PERFORMRx℠

Drug Information Update

November 2024

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Newly Available Generics

Generic Name/ Dosage Form	Brand Name	Manufacturer	Indication
Avanafil 50mg, 100mg, 200mg oral tablets	Stendra	Camber Pharmaceuticals	For the treatment of erectile dysfunction.
Timolol hemihydrate ophthalmic solution 0.5 % 5ml, 10ml, 15ml bottle	Betimol	Somerset Therapeutics	For the treatment of elevated intraocular pressure in patients with ocular hypertension or open-angle glaucoma.
Clomiphene Citrate Oral Tablet 50 MG	Clomid	Rising Pharmaceuticals	For the treatment of ovulatory dysfunction in women desiring pregnancy.

New Drug Entities/Strengths/Combinations

Drug Name	Generic Name	Description
Erzofri intramuscular suspension prefilled syringe 39 mg/0.25ml, 78 mg/0.5ml, 117 mg/0.75ml, 156mg/ml, 234 mg/1.5ml, 351 mg/2.25ml	paliperidone palmitate	Extended-release injectable suspension for treatment of schizophrenia in adults and for treatment of schizoaffective disorder in adults as monotherapy and as an adjunct to mood stabilizers or antidepressants. Approved in July 2024, just now launching. 505b2 approval.
Ebglyss subcutaneous solution prefilled syringe 250 mg/2ml	lebrikizumab	New dosage form. Also available as auto-injector. IL13 inhibitor for the treatment of adults and children 12 years of age and older who weigh at least 88 pounds (40 kg) with moderate to severe atopic dermatitis (AD) that is not well controlled with topical prescription therapies
Pavblu Intravitreal Solution Prefilled Syringe and vial 2 mg/0.05ml	aflibercept-ayyh	Eylea biosimilar approved for the treatment of retinal conditions, including neovascular age-related macular degeneration (wet AMD), macular edema following retinal vein occlusion, diabetic macular edema, and diabetic retinopathy. Unlike Eylea, Pavblu is not aproved to treat retinopahty of prematurity (ROP). 5th Eylea biosimilar approved, but first to launch. Not interchangeable with Eylea.
Itovebi Oral Tablet 3 mg, 9 mg	inavolisib	Kinase inhibitor indicated for combination therapy with palbociclib and fulvestrant for the treatment of adults with endocrine-resistant, PIK3CA-mutated, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer, as detected by an FDA-approved test, following recurrence on or after completing adjuvant endocrine therapy. Will compete with Piqray and Truqap.
Augtyro Oral Capsule 160 mg	repotrectinib	New dosage strength. Also available in 40mg capsules. Kinase inhibitor indicated for adult patients with locally advanced or metastatic ROS1-positive nonsmall cell lung cancer (NSCLC) and adult/pediatric patients 12 and older with neurotrophic tyrosine receptor kinase (NTRK) cancers.
Hympavzi Subcutaneous Solution Auto-injector 150 mg/ml	marstacimab-hncq	Indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults and pediatric patients 12 years of age and older with hemophilia A (congenital factor VIII deficiency) without factor VIII (FVIII) inhibitors, or hemophilia B (congenital factor IX deficiency) without factor IX (FIX) inhibitors. First and only anti-tissue factor pathway inhibitor (anti-TFPI) approved in the U.S. for the treatment of hemophilia A or B

