PERFORMRx℠

Drug Information Update

January 2023

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NEWLY AVAILABLE GENERICS

Generic Name/ Dosage Form	Brand Name	Manufacturer	Indication
Sodium oxybate 500 mg/mL oral solution	Xyrem	Jazz Pharms	For the treatment of cataplexy or excessive daytime sleepiness (EDS) in patients 7 years of age and older with narcolepsy
Diclofenac potassium 50 mg powder pack	Cambia	Assertio	For the acute treatment of migraine attacks with or without aura in adults 18 years of age or older
Minocycline 105 mg, 135 mg ER tablet	Minolira ER	Dr. Reddy's Laboratories Limited	For the treatment of moderate to severe acne in patients 12 years and older
Sodium chloride 3.5% vials for nebulization	Hyper-sal	Pari respirator	Cystic fibrosis
Topiramate 25 mg, 50 mg, 100 mg ER capsules	Trokendi XR	Supernus	• For the treatment of partial-onset or primary generalized tonic-clonic seizures in patients 6 years of age and older • Adjunctive therapy for the treatment of partial-onset, primary generalized tonic-clonic seizures, or seizures associated with Lennox-Gastaut syndrome (LGS) in patients 6 years of age and older • Preventive treatment of migraine in patients 12 years of age and older
Tasimelteon 20 mg oral capsule	Hetlioz	Vanda	• Non-24-Hour Sleep-Wake Disorder (Non-24) in adults • Nighttime sleep disturbances in Smith-Magenis Syndrome (SMS) in patients 16 years of age and older
Brimonidine 0.33% gel with pump	Mirvaso	Galderma Laboratories	For the topical treatment of persistent (nontransient) facial erythema of rosacea in adults 18 years of age or older
Dextranomer/hyaluronate/ NaCl 50 mg-15 mg/mL gel implant	Solesta	Oceana Therapeutics	For fecal incontinence
Pirfenidone 267 mg oral capsule	Esbriet	Genentech	For the treatment of idiopathic pulmonary fibrosis (IPF)

NEW DRUG ENTITIES/STRENGTHS/COMBINATIONS

Drug Name	Generic Name	Description	Comments
Skyrizi 180 mg/1.2 mL (150 mg/mL) SQ wearable injector	risankizumab-rzaa	New strength of wearable injector. Previously only available as 150 mg/mL pen or syringe, 600 mg/10 mL vials, and 360 mg/2.4 mL on body injector. Indicated for moderately to severely active Crohn's disease in adults.	New Strength
Pylarify 296 MBq to 370 MBq IV syringe	piflufolastat f 18	New diagnostic agent for PET scans to be used in prostate cancer.	New Dosage Form and Strength
Naloxone 10 mg/0.4 mL auto-injector	naloxone	New strength and dosage form. Previously only available as nasal spray, syringe, vials, and carpuject and at doses of 2 mg/2 mL or 0.4 mg/mL.	New Strength and Dosage Form
Sunlenca 309 mg/mL SQ solution	lenacapavir sodium	Novel mechanism for multidrug-resistant (MDR) HIV-1 and has a 6-month maintenance dose following initial oral treatment. To be used in combination with other antiretroviral(s) for the treatment of HIV-1 infection in heavily treatment-experienced adults with MDR HIV-1 infection failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations. Price is $19,500 every 6 months.	New Entity
Sunlenca 300 mg oral tablet	lenacapavir sodium	Novel mechanism for multidrug-resistant (MDR) HIV-1 and has a 6-month maintenance dose following initial oral treatment. To be used in combination with other antiretroviral(s) for the treatment of HIV-1 infection in heavily treatment-experienced adults with MDR HIV-1 infection failing their current antiretroviral regimen	New Entity

Drug Name	Generic Name	Description	Comments
		due to resistance, intolerance, or safety considerations. Price is $19,500 every 6 months.	
Oxbryta 300 mg oral tablet	voxelotor	New oral tablet version. Was previously only available as tablets for oral suspension. Indicated for the treatment of sickle cell disease in adults and pediatric patients 4 years of age and older (was previously 12 years and older).	New Strength
Lunsumio 1 mg/mL intravenous solution	mosunetuzumab-axgb	Bispecific CD20-directed CD3 T-cell engager indicated for the treatment of adult patients with relapsed or refractory follicular lymphoma after two or more lines of systemic therapy. Accelerated approval pathway.	New Entity
Turalio 125 mg oral capsule	pexidartinib hydrochloride	New strength, was previously available as 200 mg capsules. Kinase inhibitor indicated for the treatment of adult patients with symptomatic tenosynovial giant cell tumor (TGCT) associated with severe morbidity or functional limitations and not amenable to improvement with surgery.	New Strength
Briumvi 25 mg/mL intravenous solution	ublituximab-xiiy	New anti-CD20 monoclonal antibody for the treatment of relapsing forms of multiple sclerosis (RMS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults. Maintenance dosing is every 6 months dosing and will compete directly with Ocrevus (ocrelizumab).	New Entity
Leqembi 100 mg/mL intravenous solution	lecanemab-irmb	Amyloid beta-directed antibody indicated for the treatment of Alzheimer's disease. Treatment with Leqembi is intended for patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in clinical	New Entity

Drug Name	Generic Name	Description	Comments
		trials. Accelerated approval based on reduction in amyloid beta plaques. Confirmatory trial underway.	
Sezaby 100 mg IV solution	phenobarbital sodium	New strength of IV dosage form (previously available as 130 mg/mL). This specific strength is only indicated for the treatment of neonatal seizure in term and preterm infants.	New Route and Strength
NexoBrid 8.8 % topical gel	anacaulase-bcdb	New entity indicated for eschar removal in adults with deep partial thickness (DPT) and/or full thickness (FT) thermal burns. Clinical safety and efficacy have not been established for treatment of chemical or electrical burns, burns on the face, perineum, or genitalia, burns on the feet of patients with diabetes mellitus or on the feet of patients with occlusive vascular disease, circumferential burns or burns in patients with significant cardiopulmonary disease, including inhalation injury.	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†
Vraylar	cariprazine 1.5 mg, 3 mg, 4.5 mg, 6 mg oral capsules; 1.5 mg-3 mg dose pack	Allergan	• Treatment of schizophrenia in adults • Acute treatment of manic or mixed episodes associated with bipolar I disorder in adults • Treatment of depressive episodes associated with bipolar I disorder (bipolar depression) in adults • **Adjunctive therapy to antidepressants for the treatment of major depressive disorder (MDD) in adults**
Avycaz	ceftazidime/avibactam 2.5 g IV vial	Allergan	Combination of ceftazidime, a cephalosporin, and avibactam, a beta-lactamase inhibitor, indicated for the treatment of the following infections caused by designated susceptible Gram-negative microorganisms **in adult and pediatric patients aged 3 months and older**: • Complicated Intra-abdominal Infections (cIAI), used in combination with metronidazole, ~~in adult and pediatric patients 3 months and older~~ • Complicated Urinary Tract Infections (cUTI), including Pyelonephritis, ~~in adult and pediatric patients 3 months and older~~ • Hospital-acquired Bacterial Pneumonia and Ventilator-associated Bacterial Pneumonia (HABP/VABP) ~~in patients 18 years and older~~
Pretomanid	pretomanid 200 mg oral tablet	Mylan Ireland	To be used as part of a combination regimen with bedaquiline and linezolid for the treatment of adults **with pulmonary tuberculosis (TB) that is resistant to isoniazid, rifamycins, a fluoroquinolone and a second line injectable antibacterial drug OR adults with pulmonary TB resistant to isoniazid and rifampin, who are treatment-intolerant or nonresponsive to standard therapy** ~~with pulmonary extensively drug resistant (XDR), treatment intolerant or nonresponsive multidrug resistant (MDR) tuberculosis (TB).~~ Approval of this indication is based on limited clinical safety and efficacy data. This drug is indicated for use in a limited and specific population of patients.

Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication†
Actemra	tocilizumab 80 mg/4 mL, 200 mg/10 mL, 400 mg/20 mL SQ vial; 162 mg/0.9 mL SQ syringe	Genentech	Interleukin-6 (IL-6) receptor antagonist indicated for treatment of: • Rheumatoid Arthritis (RA): Adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more Disease-Modifying Anti-Rheumatic Drugs (DMARDs) • Giant Cell Arteritis (GCA): Adult patients with giant cell arteritis • Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD): Slowing the rate of decline in pulmonary function in adult patients with SSc-ILD • Polyarticular Juvenile Idiopathic Arthritis (PJIA): Patients 2 years of age and older with active PJIA • Systemic Juvenile Idiopathic Arthritis (SJIA): Patients 2 years of age and older with active SJIA • Cytokine Release Syndrome (CRS): Adults and pediatric patients 2 years of age and older with chimeric antigen receptor (CAR) T cell-induced severe or life-threatening CRS • **Coronavirus Disease 2019 (COVID-19): Hospitalized adult patients with COVID-19 who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO)**
Wegovy	semaglutide 0.25 mg/0.5 ml, 0.5 mg/0.5 ml, 1 mg/0.5 ml, 1.7 mg/0.5 ml, 2.4 mg/0.75 ml SQ pen	Novo Nordisk	Glucagon-like peptide-1 (GLP-1) receptor agonist indicated as an adjunct to a reduced calorie diet and increased physical activity for chronic weight management in: • Adult patients with an initial body mass index (BMI) of o 30 kg/m2 or greater (obesity) or o 27 kg/m2 or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia) • **Pediatric patients aged 12 years and older with an initial BMI at the 95th percentile or greater for age and sex (obesity)**

Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication†
Oxbryta	voxelotor 300 mg, 500 mg oral tablet; 300 mg tablet for suspension	Global Blood Therapeutics	Hemoglobin S polymerization inhibitor indicated for the treatment of sickle cell disease in adults and pediatric patients ~~12~~ **4** years of age and older. This indication is approved under accelerated approval based on increase in hemoglobin (Hb). Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

