Name	Description	Comments
Qalsody 100 mg/15 mL (6.7 mg/mL) intrathecal solution	tofersen	Injection for the treatment of amyotrophic lateral sclerosis (ALS) in adults who have a mutation in the superoxide dismutase 1 (SOD1) gene. This indication is approved under accelerated approval based on reduction in plasma neurofilament light chain (NfL) observed in patients treated with Qalsody. This is the is the first approved treatment to target a genetic cause of ALS. Maintenance dosing costs $14,230 per month.	New Entity
Trikafta 80 mg-40 mg-60 mg (day)/59.5 mg (night), 100 mg-50 mg-75 mg (day)/75 mg (night) oral granules	elexacaftor/tezacaftor/ ivacaftor	New dosage form. Updated indication for patients 2 years and older with cystic fibrosis (previously indicated in 6 years and older)	New Dosage Form
Gralise 450 mg, 750 mg, 900 mg ER tablets	gabapentin	New strength of gabapentin. Already supplied in 300 mg and 600 mg oral tablets.	New Strength
Lupron Depot-Ped 45 mg IM syringe kit	leuprolide acetate	Gonadotropin releasing hormone (GnRH) agonist indicated for the treatment of pediatric patients with central precocious puberty.	New Kit
Vowst oral capsule	fecal microbio spore,live-brpk	First fecal microbiota product that is taken orally. Indicated to prevent the recurrence of Clostridioides difficile infection (CDI) in individuals 18 years of age. Cost is $17,500 per treatment course (4 capsules once daily for 3 consecutive days).	New Entity
Abilify Asimtufii 720 mg/2.4 ml, 960 mg/3.2 mL IM syringe	aripiprazole	Extended-release injectable suspension for intramuscular use. Dosed once every two months for the treatment of schizophrenia in adults or for maintenance monotherapy treatment of bipolar I disorder in adults.	New Strength

Drug Name	Generic Name	Description	Comments
Lumryz 4.5 g, 6 g, 7.5 g, 9 g ER oral granules	sodium oxybate	Central nervous system depressant indicated for the treatment of cataplexy or excessive daytime sleepiness (EDS) in adults with narcolepsy. First sodium oxybate medication approved for once-at-bedtime dosing. Will compete with Xyrem and Xywav. Received tentative FDA approval in July 2022 but just granted full approval in May 2023.	New Strength and Dosage Form
Kalydeco 13.4 mg oral granules	ivacaftor	New strength due to expanded age indication. Can now be used in patients 1 month and older (previously indicated in patients 4 months and older).	New Strength
zolpidem 7.5 mg capsule	zolpidem tartrate	Unique strength and dosage form (capsule) of already existing multi-source generic product.	New Strength and Dosage Form
Uzedy 50 mg/0.14 ml, 75 mg/0.21 ml, 100 mg/0.28 ml, 150 mg/0.42 ml, 200 mg/0.56 ml, 250 mg/0.7 mL SQ syringe	risperidone	Extended-release injectable suspension for the treatment of schizophrenia in adults. 505(b)(2) approval, can be dosed monthly or every 2 months.	New Strength
Prevduo 0.6 mg-3 mg/3 mL IV syringe	glycopyrrolate/neostigmine	505(b)(2) approval. Product indicated for the reversal of the effects of nondepolarizing neuromuscular blocking agents (NMBAs) after surgery, while decreasing the peripheral muscarinic effects (e.g., bradycardia and excessive secretions) associated with cholinesterase inhibition following NMBA reversal administration.	New Combination
Udenyca Autoinjector 6 mg/0.6 mL SQ auto-injector	pegfilgrastim-cbqv	New autoinjector formulation.	New Dosage Form
Sogroya 5 mg/1.5 ml, 10 mg/1.5 ml, 15 mg/1.5 mL SQ pen injector	somapacitan-beco	Human growth hormone analog indicated for treatment of pediatric patients aged 2.5 years and older who have growth failure due to inadequate secretion of endogenous growth hormone. Also	New Entity

Drug Name	Generic Name	Description	Comments
		indicated as replacement of endogenous growth hormone in adults with growth hormone deficiency. Provides once weekly dosing.	
Liqrev 10 mg/mL oral suspension	sildenafil citrate	Oral liquid formulation of sildenafil for pulmonary arterial hypertension treatment.	New Dosage Form
Veozah 45 mg oral tablet	fezolinetant	An oral, nonhormonal treatment for moderate to severe vasomotor symptoms (VMS) due to menopause. A small-molecule neurokinin 3 (NK3) receptor antagonist and modulates neuronal activity in the thermoregulatory center of the brain to mimic the effects of estrogen.	New Entity
Amjevita (CF) 10 mg/0.2 mL SQ syringe	adalimumab-atto	New strength of Humira biosimilar.	New Strength
Tafinlar 10 mg tablet for oral suspension	dabrafenib mesylate	Oral suspension for the treatment of pediatric patients 1 year of age and older with low-grade glioma with a BRAF V600E mutation who require systemic therapy.	New Strength and Dosage Form
Mekinist 0.05 mg/mL oral solution	trametinib dimethyl sulfoxide	Oral solution for the treatment of pediatric patients 1 year of age and older with low-grade glioma with a BRAF V600E mutation who require systemic therapy.	New Strength and Dosage Form
Elfabrio 2 mg/mL IV solution	pegunigalsidase alfa-iwxj	A hydrolytic lysosomal neutral glycosphingolipid-specific enzyme indicated for the treatment of adults with Fabry Disease. Elfabrio is a "biobetter" of Fabrazyme and is a PEGylated enzyme replacement therapy and is designed to provide a long half-life. Demonstrated non-inferiority to Fabrazyme.	New Entity

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†
Trikafta	elexacaftor/tezacaftor/ivacaftor 50 mg-25 mg-37.5 mg (day)/75 mg (night), 100 mg-50 mg-75 mg (day)/150 mg (night) oral tablets; 80 mg-40 mg-60 mg (day)/59.5 mg (night), 100 mg-50 mg-75 mg (day)/75 mg (night) oral granules	Vertex Pharmaceuticals	Treatment of cystic fibrosis (CF) in patients aged ~~6 years~~ **2 years** and older who have at least one F508del mutation in the CFTR gene or a mutation in the CFTR gene that is responsive based on in vitro data
Prevnar 20	pneumococcal 20-valent conjugate vaccine 0.5ml syringe	Pfizer	• **Prevention of invasive disease caused by Streptococcus pneumoniae serotypes 1, 3, 4, 5, 6A, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F, and 33F in individuals 6 weeks of age and older** • **Prevention of otitis media caused by S. pneumoniae serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F in individuals 6 weeks through 5 years of age** • Prevention of pneumonia caused by S. pneumoniae serotypes 1, 3, 4, 5, 6A, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F, and 33F in individuals 18 years of age and older
Kalydeco	ivacaftor 150 mg oral tablets; 5.8 mg, 13.4 mg, 25 mg, 50 mg, 75 mg oral granules	Vertex Pharmaceuticals	Treatment of cystic fibrosis (CF) in patients age ~~**4 months**~~ **1 month** and older who have at least one mutation in the CFTR gene that is responsive to ivacaftor based on clinical and/or in vitro assay data
Farxiga	dapagliflozin 5 mg, 10 mg oral tablets	AztraZeneca	• To reduce the risk of sustained eGFR decline, end stage kidney disease, cardiovascular death, and hospitalization for heart failure in adults with chronic kidney disease at risk of progression

Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication†
			• ~~To reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure with reduced ejection fraction (NYHA class II-IV)~~ • **To reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visit in adults with heart failure** • To reduce the risk of hospitalization for heart failure in adults with type 2 diabetes mellitus and either established cardiovascular disease or multiple cardiovascular risk factors • As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus
Rexulti	brexpiprazole 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg, 4 mg oral tablets	Otsuka Pharmaceutical	• Adjunctive therapy to antidepressants for the treatment of major depressive disorder (MDD) in adults • Treatment of schizophrenia in adults and pediatric patients ages 13 years and older • **Treatment of agitation associated with dementia due to Alzheimer's disease Limitations of Use: Rexulti is not indicated as an as needed ("prn") treatment for agitation associated with dementia due to Alzheimer's disease**
Breo Ellipta	fluticasone furoate/ vilanterol 50 mcg/25 mcg, 100 mcg/25 mcg, 200 mcg/25 mcg inhalation powder	GlaxoSmithKline	• Maintenance treatment of patients with chronic obstructive pulmonary disease • Maintenance treatment of asthma in patients aged **5 years** ~~18 years~~ and older
Caldolor	Ibuprofen 800 mg/8 ml IV vial; 800 mg/200 ml IV bag	Cumberland Pharmaceuticals	Indicated in adults and pediatric patients aged **3 months and older** ~~6 months and older~~ for the: • Management of mild to moderate pain and the management of moderate to severe pain as an adjunct to opioid analgesics • Reduction of fever
Rinvoq	upadacitinib 10 mg, 30 mg, 45 mg ER tablets	AbbVie	• Adults with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to one or more TNF blockers

Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication†
			• Adults with active psoriatic arthritis who have had an inadequate response or intolerance to one or more TNF blockers • Adults and pediatric patients 12 years of age and older with refractory, moderate to severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies are inadvisable • Adults with moderately to severely active ulcerative colitis who have had an inadequate response or intolerance to one or more TNF blockers • Adults with active ankylosing spondylitis who have had an inadequate response or intolerance to one or more TNF blockers • Adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation who have had an inadequate response or intolerance to TNF blocker therapy • **Adults with moderately to severely active Crohn's disease who have had an inadequate response or intolerance to one or more TNF blockers**

FDA DRUG SAFETY COMMUNICATIONS

[05/11/2023] FDA updating warnings to improve safe use of prescription stimulants used to treat ADHD and other conditions

To address continuing concerns of misuse, abuse, addiction, and overdose of prescription stimulants, the U.S. Food and Drug Administration (FDA) is requiring updates to the Boxed Warning and other information to ensure the prescribing information is made consistent across the entire class of these medicines. The current prescribing information for some prescription stimulants does not provide up to date warnings about the harms of misuse and abuse, and particularly that most individuals who misuse prescription stimulants get their drugs from other family members or peers. Further, individuals who are prescribed stimulants are often faced with requests to share their medication. Sharing these medicines with others can lead to development of substance use disorder and addiction in those with whom these drugs are shared.

Prescription stimulants can be an important treatment option for disorders for which they are indicated. However, even when prescribed to treat an indicated disorder, their use can lead to misuse or abuse. Misuse and abuse, also called nonmedical use, can include taking your own medicine differently than prescribed or using someone else's medicine. For this reason, sharing prescription stimulants with those for whom they are not prescribed is an important concern and a major contributor to nonmedical use and addiction. Misuse and abuse of prescription stimulants can result in overdose and death, and this risk is increased with higher doses or unapproved methods of taking the medicine such as snorting or injecting.

Patients should always take your prescription stimulant exactly as prescribed by your health care professional. Do not take more of the medicine or take it more often than prescribed. Never provide any of your prescription stimulant medicine to anyone else as it can have serious risks for those for whom it was not prescribed. Store your prescription stimulant medicines securely, out of sight and reach of children and in a location not accessible by others, including visitors to the home. Immediately dispose of unused or expired prescription stimulants properly or take them to a drug take-back site, location, or program. Talk to your health care professional if your use of prescription stimulants has resulted in problems with your health, relationships, responsibilities, or the law, or if you are struggling with misusing these or other medicines. Go to an emergency room or call 911 if you experience symptoms of stimulant overdose, including new tremors or change in existing tremors, seizures, restless or aggressive behavior, overactive reflexes, fast breathing, fast or irregular pulse rate, confusion, stomach cramps, or more serious symptoms such as heart attack or stroke. Talk to your health care professional if you have questions or concerns about risks of taking prescription stimulants.

Health care professionals should assess patient risk of misuse, abuse, and addiction before prescribing stimulant medicines. Counsel patients not to share their prescribed stimulant with anyone else. Educate patients and their families on these serious risks, proper storage of the medicine, and proper disposal of any unused medicine. Throughout treatment, regularly assess and monitor them for signs and symptoms of

nonmedical use, addiction, and potential diversion, which may be evidenced by more frequent renewal requests than warranted by the prescribed dosage.

RECALLS

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Pro Power Knight Plus capsule, 2550mg, 1-count blister card, Distributed by Beyond Health and youth Inc, Seattle, WA 98110, UPC 4 94922 90522 0.	Class I	Drugs	No lot number, Exp: 06/2026	Marketed without an Approved NDA/ANDA: FDA analysis found product to be tainted with undeclared sildenafil and tadalafil, ingredients found in FDA approved products for the treatment of male sexual enhancement, making this an unapproved drug.	Gadget Island, Inc
NUX Male Enhancement capsule, 1-count blister card, distributed by SX Power CO., Chicago, Il 60612, UPC 6 01577 51236 3.	Class I	Drugs	Lot#: RO 927996, Exp: 12/25/2024	Marketed without an Approved NDA/ANDA: FDA analysis found product to be tainted with undeclared sildenafil and tadalafil, ingredients found in FDA approved products for the treatment of male sexual enhancement, making this an unapproved drug.	Gadget Island, Inc
DYNAMITE SUPER capsule, 58,000 MG, 1-count blister card, Made in America, UPC 6 75799 37602 7.	Class I	Drugs	Lot/Item#: OMS760-B, Exp: 12/2025	Marketed without an Approved NDA/ANDA: FDA analysis found product to be tainted with undeclared sildenafil and tadalafil, ingredients found in FDA approved products for the treatment of male sexual enhancement, making this an unapproved drug.	Gadget Island, Inc