Drug Name	Generic Name	Description
		and the first hemophilia medicine approved in the U.S. to be administered via a pre-filled, auto-injector pen.
Lumakras Oral Tablet 240 mg	sotorasib	New dosage strength. Also available in 120mg and 320mg tablets. Indicated for the treatment of adults with KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC).
Aurlumyn Intravenous Solution 100 mcg/ml	iloprost	First drug indicated to treat severe frostbite in adults to reduce the risk of finger or toe amputation. Approved in February 2024, just now launching. Given by continuous IV infusion for a max of 8 consecutive days.
Azmiro Intramuscular Solution Prefilled Syringe 200 mg/ml	testosterone cypionate	Androgen indicated for testosterone replacement therapy in males for conditions associated with a deficiency or absence of endogenous testosterone. Approved in June 2022, just now launching. 505b2 approval.
Opipza Oral Film 2mg, 5 mg, 10 mg	aripiprazole	Atypical antipsychotic indicated for schizophrenia in patients 13 and older, MDD in adults, irritability associated with autistic disorder in patients 6 and older, and treatment of Tourette's in patients 6 and older. Approved in July 2024, just now launching. Doses are indication dependent and range from 2mg/day to 30mg/day.
Edaravone Intravenous Solution 60 mg/100 ml	edaravone	New strength. Already available in 30mg/100ml IV solution.
Emrosi Oral Capsule Extended Release 24 Hour 40 mg	minocycline hydrochloride	Extended-release capsules for the treatment of inflammatory lesions of rosacea in adults. Will compete with Oracea (doxycycline). 505b2 approval.
Tramadol HCl Oral Tablet 75 mg	tramadol	New strength. Already available in 25mg, 50mg, and 100mg oral tablets.
Revuforj Oral Tablet 110 mg, 160 mg	revumenib	Menin inhibitor indicated for the treatment of relapsed or refractory acute leukemia with a lysine methyltransferase 2A gene (KMT2A) translocation in adult and pediatric patients 1 year and older. Dose varies by patient weight and concomitant use of strong CYP3A4 inhibitors. First FDA approved menin inhibitor. Will compete with traditional chemotherapy and Venflexta (venetoflax).
Aucatzyl Intravenous Suspension 410000000 CELLS	obecabtagene autoleucel	CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of adults with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL). First CAR-T therapy approved by the FDA with no requirement for a REMS program. Will compete with Tecartus.
Danziten Oral Tablet 71 mg, 95 mg	nilotinib	For the treatment of adult patients with newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase. Will provide equivalent efficacy to Tasigna but with enhanced bioavailability, enabling a lower dosage. 505b2 approval.

Drug Name	Generic Name	Description
Ziihera Intravenous Solution Reconstituted 300 mg	zanidatamab-hrii	New entity for the treatment of adults with previously treated, unresectable or metastatic HER2-positive (IHC 3+) biliary tract cancer (BTC), as detected by an FDA-approved test. Ziihera is the first and only dual HER2-targeted bispecific antibody approved for HER2+ BTC in the US. Will compete with Enhertu.
Nypozi Injection Solution Prefilled Syringe 300 mcg/0.5ml, 480 mcg/0.8ml	filgrastim-txid	Leukocyte growth factor indicated for decreased incidence of infection, reduced time to neutrophil recovery, reduced duration of neutropenia, mobilization of autologous hematopoietic progenitor cells, increased survival in patients acutely exposed to myelosuppressive doses of radiation (see PI for full indications). Approved in June 2024, just now launching. Fourth approved Neupogen biosimilar.
Attruby Oral Tablet Therapy Pack 356 mg	acoramidis	New entity for the treatment of adults with transthyretin amyloid cardiomyopathy (ATTR-CM) to reduce cardiovascular death and cardiovascular-related hospitalization. Attruby is the first and only approved product with a label specifying near-complete stabilization of TTR (≥90%). Will compete with Vyndaqel and Vyndamax.
Pemetrexed Dipotassium Intravenous Solution Reconstituted 100 mg, 500 mg	pemetrexed dipotassium	New salt form of folate analog metabolic inhibitor indicated for non-squamous NSCLC.
Simlandi (2 Syringe) Subcutaneous Prefilled Syringe Kit 40 mg/0.4ml	adalimumab-ryvk	New dosage form of Humira biosimilar. Only available in high concentration strength. Interchangeable with Humira.
Boruzu Injection Solution 3.5 mg/1.4ml	bortezomib	Proteasome inhibitor indicated for the treatment of multiple myeloma and mantle cell lymphoma. Approved in September 2024, just now launching. 505b2 approval.

