PERFORMRx℠

Drug Information Update

June 2024

TABLE OF CONTENTS

NEWLY AVAILABLE GENERICS

Generic Name/ Dosage Form	Brand Name	Manufacturer	Indication
iopamidol 41% intravenous vial	Isovue	Slate Run Pharmaceuticals	• For angiography throughout the cardiovascular system, including cerebral and peripheral arteriography, coronary arteriography and ventriculography, pediatric angiocardiography, selective visceral arteriography and aortography, peripheral venography (phlebography), and adult and pediatric intravenous excretory urography and intravenous adult and pediatric contrast enhancement of computed tomographic (CECT) head and body imaging
deflazacort oral suspension 22.75 mg/ml	Emflaza	PCT Therapeutics	• For the treatment of Duchenne muscular dystrophy (DMD) in patients 2 years of age and older
carbinoxamine maleate ER oral suspension 4 mg/5 mL	Karbinal ER (authorized generic)	Aytu Therapeutics	• For adults and pediatric patients 2 years of age and older for the symptomatic treatment of: ○ Seasonal and perennial allergic rhinitis ○ Vasomotor rhinitis ○ Allergic conjunctivitis due to inhalant allergens and foods ○ Mild, uncomplicated allergic skin manifestations of urticaria and angioedema ○ Dermatographism ○ As therapy for anaphylactic reactions adjunctive to epinephrine and other standard measures after the acute manifestations have been controlled ○ Amelioration of the severity of allergic reactions to blood or plasma
hydrocortisone external lotion 2%	Ala-Scalp	Derm Ventures	• For the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses

NEW DRUG ENTITIES/STRENGTHS/COMBINATIONS

Drug Name	Generic Name	Description
Imdelltra intravenous solution reconstituted 1 mg, 10 mg	tarlatamab-dlle	New entity. Accelerated approval for the treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC) with disease progression on or after platinum-based chemotherapy. First and only bispecific delta-like ligand 3 (DLL3)–directed CD3 T-cell engager therapy that activates the patient's own T cells to attack DLL3-expressing tumor cells.
Hepzato w/50mm catheter intra-arterial solution reconstituted 50 mg Hepzato w/62mm catheter intra-arterial solution reconstituted 50 mg	melphalan	Liver-directed treatment for adult patients with metastatic uveal melanoma with unresectable hepatic metastases affecting less than 50% of the liver and no extrahepatic disease, or extrahepatic disease limited to the bone, lymph nodes, subcutaneous tissues, or lung that is amenable to resection or radiation. Dosed using ideal body weight for a maximum of 6 infusions. Approved via the 505(b)(2) pathway.
Adalimumab-fkjp(cf) 20 mg syrg	adalimumab-fkjp	New package size. Unbranded Hulio.
Adalimumab-adbm(cf) ps-uv 40mg	adalimumab-adbm	New package size. Unbranded Cyltezo, a biosimilar Humira.
Cyltezo(cf) pen psoria-uv 40mg Cyltezo(cf) pen crh-uc-hs 40mg	adalimumab-adbm	New package size. Humira biosimilar.
Adalimumab-adbm(cf) crhn 40mg	adalimumab-adbm	New package size. Unbranded Cyltezo, a Humira biosimilar.
Myhibbin oral suspension 200 mg/ml	mycophenolate mofetil	Antimetabolite immunosuppressant indicated for the prophylaxis of organ rejection in adult and pediatric recipients 3 months of age and older of allogeneic kidney, heart or

Drug Name	Generic Name	Description
		liver transplants, in combination with other immunosuppressants. First and only ready-to-use, oral suspension formulation of mycophenolate mofetil.
Austedo XR oral tablet extended release 24 hour 30 mg, 36 mg, 42 mg, 48 mg	deutetrabenazine	New strength of Austedo XR. Austedo is a vesicular monoamine transporter 2 inhibitor, for the treatment of adults with tardive dyskinesia and chorea associated with Huntington disease. Previously only supplied in 6mg, 12mg, 24mg.
Focinvez intravenous solution 150 mg/50ml	fosaprepitant dimeglumine	Ready to use single-dose vial and is indicated in adults and pediatric patients 6 months of age and older, in combination with other antiemetic agents, for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy including high-dose cisplatin or delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy.
Rinvoq LQ oral solution 1 mg/ml	upadacitinib	New formulation, oral liquid. New indication for the treatment of patients 2 years of age and older with active polyarticular juvenile idiopathic arthritis who have had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers, and for the treatment of patients 2 years of age and older with active psoriatic arthritis who have had an inadequate response or intolerance to one or more TNF blockers.
Vijoice oral packet 50 mg	alpelisib	New formulation, oral granules. Vijoice is approved for treatment of adult and pediatric patients 2 years of age and older with severe manifestations of PIK3CA-Related Overgrowth Spectrum (PROS) who require systemic therapy. Alpelisib is also marketed under brand name Piqray for breast cancer.
Duvyzat oral suspension 8.86 mg/ml	givinostat	Histone deacetylase (HDAC) inhibitor indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients 6 years of age and older. First nonsteroidal drug approved to treat patients with all genetic variants of DMD. Duvyzat offers a new mechanism of action to treat all patients with DMD

