PERFORMRx℠

Drug Information Update

March 2024

TABLE OF CONTENTS

NEWLY AVAILABLE GENERICS

Generic Name/ Dosage Form	Brand Name	Manufacturer	Indication
nitroglycerin 0.4% rectal ointment	Rectiv	Cosette Pharmaceuticals	• Treatment of moderate to severe pain associated with chronic anal fissure
tiopronin 100 mg, 300 mg delayed-release tablets	Thiola EC	Torrent Pharmaceuticals	• To be used in combination with high fluid intake, alkali, and diet modification, for the prevention of cystine stone formation in adults and pediatric patients 20 kg and greater with severe homozygous cystinuria, who are not responsive to these measures alone
sodium nitroprusside/sodium chloride 20 mg-0.9 mg/100 ml, 50 mg-0.9 mg/100 ml intravenous vials	Nipride RTU	Slate Run Pharmaceuticals	• Immediate reduction of blood pressure • Producing controlled hypotension to reduce bleeding during surgery • Treatment of acute heart failure to reduce left ventricular end-diastolic pressure, pulmonary capillary wedge pressure, peripheral vascular resistance and mean arterial blood pressure

NEW DRUG ENTITIES/STRENGTHS/COMBINATIONS

Drug Name	Generic Name	Description
Amtagvi Intravenous Suspension 72000000000 CELLS	Lifileucel	New entity. Tumor-derived autologous T-cell immunotherapy indicated for the treatment of adult patients with unresectable or metastatic melanoma previously treated with a programmed cell death protein-1 (PD-1) blocking antibody, and if BRAF V600 mutation–positive, a BRAF inhibitor with or without a MEK inhibitor. Approved under accelerated approval pathway based on objective response rate. First cellular therapy approved for unresectable or metastatic melanoma. Amtagvi is manufactured using tumor-infiltrating leukocyte (TIL) cells that are collected from a patient's tumor tissue, treated in culture, and then infused back to the patient following lymphodepletion. Manufacturing process takes approximately 34 days.
Filsuvez External Gel 10 %	Birch Triterpenes	New entity. Topical gel indicated for the treatment of wounds associated with dystrophic epidermolysis bullosa (DEB) and junctional epidermolysis bullosa (JEB) in adult and pediatric patients 6 months of age and older. First FDA-approved treatment for wounds associated with JEB. Will compete with Vyjuvek (beremagene geperpavec-svdt), an off-the-shelf topical gel gene therapy for the treatment of DEB.
Zymfentra (1 Pen) Subcutaneous Auto-injector Kit 120 MG/ML Zymfentra (2 Pen) Subcutaneous Auto-injector Kit 120 MG/ML Zymfentra (2 Syringe) Subcutaneous Prefilled Syringe Kit 120 MG/ML	Infliximab-dyyb	New dosage form. Subcutaneous formulation of infliximab indicated for maintenance therapy in adults with moderately to severely active ulcerative colitis (UC) and Crohn's disease (CD) following treatment with an infliximab product administered intravenously. Zymfentra is a self-administered subcutaneous formulation of Inflectra, which was approved in 2016 as the first biosimilar to Remicade. It is considered a biobetter of Inflectra, however, it does not share the pediatric CD, pediatric UC, rheumatoid arthritis, ankolysing spondalytis, psoriatic arthritis, and plaque psoriasis indications that Inflectra has.
Hemlibra Subcutaneous Solution 12 MG/0.4ML	Emicizumab-kxwh	New strength. Previously only available as 30 mg/mL, 60 mg/0.4 mL, 105 mg/0.7 mL, 150 mg/mL, and 300 mg/2 ml single-dose vials.

Drug Name	Generic Name	Description
Pemrydi RTU Intravenous Solution 100 MG/10ML Pemrydi RTU Intravenous Solution 500 MG/50ML	Pemetrexed Disodium	New entity. 505(b)(2) approval. New ready-to-use formulation of pemetrexed that does not require reconstitution, dilution, or refrigeration. Indicated, in combination with pembrolizumab and platinum chemotherapy, for the initial treatment of patients with metastatic non-squamous non-small cell lung cancer with no EGFR or ALK genomic tumor aberration and for initial treatment, in combination with cisplatin, of patients with malignant pleural mesothelioma whose disease is unresectable or who are otherwise not candidates for curative surgery.
Yuflyma (2 Syringe) Subcutaneous Prefilled Syringe Kit 20 MG/0.2ML	Adalimumab-aaty	New strength. Humira biosimilar. Only available in high concentration strengths.

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†
Biktarvy	bictegravir/emtricitabine/tenofovir alafenamide 30 mg-120 mg-15 mg, 50 mg-200 mg-25 mg oral tablets	Gilead Sciences	To be used as a complete regimen for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 14 kg: ○ Who have no antiretroviral treatment history or ○ To replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen with ~~no history of treatment failure and~~ no known **or suspected** substitutions associated with resistance to ~~the individual components of Biktarvy~~ **bictegravir or tenofovir**
Opdivo	nivolumab 40 mg/4 ml, 100 mg/10 ml, 120 mg/12 ml, 240 mg/24 ml intravenous vials	Bristol-Myers Squibb	○ **In combination with cisplatin and gemcitabine for the first-line treatment of adult patients with unresectable or metastatic urothelial carcinoma (UC)** *Note: Opdivo has many other approved indications not mentioned here; see full prescribing information for details.*
Brukinsa	zanubrutinib 80 mg oral capsules	BeiGene	Kinase inhibitor indicated for the treatment of adult patients with: ○ Mantle cell lymphoma (MCL) who have received at least one prior therapy[1] ○ Waldenström's macroglobulinemia ○ Relapsed or refractory marginal zone lymphoma (MZL) who have received at least one anti–CD20-based regimen[1] ○ Chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma

Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication†
			○ **Relapsed or refractory follicular lymphoma (FL), in combination with obinutuzumab, after two or more lines of systemic therapy[2]** [1]This indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial. **[2]This indication is approved under accelerated approval based on response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.**
Wegovy	semaglutide 0.25 mg/0.5 ml, 0.5 mg/0.5 ml, 1 mg/0.5 ml, 1.7 mg/0.75 ml, 2.4 mg/0.75 ml subcutaneous pen-injector	Novo Nordisk	To be used in combination with a reduced calorie diet and increased physical activity: • **To reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established cardiovascular disease and either obesity or overweight** • To reduce excess body weight and maintain weight reduction long term in: ○ Adults and pediatric patients aged 12 years and older with obesity ○ Adults with overweight in the presence of at least one weight-related comorbid condition
Praluent	alirocumab 75 mg/ml, 150 mg/ml subcutaneous pen-injector	Regeneron Pharmaceuticals	○ To reduce the risk of myocardial infarction, stroke, and unstable angina requiring hospitalization in adults with established cardiovascular disease

Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication†
			○ As adjunct to diet, alone or in combination with other low-density lipoprotein cholesterol (LDL-C)-lowering therapies, in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH), to reduce LDL-C ○ As an adjunct to other LDL-C-lowering therapies in adult patients with homozygous familial hypercholesterolemia (HoFH) to reduce LDL-C ○ **As an adjunct to diet and other LDL-C-lowering therapies in pediatric patients aged 8 years and older with HeFH to reduce LDL-C**
Breyanzi	lisocabtagene maraleucel 1.5 x 10^6 to 70 x 10^6 CAR T-cells/ml intravenous suspension	Bristol-Myers Squibb	• Treatment of adult patients with large B-cell lymphoma (LBCL), including diffuse large B-cell lymphoma (DLBCL) not otherwise specified (including DLBCL arising from indolent lymphoma), high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B, who have: ○ Refractory disease to first-line chemoimmunotherapy or relapse within 12 months of first-line chemoimmunotherapy (1.1); or ○ Refractory disease to first-line chemoimmunotherapy or relapse after first-line chemoimmunotherapy and are not eligible for hematopoietic stem cell transplantation (HSCT) due to comorbidities or age; or ○ Relapsed or refractory disease after two or more lines of systemic therapy <u>Limitations of Use:</u> Breyanzi is not indicated for the treatment of patients with primary central nervous system lymphoma • **Treatment of adult patients with relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL)**

Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication†
			who have received at least 2 prior lines of therapy, including a Bruton tyrosine kinase (BTK) inhibitor and a B-cell lymphoma 2 (BCL-2) inhibitor[1] **[1]This indication is approved under accelerated approval based on response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).**
Livmarli	maralixibat	Mirum Pharmaceuticals	• Treatment of cholestatic pruritus in patients **3 months** ~~1 year~~ of age and older with Alagille syndrome (ALGS) • **Treatment of cholestatic pruritus in patients 5 years of age and older with progressive familial intrahepatic cholestasis (PFIC)** ○ **Limitations of Use:** **Livmarli is not recommended in a subgroup of PFIC type 2 patients with specific ABCB11 variants resulting in nonfunctional or complete absence of bile salt export pump (BSEP) protein**
Xhance	fluticasone propionate 93 mcg nasal spray	OptiNose US, Inc.	○ Treatment of chronic rhinosinusitis with nasal polyps (CRSwNP) in adult patients 18 years of age or older ○ **Treatment of chronic rhinosinusitis without nasal polyps in patients 18 years of age and older**

RECALLS

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Neptune's Fix, Tianeptine Elixir, Fast Acting, 0.338 fl oz (10 mL) bottle, Distributed By Neptune Resources, LLC, 30 N. Gould Street, Ste R, Sheridan, WY 82801.	Class I	Drugs	All lots	Marketed without an approved NDA/ANDA: Product contains tianeptine, a substance not FDA-approved for any medical use in the United States.	Neptune Resources, LLC
Neptune's Fix, Tianeptine Extra Strength Elixir, 0.338 fl oz (10 mL) bottle, Distributed By Neptune Resources, LLC, 30 N. Gould Street, Ste R, Sheridan, WY 82801.	Class I	Drugs	All lots	Marketed without an approved NDA/ANDA: Product contains tianeptine, a substance not FDA-approved for any medical use in the United States.	Neptune Resources, LLC
Neptune's Fix, Tianeptine Tablets Extended Relief, Twenty Tablets per Box, Wide Awake, 3000 mg (150 mg Per Tablet), Distributed By Neptune Resources, LLC, 30 N. Gould Street, Ste R, Sheridan, WY 82801.	Class I	Drugs	All lots	Marketed without an approved NDA/ANDA: Product contains tianeptine, a substance not FDA-approved for any medical use in the United States.	Neptune Resources, LLC
TING 1% Tolnaftate Athlete's Foot Spray Antifungal Spray Liquid, NET WT 4.5 oz. (128 g) cans, Distributed by: Insight Pharmaceuticals LLC, a Prestige Consumer Healthcare company, Tarrytown, NY 10591 UPC 3 63736 81961 3	Class I	Drugs	Lot # 0H50545, Exp. date 07/31/24; 1G50645, Exp. date 06/30/25	Chemical Contamination; presence of benzene.	Insight Pharmaceuticals LLC, a Prestige Consumer Healthcare company
Sustain Herbal Dietary Supplement, packaged in 10 capsules per box, Distributed by VSD Productions, Inc. Las Vegas, Nevada	Class I	Drugs	Lot #: BTH:230551, Exp. Date 12.05.2026; BTH:230571, Exp. Date 14.05.2026	Marketed Without An Approved NDA/ANDA: FDA analysis found this product to be tainted with	Today The World

