PERFORMRx℠

Drug Information Update

December 2024

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Newly Available Generics

Generic Name/ Dosage Form	Brand Name	Manufacturer	Indication
Hydrocortisone External Solution 2.5%	Texacort	Trifluent Pharma	For the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses
Alprostadil injection solution 500 mcg/ml	Prostin VR	Meitheal Pharmaceuticals	For palliative, not definitive, therapy to temporarily maintain the patency of the ductus arteriosus until corrective or palliative surgery can be performed in neonates who have congenital heart defects and who depend upon the patent ductus for survival
Methohexital sodium injection solution reconstituted 500 mg	Brevital Sodium	Avet Pharmaceuticals	Used in adults as follows: • For intravenous induction of anesthesia prior to the use of other general anesthetic agents • For intravenous induction of anesthesia and as an adjunct to subpotent inhalational anesthetic agents (such as nitrous oxide in oxygen) for short surgical procedures; Methohexital Sodium for Injection may be given by infusion or intermittent injection • For use along with other parenteral agents, usually narcotic analgesics, to supplement subpotent inhalational anesthetic agents (such as nitrous oxide in oxygen) for longer surgical procedures • As intravenous anesthesia for short surgical, diagnostic, or therapeutic procedures associated with minimal painful stimuli • As an agent for inducing a hypnotic state Used in pediatric patients older than 1 month as follows: • For rectal or intramuscular induction of anesthesia prior to the use of other general anesthetic agents • For rectal or intramuscular induction of anesthesia and as an adjunct to subpotent inhalational anesthetic agents for short surgical procedures • As rectal or intramuscular anesthesia for short surgical, diagnostic, or therapeutic procedures associated with minimal painful stimuli

New Drug Entities/Strengths/Combinations

Drug Name	Generic Name	Description
Hercessi Intravenous Solution Reconstituted 150 MG, 420 MG	trastuzumab-strf	Biosimilar to Herceptin (trastuzumab) for treatment of several forms of HER2-overexpressing cancer. Approved in April 2024.
Axtle Intravenous Solution Reconstituted 100 MG, 500 MG	pemetrexed dipotassium	New salt form of pemetrexed. Approved in June 2024. 505b2 approval.
Imkeldi Oral Solution 80 MG/ML	imatinib mesylate	First oral liquid form of imatinib to treat certain forms of leukemia and other cancers. 505b2 approval.
Bimzelx Subcutaneous Solution Prefilled Syringe, Auto-injector 320 MG/2ML	bimekizumab-bkzx	New strength. Already available in 160mg/ml. New indication for hidradenitis suppurativa.
Qlosi Ophthalmic Solution 0.4 %	pilocarpine HCl	Cholinergic agonist indicated for the treatment of presbyopia in adults. Second eye drop indicated for presbyopia after Vuity. Lower concentration than Vuity for fewer adverse effects. Approved in October 2023.
Wezlana Subcutaneous Solution 45 MG/0.5ML; Wezlana Intravenous Solution 130 MG/26ML; Wezlana Subcutaneous Solution Prefilled Syringe 45 MG/0.5ML, 90 MG/ML	ustekinumab-auub	Stelara biosimilar. Approved to treat all the same indications as Stelara and has an interchangeability designation. Approved in November 2023. Will compete with the other Stelara biosimilars (Selarsdi, Pyzchiva, Otulfi, Imuldosa, and Steqeyma) which are expected to launch in early 2025.

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†
Imfinzi	durvalumab 500mg/10ml, 120mg/2.4ml vials	AstraZeneca	• **As a single agent, for the treatment of adult patients with limited-stage small cell lung cancer (LS-SCLC) whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy.** *Note: Imfinzi has many other approved indications not mentioned here; see full prescribing information for details.*
Vtama	tapinarof cream 1%	Dermavant Sciences	• The topical treatment of plaque psoriasis in adults • **The topical treatment of atopic dermatitis in adults and pediatric patients 2 years of age and older**
Zepbound	tirzepatide 2.5 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg, or 15 mg per 0.5 mL in single-dose pen or single-dose vial	Eli Lilly and Company	• To reduce excess body weight and maintain weight reduction long term in adults with obesity or adults with overweight in the presence of at least one weight-related comorbid condition • **To treat moderate to severe obstructive sleep apnea (OSA) in adults with obesity**
Trikafta	elexacaftor/tezacaftor/ivacftor and ivacaftor oral tablet therapy pack 100-50-75&150mg, 50-25-37.5&75mg, and oral therapy pack 80-40-60&59.5mg, 100-50-75&75mg	Vertex Pharmaceuticals	• For the treatment of cystic fibrosis (CF) in patients aged 2 years and older who have at least one F508del mutation in the CFTR gene or a mutation in the CFTR gene that is responsive based on in vitro data. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to confirm the presence of at least **one indicated mutation**. ~~F508del mutation or a mutation that is responsive based on in vitro data~~
Imcivree	setmelanotide subcutaneous solution 10mg/ml	Rhythm Pharmaceuticals	To reduce excess body weight and maintain weight reduction long term by reducing hunger and food intake and increasing energy expenditure in

Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication†
			adults and pediatric patients ~~6~~ **2** years of age and older with syndromic or monogenic obesity due to: • Bardet-Biedl syndrome (BBS) • Pro-opiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency as determined by an FDA-approved test demonstrating variants in POMC, PCSK1, or LEPR genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance (VUS) <u>Limitations of Use:</u> Imcivree is not indicated for the treatment of patients with the following conditions as Imcivree would not be expected to be effective: • Obesity due to suspected POMC, PCSK1, or LEPR deficiency with POMC, PCSK1, or LEPR variants classified as benign or likely benign. • Other types of obesity not related to BBS or POMC, PCSK1 or LEPR deficiency, including obesity associated with other genetic syndromes and general (polygenic) obesity
Braftovi	encorafenib 75mg capsule	Pfizer Inc.	• **In combination with cetuximab and mFOLFOX6, for the treatment of patients with metastatic colorectal cancer (mCRC) with a BRAF V600E mutation, as detected by an FDA-approved test. This indication is approved under accelerated approval based on response rate and durability of response.** *Note: Braftovi has other approved indications not mentioned here; see full prescribing information for details.*
Tevimbra	tislelizumab-jsgr	BeiGene	Esophageal Cancer • as a single agent in adults with unresectable or metastatic esophageal squamous cell carcinoma (ESCC) after prior systemic chemotherapy that did not include a PD-(L)1 inhibitor

Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication†
			Gastric Cancer • **in combination with platinum and fluoropyrimidine-based chemotherapy in adults for the first line treatment of unresectable or metastatic HER2negative gastric or gastroesophageal junction adenocarcinoma whose tumors express PD-L1**

Recalls

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
VitalityXtra Capsules, 500 mg, packaged in 10 count blisters in cartons, Distributed by: VitalityXtra, San Francisco, CA www.vitalityxtra.com	Class I	Drugs	Lot #: 230811, Exp: 08/11/2025	Marketed without an approved NDA/ANDA: Products found to contain undeclared sildenafil and diclofenac.	Boulla LLC
PeakMax Capsules, 500 mg, packaged in 10 count blisters in cartons, Distributed by: PeakMax, San Francisco, CA, www.PeakMax.com	Class I	Drugs	Lot #: 230811, Exp: 08/11/2025	Marketed without an approved NDA/ANDA: Products found to contain undeclared sildenafil and diclofenac.	Boulla LLC
ZoomMax Capsules, 500 mg, 10 count blisters in cartons, Distributed by: ZoomMax, 2108 N St. Sacramento, CA 95816, www.zoommax.com	Class I	Drugs	Lot #: YZM240406, Exp: 04/05/2027	Marketed without an approved NDA/ANDA: Products found to contain undeclared sildenafil and diclofenac.	Boulla LLC
ZapMax Capsules, 500 mg, 10 count blisters in cartons, Distributed by: ZapMax, 2108 N St. Sacramento, CA 95816, www.zapmax.com	Class I	Drugs	Lot #: YZM240406, Exp: 04/05/2027	Marketed without an approved NDA/ANDA: Products found to contain undeclared sildenafil and diclofenac.	Boulla LLC
ABSORBINE jr. Extra Large BACK PATCH, Menthol 5%, 1 extra large patch per box, Distributed By: Absorbine Jr., LLC, Chattanooga, TN 37402 UPC 8 89476 41218 6, UPC 8 89476 41236 0	Class II	Drugs	UPC 8 89476 41218 6, UPC 8 89476 41236 0	cGMP Deficiencies	Unexo Life Sciences Private Limited
ABSORBINE jr ULTRA STRENGTH PAIN PATCH, Menthol 6.5%, 1 patch per box, Distributed By: Absorbine Jr. LLC, Chattanooga, TN 37402 UPC 8 89476 41318 3, UPC 8 89476 41336 7	Class II	Drugs	UPC 8 89476 41318 3, UPC 8 89476 41336 7	cGMP Deficiencies	Unexo Life Sciences Private Limited
a) ABSORBINE JR PAIN RELIEVING KNEE PATCH, Camphor 7%, Menthol 7%, packaged in 1 patch (UPC 8 89476 41251 3) and b) 6 patches (UPC 8 89476 41306	Class II	Drugs	a) UPC 8 89476 41251 3 b) UPC 8 89476 41306 0	cGMP Deficiencies	Unexo Life Sciences Private Limited