RECALLS

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Daptomycin for Injection 350 mg/vial 1 Single-dose vial, Rx only, Manufactured for: Accord Healthcare, Inc., Durham, NC 27703 Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad-382 213, India. NDC 16729-0434-05	Class I	Drugs	Lot: R2200232 Exp. 01/2025	Labeling mixup: cartons labeled as Daptomycin 350 mg/vial were found to contain vials of Daptomycin 500 mg per vial	Accord Healthcare, Inc.
Quinapril Tablets USP, 20 mg (90 pack), Rx Only, Manufactured for: Lupin Pharmaceuticals, Inc. Baltimore, Maryland 21202, by: Lupin Limited, Goa 403 722 India, NDC# 68180-558-09	Class II	Drugs	Lot #: G102929, Exp 04/2023	CGMP Deviations: Detection of N-Nitroso-quinapril impurity above the acceptable daily intake limit.	Lupin Pharmaceuticals Inc.
Quinapril Tablets USP, 40 mg (90 pack), Rx Only, Manufactured for: Lupin Pharmaceuticals, Inc. Baltimore, Maryland 21202, by: Lupin Limited, Goa 403 722 India, NDC# 68180-554-09	Class II	Drugs	Lot #: G100533, G100534, Exp. 12/2022; G203071, Exp. 03/2024	CGMP Deviations: Detection of N-Nitroso-quinapril impurity above the acceptable daily intake limit.	Lupin Pharmaceuticals Inc.
Alcohol Antiseptic 80% Topical Solution Hand Sanitizer, Non-Sterile Solution, packaged as a a) 2.5 gallon bottle (9,464 ml), NDC 55533-524-02, and b) 55 gallon bottle (208,198 ml), NDC 55533-524-03, Manufactured for: Multi-Mist Products A Division of NCH Corporation 1618 Northgate, Irving, Texas 75062	Class II	Drugs	Lots: 12032504, 12014282, 12013501, 12104039, 12013505, 12032523, 12013510, 12014804, 12015401, and 12014113	CGMP Deviations: Impurities of acetal and acetaldehyde were discovered in the product in excess of allowed limits.	NCH Life Sciences LLC
Ganciclovir for Injection, USP, 500mg per vial, packaged in a 10-count carton, Rx Only, Mfd. by: THYMOORGAN PHARMAZIE GmbH,	Class II	Drugs	Lot#: BQ0006, Exp 08/2023	Labeling: Label mix-up - one vial was mislabeled as Cladribine Injection 10mg/mL inside a 10-	Hikma Pharmaceuticals USA Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Germany, Distributed by Hikma Berkeley Heights, NJ 07922, NDC 0143-9299-01				count carton of Ganciclovir 500 mg.	
Glycopyrrolate Tablets, USP, 1 mg, 50 Tablets (5x10) Unit Dose carton, Rx Only, Manufactured for: AvKARE Pulaski, TN 38478, NDC 50268-363-15	Class II	Drugs	Lot#: 43313, 43342, Exp 12/2023	Failed impurities/degradation specifications: Out of specification for unknown impurities.	AVKARE LLC
Epi-Caine, Epinephrine 0.025% Lidocaine HCL 0.75% Solution for Intraocular Injection, 1 ml, Single Dose Vial, Compounded by Pine Pharmaceuticals, 355 Riverwalk Pkwy, Tonawanda, NY 14150. NDC 69194-0948-1	Class II	Drugs	Lot # 62881, Exp 12/25/2022; 62923, Exp 12/26/2022; 63066, Exp 01/03/2023; 63067, Exp 01/01/2023; 63103, Exp 01/02/2023; 63120, Exp 01/03/2023; 63219, 63226, Exp 01/08/2023; 63263, Exp 01/09/2023; 63380, 63381, Exp 01/15/2023; 63433, Exp 01/16/2023; 63455, Exp 01/17/2023; 63537, Exp 01/22/2023; 63580, Exp 01/23/2023; 63721, Exp 01/29/2023; 63792, Exp 01/31/2023; 63888, Exp 02/05/2023; 63930, Exp 02/06/2023; 63959, Exp 02/07/2023; 64079, Exp 02/13/2023; 64109, Exp 02/14/2023; 64239, Exp 02/21/2023.	CGMP Deviations: Raw material recalled by repackager, due to discoloration.	Pine Pharmaceuticals, LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Heparin Sodium 2,000, USP Units, per 1,000 mL (2 USP Units/mL) in 0.9% Sodium Chloride Injection, 1,000 mL bags, a) Case (NDC 0409-7620-59), b) Single Unit (NDC 0409-7620-49), Rx only, Distributed By Hospira, Inc., Lake Forest, IL 60045 USA,	Class II	Drugs	Lot: 5935283, Exp. 12/01/2023	Lack of assurance of sterility: Bags have the potential to leak.	Pfizer Inc.
Acyclovir Sodium Injection 1,000 mg per 20 mL* (50 mg/mL); Single Dose 20mL Vial, Rx only, Distributed by: AuroMedics Pharma LLC, 279 Princeton-Hightstown Rd, E. Windsor, NJ 08520; Made in India. NDC 55150-155-20	Class II	Drugs	Lot # AC22004, Expiry: 08/2023	Presence of Particulate Matter: Customer complaint of dark particles found inside the vial	Eugia US LLC
Moxifloxacin Ophthalmic Solution, 0.5%, 3 mL, Rx Only, Packaged and Distributed By: Direct Rx, LLC 94 Worldwide Drive, Dawsonville, GA 30534, NDC 72189-0334-05	Class II	Drugs	Lot #: 07MA2232, Exp. 4/30/23	cGMP deviation: discontinue of stability support for product.	Direct Rx
Rifampin Capsules USP, 300 mg, 30-count bottle; Rx Only, Manufactured for: Lupin Pharmaceuticals Baltimore, Maryland 21202, Manufactured by: Lupin Limited Aurangabad 431 210 India. NDC 68180-659-06	Class II	Drugs	Lot # A200171, Exp 12/2023	Failed Impurities/Degradation Specifications: Failure observed in related substance testing during long term stability study.	Lupin Pharmaceuticals Inc.
Rifampin Capsules, 300 mg, 30 count blister card, Rx only, Mfg: Lupin Pharma, Baltimore, MD 21202, original NDC 68180-0659-07, Repackaged by: RemedyRepack Inc., Indiana, PA 15701, Repackaged NDC 70518-2404-00.	Class II	Drugs	Lot #: J0599794-022322, exp. date 02/28/2023; J0621369-052622, exp. date 06/30/2023	Failed Impurities/Degradation specifications	RemedyRepack Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Mitomycin Injection Solution, 4mg/ml, packaged in a 10 mL Multiple-Dose vial, Rx Only, Compounded by: Akina Pharmacy, 23475 Rock Haven Way Suite 105, Sterling, VA 20166.	Class II	Drugs	Lot#: 12062022@7, Exp 1/20/2023; 12072022@32, Exp 1/22/2023	Lack of Assurance of Sterility	Northern VA Compounders PLLC
QuadMix Plus (PGE1/Papaverine HCl/Phentolamine Mesylate/Atropine) 20mcg/30mg/2mg/0.2mg/mL INJECTABLE, packaged in 2.5 mL Multiple-Dose vials, Rx Only, Compounded by: Akina Pharmacy, 23475 Rock Haven Way Suite 105, Sterling, VA 20166.	Class II	Drugs	Lot#: 11182022@1, Exp 1/2/2023; 12012022@9, Exp 1/15/2023; 11142022@8, Exp 12/29/2022; 11292022@10, Exp 1/13/2023	Lack of Assurance of Sterility	Northern VA Compounders PLLC
QuadMix Standard 002 (PGE1/Papaverine HCl/Phentolamine Mesylate/Atropine) 10mcg/30mg/2mg/0.2MG/ML INJECTABLE, packaged in 2.5 mL Multiple-Dose vials, Rx Only, Compounded by: Akina Pharmacy, 23475 Rock Haven Way Suite 105, Sterling, VA 20166.	Class II	Drugs	Lot#: 12012022@11, Exp 1/15/2023	Lack of Assurance of Sterility	Northern VA Compounders PLLC
QuadMix Super 001 (PGE1/Papaverine HCl/Phentolamine Mesylate/Atropine) 40mcg/30mg/2mg/0.4mg/mL INJECTABLE, packaged in 2.5 mL Multiple-Dose vials, Rx Only, Compounded by: Akina Pharmacy, 23475 Rock Haven Way Suite 105, Sterling, VA 20166.	Class II	Drugs	Lot#: 11162022@7, Exp 12/31/2022	Lack of Assurance of Sterility	Northern VA Compounders PLLC