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
				undeclared tadalafil, an ingredient found in FDA approved products for the treatment of male sexual enhancement, making this drug an unapproved drug.	
SCHWINNNG Herbal Dietary Supplement, packaged in 10 capsules per box, Distributed by: Today the World LLC, Vancouver, WA 98683	Class I	Drugs	Lot #: 2108, Exp. Date 10/31/2024.	Marketed Without An Approved NDA/ANDA: FDA analysis found the product to be tainted with undeclared nortadalafil, an ingredient found in FDA approved product for the treatment of male sexual enhancement, making this drug an unapproved drug.	Today The World
Arize Herbal Dietary Supplement, packaged in 10 capsules per box, Distributed by: Natural Herbal Remedies, LLC, Cheyenne, WY 82001, www.getarize.com	Class I	Drugs	Lot #: 2107, Exp. Date 10/31/2024.	Marketed Without An Approved NDA/ANDA: FDA analysis found the product to be tainted with undeclared nortadalafil, an ingredient found in FDA approved product for the treatment of male sexual enhancement, making this drug an unapproved drug.	Today The World
Fosfomycin Tromethamine Granules for Oral Solution, (equivalent to 3 grams of fosfomycin), single-dose sachet, Rx Only, Manufactured by: Alkem Laboratories Ltd., INDIA. Distributed by:	Class II	Drugs	lOTS #: 22121458, 22121459, 22121460, 22121461, 22121462, 22121463, 22121464,	Failed Impurities/Degradation Specification: Out of	Ascend Laboratories, LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Ascend Laboratories, LLC. Parsippany, NJ 07054. NDC 67877-749-57			Exp 4/2024; 22121176, 22121407, 22121465, Exp 3/2024; 22121761, 22121762, 22121763, 22121764, 22121766, 22121968, 22121969, Exp 5/2024.	specification for organic impurities	
Adrenalin (epinephrine) Injection 1mg/mL, 1mL single dose vial, Rx only, Packaged By: Henry Schein, Inc., 80 Summit View Lane, Bastian, VA 24314, Original NDC 42023-159-25 Repack NDC 0404-9810-01	Class II	Drugs	Original Lot # 64103, exp. date 11/24 Repackaged Lot # 39747, exp. date 01/26	Labeling: Incorrect or Missing Lot and/or Exp Date. The expiration date listed on the Repack Pouch Label is incorrect.	Henry Schein Inc. and Glove Club HSI Gloves Inc.
Norepinephrine Bitartrate in 5% Dextrose Injection, 8 mg/ 250 mL (32 mcg/mL), For Intravenous Infusion Only, 250 mL vial, Rx Only, Baxter Healthcare Corporation, Deerfield, IL 60015. Made in Ireland. NDC: 0338-0108-20	Class II	Drugs	Lot 23I21G64; Exp. 07/31/2024	Incorrect product concentration on the overwrap label: The overwrap label incorrectly identified the product strength as 4 mg / 250 mL; however, the primary bag label correctly identified the product strength as 8 mg / 250 mL.	Baxter Healthcare Corporation
CVS Health Cherry Cough Drops, Menthol cough suppressant/Oral Anesthetic, 160 drops per bag, item number 20001089, Bestco, 288 Mazeppa Road, Mooresville, NC 28115	Class II	Drugs	100042059, Exp 12/31/2026	CGMP Deviations: Potential Glass and Silicone particulates in product	Bestco LLC
Meijer Cherry Cough Drops, Menthol cough suppressant/Oral Anesthetic, 200 drops per	Class II	Drugs	100042236, Exp 12/31/2026	CGMP Deviations: Potential Glass and Silicone particulates in product	Bestco LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
bag, item number 20000345, Bestco, 288 Mazeppa Road, Mooresville, NC 28115					
Kroger Cherry Cough Drops, Menthol cough suppressant/Oral Anesthetic, 200 drops per bag, item number 20000064, Bestco, 288 Mazeppa Road, Mooresville, NC 28115	Class II	Drugs	100042238, Exp 12/31/2026	CGMP Deviations: Potential Glass and Silicone particulates in product	Bestco LLC
Family Wellness Cherry Cough Drops Menthol cough suppressant/Oral Anesthetic, 80 drops per bag, item number 20001187, Bestco, 288 Mazeppa Road, Mooresville, NC 28115	Class II	Drugs	100042290, Exp 12/31/2026	CGMP Deviations: Potential Glass and Silicone particulates in product	Bestco LLC
Equate Cherry Cough Drops, Menthol cough suppressant/Oral Anesthetic, a) 30 drops per bag, item number 20000462, b) 160 drops per bag, item number 20000463, Bestco, 288 Mazeppa Road, Mooresville, NC 28115	Class II	Drugs	a) 100041954, Exp 12/31/2026; b) 100042048, 100042060, Exp 12/31/2026	CGMP Deviations: Potential Glass and Silicone particulates in product	Bestco LLC
Pure Care Foaming Mint Hand Sanitizer 62%, Distributed by: Air Scent International, 290 Alpha Drive, RIDC Industrial Park, Pittsburg, PA 15238 USA, www.airscent.com, NDC 75009-562.	Class II	Drugs	Lot # 2022-012884 Lot # 2023-002020 Lot # 2023-003532 Lot # 2023-003761	CGMP Deviations	Alpha Aromatics
Voriconazole for Oral Suspension, 40mg/mL, Orange-Flavored, 49g/75mL when reconstituted. Mixing Directions: Tap the bottle to release the powder. Add 50mL of water to the bottle and shake vigorously for 1 minute. Manufactured by: Novel Laboratories, Inc. Somerset, NJ 08873. Manufactured for: Lupin Pharmaceuticals Inc. Baltimore, MD 21202. NDC: 43386-038-60.	Class II	Drugs	Lot#: S200756; Exp. 10/2024 Lot#: S300218; Exp. 04/2025 Lot#: S300633; Exp. 09/2025	Labeling: Incorrect or Missing Package Insert	Lupin Pharmaceuticals Inc.
Acthar Gel (repository corticotropin injection) 400 USP units/5mL (80 USP units/mL), 5mL	Class II	Drugs	Lot #: 1564-103, Exp 9/30/2024	cGMP deviations: Temperature excursion due	Mallinckrodt Hospital Products Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
multiple-dose vial, Rx only, Mfd. for: Mallinckrodt ARD LLC, Bridgewater, NJ 08807, NDC 63004-8710-1				to shipping delay from manufacturer to distributor. Affected distributor has been notified.	
Terlivaz (terlipressin for injection), 0.85mg/vial, Single-Dose Vial, Rx only, Distributed by: Mallinckrodt Hospital Products Inc., Bridgewater, NJ 08807, USA, NDC 43825-200-01	Class II	Drugs	Lot #: 22TRP01-F2, Exp 6/30/2024	cGMP deviations: Temperature excursion due to shipping delay from manufacturer to distributor. Affected distributor has been notified.	Mallinckrodt Hospital Products Inc.
Oseltamivir Phosphate for Oral Suspension 6mg/ml, 60 mL (reconstituted) bottle, RX only, Distributed by Amneal Pharmaceuticals LLC, Bridgewater, NJ 08807. NDC# 69238-1273-6	Class II	Drugs	Lot # BF22722A, Exp. 08/31/2024; BJ15122A, Exp. 09/30/2024	Failed Impurities/Degradation Specifications: Out-of-specification test results.	Amneal Pharmaceuticals of New York, LLC
Fluticasone Propionate Nasal Spray USP 50mcg, 120 Metered Sprays - 16 g net fill, Rx Only, Manufactured by: Apotex Inc. Toronto, Ontario Canada M9L 1T9, Manufactured for: Apotex Corp Weston, FL 33326. NDC 60505-0829-1	Class II	Drugs	Lot number # TX5274 Exp. 09/30/2026	Potential presence of Burkholderia cepacia complex (BCC)	Apotex Corp.
Clobazam Tablets 10mg, 100-count bottle, Rx Only, Manufactured by: Micro Labs Limited Goa-403 722, India. Manufactured for: Micro Labs USA, Inc. Somerset, NJ 08873. NDC 42571-315-01	Class II	Drugs	ZOAG043	CGMP Deviations: Out of specification for residual solvents.	Micro Labs Limited
CABTREO (clindamycin phosphate, adapalene and benzoyl peroxide) Topical Gel 1.2%/0.15%/3.1%, Not for Oral, Ophthalmic or Intravaginal Use, Rx Only, Net Wt. 50g, Distributed by Bausch Health US, LLC Bridgewater, NJ 08807 USA, Manufactured by:	Class II	Drugs	Lot: 7001796, Exp 05/31/2025	CGMP Deviations: Product was stored outside labeled storage temperature requirements. Product was exposed to controlled room temperature environment	MCKESSON CORPORATION