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
0), Distributed By: Absorbine Jr., LLC, Chattanooga, TN 37402					
THERACARE MAXIMUM STRENGTH PAIN RELIEF 4% LIDOCAINE PATCH, a) 1 patch (NDC 71101-001-24, UPC 8 45717 00878 5) and b) 6 patches (NDC 71101-001-06, UPC 8 45717 01056 6), Manufactured for: Veridian Healthcare, LLC, Gurnee, IL 60031	Class II	Drugs	a) UPC 8 45717 00878 5 b) UPC 8 45717 01056 6	cGMP Deficiencies	Unexo Life Sciences Private Limited
THERACARE Cold Hot Medicated Patch, Menthol 5%, 5 patches per box, Manufactured for: Veridian Healthcare, LLC, Gurnee, IL 60031 NDC 71101-954-05, UPC 8 45717 00818 1	Class II	Drugs	UPC 8 45717 00818 1	cGMP Deficiencies	Unexo Life Sciences Private Limited
HealthWise PERIOD PATCH Menstrual Pain Relief, Menthol 10%, 10 patches per box, Manufactured for Veridian Healthcare, LLC, Gurnee, IL 60031 NDC 71101-947-10, UPC 8 45717 01072 6	Class II	Drugs	UPC 8 45717 01072 6	cGMP Deficiencies	Unexo Life Sciences Private Limited
EQUATE MAXIMUM STRENGTH LIDOCAINE PAIN RELIEVING PATCH Lidocaine 4% Topical Anesthetic, 6 patches per box PATCHES, LIDOCAINE 4%, Distributed by: Walmart Inc., Bentonville, AR 72716 NDC 79903-106-06	Class II	Drugs	UPC 6 81131 07127 7	cGMP Deficiencies	Unexo Life Sciences Private Limited
LILAS Feminine Pain Relief Patch, Menthol 10%, a) 5 patches per box (UPC 7 87099 48212 1) and 10 patches per box (UPC 7 87099 48211 4), Distributed by: Lilas Wellness, Inc., Beaverton, Oregon 97008-7105	Class II	Drugs	a) UPC 7 87099 48212 1 b) UPC 7 87099 48211 4	cGMP Deficiencies	Unexo Life Sciences Private Limited
JR WATKINS COOLING PAIN RELIEF PATCHES, Menthol 7.5%, 5 patches per	Class II	Drugs	UPC 8 56294 00878 5	cGMP Deficiencies	Unexo Life Sciences Private Limited

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
box, Distributed By: J.R. Watkins, LLC, Oakland, CA 94612 UPC 8 56294 00878 5					
CHEEKY BONSAI PAIN RELIEF PATCHES, Menthol 10%, 4 patches per box, Distributed by Cheeky Bonsai, San Francisco, CA UPC 8 60006 57564 9	Class II	Drugs	UPC 8 60006 57564 9	cGMP Deficiencies	Unexo Life Sciences Private Limited
PARCHE LEON PAIN RELIEVING HOT PATCH, Camphor 3%, Menthol 1.25%, Capsaicin 0.025%, 6 patches per box, Distributed by: Pharmadel LLC, Georgetown, DE 19947 NDC 55758-039-01, UPC 8 59424 00433 6	Class II	Drugs	UPC 8 59424 00433 6	cGMP Deficiencies	Unexo Life Sciences Private Limited
Cooling Menthol Extra Strength Pain Relief Patch, Menthol 7.5%, packaged in box of 5, Distributed by J.R. Watkins LLC, Oakland CA 94612 UPC 8 56294 00878 5, NDC 72342-100-05	Class II	Drugs	Lot # JC101, JC102 and JC103, exp. date Oct 31, 2025	cGMP Deviations	JR Watkins
LICEOUT, Liquid Lice Treatment for Human Use, Contents: 1 FL. OZ. (29.6 mL) per sachet, Distributed By: Bob Barker Company, Inc., 7925 Purfoy Road, Fuquay-Varina, NC 27526. NDC: 53427-124-01	Class II	Drugs	Lot LO09530; Exp 9/5/2025	CGMP violations.	Neogen Corporation
LICEOUT, Liquid Lice Treatment for Human Use, Contents: 128 FL OZ. (3785.4 mL mL) per jug, Distributed By: Bob Barker Company, Inc., 7925 Purfoy Road, Fuquay-Varina, NC 27526. NDC: 53247-124-02	Class II	Drugs	Lot, expiry: LO09530, exp 11/3/2024; LO13412, exp 12/7/2024; LO10263, exp 1/26/2025; LO11303, exp 5/10/2025; LO12153, exp 8/3/2025; LO12483, exp 9/5/2025; LO13183, exp 11/14/2025; LO106024, exp 2/29/2026; LO108624, exp 3/26/2026; LO110224, exp 4/11/2026	CGMP violations.	Neogen Corporation