TriMix Original (PGE1/Papaverine HCl/Phentolamine Mesylate) 5.88mcg/18mg/0.6mg/mL INJECTABLE, packaged in 2.5 mL Multiple-Dose vials, Rx	Class II	Drugs	Lot#: 11142022@17, Exp 12/29/2022; 11262022@7, Exp	Lack of Assurance of Sterility	Northern VA Compounders PLLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Only, Compounded by: Akina Pharmacy, 23475 Rock Haven Way Suite 105, Sterling, VA 20166.			1/10/2023; 12022022@3, Exp 1/16/2023		
QuadMix Standard 001 (PGE1/Papaverine HCl/Phentolamine Mesylate/Atropine) 10mcg/30mg/1mg/0.2mg/mL INJECTABLE, packaged in 2.5 mL Multiple-Dose vials, Rx Only, Compounded by: Akina Pharmacy, 23475 Rock Haven Way Suite 105, Sterling, VA 20166.	Class II	Drugs	Lot#: 11162022@10, Exp 12/31/2022; 12052022@9, Exp 1/19/2023	Lack of Assurance of Sterility	Northern VA Compounders PLLC
QuadMix Super 002 (PGE1/Papaverine HCl/Phentolamine Mesylate/Atropine) 40mcg/30mg/4mg/0.4mg/mL INJECTABLE, packaged in 2.5 mL Multiple-Dose vials, Rx Only, Compounded by: Akina Pharmacy, 23475 Rock Haven Way Suite 105, Sterling, VA 20166.	Class II	Drugs	Lot#: 12062022@1, Exp 1/20/2023	Lack of Assurance of Sterility	Northern VA Compounders PLLC
Prostaglandin (E1) Injection Solution, 10 mcg/ml, packaged in 2.5 mL Multiple-Dose vials, Rx Only, Compounded by: Akina Pharmacy, 23475 Rock Haven Way Suite 105, Sterling, VA 20166.	Class II	Drugs	Lot#: 12012022@7, Exp 1/15/2023	Lack of Assurance of Sterility	Northern VA Compounders PLLC
Prostaglandin (E1) Injection Solution, 20 mcg/ml, 2.5 mL Multiple-Dose vials, Rx Only, Compounded by: Akina Pharmacy, 23475 Rock Haven Way Suite 105, Sterling, VA 20166.	Class II	Drugs	Lot#: 11212022@5, Exp 1/5/2023	Lack of Assurance of Sterility	Northern VA Compounders PLLC
Prostaglandin (E1) Injection Solution, 25mcg/ml, 2.5 mL Multiple-Dose vials, Rx Only, Compounded by: Akina Pharmacy,	Class II	Drugs	Lot#: 11252022@12, Exp 1/9/2023	Lack of Assurance of Sterility	Northern VA Compounders PLLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
23475 Rock Haven Way Suite 105, Sterling, VA 20166.					
Prostaglandin (E1) Injection Solution, 40mcg/ml, 2.5 mL Multiple-Dose vials, Rx Only, Compounded by: Akina Pharmacy, 23475 Rock Haven Way Suite 105, Sterling, VA 20166.	Class II	Drugs	Lot#: 12052022@11, Exp 1/19/2023	Lack of Assurance of Sterility	Northern VA Compounders PLLC
TriMix Injection (PGE1/Papaverine HCl/Phentolamine Mesylate) 30mcg/60mg/2mg/mL INJECTABLE, 2.5 mL Multiple-Dose vials, Rx Only, Compounded by: Akina Pharmacy, 23475 Rock Haven Way Suite 105, Sterling, VA 20166.	Class II	Drugs	Lot#: 11142022@12, Exp 12/29/2022	Lack of Assurance of Sterility	Northern VA Compounders PLLC
TriMix Injection (PGE1/Papaverine HCl/Phentolamine Mesylate) 40mcg/30mg/2mg/mL INJECTABLE, 2.5 mL Multiple-Dose vials, Rx Only, Compounded by: Akina Pharmacy, 23475 Rock Haven Way Suite 105, Sterling, VA 20166.	Class II	Drugs	Lot#: 11142022@11, Exp 12/29/2022	Lack of Assurance of Sterility	Northern VA Compounders PLLC
TriMix Injection (PGE1/Papaverine HCl/Phentolamine Mesylate) 60mcg/30mg/3mg/mL INJECTABLE, 2.5 mL Multiple-Dose vials, Rx Only, Compounded by: Akina Pharmacy, 23475 Rock Haven Way Suite 105, Sterling, VA 20166.	Class II	Drugs	Lot#: 11182022@2, Exp 1/2/2023	Lack of Assurance of Sterility	Northern VA Compounders PLLC
TriMix Injection (PGE1/Papaverine HCl/Phentolamine Mesylate) 100mcg/30mg/3mg/mL INJECTABLE, 2.5 mL Multiple-Dose vials, Rx Only, Compounded	Class II	Drugs	Lot#: 11212022@7, Exp 1/5/2023	Lack of Assurance of Sterility	Northern VA Compounders PLLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
by: Akina Pharmacy, 23475 Rock Haven Way Suite 105, Sterling, VA 20166.					
TriMix Plus 001 (PGE1/Papaverine HCl/Phentolamine Mesylate) 20mcg/30mg/2mg/mL INJECTABLE, 2.5 mL Multiple-Dose vials, Rx Only, Compounded by: Akina Pharmacy, 23475 Rock Haven Way Suite 105, Sterling, VA 20166.	Class II	Drugs	Lot#: 11252022@5, Exp 1/9/2023; 12012022@12, Exp 1/15/2023	Lack of Assurance of Sterility	Northern VA Compounders PLLC
TriMix Injection (PGE1/Papaverine HCl/Phentolamine Mesylate) 11.8mcg/18mg/0.6mg/mL INJECTABLE, packaged in 2.5 mL Multiple-Dose vials, Rx Only, Compounded by: Akina Pharmacy, 23475 Rock Haven Way Suite 105, Sterling, VA 20166.	Class II	Drugs	Lot#: 11262022@8, Exp 1/10/2023; 11302022@12, Exp 1/14/2023	Lack of Assurance of Sterility	Northern VA Compounders PLLC
Methylcobalamin Injection Solution, 12.5mg/ml, packaged in 2 mL Multiple-Dose vials, Rx Only, Compounded by: Akina Pharmacy, 23475 Rock Haven Way Suite 105, Sterling, VA 20166.	Class II	Drugs	Lot#: 11292022@16, Exp 1/13/2023	Lack of Assurance of Sterility	Northern VA Compounders PLLC
QuadMix Injectable (PGE1/Papaverine HCl/Phentolamine Mesylate/Atropine) 20mcg/20mg/2mg/0.2mg/mL INJECTABLE, 2.5 mL Multiple-Dose vials, Rx Only, Compounded by: Akina Pharmacy, 23475 Rock Haven Way Suite 105, Sterling, VA 20166.	Class II	Drugs	Lot#: 11292022@12, Exp 1/13/2023	Lack of Assurance of Sterility	Northern VA Compounders PLLC
TriMix Injection (PGE1/Papaverine HCl/Phentolamine) 100mcg/30mg/2mg/mL INJECTABLE, packaged in 2.5 mL Multiple-	Class II	Drugs	Lot#: 11252022@15, Exp 1/9/2023; 11302022@9, Exp 1/14/2023;	Lack of Assurance of Sterility	Northern VA Compounders PLLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Dose vials, Rx Only, Compounded by: Akina Pharmacy, 23475 Rock Haven Way Suite 105, Sterling, VA 20166.			12022022@5, Exp 1/16/2023		
BiMix Injection (Papaverine HCl/Phentolamine Mesylate) 30mg/0.5mg/mL INJECTABLE, packaged in 2.5 mL Multiple-Dose vials, Rx Only, Compounded by: Akina Pharmacy, 23475 Rock Haven Way Suite 105, Sterling, VA 20166.	Class II	Drugs	Lot#: 12062022@3, Exp 1/20/2023	Lack of Assurance of Sterility	Northern VA Compounders PLLC
TriMix Plus 002 (PGE1/Papaverine HCl/Phentolamine Mesylante) 25mcg/30mg/2mg/mL INJECTABLE, packaged in 2.5 mL Multiple-Dose vials, Rx Only, Compounded by: Akina Pharmacy, 23475 Rock Haven Way Suite 105, Sterling, VA 20166.	Class II	Drugs	Lot#: 12062022@4, Exp 1/20/2023	Lack of Assurance of Sterility	Northern VA Compounders PLLC
QuadMix Injectable (PGE1/Papaverine HCl/Phentolamine Mesylate/Atropine) 50mcg/40mg/4mg/0.4mg/mL INJECTABLE, packaged in 2.5 mL Multiple-Dose vials, Rx Only, Compounded by: Akina Pharmacy, 23475 Rock Haven Way Suite 105, Sterling, VA 20166.	Class II	Drugs	Lot#: 12082022@8, Exp 1/22/2023	Lack of Assurance of Sterility	Northern VA Compounders PLLC
BiMix STD 001 (Papaverine HCl/Phentolamine Mesylate) 30mg/1mg/mL INJECTABLE, 2.5 mL Multiple-Dose vials, Rx Only, Compounded by: Akina Pharmacy, 23475 Rock Haven Way Suite 105, Sterling, VA 20166.	Class II	Drugs	Lot#: 10252022@3, Exp 1/31/2023	Lack of Assurance of Sterility	Northern VA Compounders PLLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