Drug Name	Generic Name	Description
Iqirvo oral tablet 80 mg	elafibranor	Indicated for the treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults who have an inadequate response to UDCA, or as monotherapy in patients unable to tolerate UDCA. Iqirvo is a first-in-class oral, once-daily peroxisome proliferator-activated receptor (PPAR) agonist.
Capvaxive intramuscular solution prefilled syringe 0.5 ml	pneumococcal 21-valent conjugate vaccine	New entity. Pneumococcal vaccine indicated for active immunization of individuals 18 years of age and older for the prevention of the following: invasive disease caused by Streptococcus pneumoniae serotypes 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15B, 15C, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F and 35B; and pneumonia caused by S. pneumoniae serotypes 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15C, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F and 35B. Capvaxive covers the serotypes responsible for 84%–85% of cases of invasive pneumococcal disease, compared to 51%–52% of cases for Prevnar 20 (pneumococcal 20-valent conjugate vaccine), based on 2018–2021 data from the Centers for Disease Control and Prevention (CDC).
Tyenne subcutaneous solution auto-injector 162 mg/0.9ml	tocilizumab-aazg	New dosage form and strength. Previously only available as 80 mg/4 ml, 200 mg/10 ml, and 400 mg/20 ml intravenous vials. Actemra biosimilar.
Sitagliptin base-metformin hcl oral tablet 50-500 mg, 50-1000 mg	sitagliptin/metformin	New entity. 505(b)(2) approval. Same active ingredient and strength as Janumet (sitagliptin phosphate/metformin), however, it has a different salt formulation of sitagliptin. Approved under brand name Zituvimet but will launch as an authorized generic.
mResvia intramuscular suspension prefilled syringe 50 mcg/0.5ml	respiratory syncytial virus vaccine	New entity. Respiratory syncytial virus (RSV) vaccine indicated to protect adults aged 60 years and older from lower respiratory tract disease caused by RSV infection. Third FDA-approved RSV vaccine, after Arexvy (respiratory syncytial virus vaccine, adjuvanted) and Abrysvo (respiratory syncytial virus vaccine) were both approved in May 2023.

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†
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 Limitations of Use: 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) 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] • **Treatment of adult patients with relapsed or refractory follicular lymphoma (FL) who have received two or more prior lines of systemic therapy[1]**

Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication†
			[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).
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 Limitations of Use: 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) 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] • Treatment of adult patients with relapsed or refractory follicular lymphoma (FL) who have received two or more prior lines of systemic therapy[1]

Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication†
			• **Treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL) who have received at least 2 prior lines of systemic therapy, including a Bruton tyrosine kinase (BTK) inhibitor.** [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
Arexvy	respiratory syncytial virus vaccine, adjuvanted	GSK	Indicated for active immunization for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in: • individuals 60 years of age and older; • **individuals 50 through 59 years of age who are at increased risk for LRTD caused by RSV.**
Kevzara	sarilumab prefilled syringe, auto-injector 150 mg/1.14 ml	Sanofi-Aventis	• Treatment of adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to one or more diseasemodifying antirheumatic drugs (DMARDs). • Treatment of adult patients with polymyalgia rheumatica (PMR) who have had an inadequate response to corticosteroids or who cannot tolerate corticosteroid taper. • **Treatment of patients who weigh 63 kg or greater with active polyarticular juvenile idiopathic arthritis (pJIA).**
Rinvoq LQ	upadacitinib oral solution 1 mg/ml	AbbVie	• **Treatment of adults and pediatric patients 2 years of age and older with active psoriatic 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†
			• **Treatment of patients 2 years of age and older with active polyarticular juvenile idiopathic arthritis who have had an inadequate response or intolerance to one or more TNF blockers**
Farxiga	dapagliflozin tablet 5mg, 10 mg	AstraZeneca	• 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. • 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 **and pediatric patients aged 10 years and older** with type 2 diabetes mellitus
Xigduo XR	dapagliflozin and metformin er tablet, 2.5 mg/1000 mg, 5 mg/500 mg, 5 mg/1000 mg, 10 mg/1000 mg, 10 mg/500 mg	AstraZeneca	• Indicated as an adjunct to diet and exercise to improve glycemic control in adults **and pediatric patients aged 10 years and older** with type 2 diabetes mellitus. • Dapagliflozin is indicated to reduce: ○ The risk of hospitalization for heart failure in adults with type 2 diabetes mellitus and established cardiovascular disease or multiple cardiovascular risk factors.

Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication†
			○ The risk of cardiovascular death and hospitalization for heart failure in adults with heart failure (NYHA class II-IV) with reduced ejection fraction. ○ 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.
Augtyro	repotrectinib capsules, 40 mg, 160 mg	Bristol Myers Squibb	• Adult patients with locally advanced or metastatic ROS1-positive non-small cell lung cancer (NSCLC). • **Adult and pediatric patients 12 years of age and older with solid tumors that:** ○ **have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion and** ○ **are locally advanced or metastatic or where surgical resection is likely to result in severe morbidity.** ○ **have progressed following treatment or have no satisfactory alternative therapy.**
Blincyto	blinatumomab for injection: 35 mcg of lyophilized powder in a single-dose vial for reconstitution	Amgen	Treatment of adult and pediatric patients one month and older with: • CD19-positive B-cell precursor acute lymphoblastic leukemia (ALL) in first or second complete remission with minimal residual disease (MRD) greater than or equal to 0.1%. • Relapsed or refractory CD19-positive B-cell precursor acute lymphoblastic leukemia (ALL).

Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication†
			• **CD19-positive Philadelphia chromosome-negative B-cell precursor acute lymphoblastic leukemia (ALL) in the consolidation phase of multiphase chemotherapy**.
Imfinzi	durvalumab injection, 500 mg/10 ml, 120 mg/2.4 ml	AstraZeneca	• **In combination with carboplatin and paclitaxel followed by Imfinzi as a single agent, for the treatment of adult patients with primary advanced or recurrent endometrial cancer that is mismatch repair deficient (dMMR).** *Note: Imfinzi has many other approved indications not mentioned here; see full prescribing information for details.*
Keytruda	pembrolizumab	Merck	• **In combination with carboplatin and paclitaxel, followed by Keytruda as a single agent, for the treatment of adult patients with primary advanced or recurrent endometrial carcinoma** *Note: Keytruda has many other approved indications not mentioned here; see full prescribing information for details.*