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Atovaquone Oral Suspension USP, 750 mg/5 mL, Packaged in 210 mL bottle, Manufactured for: Camber Pharmaceuticals, Inc., Piscataway, NJ 08854, Manufactured by: Hetero Labs Limited, Jeedimetla, Hyderabad - 500 055, India, NDC# 31722-629-21.	Class I	Drugs	Lot# E220182, Exp. 12/31/2023	Microbial Contamination of Non-Sterile Product: Objectionable organism, identified as Bacillus cereus, found in product during testing of repackaged product.	Camber Pharmaceuticals Inc.
Dianeal Low Calcium (2.5 mEq/L) Peritonial Dialysis Solution with 1.5% Dextrose, packaged in a) 5000 mL per Ambu-Flex II Container bag, Product Code L5B4826, NDC 0941-0409-07; and b) 6000 mL per Ambu-Flex II Container bag, Product Code L5B9770, NDC 0941-0409-01, Rx Only, Baxter Healthcare Corporation, Deerfield, IL 60015 USA.	Class II	Drugs	Lot #: a) Y406130, Exp 31-Oct-2024; b) Lots Y406314, Y406314A, Y406963, Y407199, Exp 31-Oct-2024	Lack of Assurance of Sterility: Potential presence of leaks originating from the Luer component.	Baxter Healthcare Corporation
Dianeal PD-2 Peritonial Dialysis Solution with 1.5% Dextrose, 3000 mL per Ambu-Flex II Container bag, Rx Only, Baxter Healthcare Corporation, Deerfield, IL 60015 USA. Product Code L5B5169, NDC 0941-0411-04.	Class II	Drugs	Lot Y405201, Exp 31-Oct-2024	Lack of Assurance of Sterility: Potential presence of leaks originating from the Luer component.	Baxter Healthcare Corporation
Atorvastatin Calcium Tablets, USP, 10 mg, 30-count bottles, Rx Only, Repackaged By: Northwind Pharmaceuticals, Indianapolis, IN 46203. NDC 51655-946-52	Class II	Drugs	Lot # F117192201, Exp. Date 4/30/2023	CGMP Deviations	Northwind Pharmaceuticals LLC
BusPIRone Hydrochloride Tablets USP, 7.5 mg, 30-count bottles, Rx Only, Repackaged By: NOrthwind Pharmaceuticals, Indianapolis, IN 46203. NDC 51655-511-52	Class II	Drugs	Lot#: F117312201, Exp. Date 06/30/2024	CGMP Deviations	Northwind Pharmaceuticals LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Doxazosin Tablets, USP, 4mg, 30-count bottles, Rx Only, Repackaged By: Northwind Pharmaceuticals, Indianapolis, IN 46203. NDC 51655-109-52	Class II	Drugs	Lot#: F107752201, Exp. Date 05/31/2024	CGMP Deviations	Northwind Pharmaceuticals LLC
Glimepiride Tablets, USP 2mg, packaged in a) 30-count bottles (NDC 51655-383-52), and b)90-count bottles (NDC 51655-383-26), Rx Only, Repackaged By: Northwind Pharmaceuticals, Indianapolis, IN 46203.	Class II	Drugs	a) Lot #: F106252201, Exp. Date 09/30/2024; F106252301, F106252303, Exp. Date 5/31/2025; F106252304, Exp. Date 07/31/2025 b) Lot #: F106252302, Exp. Date 07/31/2025	CGMP Deviations	Northwind Pharmaceuticals LLC
Glimepiride Tablets, USP 4mg, packaged in a) 30-count bottles (NDC 51655-120-52), and b) 90-count bottles (NDC 51655-120-26), Rx Only, Repackaged By: Northwind Pharmaceuticals, Indianapolis, IN 46203.	Class II	Drugs	a) Lot #: F105692201, Exp. Date 09/30/2024; F105692203, Exp. Date 02/28/2025 b) Lot #: F105692202, Exp. Date 02/28/2025	CGMP Deviations	Northwind Pharmaceuticals LLC
Tadalafil Tablets, USP 20 mg, packaged in a) 6-count bottles (NDC 51655-473-87), and b) 15-count bottles (NDC 51655-473-54), Rx Only, Repackaged By: Northwind Pharmaceuticals, Indianapolis, IN 46203.	Class II	Drugs	a) Lot #: F113892002, Exp. Date 08/31/2023; F113892201, Exp. Date 11/30/2023 b) Lot #: F113892001, Exp. Date 08/31/2023; F113892202, Exp. Date 11/30/2023; F113892203, Exp. Date 12/31/2023	CGMP Deviations	Northwind Pharmaceuticals LLC
Tadalafil Tablets, USP 5 mg, 30-count bottles, Rx Only, Repackaged By: Northwind	Class II	Drugs	Lot #: F114302001, Exp. Date 05/31/2023	CGMP Deviations	Northwind Pharmaceuticals LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Pharmaceuticals, Indianapolis, IN 46203. NDC 51655-487-52					
CBD Metered Dose Inhaler (CBD) 5 mg Dose, 1 Metered Dose Inhaler, 100 Metered Sprays, Wellness BioSciences Rx	Class II	Drugs	All lots	Marketed Without an Approved NDA/ANDA	Wellness BioSciences
Pantoprazole sodium for Injection 40 mg*/vial, Single-dose Vial, Rx only, For Intravenous Infusion Only, Mfd. for Methapharm, Inc. Coral Springs, FL, 33065, NDC 67850-150-10 (carton), NDC 67850-150-00 (vial).	Class II	Drugs	Lots: 220801; 220802; 220803 Exp. July 2024	CGMP Deviations; The impacted product and lot number was inadvertently placed into saleable inventory, which does not comply with approved procedures.	Methapharm Inc
Fyremadel (ganirelix acetate) injection, 250 mcg/0.5 mL, One Single Dose Sterile Prefilled Syringe 0.5 mL, For Subcutaneous Use, Rx Only, Sterile, Distributor: Ferring Pharmaceuticals Inc., Parsippany, NJ 07054, USA, NDC 55566-1010-1	Class II	Drugs	Lot #: HAD1190A, Exp. 02/2024	Presence of Particulate Matter: A piece of glass was found in a prefilled syringe.	Sun Pharmaceutical Industries Ltd.
Montelukast Sodium USP, 10 mg, 30 count-bottles, Rx only, Intas Pharm, Limited Ahmedabad 380 054 India Pkg By: PD-Rx Pharmaceuticals Incorporated Oklahoma City, OK 73127, NDC 43063-0762-30	Class II	Drugs	Lots: L22C80, I22D93, K21C72 Exp. 11/30/23; A23A90, B23A09 Exp. 07/31/24; K22C33 Exp. 05/31/24; G22E88, G22F66, I22E27, C22B27, D22B94, E22C71 Exp. 02/28/24; I21E36 Exp. 09/30/23	CGMP deviations.	PD-Rx Pharmaceuticals, Inc.
Simvastatin USP, 10 mg, Rx only, Intas Pharm, Limited Ahmedabad 380 054 India Pkg By: PD-Rx Pharmaceuticals Incorporated Oklahoma City, OK 73127 a) 30 count-bottle	Class II	Drugs	Lots: a) K22E32 Exp. 10/31/23; b) H22C33 Exp. 09/30/23; H22C81,	CGMP deviations.	PD-Rx Pharmaceuticals, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
(NDC 43063-0727-30) b) 90 count-bottle (NDC 43063-0727-90)			J22C83, K22E36 Exp. 10/31/23		
Glimepiride USP, 4 mg, 90 count-bottles, Rx only, Intas Pharm. Limited Pkg By: PD-Rx Pharmaceuticals Incorporated Oklahoma City, OK 73127, NDC 43063-0587-90	Class II	Drugs	Lots: A22B45 Exp. 01/31/24; C22A73, E22E41, C22D28, F22B68, G22A29, H22B97, K22A36 Exp. 03/31/24; K22B99, A23D07, B23B25 Exp. 10/31/24; B23B55 Exp. 06/30/25	CGMP deviations.	PD-Rx Pharmaceuticals, Inc.
Simvastatin USP 20 mg, Rx only, Intas Pharm. Limited Ahmedabad 380 054 India Pkg By: PD-Rx Pharmaceuticals Incorporated Oklahoma City, OK 73127 a) 30 count-bottles (NDC 43063-008-30), b) 90 count-bottles (NDC: 43063-0008-90)	Class II	Drugs	Lots: a) G22B32, D22B92, D22F82, Exp. 06/30/23; G22F41, J22F25, L22C14, Exp. 01/31/24; D22B92, D22F82 Exp. 06/30/23; B22A12, Exp. 03/31/23 b) H22A32, I22E83, J22E94, K22E34 Exp. 01/31/24; C22F31, D22G16, E22D75, F22E06, Exp. 06/30/23; L21E09, B22C61, Exp. 01/31/23.	CGMP deviations.	PD-Rx Pharmaceuticals, Inc.
Simvastatin USP 40 mg, Rx only, Intas Pharm. Limited Ahmedabad 380 054 India Pkg By: PD-Rx Pharmaceuticals Incorporated Oklahoma City, OK 73127 a) 30 count-bottle (NDC 43063-0726-30) b) 90 count-bottle (NDC 43063-0726-90)	Class II	Drugs	Lots: a) A22A17, D22C21 Exp. 07/31/23; K22D89, L22B26, L22D14 Exp. 03/31/24; L22D96 Exp. 04/30/24; b) L21E06 Exp. 05/31/23; B22C05, D22B91, E22C82 Exp. 07/31/23; G22B03	CGMP deviations.	PD-Rx Pharmaceuticals, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			G22B79, H22A30, J22B81 Exp. 08/31/23; J22F27, K22B37, K22B88 Exp. 10/31/23; L22D32 Exp. 03/31/24; B23E07 Exp. 04/30/24		
Seatex Alcohol Antiseptic 80% Topical Solution Hand Sanitizer Non-Sterile Solution Net Contents: 3.785 L (1 Gallon) Container, UPC 6 12592 01480 0 Seatex, LLC. 445 TX Hwy 36 Rosenberg, TX 77471.	Class II	Drugs	Lot: 220888, Exp. 05/20/2023	Subpotent Drug: Ethanol sup-potency and Impurities out of specification for allowable limit.	Seatex LLC
Advil Ibuprofen Tablets, 200 mg Pain Reliever/Fever Reducer (NSAID) packaged in a) 100-count bottles, b) 50-count bottles, and c) 3 (2 count) packets.	Class II	Drugs	SKUs a) 0901458; b) 0913023; c) 0999259 stored and distributed from DCs 07/28/2022 through 03/31/2023.	CGMP deviation: product outside labeled storage temperature requirements.	Family Dollar Stores, Llc.
Advil Ibuprofen Tablets, 200 mg Pain Reliever/Fever Reducer (NSAID) 24-count Caplets	Class II	Drugs	SKU 0901839 stored and distributed from DCs 07/28/2022 through 03/31/2023.	CGMP deviation: product outside labeled storage temperature requirements.	Family Dollar Stores, Llc.
Advil Dual Action with Acetaminophen Acetaminophen 250 mg and Ibuprofen (NSAID) 125 mg Tablets Pain Reliever, 36 Caplets bottles	Class II	Drugs	SKUs 0902867 stored and distributed from DCs 07/28/2022 through 03/31/2023.	CGMP deviation: product outside labeled storage temperature requirements.	Family Dollar Stores, Llc.
Advil Liqui-Gels Solubilized Ibuprofen Capsules, 200 mg Pain Reliever/Fever Reducer (NSAID) a) 20-count Liquid Filled Capsule bottles; b) 40-count Liquid Filled Capsule bottles.	Class II	Drugs	SKUs a) 0999841; b) 0916071 stored and distributed from DCs 07/28/2022 through 03/31/2023.	CGMP deviation: product outside labeled storage temperature requirements.	Family Dollar Stores, Llc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Calcitonin Salmon (synthetic origin) Nasal Spray, 2200 USP Calcitonin Salmon Units/mL, 200 USP Calcitonin Salmon Units/spray, 3.7 mL bottle, Rx only, Manufactured by: Apotex Corp., Toronto, Ontario, Canada, M9L 1T9, NDC 60505-0823-6	Class II	Drugs	Lot #: TH5645, Exp. 01/2025	Presence of Foreign Substance: Glass splinter particle entrapped inside the pump ball seat rendered the pump inoperable.	Apotex Corp.
Admelog, insulin lispro injection, 100 units/mL (U-100), 3mL multi-dose vial, Rx Only, Sanofi-Aventis U.S. LLC, Bridgewater, NJ 08807 A Sanofi Company. NDC 0024-5926-05	Class II	Drugs	Lot # 3F497B, EXP 12-31-2025	Lack of Assurance of Sterility: Malformed crimped collar seal	Sanofi-Aventis U.S. LLC
LORazepam Injection, 2mg / mL Single Dose vial 1ml vial, Rx Only, MFG Akorn Lake Forest IL 60045, Repackaged by: RemedyRepack Inc., Indiana PA 15701, Source NDC # 17478-0040-001, Remedy NDC 70518-2268-00	Class II	Drugs	Lot # B2169656-032223, B2169663-032223, B2169680-032223, B2169713-032223, B2109085-021423, B2109094-021423, B2049229-010623, B2049235-010623, Exp. Date 04/30/2025; B2049224-010623, B2027905-122222, B2027920-122222, B2027941-122222, B2027968-122222, B2027979-122222, B2027989-122222, B2005343-120922, B2005333-120922, Exp.	CGMP Deviations: Discontinuation of the Quality program by manufacturer that would assure product meet the identity, strength, quality, and purity characteristics that they are purported or represented to possess.	RemedyRepack Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			Date 03/31/2025; B1970782-112122, Exp. Date 01/31/2025; B1878510-092922, Exp. Date 11/30/2024; B1904609-101322, B1866210-092222, Exp. Date 12/31/2024; B1711316-060222, B1711328-060222, Exp. Date 09/30/2024; B1660244-042522, Exp. Date 07/31/2024; B1660288-042522, B1617673-032422, Exp. Date 06/30/2024; B1617737-032422, B1617744-032422, B1563407-021422, B1563498-021422, Exp. Date 05/31/2024; B1539158-012822, B1518050-011222, B1498175-122921, Exp. Date 04/30/2024; B1498194-122921, B1455889-112621, B1455918-112621, Exp. Date 03/31/2024; B1455901-112621,		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			B1396346-101421, B1383216-100721, Exp. Date 01/31/2024; B1383214-100721, B1353451-091721, B1353463-091721, B1353480-091721, B1274069-071521, B1274079-071521, B1274052-071521, B1234313-061721, B1234339-061721, B1203592-052721, B1203608-052721, B1163740-042921, Exp. Date 09/30/2023; B1163745-042921, B1163747-042921, B1140139-040821, Exp. Date 05/31/2023.		
Ketotifen Fumarate 0.025 %, Antihistamine eye drops, 5mL bottle, MFG: Akorn, Lake Forrest IL 60045, Repackaged by: RemedyRepack Inc., Indiana, PA 15701, NDC 70518-1142-00; Source NDC # 17477-0717-10;	Class II	Drugs	Lot # B1643789-041022, EXP 03/31/2024; B1894150-100722, B1891573-100622, EXP. 7/31/2024	CGMP Deviations: Discontinuation of the Quality program by manufacturer that would assure product meet the identity, strength, quality, and purity characteristics that they are purported or represented to possess.	RemedyRepack Inc.
Pyrazinamide, 500 mg Tablet, packaged in a) 29 x 30-count card, NDC # 70518-2534-01;	Class II	Drugs	Lot: a) B2110254-021423, exp. date 08/17/2023; b)	CGMP Deviations: Discontinuation of the Quality program by	RemedyRepack Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
b) 1 x 100 UD box, NDC # 70518-2534-00, MFG: Akorn, Lake Forest, IL 60045, Repackaged by : RemedyRepack Inc., PA 15701. Mfg NDC # 61748-0012-01			J0684183-022323, exp. date 02/28/2024;	manufacturer that would assure product meet the identity, strength, quality, and purity characteristics that they are purported or represented to possess.	
Heparin Sodium, 25,000 USP units per 250mL, (100 USP units per mL) in 5% Dextrose injection, 250 ml Excel Container, B. Braun Medical Inc. Bethlehem, PA 18018, USA; API from Spain NDC: 0264-9587-20,	Class II	Drugs	Lot Number: J1P154N, Exp: 31 May, 2023,	Subpotent: Low anti-factor IIa Potency.	B. Braun Medical Inc
Lorazepam Injection, USP, 2mg/mL, 1 mL vial (NDC 0641-6044-01), packaged in 25 x 1 mL Vials per carton (NDC 0641-6044-25), Rx only, Manufactured by West-Ward, Eatontown, NJ 07724.	Class II	Drugs	Lots: 070086, 070128, Exp. 07/2023	Failed Impurities/Degradation Specifications: Out-of-specification results for total related compounds observed during retain steting due to the elevated Related Compound-C.	Hikma Pharmaceuticals USA Inc.
Ampicillin for Injection, USP 250 mg per vial, Rx only, Mfg. for: Piramal Critical Care, Bethlehem, PA 18017 USA, NDC 66794-220-41	Class II	Drugs	All lots within expiry.	Lack of Assurance of Sterility	Astral SteriTech Private Ltd.
Ampicillin for Injection, USP 500 mg per vial, Rx only, Mfg. for: Piramal Critical Care, Bethlehem, PA 18017 USA, NDC 66794-221-41	Class II	Drugs	All lots within expiry.	Lack of Assurance of Sterility	Astral SteriTech Private Ltd.
Ampicillin for Injection, USP 1g per vial, Rx only, Mfg. for: Piramal Critical Care, Bethlehem, PA 18017 USA, NDC 66794-222-41	Class II	Drugs	All lots within expiry.	Lack of Assurance of Sterility	Astral SteriTech Private Ltd.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Ampicillin for Injection, USP 2g per vial, Rx only, Mfg. for: Piramal Critical Care, Bethlehem, PA 18017 USA, NDC 66794-223-41	Class II	Drugs	All lots within expiry.	Lack of Assurance of Sterility	Astral SteriTech Private Ltd.
Ampicillin for Injection, USP 10 g per Pharmacy Bulk Package, Rx only, Mfg. for: Piramal Critical Care, Bethlehem, PA 18017 USA, NDC 66794-224-15	Class II	Drugs	All lots within expiry.	Lack of Assurance of Sterility	Astral SteriTech Private Ltd.
Ampicillin for Injection, USP, 250 mg per vial, Rx only, Manufactured for: Xellia Pharmaceuticals USA, LLC, Buffalo Grove, IL 60089, NDC 70594-084-02	Class II	Drugs	All lots within expiry.	Lack of Assurance of Sterility	Astral SteriTech Private Ltd.
Ampicillin for Injection, USP 500 mg per vial, Rx only, Manufactured for: Xellia Pharmaceuticals USA, LLC, Buffalo Grove, IL 60089, NDC 70594-085-02	Class II	Drugs	All lots within expiry.	Lack of Assurance of Sterility	Astral SteriTech Private Ltd.
Ampicillin for Injection, USP 1g per vial, Rx only, Manufactured for: Xellia Pharmaceuticals USA, LLC, Buffalo Grove, IL 60089, NDC 70594-086-02	Class II	Drugs	All lots within expiry.	Lack of Assurance of Sterility	Astral SteriTech Private Ltd.
Ampicillin for Injection, USP 2 g per vial, Rx only, Manufactured for: Xellia Pharmaceuticals USA, LLC, Buffalo Grove, IL 60089, NDC 70594-087-02	Class II	Drugs	All lots within expiry.	Lack of Assurance of Sterility	Astral SteriTech Private Ltd.
Ampicillin for Injection, USP 10 grams per Pharmacy Bulk Package, Rx only, Manufactured for: Xellia Pharmaceuticals USA, LLC, Buffalo Grove, IL 60089, NDC 70594-088-01	Class II	Drugs	All lots within expiry.	Lack of Assurance of Sterility	Astral SteriTech Private Ltd.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Ampicillin and Sulbactam for Injection, USP 1.5 gram per vial, Rx only, Manufactured for: Civica Inc. Lehi Utah 84043, NDC 72572-021-10	Class II	Drugs	All lots within expiry.	Lack of Assurance of Sterility	Astral SteriTech Private Ltd.