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Bausch Health Companies, Inc. Laval Quebec H7L 448, Canada, NDC 0187-0006-25.				instead of remaining refrigerated.	
Equate Lubricant Eye Ointment (Mineral Oil 42.5%, White Petrolatum 57.3%), Packaged in 3.5 gram tubes, Distributed by Walmart Inc., Bentonville, AR 72716, NDC 79903-026-35, UPC 681131395298	Class II	Drugs	Lot #: A2E01, Exp. Date Apr-24; A2L05, Exp. Date Nov-24, A3B01, Exp. Date Jan-25; A3C01, Exp. Date Feb-25	Lack of Assurance of Sterility	Brassica Pharma Pvt Ltd
Equate Stye Lubricant Eye Ointment (Mineral Oil 31.9%, White Petrolatum 57.7%), Packaged in 3.5 g tubes, Distributed by Walmart Inc., Bentonville, AR 72716, NDC 79903-028-35, UPC 681131395304	Class II	Drugs	Lot #: A2D08, Exp. Date Mar-24; A2F02, Exp. Date May-24; A2I03, Exp. Date Aug-24; A2L03, A2L04, Exp. Date Nov-24; A3C03, A3C05, Exp. Date Feb-25 A3H01, A3H03, Exp. Date Jul-25	Lack of Assurance of Sterility	Brassica Pharma Pvt Ltd
CVS Health Lubricant Eye Ointment (Mineral oil 31.9% Emollient, White petrolatum 57.7% Emollient), Packaged in in 3.5 gram tubes, Distributed by: CVS Pharmacy, Inc. One CVS Drive Woonsocket, RI 02895, NDC 76168-707-35, UPC 050428634141	Class II	Drugs	Lot #: A2F03, Exp. Date May-24; A2I02, Exp. Date Aug-24; A2L02, Exp. Date Nov-24; A3C04, Exp. Date Feb-25; A3H04, Exp. Date Jul-25	Lack of Assurance of Sterility	Brassica Pharma Pvt Ltd
Lubricant PM Ointment (Mineral Oil 42.5% and White Petrolatum 57.3%), Packaged in 3.5 gram tubes, Distributed by: AACE Pharmaceuticals, Inc., Fairfield, NJ 07004, NDC 71406-124-35, UPC 371406124356	Class II	Drugs	Lot #: A2G01, A2G02, Exp. Date Jun-24; A3F08, A3F09, Exp. Date May-25; A3J17,	Lack of Assurance of Sterility	Brassica Pharma Pvt Ltd