RECALLS

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Phenylephrine in 0.9% Sodium Chloride Injection Preservative Free, 100mcg/mL, 5mL syringe, Rx only, Hikma Injectables USA Inc, 36 Stults Road, Dayton, NJ 08810, NDC 63037-123-25	Class I	Drugs	Lot #: 240310003D, Exp 6/4/2024	Labeling: Label mix-up - ephedrine syringes mislabeled as phenylephrine.	Hikma Injectables USA Inc
Tirzepatide 10 mg/0.5 mL Sterile Solution, 2 mL Multi-dose vial, Rx only, This is a Compounded Product By: Revive RX Pharmacy, 3831 Golf Dr A, Houston, TX 77018, internally assigned NDC 99000-9278-64	Class I	Drugs	Lot #: 748127, Exp 9/24/2024	Labeling: Label Mix-up - product labeled as tirzepatide contains testosterone cypionate	Revive Rx LLC dba Revive Rx Pharmacy
Docetaxel Injection, USP, 80 mg per 8 mL (10 mg per mL), 1 x 8 mL Multi-Dose Vial, Rx only, Mfd. for Sagent Pharmaceuticals, Schaumburg, IL 60195 (USA), Made in India. NDC 25021-254-08	Class I	Drugs	Lot #: F1040001, Exp. Date 12/31/2024	Presence of Particulate Matter: Presence of particulate matter from the stopper in the drug product.	Sagent Pharmaceuticals
Docetaxel Injection, USP, 160 mg per 16 mL (10 mg per mL), 1 x 16 mL Multi-Dose Vial, Rx only, Mfd. for Sagent Pharmaceuticals, Schaumburg, IL 60195 (USA), Made in India. NDC 25021-254-08	Class I	Drugs	Lot #: F1030001, Exp. Date 12/31/2024	Presence of Particulate Matter: Presence of particulate matter from the stopper in the drug product.	Sagent Pharmaceuticals
Haloperidol decanoate Injection 50mg/mL, packaged in a) 1 mL Single-Dose Vials (NDC 70069-381-01) and b) 10 1mL Single-Dose Vials (NDC 70069-381-10), Rx only, Manufactured for: Somerset Therapeutics, LLC, Hollywood, FL 33024, Made in India.	Class II	Drugs	Lot #: a) A230412A, Exp. Date 07/2025; b)A230412B, Exp. Date 07/2025	Presence of Foreign Substance: This oil based product may contain trace amounts of water for injection (WFI).	SOMERSET THERAPEUTICS LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Vasopressin Injection, USP, 200 Units per 10 mL (20 Units per mL), 10 mL Multiple-Dose Vial, Rx only, For Intravenous Infusion, American Regent, Inc., Shirley, NY 11967, NDC 0517-1030-01	Class II	Drugs	Lot #: 23061L1C0, Exp 1/31/2025	Subpotent product in addition to having out-of-specification results for impurities.	American Regent, Inc.
niCARdipine Hydrochloride Injection, USP, 25 mg/10 mL (2.5 mg/mL), 10 x 10 mL Single Dose Vials, Rx Only, For Intravenous Use Only, Mfd for: Civica, Inc., Lehi, UT 84043; Mfd by: American Regent, Inc., New Albany, OH 43054. NDC 72572-470-10	Class II	Drugs	Lot #: 23087N0C0, Exp. Date 11/2024	Lack of Assurance of Sterility.	American Regent, Inc.
Duloxetine Delayed-Release Cap USP 30mg, 30-count bottle, Rx only, Preferred Pharmaceutcals, Inc., NDC 68788-9301-03	Class II	Drugs	Lot #: J2022G, Exp: 01/01/2025	CGMP Deviations: Presence of Nitrosamine Drug Substance Related Impurity (NDSRI), N-nitroso-duloxetine, above the proposed interim limit.	Preferred Pharmaceuticals, Inc.
Pain Wizard, Natural Relief for Muscular & Arthritic Pain, (Camphor 3%, Menthol 3%), Enriched with Capsaicin, Camphor, Menthol & MSM, Bottle with pump, NET WT 16 fluid oz / 473.17 ml, Made in USA, www.painwizard.com Pain Wizard LLC.PO Box 1099, Johnstown, CO 80534, UPC 8 63865 00012 3	Class II	Drugs	Lot: 18723C3, Exp 06/30/2025	Out of Specification for active ingredient. Violative grade of propylene glycol used during the manufacturing process.	ARG Laboratories, Inc.
NATURAL PAIN RELIEVING CREAM, GOLDEN TIGER, (Camphor 3%, Menthol 3%) Enriched with Capsaicin, Aloe Vera, Willow Bark & MSM, Gallon Jug 128 fl. oz. (3776 ml), Manufactured for Golden Tiger LLC, Made in USA, UPC 1 82294 00005 5	Class II	Drugs	Lot: 01823C2, Exp 01/31/2025	Out of Specification for active ingredient. Violative grade of propylene glycol used during the manufacturing process.	ARG Laboratories, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Bull Frog SPF 50 Amphibious Lotion SPF 50 Amphibious Lotion with Water Armor Tech, Broad Spectrum Sunscreen with UVA/UVB Protection, NEW WT. 5 FL OZ (148ML), Distributed by: Bullfrog Brands LLC, PO Box 600207, Dallas, TX 75360 USA. UPC 8 50016 52112 5	Class II	Drugs	Lot 08623C2, 08923C2, Exp 03/31/2026	Out of Specification for active ingredient	ARG Laboratories, Inc.
ALOE GATOR, (Octocrylene 8%, Octyl Methoxycinnamate 6%, Benzophone 3 6%, Octyl Salicylate 5%), Original Formula, SPF 40+, Broad Spectrum Protective Gel, Sport Performance, NET WT 1 OZ (28 g), Manufactured for AGS Brands.	Class II	Drugs	Lot 04023C1, Exp 01/31/2025	Out of Specification for active ingredient	ARG Laboratories, Inc.
Pain Wizard, Natural Relief for Muscular & Arthritic Pain, (Camphor 3%, Menthol 3%), Enriched with Capsaicin, Camphor, Menthol & MSM, Tube, NET WT 8 oz (226.79g), Made in the USA, painwizard.com PO Box 1099, Johnstown, CO 80534, UPC 8 63865 00011 6	Class II	Drugs	Lots 19823C4, EXP 07/31/2025; 01623C1, Exp 01/31/2025	Out of Specification for active ingredient. Violative grade of propylene glycol used during the manufacturing process.	ARG Laboratories, Inc.
Pain Wizard, Natural Relief for Muscular & Arthritic Pain, (Camphor 3%, Menthol 3%), Enriched with Capsaicin, Camphor, Menthol & MSM, Tube, NET WT 4oz (113.39g), painwizard.com Made in the USA, PO Box 1099, Johnstown, CO 80534, UPC 8 63865 00019 2	Class II	Drugs	Lot , 06023C1, Exp 01/31/2025,	Out of Specification for active ingredient. Violative grade of propylene glycol used during the manufacturing process.	ARG Laboratories, Inc.
NATURAL PAIN RELIEVING CREAM, GOLDEN TIGER, (Camphor 3%, Menthol 3%)Enriched with Pump Capsaicin, Aloe Vera, Willow Bark & MSM, Bottle with Pump NET WT 32 fl. oz	Class II	Drugs	Lot 01823C2, 01823C1, Exp 01/31/2025	Out of Specification for active ingredient. Violative grade of propylene glycol used during the manufacturing process.	ARG Laboratories, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
(946.33ml), Manufactured for Golden Tiger LLC Made in USA, UPC 1 82294 00004 8					
NATURAL PAIN RELIEVING CREAM, GOLDEN TIGER, (Camphor 3%, Menthol 3%)Enriched with Capsaicin, Aloe Vera, Willow Bark & MSM, Tube 4 oz (113.39 g), Mfr. for Golden Tiger USA Albuq, NM, UPC 1 82294 00002 4	Class II	Drugs	Lot 01623C1, Exp 01/31/2025	Out of Specification for active ingredient. Violative grade of propylene glycol used during the manufacturing process.	ARG Laboratories, Inc.
Pain Wizard, Natural Relief for Muscular & Arthritic Pain, (Camphor 3%, Menthol 3%), Enriched with Capsaicin, Camphor, Menthol & MSM, Roll-On 3 fl oz (88.7ml), painwizard.com Made in the USA, PO Box 1099, Johnstown, CO 80534, UPC 8 63865 00010 9	Class II	Drugs	Lot 17323C3, Exp 06/30/2025	Out of Specification for active ingredient. Violative grade of propylene glycol used during the manufacturing process.	ARG Laboratories, Inc.
NATURAL PAIN RELIEVING CREAM, GOLDEN TIGER, (Camphor 3%, Menthol 3%)Enriched with Capsaicin, Aloe Vera, Willow Bark & MSM, Roll-On NET WT 3 fl. oz. (88.7ml), Manufactured for Golden Tiger USA Albuquerque, NM, UPC 1 82294 00006 2	Class II	Drugs	Lot 17323C3, Exp 06/30/2025	Out of Specification for active ingredient. Violative grade of propylene glycol used during the manufacturing process.	ARG Laboratories, Inc.
ALOE GATOR, (Octocrylene 8%, Octyl Methoxycinnamate 6%, Benzophone 3 6%, Octyl Salicylate 5%), SPF 40+, Broad Spectrum Protective Gel, Sport Performance, NET WT 4 OZ (113g), Manufactured for AGS Brands. UPC 0 17971 10421 7	Class II	Drugs	Lot 04023C1 Exp 01/31/2025	Out of Specification for active ingredient	ARG Laboratories, Inc.
Metoprolol Tartrate Tablets USP, 25mg, 1000 count bottle, Rx only, distributed by: TruPharma, LLC, Tampa, FL 33609, Manufactured by: Rubicon Research Private	Class II	Drugs	Lot 231037H1, exp 6/2027	Presence of Foreign Substance: metal in tablet	Rubicon Research Private Limited