TriMix Injection (PGE1/Papaverine HCl/Phentolamine Mesylate) 10mcg/20mg/1mg/mL INJECTABLE, packaged in 2.5 mL Multiple-Dose vials, Rx Only, Compounded by: Akina Pharmacy, 23475 Rock Haven Way Suite 105, Sterling, VA 20166.	Class II	Drugs	Lot#: 11212022@8, Exp 1/5/2023	Lack of Assurance of Sterility	Northern VA Compounders PLLC
Rocuronium Bromide Injection, 50 mg/5 mL (10 mg/mL), 5 x 5 mL Pre-Filled Syringe, 6 x 5 syringe carton, Rx Only, Nephron 503B outsourcing facility, 4500 12th Street Extension, West Columbia, SC 29172, NDC: 69374-924-05	Class II	Drugs	Lot: RC2011A, Exp. 2/22/2023	Lack of Assurance of Sterility	Nephron Sterile Compounding Center LLC
AK-POLY-BAC brand of Bacitracin cand Polymixin B Sulfate Ophthalmic Ointment USP, 3.5 g (1/8 oz.) tube, Rx only, Sterile, Manufactured by: Akorn, Inc., Lake Forest, IL 60045. NDC: 17478-238-35	Class II	Drugs	Lot # 0G87A, EXP 06/30/2023	CGMP Deviations	Akorn, Inc.
Artificial Tears OINTMENT, Lubricant Eye Ointment, Net Wt. 3.5 g (1/8 oz.) per tube, Sterile, Manufactured by: Akorn, Inc., Lake Forest, IL 60045. NDC: 17478-062-35	Class II	Drugs	Lot # 0A08B, EXP 12/31/2022; 0B63A, EXP 1/31/2023; 0C72A, EXP 2/28/2023; 0D14A, 0D19A, EXP 3/31/2023; 0F54A, EXP 5/31/2023; 0G80B, 0G09B, 0G97A, EXP 6/30/2023; 0J78A, EXP 8/31/2023; 0K23A, EXP 9/30/2023; 0L64A, EXP 10/31/2023;1B29A, EXP 1/31/2024; 1C59A,	CGMP Deviations	Akorn, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			1C53A, 1C72A,1C78A, EXP 2/29/2024; 1D87A, 1D89A, EXP 3/31/2024; 1G59A, 1G59B, EXP 6/30/2024; 1K60A, EXP 9/30/2024; 1J57A, EXP 8/31/2024; 1H86A, EXP 7/31/2024; 1K75A, EXP 9/30/2024; 1L12A, EXP 10/31/2024; 1M22A, EXP 11/30/2024		
Artificial Tears Solution, Lubricant Eye Drops, Polyvinyl Alcohol 1.4%, 15 mL (0.5 fl. oz.) per bottle, Sterile, Manufactured by: Akorn, Inc., Lake Forest, IL 60045. NDC: 17478-060-12	Class II	Drugs	Lot: 0L44A, 0L52A, 0L51A, 0L77A, 0L75A, EXP 10/31/2022; 0M02A, 0M01A, EXP 11/30/2022; 1C81A, EXP 2/28/2023; 1D02A, 1D03A, EXP 3/31/2023; 1E10A, 1E08A, 1E23A, 1E26A, 1E25A, 1E27A, 1E33A, EXP 4/30/2023; 1F46A, EXP 5/31/2023; 1G49A, 1G50A, 1G67A, EXP 6/30/2023; 1H04A, 1H74A,1H76A, 1H05A, 1H07A, 1H15A, 1H13A, 1H95A, EXP 7/31/2023; 1J44A, 1J20A, EXP 8/31/2023;	CGMP Deviations	Akorn, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Betaxolol Ophthalmic Solution, USP 0.5%, (Betaxolol HCl 5.6 mg/mL), 5 mL per bottle, Sterile, Rx Only, Manufactured by: Akorn, Inc., Lake Forest, IL 60045. NDC: 17478-705-10	Class II	Drugs	Lot: 1A08A, EXP 12/31/2022	CGMP Deviations	Akorn, Inc.
Ciprofloxacin Ophthalmic Solution, USP 0.3% (Ciprofloxacin HCl), 2.5mL per bottle, Rx Only, Manufactured by: Akorn, Inc., Lake Forest, IL 60045. NDC: 17478-714-25	Class II	Drugs	Lot: Lot 1E22A, EXP 10/31/2022	CGMP Deviations	Akorn, Inc.
Cromolyn Sodium Ophthalmic Solution, USP 4%, 10mL per bottle, Rx Only, Manufactured by: Akorn, Inc., Lake Forest, IL 60045. NDC: 17478-291-11	Class II	Drugs	Lot: 0G75A, 0G12A, EXP 6/30/2023; 0H50A, EXP 7/31/2023; 0J88A, EXP 8/31/2023; 1D98A, EXP 3/31/2024; 1E31A, EXP 4/30/2024; 1D97A, EXP 3/31/2024; 1H14A, EXP 7/31/2024;	CGMP Deviations	Akorn, Inc.
ERYTHROMYCIN OPHTHALMIC OINTMENT USP 0.5%, Net Weight: 3.5g (1/8 oz) per tube, Rx Only, Manufactured by: Akorn, Inc., Lake Forest, IL 60045. NDC: 17478-070-35	Class II	Drugs	Lot: 0L58A, EXP 10/31/2022; 1B21A, 1B31A, EXP 1/31/2023; 1C44A, 1C58A, 1C58B, EXP 2/28/2023; 1E13A, 1E24A, EXP 4/30/2023; 1C57A, EXP 2/28/2023; 1G60A, 1G62A, 1G63A, EXP 6/30/2023; 1J34B, 1J40A, 1J21A, EXP 8/31/2023; 1K74A, EXP 9/30/2023; 1L93A, 1L96B, 1L96A, EXP 10/31/2023; 1M25A,	CGMP Deviations	Akorn, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			1M24A, 1M31A, EXP 11/30/2023; 2A02A, 2A10A, EXP 12/31/2023; 2C07A, EXP 2/29/2024; 2D47A, EXP 3/31/2024; 2E50A, 2E51A, EXP 4/30/2024;		
Erythromycin Ophthalmic Ointment USP, 0.5%, Net Weight: 1 g per tube (50 unit-dose tubes per carton), Rx Only, Manufactured by: Akorn, Inc., Lake Forest, IL 60045. NDC: 17478-070-31	Class II	Drugs	Lot: 1B14B, EXP 1/31/2023; 1C49A, 1C49B, 1C70A, EXP 2/28/2023; 1E09A, 1E34A, 1E34B, 1E09B, EXP 4/30/2023; 1F37C, 1F37A, 1F37B, EXP 5/31/2023; 1G58A, 1G57B, 1G58B, 1G66B, 1G66A, 1G57A, EXP 6/30/2023; 1H77B, 1H80A, 1H80B, 1H77A, EXP 7/31/2023; 1J24A, EXP 8/31/2023; 1K67B, 1K67A, 1K76A, 1K87B, 1K77A, 1K76B, 1K87A, 1K77B, EXP 9/30/2023; 1L90B, 1L90A, 1L92B, 1L92A, EXP 10/31/2023; 1M28A, 1M35A, 1M28B, EXP 11/30/2023; 2D20B, EXP 3/31/2024.	CGMP Deviations	Akorn, Inc.
GONAK Hypromellose Ophthalmic Demulcent Solution, (25 mg) 2.5%, 15 mL	Class II	Drugs	Lot: 0C80A, EXP 2/28/2023; 0B71A, 1B32A,	CGMP Deviations	Akorn, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
per dropper bottle, For Professional Use in Goinoscopic Examinations, Mfd. by: Akorn, INc., Lake Forest, IL 60045. NDC: 17478-064-12			EXP 1/31/2023; 0C80B, EXP 2/28/2023; 0F68A, EXP 5/31/2023; 0G85A, 0G01A, 1G54A, 1G71A, EXP 6/30/2023; 0H32A, 0H47A, 1H75A, EXP 7/31/2023; 0K22A, EXP 9/30/2023; 0M90A, EXP 11/30/2023;		
Ketorolac Tromethamine Ophthalmic Solution, 0.5%, Packaged as a) 10 mL dropper bottle, NDC 17478-209-11; (b) 3 mL dropper bottle, NDC 17478-209-19; (c) 5 mL dropper bottle, NDC 17478-209-10; Rx only, Manufactured by: Akorn, Inc., Lake Forest, IL 60045.	Class II	Drugs	Lot: (a) 1A09A, EXP 12/31/2022; 1H01A, EXP 7/31/2023 ; (b) 1E32A, EXP 4/30/2023; 1F45A, EXP 5/31/2023; 1H99A, EXP 7/31/2023; 1K84A, EXP 9/30/2023; (c) 0L40A, EXP 10/31/2022; 1B38A, EXP 1/31/2023; 1E12A, EXP 4/30/2023; 1F41A, EXP 5/31/2023; 1G73A, 1G68A, EXP 6/30/2023; 1H08A, 1H12A, EXP 7/31/2023	CGMP Deviations	Akorn, Inc.
Levofloxacin Ophthalmic Solution 0.5%, 5 mL per bottle, Rx Only, Manufactured by: Akorn, Inc., Lake Forest, Il 60045. NDC: 17478-106-10	Class II	Drugs	Lot # 1F43A, EXP 5/31/2/023	CGMP Deviations	Akorn, Inc.
Lidocaine Hydrochloride Jelly USP, 2%, Packaged as (a) 5 mL tube (NDC 17478-711-10) x10 per box NDC 17478-711-31; (b) 30	Class II	Drugs	Lot: (a) 0A02B, 0A02D, 0A02C, 0A02A, 0A02E, EXP 12/31/2022; 0B60C,	CGMP Deviations	Akorn, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