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†
Jylamvo	Methotrexate 2mg/mL oral solution	Shorla Oncology	• Treatment of adults and pediatric patients with acute lymphoblastic leukemia (ALL) as part of a combination chemotherapy maintenance regimen. • Treatment of adults with mycosis fungoides. • Treatment of adults with relapsed or refractory non-Hodgkin lymphoma as part of a metronomic combination regimen. • Treatment of adults with rheumatoid arthritis. • **Treatment of pediatric patients with polyarticular juvenile idiopathic arthritis (pJIA).** • Treatment of adults with severe psoriasis.
Scemblix	Asciminib 20mg, 40mg, 100mg tablets	Novartis	• **Newly diagnosed** Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP). **This indication is approved under accelerated approval based on major molecular response rate. Continued approval for this indication may be contingent upon verification of clinical benefit in a confirmatory trial(s)** • Previously treated Ph+ CML in CP • Ph+ CML in CP with the T315I mutation
Bimzelx	bimekizumab-bkzx single-dose prefilled syringe or single-dose prefilled autoinjector 160mg/ml	UCB	• Treatment of moderate to severe plaque psoriasis (PSO) in adults who are candidates for systemic therapy or phototherapy • Treatment of adults with active psoriatic arthritis (PsA) • Treatment of adults with active non-radiographic axial spondyloarthritis (nraxSpA) with objective signs of inflammation • Treatment of adults with active ankylosing spondylitis (AS) • **Treatment of adults with moderate to severe hidradenitis suppurativa (HS)**