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Limited, Ambernath Dist Thane 421506 India, NDC 52817-360-00					
Epinephrine-Lidocaine HCl 0.25 mg/mL and 7.5 mg/mL Preservative-Free 1mL Single-Use vials for Intraocular Injection, Imprimis NJOF, LLC. 1705 Route 46 West, unit 6B, Ledgewood, NJ 07852, NDC 71384-640-01	Class II	Drugs	Lot #: 23APR033, Exp. Date 5/1/24; 23JUN001, Exp. Date 6/5/24	Lack of Assurance of Sterility	Imprimis NJOF, LLC
Dexamethasone-Moxifloxacin (1 mg/mL and 5mg/mL) Preservative-Free, 1mL Single-Use vials for Intraocular Injection, Rx only, Imprimis NJOF, LLC. 1705 Route 46 West, unit 6B, Ledgewood, NJ 07852, NDC 71384-512-01	Class II	Drugs	Lot #: 23MAY016, Exp. Date 5/8/24; 23JUL016, Exp. Date 7/10/24; 23AUG034, Exp. Date 8/16/24; 23DEC014, Exp. Date 12/10/24	Lack of Assurance of Sterility	Imprimis NJOF, LLC
Dexamethasone-Moxifloxacin- Ketorolac (1mg/mL, 0.5 mg/mL and 0.4 mg/mL), Preservative-Free, 1mL Single-Use vials for Intraocular Injection, Rx only, Imprimis NJOF, LLC. 1705 Route 46 West, unit 6B, Ledgewood, NJ 07852, NDC 71384-513-01	Class II	Drugs	Lot #: 23MAY008, Exp. Date 5/1/24; 23OCT011, Exp. Date 10/26/24; 23NOV035, Exp. Date 12/6/24; 24JAN024, Exp. Date 1/14/25	Lack of Assurance of Sterility	Imprimis NJOF, LLC
Moxifloxacin 0.8 mg/0.8 mL Preservative-Free 0.8mL Single-Use vials for Intraocular Injection, Rx only, Imprimis NJOF, LLC. 1705 Route 46 West, unit 6B, Ledgewood, NJ 07852, NDC 71384-509-08	Class II	Drugs	Lot #: 23OCT013, Exp. Date 10/10/2024	Lack of Assurance of Sterility	Imprimis NJOF, LLC
Moxifloxacin 4 mg/0.8 mL Preservative-Free 0.8mL Single-Use vials for Intraocular Injection, Rx only, Imprimis NJOF, LLC. 1705 Route 46	Class II	Drugs	Lot #: 23JUN003, Exp. Date 5/29/2024; 23JUL035, Exp. Date 7/24/2024;	Lack of Assurance of Sterility	Imprimis NJOF, LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
West, unit 6B, Ledgewood, NJ 07852, NDC 71384-511-08			23AUG033, Exp. Date 8/14/2024; 23AUG043, Exp. Date 8/21/2024; 23SEP001, Exp. Date 9/26/2024; 23OCT002, Exp. Date 10/4/2024; 23OCT031, Exp. Date 10/31/2024; 23NOV011, Exp. Date 11/28/2024; 24FEB027, Exp. Date 2/15/2025		
Epinephrine-Lidocaine HCl 0.25 mg/mL and 7.5 mg/mL Preservative-Free 1mL Single-Use vial for Intraocular Injection, Imprimis NJOF, LLC. 1705 Route 46 West, unit 6B, Ledgewood, NJ 07852, NDC 71384-640-01	Class II	Drugs	Lot #: 23JUL025, Exp. Date 7/17/2024; 23SEP012, Exp. Date 7/11/2024; 23OCT015, Exp. Date 7/20/2024; 23OCT020, Exp. Date 7/25/2024; 23OCT026, Exp. Date 8/22/2024; 23NOV030, Exp. Date 8/29/2024, 23DEC026, Exp. Date 9/29/2024; 24JAN011, Exp. Date 7/21/2024;	Lack of Assurance of Sterility	Imprimis NJOF, LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			24FEB033, Exp. Date 8/24/2024; 24JAN050, Exp. Date 8/30/2024		
Cefdinir for Oral Suspension USP, 250 mg/5 mL, packaged in a 60 mL bottle, Rx only, Manufactured for: Lupin Pharmaceuticals, Inc., Baltimore, MD 21202, Manufactured by: Lupin Limited, Mandideep, 462 046 India, NDC 68180-723-04	Class II	Drugs	Lot #F305184, F305185, F305186, Exp 7/31/ 2025	Defective container: lack of seal integrity.	Lupin Pharmaceuticals Inc.
EYLEA, (aflibercept) Injection, For Intravitreal injection, 2 mg (0.05mL of a 40mg/mL solution), Single-dose Pre-filled Glass Syringe, Rx only, Manufactured by: Regeneron Pharmaceuticals, Inc., 777 Old Saw Mill River Road, Tarrytown, NY 10591, NDC 61755-005-01, NDC (sample lot) 61755-005-54	Class II	Drugs	Lot # 8231500321, Exp. date Oct-24 8231500335, Exp. date Jan-25 8231500333, Exp. date Jan-25 8231500334, Exp. date Jan-25 8231500339, Exp. date Jan-25 8231500347, Exp. date Jan-25 8231500336, Exp. date Jan-25 8231500337, Exp. date Jan-25 8231500340, Exp. date Jan-25 8268700014 (sample lot) exp. date Jan-25	Lack of Assurance of Sterility: Complaints of syringe breakage	Regeneron Pharmaceuticals Inc