mL tube NDC 17478-711-30; Rx only, Manufactured by: Akorn, Inc., Lake Forest, Il 60045.			0B46B, 0B60D EXP 1/31/2023; 0B67B, 0B67D, 0B60B, 0B60A, 0B67A, 0B46D, 0B67C, 0B46A, EXP 1/31/2023; 0C78B, 0C78D, 0C78C, EXP 2/28/2023; 0D11A, 0D11C, 0D11B, 0D11D, EXP 3/31/2023 0E35C, 0E35B, 0E35A, EXP 4/30/2023; 0J63B, 0J63C, EXP 8/31/2023; 0K02A, 0K02C, 0K02D, 0K02B, EXP 9/30/2023; 0L47B, 0L47C, 0L47A, EXP 10/31/2023; 1B12B, 1B12A, 1B23A, 1B23F, 1B12C, 1B23B, 1B23D, 1B23E, 1B12D, EXP 1/31/2024; 1C66C, 1C66A, EXP 2/29/2024; 1D93B, 1D93D, 1D93C, 1D99B, 1D99C, 1D99A, 1D93A, 1D99D, EXP 3/31/2024 1H96C, 1H96D, 1H96E, EXP 7/31/2024; 1J37B, 1J47B, 1J47D, 1J37C, 1J37A, 1J47C, EXP 8/31/2024; 1L18D, 1L98C, 1L18C, 1L18A, 1L98B, 1L98D, 1L18B, 1L98E, EXP 10/31/2024; 2D21B, EXP		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			3/31/2025 (b) 0A06A, 0A37A , EXP 12/31/2022; 0B44A, EXP 1/31/2023; 0C88A, 0C84A, EXP 2/28/2023; 0D21A, 0D08A, EXP 3/31/2023; 0E46A, 0E46B, 0E31A, 0E48A, EXP 4/30/2023; 0F72A, 0F58A, EXP 5/31/2023; 0G05A, EXP 6/30/2023; 0H41A, EXP 7/31/2023; 0J67A, 0J67B, EXP 8/31/2023; 0K15B, 0K15A, EXP 9/30/2023; 0L56B, EXP 10/31/2023; 1B20A, EXP 1/31/2024; 1C47A, 1C52A, EXP 2/29/2024; 1D84B,1D84A, EXP 3/31/2024; 1G61A, 1G64A, 1G72A, EXP 6/30/2024; 1J51A, 1J28A, EXP 8/31/2024; 1K63A, 1K69A, 1K73A, 1K69B, 1K69C, EXP 9/30/2024; 1L15B, EXP 10/31/2024; 2C08A,EXP 2/28/2025;		
Moxifloxacin Ophthalmic Solution, USP, 0.5%, 3 mL per dropper bottle, Rx only, Manufactured by: Akorn, Lake Forest, IL 60045. NDC: 17478-519-19	Class II	Drugs	Lot, Expiry: Lots 1E28A, exp 4/30/2023	CGMP Deviations	Akorn, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Neomycin and Polymyxin B Sulfates, and Bacitracin Zinc Ophthalmic Ointment, USP, Net Wt. 3.5 g (1/8 oz.), Rx Only, Manufactured by: Akorn, INC., Lake Forest, IL 60045. NDC: 17478-235-35	Class II	Drugs	Lot: Lot 1K64A, EXP 9/30/2023	CGMP Deviations	Akorn, Inc.
Ofloxacin Ophthalmic Solution, USP 0.3%, 5 mL per bottle, Rx Only, Manufactured by: Akorn, Inc., Lake Forest, IL 60045; Distributed by: MWI, Boise, ID 83705. NDC: 13985-602-05	Class II	Drugs	Lot: 11B26A, EXP 1/31/2023; 1H02A, EXP 7/31/2023;	CGMP Deviations	Akorn, Inc.
Olopatadine HCl Ophthalmic Solution, USP 0.1%, 5 mL per dropper bottle, Rx Only, Manufactured by: Akorn, Inc., Lake Forest, IL 60045. NDC: 17478-105-05	Class II	Drugs	Lot: Lot 1B41A, EXP 1/31/2023	CGMP Deviations	Akorn, Inc.
Olopatadine HCL Ophthalmic Solution, USP 0.1%, Antihistamine and Redness Reliever, 5 mL (0.17 FL OZ) per bottle, Manufactured by: Akorn, Inc., Lake Forest, IL 60045. NDC: 17478-308-05	Class II	Drugs	Lot: 1L03A, EXP 10/31/2023	CGMP Deviations	Akorn, Inc.
Olopatadine HCl Ophthalmic Solution, USP 0.2%, 2.5 mL per bottle, Rx Only, Manufactured by: Akorn, Inc., Lake Forest, IL 60045. NDC: 17478-305-12	Class II	Drugs	Lot: 0L48A, EXP 10/31/2022; 0L55A, EXP 10/31/2022; 1C75A, EXP 2/28/2023; 1E18A, 1E20A , EXP 4/30/2023;	CGMP Deviations	Akorn, Inc.
Olopatadine HCl Ophthalmic Solution, USP 0.1%, 5 mL (0.17 FL OZ) per bottle, Antihistamine and Redness Reliever, Manufactured by: Akorn, Inc., Lake Forest, IL 60045. Marketed by: GSMS, Incorporated, Camarillo, CA 93012. NDC: 51407-499-05	Class II	Drugs	Lot: 1L16A, 1L17A, EXP 10/31/2023; 1M29A, EXP 11/30/2023; 2A05A, EXP 12/31/2023;	CGMP Deviations	Akorn, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Olopatadine HCl Ophthalmic Solution, USP 0.1%, 5 mL per bottle, Rx Only, Manufactured by: Akorn, Inc., Lake Forest, IL 60045. Marketed by: GSMS, Incorporated, Camarillo, CA 93012. NDC: 60429-957-05	Class II	Drugs	Lot: 1C61A, EXP 2/28/2023; 1D86A, 1D07A, EXP 3/31/2023;	CGMP Deviations	Akorn, Inc.
PAREMYD (hydroxyamphetamine hydrobromide/ tropicamide ophthalmic solution) 1%/0.25%, 15 mL per dropper bottle, Rx only, Manufactured by: Akorn, Inc., Lake Forest, IL 60045. NDC: 17478-704-12	Class II	Drugs	Lot: 0B55A, EXP 1/31/2023; 0D16A, 0D23A, EXP 3/31/2023; 0E51A, EXP 4/30/2023; 1C46A, EXP 2/29/2024;	CGMP Deviations	Akorn, Inc.
Proparacaine Hydrochloride Ophthalmic Solution, USP 0.5%, 15 mL per dropper bottle, Rx only, Distributed by: Akorn Operating Company LLC, Gurnee, IL 60031 NDC: 17478-263-12	Class II	Drugs	Lot: 0L42A, 0L50A, EXP 10/31/2022; 1C64A, 1C76A, EXP 2/28/2023; 1G53A, EXP 6/30/2023; 1J26A, 1J25A, 1J48A, 1J54A, EXP 8/31/2023	CGMP Deviations	Akorn, Inc.
Proparacaine Hydrochloride Ophthalmic Solution, USP 0.5%, 15 mL per bottle, Rx only, Manufactured by: Akorn, Inc., Lake Forest, IL 60045. Distributed By: MWI Boise, ID 83705, NDC: 13985-611-15	Class II	Drugs	Lot: 0L53A, EXP 10/31/2022; 1J49A, EXP 8/31/2023;	CGMP Deviations	Akorn, Inc.
Sodium Chloride Ophthalmic Ointment, USP, 5%, Net Wt. 3.5 g (1/8 oz.) per tube, Manufactured by: Akorn, Inc., Lake Forest, IL 60045. NDC: 17478-622-35	Class II	Drugs	Lot: 0F69A, EXP 5/31/2023; 0G92B, 0G92A, EXP 6/30/2023; 0J69A, EXP 8/31/2023; 0K29A, 0K24A, EXP 9/30/2023; 0M93A, 0M92A, 0M92B, EXP 11/30/2023; 1B25A, EXP	CGMP Deviations	Akorn, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			1/31/2024; 1C74A, EXP 2/29/2024; 1E19A, EXP 4/30/2024; 1C77A, EXP 2/29/2024;		
Timolol Maleate Ophthalmic Solution, USP, 0.5%, Packaged in (a) 5 mL dropper bottle, NDC 17478-288-10; (b) 10 mL dropper bottles: NDC 17478-288-11; (c) 15 mL dropper bottles, NDC 17478-288-12; Rx Only, Sterile, Manufactured by: Akorn, Inc., Lake Forest, IL 60045.	Class II	Drugs	Lot: (a) 0B50A, 0B69A, EXP 1/31/2023; 0C74A, EXP 2/28/2023; 0D04A, EXP 3/31/2023; 0E37A, EXP 4/30/2023; 0G07A, 0G82A, EXP 6/30/2023; 0H26A, 0H28A, 0H53A, 0H36A, EXP 7/31/2023; 0J64A, 0J58A, 0J66A, EXP 8/31/2023; 0K96A, 0K06A, 0K98A, 0K04A, 0K03A, 0K99A, EXP 9/30/2023; 0L72A, EXP 10/31/2023; 0M81A, 0M85A, 0M80A, 0M84A, 0M82A, 0M83A, EXP 11/30/2023; 1A01A, 1A02A, EXP 12/31/2023; 1B16A, 1B13A, 1B17A, EXP 1/31/2024; 1C51A, EXP 2/29/2024; (b) 0B59A , EXP 1/31/2023;0E49A, EXP 4/30/2023; 0G14A, EXP 6/30/2023; 0H38A, EXP 7/31/2023; 0J84A, EXP 8/31/2023; 0K05A, EXP 9/30/2023; 0L59A,	CGMP Deviations	Akorn, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			EXP 10/31/2023; 0M86A, 0M87A, EXP 11/30/2023; 1A03A, EXP 12/31/2023; 1B37A, EXP 1/31/2024; 1C63A, EXP 2/29/2024; 1C54A, EXP 2/29/2024; 1D83A, EXP 3/31/2024; (c) 0C82A, EXP 2/28/2023; 0G84A, EXP 6/30/2023; 0H49A, EXP 7/31/2023; 0J77A, EXP 8/31/2023; 0J75A, EXP 8/31/2023; 0L57A, EXP 10/31/2023; 0L74A, EXP 10/31/2023; 0L46A, EXP 10/31/2023; 1G52A, EXP 6/30/2024; 1J52A, EXP 8/31/2024;		
Tobramycin Ophthalmic Solution, USP, 0.3%, 5 mL per dropper bottle, Rx Only, Manufactured by: Akorn, Inc., Lake Forest, IL 60045. NDC 17478-290-10	Class II	Drugs	Lot: 1C56A, EXP 2/28/2023; 1J50A, EXP 8/31/2023; 1K61A, EXP 9/30/2023 ; 1M27A, EXP 11/30/2023;	CGMP Deviations	Akorn, Inc.
Tobramycin Ophthalmic Solution, USP, 0.3%, 5 mL per bottle, Rx Only, Manufactured by: Akorn, Inc., Lake Forest, IL 60045; Distributed by: MWI, Boise, ID 83705. NDC 13985-604-05	Class II	Drugs	Lot: 1D94A, EXP 3/31/2023; 1E35A, EXP 4/30/2023; 2A06A, EXP 12/31/2023	CGMP Deviations	Akorn, Inc.
SIREtizer Hand Sanitizer (Ethyl Alcohol) 80%, packaged in a) 3.38 oz (100 mL), b) 10 oz (295 ml), UPC 8 60003 85882 0, and c) 16.9	Class II	Drugs	Lots: 0001, 0005, 0007	CGMP Deviations and Superpotent Drug: Levels of acetal and acetaldehyde above allowable	Southwest Iowa