Recalls

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Ascorbic Acid Inj. Solution, 25,000mg/50mL (500mg/mL), 50mL single use vial, Rx only, Staska Pharmaceuticals, 742 Evergreen Drive, Bennet, NE 68317	Class I	Drugs	Lot #SP2400058, Exp 12/31/2024	Presence of Particulate Matter: Presence of glass particulates.	Staska Pharmaceuticals, Inc.
Cinacalcet Tablets, 30 mg, 30-count bottle, Rx Only, Dr. Reddy's Laboratories Inc, Princeton, NJ 08540, Made in India, NDC 43598-367-30.	Class II	Drugs	Lot# T2200120, T2200121, T2200119, T2200116, T2200118, T2200117, Exp 11/2024; T2200695, T2200694, T2200696, T2200697, Exp 01/2025; T2201426, T2201428, T2201432, T2201427, T2201430, T2201429, T2201431, Exp 03/2025; T2202743, T2202742, T2202741, & T2202740, Exp 06/2025; T2203081, T2203079, T2203080, T2203082, T2203083 & T2203084, Exp 07/2025; T2300770, T2300771, T2300769, T2300766, T2300767 & T2300768, Exp 12/2025 Lots T2301663, T2301665, T2301662, T2301664, T2301667, T2301661, T2301666, T2301660, T2301658 & T2301659, Exp Date 02/2026 Lots T2304704, T2304703, T2304705, T2304706, Exp Date 08/2026 Lots T2400468, T2400469, T2400473 & T2400474 Exp Date 11/2026	CGMP Deviations: Presence of N-nitroso Cinacalcet impurity above FDA recommended interim limit	Dr. Reddy's Laboratories, Inc.
Cinacalcet Tablets, 60 mg, 30-count bottles, Rx Only, Dr. Reddy's Laboratories Inc, Princeton, NJ 08540, Made in India, NDC 43598-368-30.	Class II	Drugs	Lot# T2200698, Exp 01/2025; T2201444, Exp 03/2025; T2202827, Exp 06/2025; T2300531, Exp 12/2025; T2301696, Exp 02/2026;	CGMP Deviations: Presence of N-nitroso Cinacalcet impurity above FDA recommended interim limit	Dr. Reddy's Laboratories, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			T2304726, Exp 08/2026; T2400480, Exp 11/2026.		
Cinacalcet Tablets, 90 mg, 30-count bottle, Rx Only, Dr. Reddy's Laboratories Inc, Princeton, NJ 08540, Made in India., NDC 43598-369-30.	Class II	Drugs	Lot# T2201443, Exp 03/2025; T2300664, Exp 12/2025.	CGMP Deviations: Presence of N-nitroso Cinacalcet impurity above FDA recommended interim limit	Dr. Reddy's Laboratories, Inc.
Cinacalcet Tablets 30 mg, Rx Only, a) 30 Tablets per bottle, NDC: 16729-440-10, b) 90 Tablets per bottle, NDC: 16729-440-15, Manufactured for: Accord Healthcare, Inc., Durham, NC 27703, Manufactured by: Intas Pharmaceuticals Limited, Ahmedabad - 382 210, INDIA.	Class II	Drugs	a) Lot #: Expiry Date: M2118190 11/2024 M2201091 11/2024 M2206241 11/2024 M2206451 04/2025 M2208674 06/2025 M2213850 08/2025 M2215221 09/2025 M2216236 11/2025 M2217098 11/2025 M2300664 11/2025 b) Lot #: Expiry Date: M2210808 06/2025 M2212212 08/2025 M2214435 09/2025 M2217097 11/2025 M2301921 01/2026	Failed Impurities/Degradation Specifications: the presence of a nitrosamine impurity, N-nitroso-cinacalcet, above the acceptable daily intake (ADI) limits.	ACCORD HEALTHCARE, INC.
Cinacalcet Tablets, 60 mg, Rx Only, a) 30 Tablets per bottle, NDC: 16729-441-10, b) 90 Tablets per bottle, NDC: 16729-441-15, Manufactured for: Accord Healthcare, Inc., Durham, NC 27703. Manufactured by: Intas Pharmaceuticals Limited, Ahmedabad - 382 210, INDIA.	Class II	Drugs	a) Lot #: Expiry Date: M2204481 02/2025 M2212389 08/2025 M2214271 09/2025 M2215970 10/2025 M2216458 10/2025 b) Lot #: Expiry Date: M2212869 08/2025 M2216362 09/2025 M2215969 10/2025	Failed Impurities/Degradation Specifications: the presence of a nitrosamine impurity, N-nitroso-cinacalcet, above the acceptable daily intake (ADI) limits.	ACCORD HEALTHCARE, INC.
Cinacalcet Tablets, 90 mg, Rx Only, a) 30 Tablets per bottle, NDC: 16729-442-10, b) 90 Tablets per bottle, NDC: 16729-442-15, Manufactured for: Accord Healthcare, Inc.,	Class II	Drugs	a) Lot #: Expiry Date: M2303264 01/2026 b) Lot #: Expiry Date: M2306979 04/2026	Failed Impurities/Degradation Specifications: the presence of a nitrosamine impurity, N-nitroso-	ACCORD HEALTHCARE, INC.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Durham, NC 27703. Manufactured by: Intas Pharmaceuticals Limited, Ahmedabad - 382 210, INDIA.				cinacalcet, above the acceptable daily intake (ADI) limits.	
Chlorpheniramine Maleate 4 mg tablets, 24-count bottle, Manufactured For: Athlete's Needs, Novi, MI 48377, NDC 53185-277-24	Class II	Drugs	Lot # 24A27724, Exp 01/31/2027	Superpotent Drug: Stability failure for assay at 6 months test time-point.	BLI International, Inc.
Morphine Sulfate Extended-Release Tablets 15 mg, 100-count per bottle, Rx Only, Manufactured by Mayne Pharma, Greenville, NC 27834, NDC 51862-185-01.	Class II	Drugs	Lot# FG14062, Exp 10/31/2025	Failed Impurities/Degradation Specification	Dr. Reddy's Laboratories, Inc.
Morphine Sulfate Extended-Release Tablets 30 mg, 100-count bottles, Rx Only, Manufactured by Mayne Pharma, Greenville, NC 27834, NDC 51862-186-01.	Class II	Drugs	Lot# FG13996, Exp 09/30/2025	Failed Impurities/Degradation Specification	Dr. Reddy's Laboratories, Inc.
Ibuprofen 800mg, Generic for: Motrin, Each tablet contains: Ibuprofen, USP 800 mg, Packaged and Distributed by: DIRECT Rx, Dawsonville, GA 30534, Mfg By: Dr. Reddy's Laboratories LA, LLC, Shreveport, LA 71106, a) NDC 61919-0621-15 (15 count bottles), b) NDC 61919-0621-30 (30 count bottles, c) NDC 61919-0621-40 (40 count bottles), d) NDC 61919-0621-60 (60 count bottles), e) NDC 61919-0621-90 (90 count bottles), f) NDC: 61919-0621-100 and NDC: 61919-0621-71 (100 count bottles), g) NDC 61919-0621-72 (120 count bottles).	Class II	Drugs	Lot #s: a) 02FE2414, Exp 11/30/26. b) 18JU2407, Exp 11/30/26; 27JY2316, Exp 02/28/27; 13SE2317, 13OC2312, 23AU2307, Exp 03/31/27. c) 25SE2308, Exp 03/31/27. d) 29MA2313, 23MA2315, Exp 12/31/26; 25MY2304, Exp 01/31/27; 26JU2313, 27JY2314, Exp 02/28/27. e) 27SE2322, 30OC2304, 12OC2301, Exp 03/31/27. f) 11SE2322, 02FE2419, 23JA2405, 10JA2426, 17MY2416, 05DE2312, 24OC2321, 05FE2433, 20MA2418, 29NO2317, Exp 11/30/26. g) 31MA2308, Exp 12/31/26; 25SE2305, Exp 03/31/27.	Failed Impurities/Degradation Specifications: Product failed impurity specifications at the 18-month stability testing.	Direct Rx
Timolol Maleate Ophthalmic Solution USP, 0.5%, Sterile, 5mL bottles, Rx only, Manufactured by: FDC Limited, Waluj,	Class II	Drugs	Lot #: 083L051, Exp. Date: 11/2025	Defective Container: Unable to get the solution out of the bottle as the	FDC Limited