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Cathflo activase (ALTEPLASE), 2mg vials, Rx only, Genentech Inc., South San Francisco, CA 94080, NDC 50242-041-64	Class II	Drugs	Lot #: 3618858, 3618873, Exp. Date 01/31/2026	Lack of Assurance of Sterility: Deformed stoppers observed during filling operations for Cathflo Activase.	Genentech, Inc.
Zoledronic Acid Injection 5mg/100mL Sterile Solution, 100mL Single-Dose vials, Rx only, Distributor: Dr. Reddy's Laboratories Inc., Princeton, NJ 08540, Made in India, NDC 55111-688-52	Class II	Drugs	Lot #: G3000010, Exp. Date 11/2025	Lack of Assurance of Sterility: Leaking vials	Dr. Reddy's Laboratories, Inc.
Rizatriptan Benzoate Tablets USP, 5mg, 18 (3 X 6) Unit-Dose Tablets, Manufactured for: Glenmark Pharmaceuticals Inc., USA Mahwah, NJ 07430 Product of India, NDC 68462-465-99	Class II	Drugs	Lot#: 19233788; Exp. 9/2025 Lot#: 19224445; Exp. 9/2024	CGMP Deviations: N-Nitroso Desmethyl Rizatriptan Impurity results that are above the FDA acceptable limit.	Glenmark Pharmaceuticals Inc., USA
Rizatriptan Benzoate Tablets USP, 10 mg, 18 (3 X 6) Unit-Dose Tablets, Manufactured for: Glenmark Pharmaceuticals Inc., USA Mahwah, NJ 07430 Product of India, NDC 68462-466-99	Class II	Drugs	Lot#: 19224217; Exp. 9/2024 Lot#: 19233789; Exp. 9/2025 Lot#: 19224444; Exp. 9/2024	CGMP Deviations: N-Nitroso Desmethyl Rizatriptan Impurity results that are above the FDA acceptable limit.	Glenmark Pharmaceuticals Inc., USA
Rizatriptan Benzoate Orally Disintegrating Tablets, USP 5mg, 18 (3 x 6) Unit-Dose Tablets, Manufactured for: Glenmark Pharmaceuticals Inc., USA Mahwah, NJ 07430, Product of India, NDC 68462-467-06	Class II	Drugs	Lot#: 19224857; Exp. 11/2024 Lot#: 19232493; Exp. 6/2025	CGMP Deviations: N-Nitroso Desmethyl Rizatriptan Impurity results that are above the FDA acceptable limit.	Glenmark Pharmaceuticals Inc., USA
Rizatriptan Benzoate Orally Disintegrating Tablets, USP 10mg, 18 (3 x 6) Unit-Dose Tablets, Manufactured for: Glenmark Pharmaceuticals	Class II	Drugs	Lot#: 19223402; Exp. 7/2024 Lot#: 19224858; Exp. 11/2024 Lot#:	CGMP Deviations: N-Nitroso Desmethyl Rizatriptan Impurity results that are	Glenmark Pharmaceuticals Inc., USA