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			A3J18, Exp. Date Sep-25		
Mesalamine Extended-Release Capsules, USP 500mg, Rx Only, 120 Capsules per bottle, Manufactured by: Sun Pharmaceutical Industries Limited, Mohali, INDIA, Distributed by: Sun Pharmaceutical Industries, Inc., Cranbury, NJ 08512, NDC 63304-089-13.	Class II	Drugs	Lot #s: MHD0606A, MHD0612A, Exp. 04/30/2024; MHD0613A, MHD0652A, MHD0657A, MHD0672A, MHD0673A, Exp. 05/31/2024; MHD0767A, MHD0768A, MHD0769A, MHD0785A, MHD0799A, MHD0800A, MHD0801A, Exp. 06/30/2024; MHD0827A, MHD0828A, MHD0875A, MHD0876A, MHD0898A, MHD0901A, Exp. 07/31/2024; MHD1081A, MHD1082A, MHD1087A Exp. 09/30/2024.	Failed Dissolution Specifications: Out of specification for dissolution.	SUN PHARMACEUTICAL INDUSTRIES INC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Omeprazole and Sodium Bicarbonate For Oral Suspension 40mg/1,680mg, This packet contains 40mg of omeprazole and 1,680mg of sodium bicarbonate, Directions for Use: Empty packet contents into a small cup containing 1 to 2 tablespoons of WATER. DO NOT USE OTHER LIQUIDS OR FOODS. Stir well and drink immediately. Rx Only, Distributed by: Oceanside Pharmaceuticals, a division of Bausch Health US, LLC, Bridgewater, NJ 08807, NDC 68682-991-30.	Class II	Drugs	Lot #0013R; Exp. 01/2026	Subpotent Drug: Out of specification for assay	Bausch Health Companies, Inc.
PROBLEND Antibacterial Foaming Silk All-In-One Foaming Hand Sanitizer & Cleanser, Benzalkonium Chloride 0.13% Antibacterial, a) 1250 mL cases, b) 1 G cases, mountain spring scent, Seatex LLC, 445 TX Hwy 36 Rosenberg, TX 77471.	Class II	Drugs	Lot #s: a) 263647, Exp. 06/09/2024; 271382, Exp. 01/18/2025; b) 261675, Exp. 04/09/2024; 263647, Exp. 06/09/2024; 272766, Exp.02/15/2025.	CGMP Deviations: deficiencies were identified during an FDA inspection of Seatex's manufacturing facility.	Seatex LLC
PROBLEND E3 Foaming Hand Sanitizer, All-In-One Foaming Hand Sanitizer & Cleanser, Seatex LLC, 445 TX Hwy 36 Rosenberg, TX 77471	Class II	Drugs	Lot #: 265029, Exp. 03/27/2024; 273759, Exp. 11/29/2024.	CGMP Deviations: deficiencies were identified during an FDA inspection of Seatex's manufacturing facility.	Seatex LLC
7 Eleven FOR GAS ISLAND USE ONLY, Hand Sanitizer, Ethanol 70% v/v Antiseptic, Mountain Spring Scent, 330 Gal. cases, Distributed by: Magnus, 16005 Gateway Drive, Suite 300, Frisco, TX 75033	Class II	Drugs	Lot #: 251176, Exp. 06/23/2024.	CGMP Deviations: deficiencies were identified during an FDA inspection of Seatex's manufacturing facility.	Seatex LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
7 Eleven Hand Sanitizer Gel, Ethanol 70% v/v Antiseptic, Mountain Spring Scent, 1250 mL cases, Magnus 16005 Gateway Drive, Ste 300, Frisco, TX 75033	Class II	Drugs	Lot #s: 266029, Exp. 03/27/2024; 255917, Exp. 06/23/2024; 261521, Exp. 06/27/2024.	CGMP Deviations: deficiencies were identified during an FDA inspection of Seatex's manufacturing facility.	Seatex LLC
PROBLEND Hand Sanitizer, Refreshing Gel Hand Sanitizer, Ethanol 70% v/v Antiseptic, mountain spring scent, 1250 mL cases, Seatex LLC, 445 TX Hwy 36 Rosenberg, YX 77471	Class II	Drugs	Lot #: 266029, Exp. 03/27/2024.	CGMP Deviations: deficiencies were identified during an FDA inspection of Seatex's manufacturing facility.	Seatex LLC
Moxifloxacin PF, 1mg/ml, in Sterile Balanced Salt Solution (BSS) Sterile injection, Intracameral Use Only, Single- Dose Vial, Leiters 13796 Compark Blvd, Englewood, CO 80112, NDC 71449-096-42	Class II	Drugs	Lot #:2331147, Exp:6-Mar-24; 2331180, Exp: 21-Mar-24; 2331256, Exp: 2-Apr-24; 2331279, Exp: 3-Apr-24; 2331283, Exp: 7-Apr-24; 2331345, Exp: 20-Apr-24; 2331422, Exp: 27-Apr-24; 2331563, Exp: 29-May-24.	Presence of Particulate Matter: glass vials from the manufacturer showed signs of glass delamination.	Denver Solutions, LLC DBA Leiters Health
Moxifloxacin 5mg/ml, 1 ml in a Single- Dose Vial, Rx Only, Leiters 13796 Compark Blvd, Englewood, CO 80112, NDC 71449-097-42	Class II	Drugs	Lot #:2331123, Exp:28-Feb-24; 2331298, Exp: 24-Mar-24.	Presence of Particulate Matter: glass vials from the manufacturer showed signs of glass delamination.	Denver Solutions, LLC DBA Leiters Health
Lidocaine HCL 1% (10mg/mL), PHENYLephrine HCL 1.5% (15mg/mL), 1 ml in a Single- Dose Vial, RX Only, Leiters 13796 Compark Blvd, Englewood, CO 80112, NDC 71449-090-42	Class II	Drugs	Lot #:2331104, Exp:9-Mar-24; 2331137, Exp: 3-Mar-24; 2331196, Exp: 11-	Presence of Particulate Matter: glass vials from the manufacturer showed signs of glass delamination.	Denver Solutions, LLC DBA Leiters Health