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Aurangabad, Maharashtra, India, Distributed by: Rising Pharmaceuticals Inc, New Jersey, NDC 64980-514-05.				spike of the cap was lodged in the nozzle of the product bottle	
Dapsone Gel 7.5%, 60 gram pump, Rx Only, Manufactured by: Zydus Lifesciences Ltd., Ahmedabad, India, Distributed by: Viona Pharmaceuticals Inc., Cranford, NJ 07016, NDC 72578-094-02.	Class II	Drugs	Lots T401151, Exp, 06/30/2026; T400806, Exp 03/31/2026	Crystallization	VIONA PHARMACEUTICALS INC
Regadenoson Injection, 0.4 mg/5 mL (0.08 mg/mL), 5mL Single-Dose Pre-filled Syringe, Rx only, Manufactured by: Baxter Pharmaceutical Solutions, LLC, Bloomington, IN 47403; Manufactured for: Baxter Healthcare Corporation, Deerfield, IL 60015. NDC: 36000-364-01	Class II	Drugs	Lot #: 945169, Exp. Date 9/25/2025; 945170, Exp. Date 10/24/2025	Labeling: Missing Label	Baxter Healthcare Corporation
Trinity Gold Nutrition, 60 Capsule, 30 day Supply, Distributed by Trinity Gold Nutrition 201 Tom Hall St. Ste. 2107, Fortmill, SC 29716, USA, Ph: 704-629-8203, www.trinitygold.com, Made in India, UPC 802992001009	Class II	Drugs	Lot #: IN-030, Exp. Date: NOV 2027	Marketed without an Approved NDA/ANDA: FDA analysis found product to be tainted with undeclared acetaminophen, diclofenac and phenylbutazone.	Trinity Gold Nutrition
Lanthanum Carbonate Chewable Tablets, 1000mg, 10-count bottle, Rx only, Manufactured for Cipla USA, NDC 69097-0936-98	Class II	Drugs	Lot # NB240316, Exp 12/31/25	Failed Tablet/Capsule Specifications: Complaints received of crushed and broken tablets.	Cipla USA, Inc.
Lanthanum Carbonate Chewable Tablets, 1000mg, 10-count bottle, Rx only, Manufactured for Exelan Pharmaceuticals, NDC 76282-0478-90	Class II	Drugs	Lot# NB240873, Exp 03/31/2026	Failed Tablet/Capsule Specifications: Complaints received of crushed and broken tablets.	Cipla USA, Inc.
Perio Maintenance Rinse 0.63% Stannous Fluoride Concentrated Solution, Rx Only, Net Wt. 10 oz. (283.5 g) pumps, Mint flavor, Manufactured by: Keystone Industries, 480 S. Democrat Rd., Gibbstown, NJ 08027, NDC 68400-202-10	Class II	Drugs	Lot #: PVC-003015, Exp. Date Sep-21-2025; PVC-003061, Exp. Date Apr-30-2026	Subpotent Drug	Keystone Industries