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Inc., USA Mahwah, NJ 07430, Product of India, NDC 68462-468-06			19232492; Exp. 6/2025	above the FDA acceptable limit.	
Prednisolone-Moxifloxacin-Bromfenac Sterile Ophthalmic Suspension, 1%, 0.5%, 0.075%, 5mL, Quantity: 20mL, Rx Only, Compounded by: Imprimis NJOF, LLC. 1705 Route 46 West, Unit 6B Ledgewood, NJ NDC 71384-310-05	Class II	Drugs	Lot: 23NOV018 Exp. 6/17/24	Lack of Assurance of Sterility	Imprimis NJOF, LLC
Klarity-C (cyclosporine) Preservative-Free Sterile Ophthalmic Emulsion 0.1% 5.5mL, Rx Only, This is a compounded drug. NOT FOR RESALE. OFFICE USE ONLY Compounded by: Imprimis NJOF, LLC., 1705 Route 46 West, unit 6B, Ledgewood, NJ 07852 NDC: 71384-514-05	Class II	Drugs	Lot:23APR005 Exp. 5/1/2024 Lot:23MAY024 Exp. 5/15/2024 Lot:23JUN010 Exp. 5/30/2024 Lot:23JUN016 Exp. 6/7/2024 Lot:23JUN047 Exp. 7/4/2024 Lot:23JUL013 Exp. 7/11/2024 Lot:23JUL029 Exp. 7/25/2024 Lot:23JUL030 Exp. 8/1/2024 Lot:23AUG016 Exp. 8/7/2024 Lot:23AUG042 Exp. 9/27/2024 Lot:23SEP017 Exp. 7/13/2024 Lot:23OCT039 Exp.	Lack of Assurance of Sterility	Imprimis NJOF, LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			8/3/2024 Lot:23NOV022 Exp. 8/24/2024 Lot:23NOV036 Exp. 8/29/2024 Lot:23DEC021 Exp. 10/4/2024 Lot:24JAN018 Exp. 10/11/2024 Lot:24JAN026 Exp. 10/24/2024 Lot:24JAN040 Exp. 11/2/2024 Lot:24FEB021 Exp. 11/16/2024 Lot:24MAR005 Exp. 12/12/2024		
Drug Vial Label: Zilretta¿ (triamcinolone acetonide extended-release injectable suspension), 32 mg per vial, Rx only, Manufactured for: Pacira Pharmaceuticals Inc., San Diego, CA 92121, NDC 65250-001-01. Diluent Vial Label: Diluent, 5mL, Sterile single use, Rx only, Manufactured for Pacira Pharmaceuticals Inc., NDC 65250-002-01. Carton Label: Drug Vial Label: Zilretta¿ (triamcinolone acetonide extended-release injectable suspension), 32 mg per vial, Rx only, Manufactured for: Pacira Pharmaceuticals Inc., San Diego, CA 92121, NDC 65250-003-01.	Class II	Drugs	Lot: 082657 (kit 23-9004), Exp: July 2024.	Failed Stability Specifications - at 12 months 2-8 degrees C followed by 6 weeks at 25 degrees C.	PACIRA PHARMACEUTICALS INC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Phenazopyridine HCl Tablets USP, 100 mg, 100-count bottles, Rx Only, Manufactured by: Winder Laboratories, LLC. 716 Patrick Industrial Lane, Winder, GA 30680, NDC 75826-114-10,	Class II	Drugs	Lot#: 1142404 Exp. Date 02/27/2027	Product Mix Up. A bottle of Phenazopyridine HCl tablets USP 100 mg contained Phenobarbital tablets 16.2 mg.	Winder Laboratories, LLC
Phenazopyridine HCl, 100mg tablets, 6 count bottles, Rx Only, Repackaged by: RemedyRepack, Inc., Indiana, PA NDC#: 70518-0218-00, Source NDC: 75826-0114-10 MFG: Winder Laboratories, LLC, Winder, GA	Class II	Drugs	Lot # B2906961-042524, exp. date 02/26/2027	Product Mix Up. A bottle labeled as Phenazopyridine HCl tablets USP 100 mg contained Phenobarbital tablets 16.2 mg.	RemedyRepack Inc.
Duloxetine Delayed-Release Capsules, USP, 60mg, 90-count bottle, Rx Only, Mfr. by: Towa Pharmaceutical Europe, S.L. Martorelles, (Barcelona), Spain, Dist. by: Breckenridge Pharmaceuticals, Inc., Berkeley Heights, NJ 07922. NDC 51991-748-90	Class II	Drugs	Lot #: 230035C, Exp. date 11/30/2025; 230101C, Exp. date 12/31/2025	CGMP Deviations: Presence of Nitrosamine Drug Substance Related Impurity (NDSRI), N-nitroso-duloxetine, above the proposed interim limit.	Breckenridge Pharmaceutical, Inc
Dexamethasone Sodium Phosphate injection USP, 120mg per 30mL (4mg/mL), 30 mL Multiple-Dose Vial, Rx only, Distributed by: AuroMedics Pharma LLC, 279 Princeton-Hightstown Rd. E. Windsor, NJ 08520, Made in India, NDC 55150-239-30	Class II	Drugs	Lot#: 3DS23001, 3DS23004, Exp 6/30/2024; 3DS23009, 3DS23011, Exp 7/31/2024	Failed Impurities/Degradation Specifications: impurity sulfonic acid adduct of dexamethasone phosphate results were above spec.	Eugia US LLC
Petroleum Jelly, White Petrolatum USP, NET WT 13 OZ (368g), sold under the following brands - Rite Aid, with UPC 0-11822-51349-4; Kroger, with UPC 0-41260-35275-1; Harris Teeter, with UPC 0-72036-75051-8; CVS, with UPC 0-50428-31702-0	Class II	Drugs	Rite Aid - lot # 0607983, expiration date: 07/2026, NDC # 11822-3135-2 Kroger- lot # 0607983, expiration date: 07/2026, NDC# 30142-069-27 Harris	Labeling: Label Mix up; product labeled as pure white petroleum jelly actually contains petroleum jelly with Lavendar and Chamomile	Consumer Product Partners, LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			Teeter - lot # 0607983, expiration date: 07/2026, NDC# 72036-069-37 CVS- lot # 0607983, expiration date: 07/2026, NDC # 59779-069-27		
Little Remedies Gas Relief Drops (Simethicone/Antigas), packaged in 1 fl. oz. (30 mL) bottle with dropper, Dist by Medtech Products Inc., Tarrytown, NY 10591, NDC 63029-103-02	Class II	Drugs	Lot #: 0855, Exp. 8/31/ 2025	cGMP deviations: Test results confirmed aypical Burkholderia Cepacia were a result of personnel error.	Denison Pharmaceuticals, LLC
OSSOS-SANS Reforzado con: Glucosamina Curcuma Ortiga tablets, packaged in a 30-count bottle, DISTRIBUIDOR POR: Naturistas Especializados, Alce Blanco 180-A Fracc. Industrial, Edo. de Mexico C.P. 53370	Class II	Drugs	Lot Number: H29585, No Expiration date	Marketed Without An Approved NDA/ANDA: FDA laboratory analysis found the product to contain undeclared diclofenac and methocarbamol,	MexHealth LLC
Cefixime for Oral Suspension USP 200 mg/5 mL (50 mL Pack size), Powder for oral suspension, Rx only, Manufactured for: Lupin Pharmaceuticals, Inc., Baltimore Maryland, Manufactured by: Lupin Limited, Mandideep, India NDC 68180-407-03	Class II	Drugs	Lot F201519, Expiry: November 2024	Failed Content Uniformity Specifications	Lupin Pharmaceuticals Inc.
Amoxicillin and Clavulanate Potassium Tablets USP, Chewable 400mg/57mg, 20-count bottles, Rx only, Manufactured in Canada By: Teva Canada Limited, Toronto, Canada M1B 2K9;	Class II	Drugs	Lot #: 100047634 Exp. Date 4/2025; 35449379A, Exp. Date 7/2024	Subpotent Drug	Teva Pharmaceuticals USA, Inc