Ampicillin and Sulbactam for Injection, USP 3 gram per vial, Rx only, Manufactured for: Civica Inc. Lehi Utah 84043, NDC 72572-022-10	Class II	Drugs	All lots within expiry.	Lack of Assurance of Sterility	Astral SteriTech Private Ltd.
Ampicillin and Sulbactam for Injection, USP 1.5 grams per vial, Rx only, Mfd for Meitheal Pharmaceuticals Chicago, IL 60631, NDC 71288-005-20	Class II	Drugs	All lots within expiry.	Lack of Assurance of Sterility	Astral SteriTech Private Ltd.
Ampicillin and Sulbactam for Injection, USP 3 grams per vial, Rx only, Mfd for Meitheal Pharmaceuticals Chicago, IL 60631, NDC 71288-006-30	Class II	Drugs	All lots within expiry.	Lack of Assurance of Sterility	Astral SteriTech Private Ltd.
Ampicillin and Sulbactam for Injection, USP 15 grams per Pharmacy Bulk Package, Rx only, Mfd for Meitheal Pharmaceuticals Chicago, IL 60631, NDC 71288-007-75	Class II	Drugs	All lots within expiry.	Lack of Assurance of Sterility	Astral SteriTech Private Ltd.
Ampicillin and Sulbactam for Injection, USP 1.5 grams per vial, Rx only, Mfg. for: Piramal Critical Care, Bethlehem, PA 18017 USA, NDC 66794-206-41	Class II	Drugs	All lots within expiry.	Lack of Assurance of Sterility	Astral SteriTech Private Ltd.
Ampicillin and Sulbactam for Injection, USP 1.5 grams per vial, Rx only, Mfg. for: Piramal Critical Care, Bethlehem, PA 18017 USA, NDC 66794-241-41	Class II	Drugs	All lots within expiry.	Lack of Assurance of Sterility	Astral SteriTech Private Ltd.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Ampicillin and Sulbactam for Injection, USP 3 grams per vial, Rx only, Mfg. for: Piramal Critical Care, Bethlehem, PA 18017 USA, NDC 66794-207-41	Class II	Drugs	All lots within expiry.	Lack of Assurance of Sterility	Astral SteriTech Private Ltd.
Ampicillin and Sulbactam for Injection, USP 15 grams per Pharmacy Bulk Package, Rx only, Mfg. for: Piramal Critical Care, Bethlehem, PA 18017 USA, NDC 66794-208-15	Class II	Drugs	All lots within expiry.	Lack of Assurance of Sterility	Astral SteriTech Private Ltd.
Ampicillin and Sulbactam for Injection, USP 15 grams per Pharmacy Bulk Package, Rx only, Mfg. for: Piramal Critical Care, Bethlehem, PA 18017 USA, NDC 66794-243-15	Class II	Drugs	All lots within expiry.	Lack of Assurance of Sterility	Astral SteriTech Private Ltd.
Ampicillin and Sulbactam for Injection, USP 3 grams vials, Rx only, Mfg. for: Piramal Critical Care, Bethlehem, PA 18017 USA, NDC 66794-242-41	Class II	Drugs	All lots within expiry.	Lack of Assurance of Sterility	Astral SteriTech Private Ltd.
Ampicillin and Sulbactam for Injection, USP 1.5 grams per vial, Rx only, Manufactured for: Xellia Pharmaceuticals USA, LLC, Buffalo Grove, IL 60089, NDC 70594-081-02	Class II	Drugs	All lots within expiry.	Lack of Assurance of Sterility	Astral SteriTech Private Ltd.
Ampicillin and Sulbactam for Injection, USP 3 grams per vial, Rx only, Manufactured for: Xellia Pharmaceuticals USA, LLC, Buffalo Grove, IL 60089, NDC 70594-082-02	Class II	Drugs	All lots within expiry.	Lack of Assurance of Sterility	Astral SteriTech Private Ltd.
Ampicillin and Sulbactam for Injection, USP 15 grams per Pharmacy Bulk Package, Rx only, Manufactured for: Xellia	Class II	Drugs	All lots within expiry.	Lack of Assurance of Sterility	Astral SteriTech Private Ltd.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Pharmaceuticals USA, LLC, Buffalo Grove, IL 60089, NDC 70594-083-01					
Cefepime for Injection, USP 1 gram per vial, Rx only, Manufactured for: Civica Inc. Lehi Utah 84043, NDC 72572-057-10	Class II	Drugs	All lots within expiry.	Lack of Assurance of Sterility	Astral SteriTech Private Ltd.
Cefepime for Injection, USP 2 grams per vial, Rx only, Manufactured for: Civica Inc. Lehi Utah 84043, NDC 72572-058-10	Class II	Drugs	All lots within expiry.	Lack of Assurance of Sterility	Astral SteriTech Private Ltd.
Cefepime for Injection, USP 2 grams per vial, Rx only, Mfd. for Meitheal Pharmaceuticals Chicago, IL 60631, NDC 71288-009-20	Class II	Drugs	All lots within expiry.	Lack of Assurance of Sterility	Astral SteriTech Private Ltd.
Cefepime for Injection, USP 1 gram per vial, Rx only, Mfg. for: Piramal Critical Care Bethlehem, PA 18017 USA, NDC 66794-209-41	Class II	Drugs	All lots within expiry.	Lack of Assurance of Sterility	Astral SteriTech Private Ltd.
Cefepime for Injection, USP 2 grams per vial, Rx only, Mfg. for: Piramal Critical Care Bethlehem, PA 18017 USA, NDC 66794-210-41	Class II	Drugs	All lots within expiry.	Lack of Assurance of Sterility	Astral SteriTech Private Ltd.
Cefepime for Injection, USP 1 gram per vial, Manufactured for: Xellia Pharmaceuticals USA, LLC, Buffalo Grove, IL 60089, NDC 70594-089-02	Class II	Drugs	All lots within expiry.	Lack of Assurance of Sterility	Astral SteriTech Private Ltd.
Cefepime for Injection, USP 2 grams per vial, Rx only, Manufactured for: Xellia Pharmaceuticals USA, LLC, Buffalo Grove, IL 60089, NDC 70594-090-02	Class II	Drugs	All lots within expiry.	Lack of Assurance of Sterility	Astral SteriTech Private Ltd.
Ceftriaxone for Injection, USP 250 mg per vial, Rx only, Mfg. for: Piramal Critical Care, Bethlehem, PA 18017, NDC 66794-211-42	Class II	Drugs	All lots within expiry.	Lack of Assurance of Sterility	Astral SteriTech Private Ltd.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Ceftriaxone for Injection, USP 500 mg per vial, Rx only, Mfg. for: Piramal Critical Care, Bethlehem, PA 18017, NDC 66794-212-42	Class II	Drugs	All lots within expiry.	Lack of Assurance of Sterility	Astral SteriTech Private Ltd.
Ceftriaxone for Injection, USP 1 gram per vial, Rx only, Mfg. for: Piramal Critical Care, Bethlehem, PA 18017, NDC 66794-213-42	Class II	Drugs	All lots within expiry.	Lack of Assurance of Sterility	Astral SteriTech Private Ltd.
Ceftriaxone for Injection, USP 2 grams per vial, Rx only, Mfg. for: Piramal Critical Care, Bethlehem, PA 18017, NDC 66794-214-42	Class II	Drugs	All lots within expiry.	Lack of Assurance of Sterility	Astral SteriTech Private Ltd.
Ceftriaxone for Injection, USP 10 grams per Pharmacy Bulk Package, Mfg. for: Piramal Critical Care, Bethlehem, PA 18017, NDC 66794-215-15	Class II	Drugs	All lots within expiry.	Lack of Assurance of Sterility	Astral SteriTech Private Ltd.
Ceftriaxone for Injection, USP 250 mg per vial, Rx only, Manufactured for: Xellia Pharmaceuticals USA, LLC, Buffalo Grove, IL 60089, NDC 70594-094-02	Class II	Drugs	All lots within expiry.	Lack of Assurance of Sterility	Astral SteriTech Private Ltd.
Ceftriaxone for Injection, USP 500 mg per vial, Rx only, Manufactured for: Xellia Pharmaceuticals USA, LLC, Buffalo Grove, IL 60089, NDC 70594-095-02	Class II	Drugs	All lots within expiry.	Lack of Assurance of Sterility	Astral SteriTech Private Ltd.
Ceftriaxone for Injection, USP, 1 grams per vial, Rx only, Manufactured for: Xellia Pharmaceuticals USA, LLC, Buffalo Grove, IL 60089, NDC 70594-096-02	Class II	Drugs	All lots within expiry.	Lack of Assurance of Sterility	Astral SteriTech Private Ltd.
Ceftriaxone for Injection, USP, 2 grams per vial, Rx only, Manufactured for: Xellia Pharmaceuticals USA, LLC, Buffalo Grove, IL 60089, NDC 70594-097-02	Class II	Drugs	All lots within expiry.	Lack of Assurance of Sterility	Astral SteriTech Private Ltd.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Ceftriaxone for Injection, USP 10 grams per Pharmacy Bulk Package, Rx only, Manufactured for: Xellia Pharmaceuticals USA, LLC, Buffalo Grove, IL 60089, NDC 70594-098-01	Class II	Drugs	All lots within expiry.	Lack of Assurance of Sterility	Astral SteriTech Private Ltd.
Piperacillin and Tazobactam for Injection, USP, 3.375 grams per vial, Rx only, Manufactured for: Civica Inc. Lehi Utah 84043, NDC 72572-576-10	Class II	Drugs	All lots within expiry.	Lack of Assurance of Sterility	Astral SteriTech Private Ltd.
Piperacillin and Tazobactam for Injection, USP, 4.5 grams per vial, Rx only, Manufactured for: Civica Inc. Lehi Utah 84043, NDC 72572-577-10	Class II	Drugs	All lots within expiry.	Lack of Assurance of Sterility	Astral SteriTech Private Ltd.
Piperacillin and Tazobactam for Injection, USP, 2.25 grams per vial, Rx only, Mfd for Meitheal Pharmaceuticals Chicago, IL 60631, NDC 71288-002-31	Class II	Drugs	All lots within expiry.	Lack of Assurance of Sterility	Astral SteriTech Private Ltd.
Piperacillin and Tazobactam for Injection, USP 3.375 grams per vial, Rx only, Mfd for Meitheal Pharmaceuticals Chicago, IL 60631, NDC 71288-003-31	Class II	Drugs	All lots within expiry.	Lack of Assurance of Sterility	Astral SteriTech Private Ltd.
Piperacillin and Tazobactam for Injection, USP 4.5 grams per vial, Rx only, Mfd for Meitheal Pharmaceuticals Chicago, IL 60631, NDC 71288-004-51	Class II	Drugs	All lots within expiry.	Lack of Assurance of Sterility	Astral SteriTech Private Ltd.
Piperacillin and Tazobactam for Injection, USP, 2.25 grams per vial, Rx only, Mfg. for: Piramal Critical Care, Bethlehem, PA 18017, NDC66794-216-41	Class II	Drugs	All lots within expiry.	Lack of Assurance of Sterility	Astral SteriTech Private Ltd.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Piperacillin and Tazobactam for Injection, USP, 3.375 grams per vial, Rx only, Mfg. for: Piramal Critical Care, Bethlehem, PA 18017, NDC 66794-217-41	Class II	Drugs	All lots within expiry.	Lack of Assurance of Sterility	Astral SteriTech Private Ltd.
Piperacillin and Tazobactam for Injection, USP, 4.5 grams per vial, Rx only, Mfg. for: Piramal Critical Care, Bethlehem, PA 18017, NDC 66794-218-41	Class II	Drugs	All lots within expiry.	Lack of Assurance of Sterility	Astral SteriTech Private Ltd.
Piperacillin and Tazobactam for Injection, USP 2.25 g per vial,s Rx only, Manufactured for: Xellia Pharmaceuticals USA, LLC, Buffalo Grove, IL 60089, NDC 70594-078-02	Class II	Drugs	All lots within expiry.	Lack of Assurance of Sterility	Astral SteriTech Private Ltd.
Piperacillin and Tazobactam for Injection, UPS, 3.375 grams per vial, Rx only, Manufactured for: Xellia Pharmaceuticals USA, LLC, Buffalo Grove, IL 60089, NDC 70594-079-02	Class II	Drugs	All lots within expiry.	Lack of Assurance of Sterility	Astral SteriTech Private Ltd.
Piperacillin and Tazobactam for Injection, USP, 4.5 grams per vial, Rx only, Manufactured for: Xellia Pharmaceuticals USA, LLC, Buffalo Grove, IL 60089, NDC 70594-080-02	Class II	Drugs	All lots within expiry.	Lack of Assurance of Sterility	Astral SteriTech Private Ltd.
PHENYLephrine HCl Injection, 1 mg per 10 mL (100 mcg/mL), Single-Use Syringe, Solution for IV Use Only. Apollo Care, LLC, 3801 Mojae Ct., Suite 101, Columbia, MO 65202. NDC: 71170-010-10	Class II	Drugs	Lot #: AC-016606, Exp. Date 05/06/2023; AC-016636, Exp. Date 07/09/2023; AC-016643, Exp. Date 07/31/2023	Lack of Assurance of Sterility	Apollo Care, LLC
Succinylcholine Cl Injection, 100 mg per 5 mL (20 mg/mL), Single-Use Syringe, Rx only,	Class II	Drugs	Lot #: AC-016607, Exp. Date 05/09/2023	Lack of Assurance of Sterility	Apollo Care, LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Apollo Care, LLC, 3801 Mojave Ct., Suite 101, Columbia, MO 65202. NDC 71170-020-05					
FentaNYL 50 mcg/mL (2,500mcg Total Dose), 50 mL Syringe, Rx Only, Apollo Care, LLC, 3801 Mojave Ct., Suite 101, Columbia, MO 65202. NDC 71170-910-25	Class II	Drugs	Lot #: AC-016624, Exp. Date 06/10/2023	Lack of Assurance of Sterility	Apollo Care, LLC
Ketamine Injection, 50 mg per 5 mL (10 mg/mL), Single-Use Syringe, Rx only, Apollo Care, LLC, 3801 Mojave Ct., Suite 101, Columbia, MO 65202. NDC 71170-050-05	Class II	Drugs	Lot #: AC-016627, Exp. Date 06/17/2023; AC-016635, Exp. Date 07/08/2023; AC-016662, Exp. Date 09/30/2023	Lack of Assurance of Sterility	Apollo Care, LLC
VANComycin 1.5g added to 500 mL of 0.9% Sodium Chloride Injection, Rx only, Apollo Care, LLC, 3801 Mojave Ct., Suite 101, Columbia, MO 65202. NDC 71170-185-50	Class II	Drugs	Lot#: AC-016629, Exp. Date 05/13/2023; AC-016646, Exp. Date 06/24/2023	Lack of Assurance of Sterility	Apollo Care, LLC
Norepinephrine 8 mg added to 250 mL 0.9% Sodium Chloride Injection, Rx Only, Apollo Care, LLC, 3801 Mojave Ct., Suite 101, Columbia, MO 65202. NDC 71170-550-25	Class II	Drugs	Lot#: AC-016631, Exp. Date 05/29/2023; AC-016655, Exp. Date 08/07/2023	Lack of Assurance of Sterility	Apollo Care, LLC
VANComycin 1.25g added to 250 mL of 0.9% Sodium Chloride Injection, Rx Only, Apollo Care, LLC, 3801 Mojave Ct., Suite 101, Columbia, MO 65202. NDC 71170-284-25	Class II	Drugs	Lot #: AC-016647, Exp. Date 06/28/2023	Lack of Assurance of Sterility	Apollo Care, LLC
VANComycin 1.25g added to 250 mL of 0.9% Sodium Chloride Injection, Rx Only, Apollo Care, LLC, 3801 Mojave Ct., Suite 101, Columbia, MO 65202. NDC 71170-264-25	Class II	Drugs	Lot #: AC-016647, Exp. Date 06/28/2023	Lack of Assurance of Sterility	Apollo Care, LLC
VANComycin 1 g added to 250 mL of 0.9% Sodium Chloride Injection, Rx Only, Apollo	Class II	Drugs	Lot #: AC-016641, Exp. Date 06/03/2023; AC-	Lack of Assurance of Sterility	Apollo Care, LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Care, LLC, 3801 Mojave Ct., Suite 101, Columbia, MO 65202. NDC 71170-254-25			016653 Exp. Date 07/26/2023		
VANComycin 1.75 g added to 500 mL of 0.9% Sodium Chloride Injection, Rx Only, Apollo Care, LLC, 3801 Mojave Ct., Suite 101, Columbia, MO 65202. NDC 71170-194-50	Class II	Drugs	Lot #: AC-016648, Exp. Date 07/01/2023	Lack of Assurance of Sterility	Apollo Care, LLC
VANComycin 2g added to 500 mL of 0.9% Sodium Chloride Injection, Rx Only. Apollo Care, LLC, 3801 Mojave Ct., Suite 101, Columbia, MO 65202. NDC 71170-204-50	Class II	Drugs	Lot #: AC-016638, Exp. Date 05/27/2023	Lack of Assurance of Sterility	Apollo Care, LLC
VANComycin 2.5 g added to 500 mL of 0.9% Sodium Chloride Injection, Rx Only, Apollo Care, LLC, 3801 Mojave Ct., Suite 101, Columbia, MO 65202. NDC 71170-224-50	Class II	Drugs	Lot #: AC-016649, Exp. Date 07/01/2023	Lack of Assurance of Sterility	Apollo Care, LLC
Norepinephrine 4 mg added to 250 mL of 5% Dextrose Injection, Rx Only, Apollo Care, LLC, 3801 Mojave Ct., Suite 101, Columbia, MO 65202. NDC 71170-500-25	Class II	Drugs	Lot #: AC-016640, Exp. Date 06/16/2023; AC-016670, Exp. Date 08/29/2023	Lack of Assurance of Sterility	Apollo Care, LLC
VANComycin 750mg added to 250 mL of 0.9% Sodium Chloride Injection, Rx Only, Apollo Care, LLC, 3801 Mojave Ct., Suite 101, Columbia, MO 65202. NDC 71170-255-25	Class II	Drugs	Lot #: AC-016632, Exp. Date 05/24/2023	Lack of Assurance of Sterility	Apollo Care, LLC
FentaNYL 500 mcg (2mcg/mL) and Ropivacaine HCL 250 mg (0.1%) added to 250 mL 0.9% Sodium Chloride Injection, Rx Only, Apollo Care, LLC, 3801 Mojave Ct., Suite 101, Columbia, MO 65202. NDC 71170-950-25	Class II	Drugs	Lot #: AC-016644, Exp. Date 05/08/2023; AC-016659, Exp. Date 09/26/2023	Lack of Assurance of Sterility	Apollo Care, LLC
VANComycin 1.5g added to 250 mL of 0.9% Sodium Chloride Injection, Rx only, Apollo	Class II	Drugs	Lot #: AC-016633, Exp. Date 05/24/2023; AC-	Lack of Assurance of Sterility	Apollo Care, LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Care, LLC, 3801 Mojave Ct., Suite 101, Columbia, MO 65202. NDC 71170-184-25			016651, Exp. Date 07/22/2023		
Oxytocin 30 units added to 0.9% Sodium Chloride 500 mL, Rx Only, Single Dose Container, SCA Pharmaceuticals, Windsor, CT 06095, NDC# 70004-085-44	Class III	Drugs	Lot # 1222043028 04/11/23 1222043029 04/13/23 1222043031 04/12/23 1222043032 04/12/23 1222043033 04/13/23 1222043034 04/13/23 1222043035 04/14/23 1222043036 04/14/23 1222043037 04/18/23 1222043038 04/18/23 1222043039 04/19/23 1222043040 04/19/23 1222043041 04/20/23 1222043042 04/20/23 1222043043 04/21/23 1222043044 04/21/23 1223041990 05/03/23 1223041991 05/03/23 1223041992 05/05/23 1223041993 05/06/23 1223041996 05/11/23 1223041997 05/10/23 1223041998 05/11/23 1223041999 05/12/23 1223042000 05/12/23 1223042001 05/13/23 1223042002 05/16/23 1223042003	Subpotent Drug: Out of specification results for low potency was obtained.	SCA Pharmaceuticals