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Ramipril Capsules USP 2.5 mg, a) 90 count (NDC 68180-589-09), b) 100 count NDC 68180-589-01), and c) 500 count (NDC 68180-589-02) bottles, Rx only, Manufactured for Lupin Pharmaceuticals, Inc., Baltimore, MD, Manufactured by Lupin Limited, Goa, India	Class II	Drugs	a) NDC 68180-589-09; Lots G326781, exp. date 30-Sep-25, GA04468, exp. date 31-May-25 b) NDC 68180-589-01; Lots G326763, exp. date 30-Sep-25, GA03041, exp. date 31-Mar-26, GA03725, exp. date 30-Apr-26, GA04402, exp. date 31-May-26, c) NDC 68180-589-02; Lots G326782, exp. date 30-Sep-25, GA04462, exp. date 31-May-26	CGMP Deviations: Active pharmaceutical ingredient was sourced from an unapproved vendor	Lupin Pharmaceuticals Inc.
Ramipril Capsules USP 5 mg, a) 90 count (NDC 68180-590-09), b) 100 count NDC 68180-590-01), and c) 500 count (NDC 68180-590-02) bottles, Rx only, Manufactured for Lupin Pharmaceuticals, Inc., Baltimore, MD, Manufactured by Lupin Limited, Goa, India	Class II	Drugs	a) NDC 68180-590-09; Lots G326928, exp. date 30-Sep-25, GA00964, exp. date 31-Dec-25, b) NDC 68180-590-01, Lots G326897, G326929, exp. date 30-Sep-25, GA00854, GA00933, GA00954, exp. date 31-Dec-25, c) NDC 68180-590-02, Lot GA00955, exp. date 31-Dec-25	CGMP Deviations: Active pharmaceutical ingredient was sourced from an unapproved vendor	Lupin Pharmaceuticals Inc.
Ramipril Capsules USP 10 mg, a) 90 count (NDC 68180-591-09), b) 100 count NDC 68180-591-01), and c) 500 count (NDC 68180-591-02) bottles, Rx only, Manufactured for Lupin Pharmaceuticals, Inc., Baltimore, MD, Manufactured by Lupin Limited, Goa, India	Class II	Drugs	a) NDC 68180-591-09; Lots G327086, exp. date 30-Sep-25 GA01065, exp. date 31-Dec-25, b) NDC 68180-591-01 Lots G325033, G324987, exp. date 31-Jul-25, G325110, GA00956, GA01066, GA01126, exp. date 31-Dec-25, GA03299, GA03288, GA03287, exp. date 31-Mar-26 c) NDC 68180-591-02 Lot GA05919, exp. date 31-Jul-26 G327131, exp. date 30-Sep-25	CGMP Deviations: Active pharmaceutical ingredient was sourced from an unapproved vendor	Lupin Pharmaceuticals Inc.
Vitamin D3, 25 mcg, 1 tablet in blister card-foils, 100-count unit dose box, www.safecorhealth.com, NDC 48433-104-01	Class II	Drugs	Lot# 24A0052, exp. date 05/01/2026; 24A0057, exp. date 05/13/2026; 24A0066, exp. date 05/31/2026; 24A0067, exp. date 06/04/2026; 24A0068, exp. date	cGMP Deviations: Observations were made that some blister card-foils were separating from the blister cavity.	Safecor Health, LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			06/17/2026; 24A0069, exp. date 06/19/2026 24A0075, exp. date 07/08/2026 24A0078, exp. date 07/12/2026		
Vitamin B1, 100 mcg, 1 tablet in blister card-foils, 100-count unit dose box, www.safecorhealth.com, NDC 48433-108-01	Class II	Drugs	Lot# 24A0050, exp. date 04/25/2026; 24A0055, exp. date 05/09/2026; 24A0059, exp. date 05/16/2026; 24A0060, exp. date 05/20/2026; 24A0071, exp. date 06/24/2026; 24A0072, exp. date 06/26/2026	cGMP Deviations: Observations were made that some blister card-foils were separating from the blister cavity.	Safecor Health, LLC
Aspirin Chewable tablet 81 mg, 1 tablet in blister card-foils, 100-count unit dose box, www.safecorhealth.com, NDC 48433-129-01	Class II	Drugs	Lot# 24A0061, exp. date 05/23/2026	cGMP Deviations: Observations were made that some blister card-foils were separating from the blister cavity.	Safecor Health, LLC
Calcium Carbonate Chewable 500 mg, 1 tablet in blister card-foils, 100-count unit dose box, www.safecorhealth.com, NDC 48433-106-01	Class II	Drugs	Lot# 24A0073, exp. date 06/28/2026	cGMP Deviations: Observations were made that some blister card-foils were separating from the blister cavity.	Safecor Health, LLC
Docusate Sodium 250 mg, 1 Softgel in blister card-foils, 100-count unit dose box, www.safecorhealth.com, NDC 48433-101-01	Class II	Drugs	Lot# 34A0054, exp. date 05/07/2026	cGMP Deviations: Observations were made that some blister card-foils were separating from the blister cavity.	Safecor Health, LLC
Xelstrym (dextroamphetamine) transdermal system, 13.5 mg dextroamphetamine/9 hours, 30 individually sealed transdermal patches, inside a foil-sealed polypropylene tray, packed in a paper carton/box, MANUFACTURED BY NOVEN PHARMACEUTICALS, INC., Miami, FL 33186 United Sates, NDC 68968-0215-3	Class II	Drugs	Lot # 95598, Exp 02/28/25	Defective Delivery System: The product does not meet predetermined specifications for Coldflow (adhesive).	Noven Pharmaceuticals Inc
Guaifenesin Dextromethorphan Syrup, 200 mg/20mg per 10 mL, Major Pharmaceuticals 8401 Bearing Drive, Suite 100, Indianapolis, IN, 46268, NDC 0904-7135-72	Class II	Drugs	Lot #: C00128, Exp. Date 04/2025; C00146, Exp.Date 07/2025	Failed Impurity/Degradation Specifications	The Harvard Drug Group LLC dba Major Pharmaceuticals and Rugby Laboratories