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			Mar-24; 2331264, Exp: 6-Apr-24; 2331282, Exp: 18-Apr-24; 2331464, Exp: 8-May-24; 2331481, Exp: 16-May-24; 2331500, Exp: 20-May-24.		
Methylprednisolone acetate Injectable Suspension, USP, 400mg per 5mL (80mg/mL, 5mL Multiple-Dose Vial, Rx only, Mfd. in India for: Eugia US LLC, E. Windsor, NJ 08520, NDC 55150-314-01	Class II	Drugs	Lot #: 3MA23001, 3MA23002, 3MA23003, Exp 3/31/2025	Failed Dissolution Specifications	Eugia US LLC
Rocuronium Bromide Injection, Preservative Free, 10 mg / mL, Multiple-Dose Vial 10 mL, Rx only, Mfg: Auromedics Pharma LLC, NDC 55150-226-10	Class II	Drugs	1064081	cGMP Deviations: Products were stored outside the drug label specifications.	Mckesson Medical-Surgical Inc. Corporate Office
Infuvite Adult Multiple vitamins injection, single-dose vial 5mL, Rx only, MFG: Baxter Healthcare Corp., NDC 54643-5649-01	Class II	Drugs	519644	cGMP Deviations: Products were stored outside the drug label specifications.	Mckesson Medical-Surgical Inc. Corporate Office
Bicillin L-A (Penicillin G Benzathine) 1.2, MMU / 2 mL Injection Prefilled Syringe 2 mL, Rx only, Mfg: Pfizer Pharmaceuticals, NDC 60793-0701-10	Class II	Drugs	567951	cGMP Deviations: Products were stored outside the drug label specifications.	Mckesson Medical-Surgical Inc. Corporate Office
Telmisartan Tablets, USP 40mg, Rx Only, 30 Tablets per bottle, Manufactured by: Micro Labs Limited Goa-403 722, INDIA, Manufactured for: Micro Labs USA Inc., Somerset, NJ 08873, NDC 42571-227-30.	Class II	Drugs	Lot #s: SFBG024, SFBG025, Exp. 05/31/2024	Failed Stability Specifications: Out of specification for blend uniformity.	Micro Labs Limited