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
oz (500 ml), UPC 8 60003 85880 6 bottles, Southwest Iowa Renewable Energy, 10868 189th Street, Council Bluffs, IA 51503; Bottled by Southwest 6th Beverages, LLC, Lincoln, NE 68522 and Bottled by South Tenth Development, LLC, Lincoln, NE 68522.				limits. Additionally, lot 001 was superpotent.	Renewable Energy LLC
Sensorcaine (Bupivacaine HCl and Epinephrine Injection, USP) with Epinephrine 1:200,000 (as bitartrate), 0.25%, 125 mg per 50 mL (2.5 mg per mL), 50 mL Multiple Dose Vial (NDC 63323-461-01), packaged in 25 Multiple Dose Vials per tray (NDC 63323-461-57), Rx only, Fresenius Kabi, Lake Zurich, IL 60047.	Class II	Drugs	Batch #: 6128061, exp 03/2024; 6128663, 6128664, exp 05/2024	Subpotent Drug: Testing results below the defined limit for the epinephrine portion of this product.	Fresenius Kabi USA, LLC
Sensorcaine (Bupivacaine HCl and Epinephrine Injection, USP) with Epinephrine 1:200,000 (as bitartrate), 0.5%, 250 mg per 50 mL (5 mg per mL), 50 mL Multiple Dose Vial (NDC 63323-463-01), packaged in 25 Multiple Dose Vials per tray (NDC 63323-463-57), Rx only, Fresenius Kabi, Lake Zurich, IL 60047.	Class II	Drugs	Batch #: 6128399, 6128400, 6128401, exp 04/2024	Subpotent Drug: Testing results below the defined limit for the epinephrine portion of this product.	Fresenius Kabi USA, LLC
Sensorcaine-MPF (Bupivacaine HCl and Epinephrine Injection, USP) with Epinephrine 1:200,000 (as bitartrate), 0.25%, 25 mg per 10 mL (2.5 mg per mL), 10 mL Single Dose Vial (NDC 63323-468-01), packaged in 25 Single Dose Vials per tray (NDC 63323-468-17), Rx only, Fresenius Kabi, Lake Zurich, IL 60047.	Class II	Drugs	Batch #: 6128800, exp 12/2023	Subpotent Drug: Testing results below the defined limit for the epinephrine portion of this product.	Fresenius Kabi USA, LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Rasagiline Mesylate Tablets 1 mg; 30 tablets in HDPE bottle; Rx only; NDC 67877-260-30; Manufactured by Alkem Laboratories Ltd., India; Distributed by: Ascend Laboratories, LLC, Parsippany, NJ 07054	Class II	Drugs	Lot # 22140903. Exp. Dec. 2024	Presence of Foreign Substance- A complaint was received of black spots/shiny metallic speck on the tablets.	Ascend Laboratories, LLC
Rifampin Capsules USP, 300 mg, 100 Capsules (10 x 10) per carton, Rx Only, Distributed by: American Health Packaging, Columbus, Ohio 43217, Carton NDC 60687-586-01 (Individual Dose NDC: 60687-586-11)	Class II	Drugs	Lot #: 1007805, exp. 12/31/2023	Failed Impurities/Degradations Specifications	Amerisource Health Services LLC
Hand Sanitizer, HSANI500ML, (Isopropyl Alcohol), 75% v/v, packaged in a) 500 mL bottle and b) 6 x 500 mL bottles per case, Thermo Fisher Scientific: Janssen Pharmaceuticalaan 3a, 2440 Geel - Belgium, 1 Reagent Lane, Fair Lawn, NJ 07410.	Class II	Drugs	Lot Numbers: 202160, 202162, 202324, 202368, 202369, 202593, 202594, 202835, 202862, 202863, 202865, 202836, 202864, 203061, 203098, 203099, 203100, 203101, 203102, 203236, 203237, 203239, 203337, 203338, 203335, 203336	CGMP Deviations: Voluntary recall of all hand sanitizer distributed after March 31, 2022, due to FDA issued guidance to cease placing hand sanitizer product, produced under temporary approval, into the market after March 31, 2022.	Fisher Scientific Co., LLC
Hand Sanitizer, HSANI4LI, (Isopropyl Alcohol), 75% Topical Solution, packaged in 4 L bottles, Thermo Fisher Scientific: Janssen Pharmaceuticalaan 3a, 2440 Geel - Belgium, 1 Reagent Lane, Fair Lawn, NJ 07410.	Class II	Drugs	Lot Numbers: 202161, 202322, 202323, 202794, 202858, 203188, 203238, 203240, 203722 203723, 203724, 203725, 204852	CGMP Deviations: Voluntary recall of all hand sanitizer distributed after March 31, 2022, due to FDA issued guidance to cease placing hand sanitizer product, produced under temporary approval, into the market after March 31, 2022.	Fisher Scientific Co., LLC
Timolol Maleate Ophthalmic Solution, USP 0.5%, 2.5 mL, Rx Only, Mfg by: Apotex Inc. Toronto, Ontario Canada M9L 1T9 Mfg for:	Class III	Drugs	Lot# TA4844, Exp 03/2023	Failed Stability Specifications: Out of specification for weight loss at the 18-month stability timepoint	Apotex Corp.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Apotex Corp. Weston, FL 33326, NDC 60505-1005-4				and projected weight loss of 21.1% at shelf life.	
Prochlorperazine Maleate Tablets, USP 5mg, 100 tablets, RX Only, Jubilant Cadista Pharmaceuticals, Inc., Salisbury, Maryland 21801, NDC 59746-113-06	Class III	Drugs	Lot#: 21P0336, Exp: 04/2023	Subpotent Drug: Out of specification for assay at the 18-month stability timepoint.	Jubilant Cadista Pharmaceuticals, Inc.
Triamterene and Hydrochlorothiazide Capsules, USP (37.5 mg/25 mg), Rx Only, 1000 Capsules per bottle, Distributed by: Lannett Company, Inc., Philadelphia, PA 19136. NDC: 0527-1632-10	Class III	Drugs	Lots: 20256318A (12/2022), 20256321A (12/2022), 21000238A (01/2023)	Failed Impurity/Degradation Specifications	Lannett Company Inc.
Triamterene and Hydrochlorothiazide Capsules, USP (37.5 mg/25 mg), Rx Only, [100 or 1000] Capsules per bottle, Distributed by: Lannett Company, Inc., Philadelphia, PA 19136. NDC 100 Count bottle: 0527-1632-01; NDC 1,000 bottle: 0527-1632-10	Class III	Drugs	Lots: 21000279A (exp 01/2023), 20256320A (12/2022)	Failed Impurity/Degradation Specifications	Lannett Company Inc.
SINUVA (mometasone furoate) sinus implant, 1350 mcg, 1 implant per pouch, Rx Only, intersect ENT, 1555 Adams Drive, Menlo Park, CA 94025, NDC 10599-003-01.	Class III	Drugs	Lot #s: 10111003, Exp 12/31/2022; 10203002, Exp 01/31/2023; 10302002, 10325001, Exp 02/28/2023; 10519001, 10526002, Exp 04/30/2023; 10602002, Exp 05/31/2023; 10819004, Exp 09/30/2023; 21092101, 21111901, Exp	Failed Dissolution Specification; product did not meet the average 24-hour drug release rate (dissolution) specification stability time point at 9 months.	Intersect ENT, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			10/31/2023; 21110402, Exp 12/31/2023.		
Levofloxacin Tablets, USP 500 mg; 50-count bottles, Rx Only, Manufactured for: Macleods Pharma USA, Inc. Princeton, NJ 08540; Manufactured by: Macleods Pharmaceuticals Ltd., Baddi, Himachal Pradesh, India. NDC 33342-022-08	Class III	Drugs	Lot #: BLF2214A; Exp. 06/2025	Mismatching of the embossing on the tablets (T7) with the embossing mentioned in the package insert (ML63) in the distributed bottles.	MACLEODS PHARMA USA, INC