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			05/17/23 1223042004 05/21/23 1223042006 05/16/23 1223042007 05/06/23 1223042008 05/10/23 1223042009 05/05/23 1223042010 05/04/23 1223042766 05/18/23 1223042767 05/17/23 1223042769 05/18/23 1223042770 05/19/23 1223042771 05/19/23 1223042772 05/20/23 1223042773 05/21/23 1223042774 05/23/23 1223042776 05/23/23 1223042777 05/24/23 1223042778 05/24/23 1223042783 05/31/23 1223042784 06/01/23 1223042785 05/31/23 1223042786 06/01/23 1223044081 06/02/23 1223044082 06/02/23 1223044117 06/06/23 1223044118 06/06/23 1223044143 06/03/23 1223044144 06/03/23 1223044166 06/14/23 1223044173 06/07/23 1223044191		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			06/07/23 1223044198 06/08/23 1223044220 06/08/23 1223044225 06/13/23 1223044247 06/14/23 1223044255 06/14/23 1223044267 06/15/23 1223044302 06/15/23 1223044311 06/16/23 1223044389 06/24/23 1223044523 06/24/23 1223044552 06/28/23 1223044582 06/27/23 1223044590 06/27/23 1223044629 06/29/23 1223044636 06/29/23 1223044656 06/30/23 1223044662 06/30/23 1223044682 07/01/23 1223044687 07/01/23 1223044711 07/05/23 1223044741 07/04/23 1223044749 07/04/23 1223044774 07/05/23 1223044793 07/06/23 1223044868 07/08/23		
Avicel PH-101 NF, Microcrystalline Cellulose NF, Net Content/Gross Weight 50.0 KG / 54.5 KG bulk container, Manufactured by: DuPont Nutrition USA, Inc., 1301 Ogletown	Class III	Drugs	Batch Numbers: 2173809472, 2173811313, P120834282, P120834305, P120834313, P120834324,	Failed Impurities/Degradation Specifications: Out of specification results obtained for conductivity.	DuPont Nutrition USA, Inc