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Guaifenesin Dextromethorphan Syrup, 100 mg/10mg per 5 mL, Major Pharmaceuticals 8401 Bearing Drive, Suite 100, Indianapolis, IN, 46268, NDC 0904-7134-70	Class II	Drugs	Lot #: C00113, Exp. Date 11/2024; C00125, Exp. Date 04/2025; C00145, Exp. Date 07/2025	Failed Impurity/Degradation Specifications	The Harvard Drug Group LLC dba Major Pharmaceuticals and Rugby Laboratories
BEVACIZUMAB (AVASTIN)1.25mg/0.05mL, Sterile Injection, 0.5 mL Single-Dose Syringe, Rx Only, Repackaged by: Medivant Healthcare: 24416 N 19th Ave, Phoenix, AZ, NDC 81483-0041-1	Class II	Drugs	Lot #: D24005, Exp. Date 20 February 2025; D24006, Exp. Date 21 February 2025; D24007, Exp. Date 22 February 2025; D24008, Exp. Date 19 March 2025; D24009, Exp. Date 20 March 2025; D24012, Exp. Date 25 April 2025.	Lack of Sterility Assurance	MEDIVANT HEALTHCARE
Lisinopril Tablets, USP 10 mg, 90 tablets per bottle, Rx Only, Distributed by: Walmart, Bentonville, AR 72716, Manufactured for: Camber Pharmaceuticals, Inc., Piscataway, NJ 08854, Packaged by: Legacy Pharmaceutical Packaging LLC, Earth City, MO 63045, NDC# 68645-610-90.	Class II	Drugs	Lot #: 241103, exp. date 05/31/2026	Presence of Foreign Object: A pharmacist discovered a metal fragment embedded in a lisinopril 10 mg tablet.	Evaric Pharmaceuticals Inc.
Adult Cough and Chest Congestion (Dextromethorphan HBr USP 20 mg, Guaifenesin USP 400mg), packaged in 4 oz bottles further package in cartons, Distributed by: Genexa Inc., Alanta, GA, 30318, NDC-69676-0077-9, UPC Code # 850015736155	Class III	Drugs	Lot# 0104V, Exp 07/2025; 0106V, Exp 09/2024	Crystallization: Lack of uniformity - a change in texture, chunky, grainy, and small crystal substances inside the bottles.	Denison Pharmaceuticals, LLC
Kids' Cough and Chest Congestion (Dextromethorphan HBr, USP 5mg/ Guaifenesin, USP 100 mg), packaged in 4 oz bottles further packaged in cartons, Distributed by: Genexa Inc., Alanta, GA, 30318, NDC-69676-0077-9, UPC Code# 850015736018	Class III	Drugs	Lot#: 0813V, Exp 06/2025; 0103V, Exp 03/2025	Crystallization: Lack of uniformity - a change in texture, chunky, grainy, and small crystal substances inside the bottles.	Denison Pharmaceuticals, LLC
Hydralazine HCl Tablets, USP, 25mg, Rx only, 100 tablets per carton, Distributed by: Avet Pharmaceuticals Inc., East Brunswick, NJ	Class III	Drugs	Lot#: T04888, Exp 11/2024; T04946, Exp 12/2024; T04970, Exp 07/2025	Failed impurities/degradation specifications during routine stability testing for impurities.	The Harvard Drug Group LLC dba Major