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Broncochem Cold & Flu Syrup Kids (acetaminophen, guaifenesin, phenylephrine HCl), packaged in 120 mL bottles, Made in Dominican Republic Exclusively for Global Corporation Inc, Boca Raton, FL 33187 USA, NDC 65131-098-44	Class II	Drugs	Lot #: 223002, Exp. Date 10/2025; 223063, Exp. Date 02/2026	Stability testing failures for one or two of the four active pharmaceutical ingredients among the finished drug products, i.e., Phenylephrine HCL, and/or Chlorpheniramine Maleate.	Global Corporation
Broncochem Cold & Tea (acetaminophen, phenylephrine, HCl, chlorpheniramine maleate), packaged in 13g sachets, 25 sachets per box, Made in the Dominican Republic Exclusively for Global Corporation Inc, Boca Raton, FL 33187 USA, NDC 65131-097-12	Class II	Drugs	Lot #: 123255, 123256, Exp. Date 11/2024; 123637, Exp. Date 03/2025	Stability testing failures for one or two of the four active pharmaceutical ingredients among the finished drug products, i.e., Phenylephrine HCL, and/or Chlorpheniramine Maleate.	Global Corporation
Tobramycin for Injection, USP, 1.2 grams per Pharmacy Bulk Package, Rx Only, For Intravenous Use, PHARMACY BULK PACKAGE NOT FOR DIRECT INFUSION, Mfd. in India for: Eugia US LLC, E. Windsor, NJ 08520, Carton NDC 55150-470-06, Vial NDC 55150-470-01.	Class II	Drugs	Lot #s: 3TB23001, 3TB23002, Exp. 04/30/2025.	Failed Stability Specification: Water determination was found not complying with specification.	Eugia US LLC
Febuxostat Tablets 40mg, RX Only, 30 Tablets per bottle, NorthStarx, Manufactured for: Northstar Rx LLC., Memphis, TN 38141 , Manufactured by: Sun Pharmaceutical Industries Limited Survey No. 259/15, Dadra-396 191, (U.T. of D & NH), India, NDC 16714-059-01.	Class II	Drugs	Lot #s: DNE0865A, DNE0866A, Exp 06/30/2025	CGMP Deviations: Microbial contamination was reported in stagnant water in the duct of the manufacturing equipment.	SUN PHARMACEUTICAL INDUSTRIES INC
Febuxostat Tablets 80mg, RX Only, 30 Tablets per bottle, NorthStarx, Manufactured for: Northstar Rx LLC., Memphis, TN 38141,	Class II	Drugs	Lot #: DNE0894A, Exp 07/31/2025	CGMP Deviations: Microbial contamination was reported in stagnant water in the	SUN PHARMACEUTICAL INDUSTRIES INC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Manufactured by: Sun Pharmaceutical Industries Limited Survey No. 259/15, Dadra-396 191, (U.T. of D & NH), India, NDC 16714-060-01.				duct of the manufacturing equipment.	
TRP Natural Eyes Allergy Eyes Relief, Sterile Eye Drops, Homeopathic 0.33 FL OZ (10mL), Manufactured for TRP Company, Inc, 1575 Delucchi Lane, Suite # 208, Reno, NV, NDC # 17312-032-15.	Class II	Drugs	Lot #: A703, Exp: 02-15-2026, A704, Exp: 03-22-2026, A705, Exp: 04-05-2026	Lack of Assurance of Sterility	Optikem International, Inc.
TRP Blur Relief, Sterile Eye Drops, Homeopathic 0.5 FL OZ (15mL), Manufactured for TRP Company, Inc, 1575 Delucchi Lane, Suite # 208, Reno, NV, NDC # 17312-002-11.	Class II	Drugs	Lot #: B905, Exp: 07-13-2025	Lack of Assurance of Sterility	Optikem International, Inc.
TRP Eye Twitching Relief, Sterile Eye Drops, Homeopathic 0.33 FL OZ (10 mL), Manufactured for TRP Company, Inc, 1575 Delucchi Lane, Suite # 208, Reno, NV, NDC # 17312-040-15.	Class II	Drugs	Lot #: C303, Exp: 07-27-2025	Lack of Assurance of Sterility	Optikem International, Inc.
TRP Natural Eyes Dryness Relief, Sterile Eye Drops, 0.33 FL OZ (10 mL), Manufactured for TRP Company, Inc, 1575 Delucchi Lane, Suite # 208, Reno, NV, NDC # 17312-178-15.	Class II	Drugs	Lot #: D101, Exp: 07-01-2024, D102, Exp: 12-01-2024, D103, Ep: 04-13-2025	Lack of Assurance of Sterility	Optikem International, Inc.
TRP Eye strain Relief, Sterile Eye Drops, Homeopathic, 0.33 FL OZ (10 mL), Manufactured for TRP Company, Inc, 1575 Delucchi Lane, Suite # 208, Reno, NV, NDC # 17312-172-15.	Class II	Drugs	Lot #: E206, Exp: 09-21-2025	Lack of Assurance of Sterility	Optikem International, Inc.
TRP Natural Eyes Floaters Relief, Sterile Eye Drops, 0.33 FL OZ (10 mL), Manufactured for TRP Company, Inc, 1575 Delucchi Lane, Suite # 208, Reno, NV, NDC # 17312-098-15.	Class II	Drugs	Lot #: F404, Exp: 05-14-2025, F405, Exp: 08-24-2025, F406, Exp: 10-11-2026.	Lack of Assurance of Sterility	Optikem International, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
TRP Natural Eyes Aging Eye Relief, Sterile Eye Drops, Homeopathic, 0.33 FL OZ (10 mL), Manufactured for TRP Company, Inc, 1575 Delucchi Lane, Suite # 208, Reno, NV, NDC # 17312-027-15.	Class II	Drugs	Lot #: G806, Exp: 06-01-2025, G807, Exp: 10-27-2026.	Lack of Assurance of Sterility	Optikem International, Inc.
TRP Natural Eyes Pink Eye Relief, Sterile Eye Drops, Homeopathic, 0.33 FL OZ (10 mL), Manufactured for TRP Company, Inc, 1575 Delucchi Lane, Suite # 208, Reno, NV, NDC # 17312-013-15.	Class II	Drugs	Lot #: P516, Exp: 03-24-2024, P517, Exp: 08-31-2024, P518, Exp:10-20-2024, P519, Exp: 03-09-2025, P520, Exp: 10-19-2025, P521, Exp: 11-09-2025, P522, Exp: 11-16-2025, P523, Exp: 01-18-2026, P524, Exp: 04-26-2026, P525, Exp: 05-10-2026, P526, Exp: 06-07-2026	Lack of Assurance of Sterility	Optikem International, Inc.
TRP Natural Eyes Red Eye Relief, Sterile Eye Drops, Homeopathic, 0.33 FL OZ (10 mL), Manufactured for TRP Company, Inc, 1575 Delucchi Lane, Suite # 208, Reno, NV, NDC # 17312-158-15.	Class II	Drugs	Lot #: R608, Exp:04-21-2024, R609, Exp: 05-19-2024, R610, Exp: 07-28-2024, R611, Exp: 10-6-2024; R612, Exp: 02-02-2025, R613, Exp: 10-12-2025, R614, Exp: 11-02-2025	Lack of Assurance of Sterility	Optikem International, Inc.
hyalogic For Dry Eyes, HylaTears", Lubricant Eye Drops, 0.67 FL OZ (20mL) bottle, Manufactured	Class II	Drugs	All lots within Expiry	Lack of Assurance of Sterility	Optikem International, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
for hyalogic, 610 NW Platte Valley Dr., Riverside, MO 64150					
Betimol (timolol ophthalmic solution) 0.5%, 15mL bottles, Rx only, Manufactured for: Thea Pharma Inc. Lexington, MA 02420, NDC 82584-002-15	Class II	Drugs	Lot #: 435019, Exp. Date 11/2024	Lack of Assurance of Sterility: Out of specification for volume and compromised container closure.	Thea Pharma, Inc.
Potassium Chloride for Injection Concentrate USP, 500 mEq/250 mL (2 mEq/mL), 250 mL Bag, Rx only, B. Braun Medical Inc., Bethlehem, PA 18018, NDC 0264-1944-20	Class II	Drugs	Lot #: J2S007, Exp: 12/31/2024; J3A115, Exp: 01/31/2025.	Lack of assurance of sterility: pinholes, within the blue label characters on the EXCEL bag, specifically within the dotted characters on the label, resulting in leaks.	B. Braun Medical Inc
Mercaptopurine Tablets, USP 50 mg, packaged in: a) 25-count bottle (NDC 69076-913-02), b) 250-count bottle (NDC 69076-913-25), Rx only, Manufactured for: Quinn Pharmaceuticals, Boca Raton, FL, www.quinnrx.com	Class III	Drugs	Lot #: a)22K012, 22K013A, Exp: 04/30/2024; 23A001, 23A002A, Exp: 07/31/2024; 23D006, 23D007A, 23D007C, Exp:10/31/2024; b)22K013B, Exp: 04/30/2024; 23A002B, Exp:07/31/2024; 23D007B, Exp: 10/31/2024.	Failed Dissolution Specifications: results slightly under spec at at 9-months.	Stason Pharmaceuticals, Inc.
Clindamycin Phosphate, Topical Solution USP, 1%, 60 mL, Rx Only, Manufactured for and	Class III	Drugs	Lot #: 119466, 119467 Exp 04/2025;	Defective Container: Out of specification for weight due	Contract Pharmaceuticals Limited Canada