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Road, Newark, DE 19711, USA; Manufactured in USA; Headquarters: DuPont Nutrition Biosciences ApS, Langebrogade 1, Copenhagen, Denmark.			P120834423, P120834437, P120834443, P120834478, 2173739298, 2173740020, 2173771315, P120834254, P120834476		
Avicel PH-102 NF, Microcrystalline Cellulose NF, Net Content/Gross Weight 20.0 KG / 21.1 KG bulk container, Manufactured by: DuPont Nutrition USA, Inc., 1301 Ogletown Road, Newark, DE 19711, USA; Manufactured in USA; Headquarters: DuPont Nutrition Biosciences ApS, Langebrogade 1, Copenhagen, Denmark.	Class III	Drugs	Batch Numbers: P220834360, P220834366, P220834383, P220834440, P220834460, 2173755143, 2173771316, 2173773188, P220834401, P220834403, P220834482, P220834505, P220834543, P220834545	Failed Impurities/Degradation Specifications: Out of specification results obtained for conductivity.	DuPont Nutrition USA, Inc
Avicel PH-200 NF, Microcrystalline Cellulose NF, Net Content/Gross Weight 20.0 KG / 21.1 KG bulk container, Manufactured by: DuPont Nutrition USA, Inc., 1301 Ogletown Road, Newark, DE 19711, USA; Manufactured in USA; Headquarters: DuPont Nutrition Biosciences ApS, Langebrogade 1, Copenhagen, Denmark.	Class III	Drugs	Batch Numbers: 2173766945, 2173768895, PN20834306, 217373201, PN20834301	Failed Impurities/Degradation Specifications: Out of specification results obtained for conductivity.	DuPont Nutrition USA, Inc
Avicel DG, MCC/Dibasic Calcium Phosphate, Net Content/Gross Weight 20.0 KG / 21.1 KG bulk container, Manufactured by: DuPont Nutrition USA, Inc., 1301 Ogletown Road, Newark, DE 19711, USA; Manufactured in USA; Headquarters: DuPont Nutrition Biosciences ApS, Langebrogade 1, Copenhagen, Denmark.	Class III	Drugs	Batch Numbers: 2213749659, 2213766837, 2213776558, 2213776559	Failed Impurities/Degradation Specifications: Out of specification results obtained for conductivity.	DuPont Nutrition USA, Inc