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Manufactured For: Teva Pharmaceuticals USA, Inc., North Wales, PA 19454 NDC 0093-2272-34					
Xelpros (latanoprost ophthalmic emulsion) 0.005%, 125mcg/2.5mL, 2.5 mL bottle, Rx only, Manufactured by: Sun Pharmaceutical Ind. Ltd., India., NDC 47335-317-90	Class III	Drugs	Lot #: HAD3383A, Exp 8/31/2024	Failed Release Testing: Out of specification for particulate matter test.	SUN PHARMACEUTICAL INDUSTRIES INC
Sirolimus Tablets 1mg Tablets 100-count bottle, Rx Only, Distributed by: Dr. Reddy's Laboratories Inc., Princeton, NJ 08540, Made in India, NDC 55111-653-01	Class III	Drugs	Lot H2200493; Exp 6/30/2025	Failed Impurities/Degradation Specifications	Dr. Reddy's Laboratories, Inc.
Cephalexin for Oral Suspension, USP, 125mg per 5mL, Rx only, 100 Tablets, Relabeled by: Bryant Ranch Prepack, Inc, Burbank, CA 91504, NDC 63629-9204-1.	Class III	Drugs	Lot:225541, 226866, 227369, 227519, 229845, 231422, 234889, Exp: 03/31/2025	Labeling: Not Elsewhere Classified: Front label states 100 Tablets instead of 100 ml and on the back label 'Each Tablet contains' instead of 'Each Bottle contains' No total dose per bottle listed should be 2.5 g'	Bryant Ranch Prepack, Inc.
Cephalexin for Oral Suspension, USP, 125mg per 5mL, Rx only, 200mL (when mixed), Each contains: cephalexin monohydrate, USP equivalent to 2.5g of cephalexin in a strawberry flavored mixture. Manufactured by Alkem Laboratories Ltd, Relabeled by: Bryant Ranch Prepack, Inc, Burbank, CA 91504, NDC 63629-9205-1.	Class III	Drugs	Lot:234892, Exp:02/28/2025.	Labeling: Not Elsewhere Classified: Back label states Each contains: cephalexin monohydrate, USP equivalent to 2.5g' instead of Each Bottle contains: cephalexin monohydrate, USP equivalent to 5g	Bryant Ranch Prepack, Inc.
Cephalexin for Oral Suspension, USP, 250mg/ 5mL, Rx only, 200mL (when mixed), Each contains cephalexin monohydrate, USP equivalent to 5g cephalexin. Manufactured by	Class III	Drugs	Lot: 235287, 235629, 235805, 236292, 237022, 237308,	Labeling: Not Elsewhere Classified: Back Label states 'Each contains: cephalexin monohydrate, USP	Bryant Ranch Prepack, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Alkem Laboratories Ltd, Relabeled by: Bryant Ranch Prepack, Inc, Burbank, CA 91504, NDC 63629-8858-1.			237748, Exp: 12/31/2025;	equivalent to 5g' instead of Each Bottle contains: cephalexin monohydrate, USP equivalent to 10g'	
Cephalexin for Oral Suspension, USP, 250mg per 5mL, Rx only, 100mL (when mixed), Each contains cephalexin monohydrate, USP equivalent to 5g cephalexin. Manufactured by Alkem Laboratories Ltd, Relabeled by: Bryant Ranch Prepack, Inc, Burbank, CA 91504, NDC 63629-9206-1.	Class III	Drugs	Lot: 235288, 235294, 235368, 235806, 236058, 236138, 236139, 236351, 236490, 236757, 236877, Exp:11/30/2025; 236758, 236762, 237254, 237349, 237401, 237807, Exp: 12/31/2025.	Labeling: Not Elsewhere Classified: Back Label states Each contains: cephalexin monohydrate, USP equivalent to 5g' on the back label instead of Each Bottle contains: cephalexin monohydrate, USP equivalent to 5g'	Bryant Ranch Prepack, Inc.
Cephalexin for Oral Suspension, USP, 250mg/5mL, Rx only, 200mL (when mixed), Each contains cephalexin monohydrate, USP equivalent to 5g cephalexin. Manufactured by Alkem Laboratories Ltd, Relabeled by: Bryant Ranch Prepack, Inc, Burbank, CA 91504, NDC 63629-9207-1.	Class III	Drugs	Lot: 235067, Exp 12/31/2025; 235289, Exp 11/30/2025; 235290, Exp 12/31/2025	Labeling: Not Elsewhere Classified: Back Label states 'Each contains: cephalexin monohydrate, USP equivalent to 5g' instead of Each Bottle contains: cephalexin monohydrate, USP equivalent to 10g'	Bryant Ranch Prepack, Inc.
Tivicay PD (dolutegravir) 5mg Tablets for Oral Suspension, 60-count bottles, Each carton contains one bottle of 60 tablets, one 30-mL dosing cup and one 10-mL oral dosing syringe, Rx Only, Mfd for: ViiV Healthcare Durham, NC, 27701, By: GlaxoSmithKline Durham, NC 27701, NDC 49702-255-37	Class III	Drugs	Lot #: AG4M, Labeled Expiry date on carton May 2026, correct Exp. Date 04/2025	Labeling: Incorrect Lot and/or Expiration Date: The carton has incorrect expiration of 2026-MAY*, whereas the correct expiration date, which is on	GlaxoSmithKline LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
				the tablet bottle label, is 2025-APR.	
Pregabalin Capsules 50mg, 1000-count bottle, Rx Only, Manufactured for: Rising Pharma Holdings, Inc., East Brunswick, NJ 08816, Manufactured by: Laurus Labs Limited, Anakapalli-531011, India, NDC 64980-411-10	Class III	Drugs	Lot: 23132611, Exp 07/31/2026	Presence of Foreign Tablets/Capsules: Complaint received from a re-packager, American Health Packaging (AHP), where a foreign tablet was discovered in one of the bottles during packaging set up. Tablet identified as pantoprazole tablet 20mg.	Rising Pharma Holding, Inc.
Estradiol Transdermal System, USP (Twice-Weekly) 0.0375mg/day, Rx Only, Manufactured by: Cadila Healthcare Limited, Ahmedabad, India, Distributed by: Zydus Pharmaceuticals (USA) Inc., Pennington, NJ 08534, NDC 70710-1192-8	Class III	Drugs	Lot #: M310493, Exp. Date 01/2025; M308397, Exp. Date 11/2024; M305337, Exp. Date 10/2024; M400155, Exp. Date 06/2025; M314660, Exp. Date 05/2025	Failed Impurities/Degradation Specifications.	Zydus Pharmaceuticals (USA) Inc
Estradiol Transdermal System, USP (Twice-Weekly) 0.025mg/day, Rx Only, Manufactured by: Cadila Healthcare Limited, Ahmedabad, India, Distributed by: Zydus Pharmaceuticals (USA) Inc., Pennington, NJ 08534, NDC 70710-1191-8	Class III	Drugs	Lot #: M311202, Exp. Date 2/25; M311201, Exp. Date 1/25	Failed Impurities/Degradation Specifications.	Zydus Pharmaceuticals (USA) Inc
Asmanex Twisthaler, mometasone furoate inhalation powder, 220 mcg per actuation, 60 Metered Doses, Rx Only, Manuf. for: Organon	Class III	Drugs	Lot #: X025346, Exp 3/3/2025	Defective Container	Organon Llc