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Distributed by: Marlex Pharmaceuticals, Inc., New Castle, DE 19720, NDC 10135-0691-61			120351 Exp 08/2025; 121712 Exp 11/2025	to a slow leakage at the 12-month stability timepoint.	
Clindamycin Phosphate Topical Solution USP, 1%, 60 mL bottle, Manufactured for: Glasshouse Pharmaceuticals Limited Canada, Mississauga, Ontario, Canada, L5N 6R8, NDC 71428-0003-60	Class III	Drugs	Lot #: 119874; Exp 06/30/2025	Defective Container: Out of specification for weight due to a slow leakage at the 12-month stability timepoint.	Contract Pharmaceuticals Limited Canada

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

CURRENT DRUG SHORTAGES

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

Generic Name or Active Ingredient

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

Disopyramide Phosphate Capsule
Dobutamine Hydrochloride Injection
Dopamine Hydrochloride Injection
Dulaglutide Injection
Echothiophate Iodide Ophthalmic Solution
Enalaprilat Injection
Epinephrine Bitartrate, Lidocaine Hydrochloride Injection
Epinephrine Injection
Erythromycin Ointment
Etomidate Injection
Fentanyl Citrate Injection
Fluconazole Injection
Fludarabine Phosphate Injection
Flurazepam Hydrochloride Capsule
Furosemide Injection
Gentamicin Sulfate Injection
Heparin Sodium Injection
Hydrocortisone Sodium Succinate Injection
Hydromorphone Hydrochloride Injection
Hydroxypropyl Cellulose (1600000 Wamw) Insert
Isoniazid Tablet
Ketamine Hydrochloride Injection
Ketorolac Tromethamine Injection
Leucovorin Calcium Injection
Lidocaine Hydrochloride Injection
Lidocaine Hydrochloride Solution
Liraglutide Injection
Lisdexamfetamine Dimesylate Capsule
Lisdexamfetamine Dimesylate Tablet, Chewable
Lorazepam Injection
Methamphetamine Hydrochloride Tablet
Methotrexate Sodium Injection
Methotrexate Sodium Tablet
Methylphenidate Hydrochloride Tablet, Extended Release
Methylprednisolone Acetate Injection
Metronidazole Injection
Midazolam Hydrochloride Injection
Morphine Sulfate Injection
Naltrexone Hydrochloride Tablet
Neomycin Sulfate Tablet
Nitroglycerin Injection
Oxybutynin Chloride Syrup
Parathyroid Hormone Injection
Penicillin G Benzathine Injection
Potassium Acetate Injection
Potassium Chloride Injection

Promethazine Hydrochloride Injection
Propranolol Hydrochloride Injection
Quinapril Hydrochloride Tablet
Quinapril/Hydrochlorothiazide Tablet
Remifentanil Hydrochloride Injection
Rifampin Capsule
Rifampin Injection
Rifapentine Tablet, Film Coated
Riluzole Oral Suspension
Rocuronium Bromide Injection
Ropivacaine Hydrochloride Injection
Semaglutide Injection
Sodium Acetate Injection
Sodium Bicarbonate Injection
Sodium Chloride 0.9% Injection
Sodium Chloride 0.9% Irrigation
Sodium Chloride 14.6% Injection
Sodium Chloride 23.4% Injection
Sodium Phosphate, Dibasic, Anhydrous, Sodium Phosphate, Monobasic, Monohydrate Injection, Solution
Somatropin Injection
Sterile Water Injection
Sterile Water Irrigant
Streptozocin Powder, For Solution
Sucralfate Tablet
Sufentanil Citrate Injection
Sulfasalazine Tablet
Technetium TC-99M Pyrophosphate Kit Injection
Tirzepatide Injection
Triamcinolone Acetonide Injection
Triamcinolone Hexacetonide Injection
Valproate Sodium Injection
Vecuronium Bromide Injection
Vinblastine Sulfate Injection