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Lidocaine Patch 5%, 1 patch (63629-8755-20) packaged in 30-count patches per carton (63629-8755-1), Rx only, each patch contains: 700 mg (50mg per gram adhesive) in an aqueous base, Manufactured by: Actavis Laboratories UT, Inc., Relabeled by: Bryant Ranch Prepack, Inc. Burbank, CA 91504 USA	Class III	Drugs	Lot: 204603, Exp: 09/30/2024; Lots:208608, 208749, 208445, 209101, 208609, 208295, 209106, 209102, 209212, 208975, 209211, 209706, 209779, 209624, 209839, 209548, Exp: 12/31/2024; Lots: 204604, 204601, 204550, 204599, 204871, 204555, 205616, Exp: 11/30/2024; Lots: 205612, 204832, 205127, 204996, 205615, 205324, 205494, 205611, 206232, Exp: 10/31/2024.	Labeling: Typographical error on the upper left-hand side of the box and individual patch label that has the incorrect dosage form stating, each tablet contains instead of each adhesive patch contains.	Bryant Ranch Prepack, Inc.
Gabapentin Tablets, USP 600 mg, packaged in Cartons of 100 tablets (10 tablets per blister pack x 10), Rx Only, Distributed by: Aurobindo Pharma USA, Inc. East Windsor, NJ 08520 Distributed by: Major Pharmaceuticals 17177 N Laurel Park Dr., Suite 233 Livonia, MI 48152 USA, NDC 0904-6823-61	Class III	Drugs	Lot: T04468, Exp 10/2024	Product mixup: one foreign tablet found in product.	The Harvard Drug Group