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
LLC, a subsidiary of Organon & Co. Product of Singapore. NDC 78206-114-02					
Asmanex Twisthaler, mometasone furoate inhalation powder, 220 mcg per actuation, 14 Metered Doses, Rx Only, Manuf. for: Organon LLC, a subsidiary of Organon & Co. Product of Singapore. NDC 78206-114-03	Class III	Drugs	Lot #: X024051, Exp 04/25/2025	Defective Container	Organon Llc
Asmanex Twisthaler, mometasone furoate inhalation powder, 220 mcg per actuation, 30 Metered Doses, Rx Only, Manuf. for: Organon LLC, a subsidiary of Organon & Co. Product of Singapore. NDC 78206-0114-04	Class III	Drugs	Lot #: Y000085, Exp 4/25/2025	Defective Container	Organon Llc
Eptifibatide injection 20mg/10mL (2mg/mL), 10mL Single-Dose Vial, Rx only, Mfd. In India for: AuroMedics Pharma, LLC, E. Windsor, NJ 08520, NDC 55150-219-10	Class III	Drugs	Lot #: 3EF22003, Exp 6/30/2025	Failed Impurities/Degradation Specifications: failed related substance identified as Eptifibatide dimer.	Eugia US LLC

*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
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
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
Diltiazem Hydrochloride Injection
Dobutamine Hydrochloride Injection
Dopamine Hydrochloride Injection
Dulaglutide Injection
Echothiophate Iodide Ophthalmic Solution
Enalaprilat Injection

Epinephrine Bitartrate, Lidocaine Hydrochloride Injection
Epinephrine Injection, Syringes
Erythromycin Ointment
Etomidate Injection
Fentanyl Citrate Injection
Flurazepam Hydrochloride Capsule
Furosemide Injection
Gentamicin Sulfate Injection
Heparin Sodium Injection
Hydrocortisone Sodium Succinate Injection
Hydromorphone Hydrochloride Injection
Hydroxocobalamin 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
Mefloquine Hydrochloride Tablet
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
Nitroglycerin Injection
Oxybutynin Chloride Syrup
Parathyroid Hormone Injection
Penicillin G Benzathine Injection
Potassium Acetate 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
Vitamin A Palmitate Injection