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Sunitinib Malate Capsules, 12.5 mg, 28-count bottles, Rx Only, Manufactured for: AvKARE, Pulaski, TN 38478. NDC 42291-901-28	Class II	Drugs	Lot #: 100049371, Exp. Date 07/31/2026	Labeling: Label Mix-Up	AvKARE
Sunitinib Malate Capsules, 25 mg, 28-count bottles, Rx Only, Manufactured for: AvKARE, Pulaski, TN 38478. NDC 42291-902-28	Class II	Drugs	Lot #: 100049501, Exp. Date 07/31/2026	Labeling: Label Mix-Up	AvKARE
Lisdexamfetamine Dimesylate Capsules, 10 mg, 100 Capsules per bottle, Rx only, Distributed by: Lannet Company, Philadelphia, PA 19136, NDC: 0527-4661-37	Class II	Drugs	Lot: 23274856A, Exp 04/30/2025	Failed Content Uniformity Specifications: Product failed to meet the action limits for stratified content uniformity.	Lannett Company Inc.
Diltiazem Hydrochloride Extended-Release Capsules, USP 60 mg, Twice-a-Day Dosage, Rx Only, 100 Capsules per bottle, Manufactured for: Glenmark Pharmaceuticals Inc., USA Mahwah, NJ 07430, Product of India, NDC 68462-850-01.	Class II	Drugs	Lot #s: 17222544, Exp. Date 11/30/2024 ; 17230784, Exp Date 03/31/2025; 17231080, Exp. Date 04/30/2025	cGMP Deviations: Presence of N-nitroso-Desmethyl-Diltiazem impurity above FDA recommended interim limit.	Glenmark Pharmaceuticals Inc., USA
Diltiazem Hydrochloride Extended-Release Capsules, USP 90 mg, Rx Only, 100 Capsules, Manufactured for : Glenmark Pharmaceuticals Inc., USA Mahwah, NJ 07430, Product of India, NDC 68462-851-01.	Class II	Drugs	Lot #s 17222452, Exp. Date, 11/30/2024; 17230607, Exp. Date 02/28/2025	cGMP Deviations: Presence of N-nitroso-Desmethyl-Diltiazem impurity above FDA recommended interim limit.	Glenmark Pharmaceuticals Inc., USA
Diltiazem Hydrochloride Extended-Release Capsules, USP 120 mg, Rx Only, 100 Capsules, Manufactured for: Glenmark Pharmaceuticals Inc., USA, Mahwah, NJ 07430, Product of India, NDC 68462-562-01.	Class II	Drugs	Lot #: 17222470, 17230680, 17222547, Exp. Date 11/30/2024; 17230304, Exp. Date, 12/31/2024; 17230598, Exp. Date, 02/2025.	cGMP Deviations: Presence of N-nitroso-Desmethyl-Diltiazem impurity above FDA recommended interim limit.	Glenmark Pharmaceuticals Inc., USA