*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

0.9% Sodium Chloride Irrigation
Albuterol Sulfate Inhalational Solution
Alprostadil (Muse) Suppository
Amifostine Injection
Amino Acids
Amoxapine Tablets
Amoxicillin Oral Powder for Suspension
Amphetamine; Dextroamphetamine Tablets
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
Belladonna and Opium Suppositories
Bumetanide Injection
Bupivacaine Hydrochloride and Epinephrine Injection
Bupivacaine Hydrochloride Injection
Calcium Gluconate Injection
Capecitabine Tablets
Carboplatin Injection
Cefixime Oral Capsules
Cefotaxime Sodium Injection
Cefotetan Disodium Injection
Chloramphenicol Sodium Succinate Injection
Chloroprocaine Hydrochloride Injection
Chlorothiazide Oral Suspension
Cisplatin Injection
Clindamycin Phosphate Injection
Clonazepam Tablets
Collagenase Ointment
Conivaptan Hydrochloride (Vaprisol) in 5% Dextrose Plastic Container
Conjugated Estrogens/Bazedoxifene (DUAVEE) Tablet, Film Coated
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
Difluprednate Ophthalmic Emulsion
Digoxin Injection
Diltiazem Hydrochloride Injection
Dimercaprol (Bal in Oil) Injection
Disopyramide Phosphate (Norpace) Capsules
Dobutamine Hydrochloride Injection
Dopamine Hydrochloride Injection
Dulaglutide (Trulicity) Injection
Echothiophate Iodide (Phospholine Iodide) Ophthalmic Solution
Edetate Calcium Disodium Injection
Enalaprilat Injection
Epinephrine Injection, 0.1 mg/mL
Erythromycin Ophthalmic Ointment
Etomidate Injection
Fentanyl Citrate (Sublimaze) Injection
Fludarabine Phosphate Injection
Fluorescein Injection
Flurazepam Hydrochloride Capsules
Furosemide Injection
Gentamicin Sulfate Injection
Guanfacine Hydrochloride Tablets
Heparin Sodium and Sodium Chloride 0.9% Injection
Hydrocortisone Sodium Succinate Injection
Hydromorphone Hydrochloride Injection
Hydroxypropyl (Lacrisert) Cellulose Ophthalmic Insert
Ibutilide Fumarate Injection
Indigotindisulfonate Sodium Injection
Isoniazid Injection
Isoniazid Tablets
IV Fat Emulsion
Ketamine Injection
Ketorolac Tromethamine Injection
Leucovorin Calcium Lyophilized Powder for Injection
Lidocaine Hydrochloride (Viscous) Oral Topical Solution
Lidocaine Hydrochloride (Xylocaine) and Dextrose Injection Solution-Premix Bags
Lidocaine Hydrochloride (Xylocaine) Injection
Lidocaine Hydrochloride (Xylocaine) Injection with Epinephrine
Lorazepam Injection
Lutetium Lu 177 Vipivotide Tetraxetan (Pluvicto) Injection

Mannitol Injection
Mepivacaine Hydrochloride Injection
Methamphetamine Hydrochloride Tablets
Methotrexate Injection
Methyldopa Tablets
Methylprednisolone Acetate Injection
Metronidazole Injection
Midazolam Injection
Morphine Sulfate Injection
Multi-Vitamin Infusion (Adult and Pediatric)
Neomycin Sulfate Tablets
Nizatidine Capsules
Oxybutynin Chloride Syrup
Oxytocin Injection
Palifermin (Kepivance) Lyophilized Powder for Injection
Pantoprazole Sodium for Injection
Parathyroid Hormone (Natpara) Injection
Penicillin G Benzathine Injectable Suspension
Physostigmine Salicylate Injection
Potassium Acetate Injection
Potassium Chloride Concentrate Injection
Quinapril and Hydrochlorothiazide Tablets
Quinapril Hydrochloride Tablets
Remifentanil Injection
Rifampin Capsules
Rifampin Injection
Rifapentine Tablets
Rocuronium Bromide Injection
Ropivacaine Hydrochloride Injection
Semaglutide (Ozempic) 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
Somatropin Injection
Sterile Water for Injection
Sterile Water for Irrigation
Streptozocin (Zanosar) Sterile Powder
Sucralfate Tablets
Sufentanil Citrate Injection
Sulfasalazine Tablets

Technetium TC-99M Mebrofenin Injection
Tirzepatide Injection
Triamcinolone Acetonide Injectable Suspension
Triamcinolone Hexacetonide Injectable suspension
Trimethobenzamide Hydrochloride Capsules
Valproate Sodium Injection
Vecuronium Bromide for Injection