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

CURRENT DRUG SHORTAGES

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

Generic Name or Active Ingredient

Albuterol Sulfate 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
Cefixime Oral Capsules
Cefotaxime Sodium Injection
Cefotetan Disodium Injection
Chloroprocaine Hydrochloride Injection
Chlorothiazide Oral Suspension
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
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
Floxuridine for Injection
Fludarabine Phosphate Injection
Flurazepam Hydrochloride 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
Indigotindisulfonate Sodium Injection
Isoniazid Injection
IV Fat Emulsion
Ketamine Injection
Ketorolac Tromethamine Injection
Leucovorin Calcium Lyophilized Powder for Injection
Lidocaine Hydrochloride (Xylocaine) and Dextrose Injection Solution-Premix Bags
Lidocaine Hydrochloride (Xylocaine) Injection
Lidocaine Hydrochloride (Xylocaine) Injection with Epinephrine
Lithium Oral Solution
Lorazepam Injection
Mannitol Injection
Mepivacaine Hydrochloride 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
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
Quinapril and Hydrochlorothiazide Tablets
Quinapril Hydrochloride Tablets
Remifentanil Injection
Rifampin Capsules
Rifampin Injection
Rifapentine Tablets
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
Streptozocin (Zanosar) Sterile Powder
Sucralfate Tablets
Sufentanil Citrate Injection
Sulfasalazine Tablets
Technetium TC-99M Mebrofenin Injection
Teprotumumab-trbw
Tirzepatide Injection
Triamcinolone Acetonide Injectable Suspension
Triamcinolone Hexacetonide Injectable suspension
Trimethobenzamide Hydrochloride Capsules
Valproate Sodium Injection
Vecuronium Bromide for Injection
Verteporfin (Visudyne) Injection