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
08816, Distributed by: MAJOR Pharmaceuticals, Livonia, MI, 48152, USA, NDC 0904-6441-61.					Pharmaceuticals and Rugby Laboratories
COVID-19 Vaccine, mRNA	Class III	Biologics	Lots: HN0477; HN0478; LC4370; HM7006;	Pfizer confirmed that four lots of Comirnaty (Covid-19 Vaccine, mRNA), 30 mcg (2023-2024 formula) were shipped and exceeded the required 2 oC - 8 oC refrigerated box qualification for 16 deliveries of these lots potentially impacting the product.	Pfizer Manufacturing Belgium NV
IBU (ibuprofen) 600 mg tablets, 500-count bottle, Rx Only, Distributor: Dr. Reddy's Laboratories Inc., Princeton, NJ 08540, Made in India, NDC 55111-683-05	Class III	Drugs	Lot #: C5406201, Exp 03/31/2028	Failed Tablet/Capsule Specifications	Dr. Reddy's Laboratories, Inc.
Triamcinolone Acetonide Cream USP, 0.025%, 1 LB (454 g) per jar, Rx Only, Manufactured By Padagis, Minneapolis, MN 55427. NDC: 45802-0063-05	Class III	Drugs	Lot #: 2024154238, 2024174344, Exp. Date 3/31/2026	Subpotent and Superpotent Drug. Out of specification assay results recorded as part of Uniformity of Container test during long-term stability testing.	Padagis 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 . 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

Amifostine Injection

Amino Acid Injection

Amino Acids 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

Carboplatin Injection

Cefotaxime Sodium Injection

Chloroprocaine Hydrochloride Injection

Clindamycin Phosphate Injection

Clonazepam Tablet

Conivaptan Hydrochloride Injection

Cromolyn Sodium Concentrate

Cyclopentolate Hydrochloride Ophthalmic Solution

Dacarbazine Injection

Desmopressin Acetate Spray

Dexamethasone Sodium Phosphate Injection

Dexmedetomidine Hydrochloride Injection

Dextrose Monohydrate 10% Injection

Dextrose Monohydrate 25% Injection

Dextrose Monohydrate 5% Injection

Dextrose Monohydrate 50% Injection

Dextrose Monohydrate 70% Injection

Dextrose Monohydrate, Lidocaine Hydrochloride Anhydrous Injection

Dobutamine Hydrochloride Injection

Dopamine Hydrochloride Injection

Dulaglutide Injection

Echothiophate Iodide Ophthalmic Solution

Epinephrine Bitartrate, Lidocaine Hydrochloride Injection

Etomidate Injection

Fentanyl Citrate Injection

Flurazepam Hydrochloride Capsule

Furosemide Injection

Heparin Sodium Injection

Hydrocortisone Sodium Succinate Injection

Hydromorphone Hydrochloride Injection

Hydroxocobalamin Injection

Hydroxypropyl Cellulose (1600000 Wamw) Insert

Indocyanine Green Injection

Isoniazid Tablet

Ketamine Hydrochloride Injection

Ketorolac Tromethamine Injection

Lactated Ringers 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

Methylphenidate Hydrochloride Tablet, Extended Release

Methylprednisolone Acetate Injection

Metronidazole Injection

Midazolam Hydrochloride Injection

Morphine Sulfate Injection

Naltrexone Hydrochloride Tablet

Nitroglycerin Injection

Oxazepam Capsule

Parathyroid Hormone Injection

Penicillin G Benzathine Injection

Peritoneal Dialysis Solution

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

Somatropin Injection

Sterile Water Injection

Sterile Water Irrigant

Streptozocin Powder, For Solution

Sufentanil Citrate Injection

Technetium Tc-99m Pyrophosphate Kit Injection

Triamcinolone Acetonide Injection

Triamcinolone Hexacetonide Injection

Valproate Sodium Injection

Vecuronium Bromide Injection