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Diltiazem Hydrochloride Extended-Release Capsules, USP 60 mg, Twice-a-Day Dosage, Rx Only, 100 Capsules per bottle, Mfd for: Northstar Rx LLC, Memphis, TN, Mfd by: Glenmark Pharmaceuticals Limited, Pithampur, Madhya Pradesh India, NDC 16714-553-01.	Class II	Drugs	Lot #: 17222544, Exp 11/30/2024.	cGMP Deviations: Presence of N-nitroso-Desmethyl-Diltiazem impurity above FDA recommended interim limit.	Glenmark Pharmaceuticals Inc., USA
Diltiazem Hydrochloride Extended-Release Capsules, USP 90mg, Twice-a-Day Dosage, Rx Only, 100 Capsules per bottle, Mfd for: Northstar Rx LLC, Memphis, TN, Mfd by: Glenmark Pharmaceuticals Limited, Pithampur, Madhya Pradesh India, NDC 16714-554-01.	Class II	Drugs	Lot #: 17222452, Exp Date 11/30/2024; 17230607, Exp Date 02/28/2025.	cGMP Deviations: Presence of N-nitroso-Desmethyl-Diltiazem impurity above FDA recommended interim limit.	Glenmark Pharmaceuticals Inc., USA
Diltiazem Hydrochloride Extended-Release Capsules, USP 120mg, Twice-a-Day Dosage, Rx Only, 100 Capsules per bottle, Mfd for: Northstar Rx LLC, Memphis, TN, Mfd by: Glenmark Pharmaceuticals Limited, Pithampur, Madhya Pradesh India, NDC 16714-555-01.	Class II	Drugs	Lot #:17222547, Exp. Date, 11/30/2024; 17230598, Exp. Date 02/28/2025	cGMP Deviations: Presence of N-nitroso-Desmethyl-Diltiazem impurity above FDA recommended interim limit.	Glenmark Pharmaceuticals Inc., USA
Venofer (iron sucrose) Injection, USP 100 mg Elemental Iron per 5 mL (20 mg/mL), 5 mL Single-Dose Vials, Rx Only, For Intravenous Use Only, Distributed by: Fresenius Medical Care NA, Waltham, MA 02451, NDC: 49230-534-01 (vial), NDC: 49230-534-25 (25 x 5 mL/vial cartons).	Class II	Drugs	Lot#s: 4196, Exp 05/31/2026	Presence of Particulate Matter: Potential for glass delamination from the vials.	American Regent, Inc.
Venofer (iron sucrose) Injection, USP 50 mg Elemental Iron per 2.5 mL (20 mg/mL), 2.5 mL Single-Dose Vials, Rx Only, For Intravenous Use Only, Distributed by: Fresenius Medical Care NA, Waltham, MA	Class II	Drugs	Lot #s: 4206, 4210, Exp 05/31/2026; 4223, Exp 06/30/2026; 24231, 24237, Exp 07/31/2026.	Presence of Particulate Matter: Potential for glass delamination from the vials.	American Regent, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
02451, NDC: 49230-530-01 (vial), NDC: 49230-530-10 (10 x 2.5mL/vial cartons), NDC: 49230-530-25 (25 x 2.5mL/vial cartons).					
Venofer (iron sucrose) Injection, USP 100 mg Elemental Iron per 5 mL (20 mg/mL), 5 mL Single-Dose Vials, Rx Only, For Intravenous Use Only, American Regent, Inc. Shirley, NY 11967, NDC: 0517-2340-01 (vial), NDC: 0517-2340-10 (10 x 5 mL/vial cartons), NDC: 0517-2340-25 (25 x 5 mL/vial cartons).	Class II	Drugs	Lot #s: 4205, Exp 05/31/2026; 24229, 24233, 24239, Exp 07/31/2026.	Presence of Particulate Matter: Potential for glass delamination from the vials.	American Regent, Inc.
Cinacalcet Tablets, 30 mg, packaged in: a) 30-count HDPE bottle (NDC 65862-831-30); b) 500-count HDPE bottle (NDC 65862-831-05), Rx Only, Distributed by: Aurobindo Pharma USA, Inc. 279 Princeton-Hightstown Road, East Windsor, NJ 08520, Made in India.	Class II	Drugs	Lot #: a) CFSA23001A, CFSA23002A, CFSA23003A, Exp 03/31/2025; CFSA23004A, Exp 07/31/2025; CFSA23005A, Exp 10/31/2025; b) P2300191, P2300192, P2300193, P2300194, Exp 12/31/2024	cGMP Deviations: Presence of N-nitroso Cinacalcet impurity above FDA recommended interim limit	Aurobindo Pharma USA Inc
Cinacalcet Tablets, 60mg, packaged in: a) 30-count HDPE bottle (NDC 65862-832-30), b) 500-count HDPE bottle (NDC 65862-832-05), Rx Only, Distributed by: Aurobindo Pharma USA, Inc. 279 Princeton-Hightstown Road, East Windsor, NJ 08520, Made in India.	Class II	Drugs	Lot #: a) CFSB23001A, Exp 03/31/2025, CFSB23002A, Exp 07/31/2025; CFSB23003A, Exp 10/31/2025; CFSB23004A, Exp 10/31/2025; b) P2300196, 12/31/2024	cGMP Deviations: Presence of N-nitroso Cinacalcet impurity above FDA recommended interim limit	Aurobindo Pharma USA Inc
Cinacalcet Tablets, 90 mg, packaged in: a) 30-count HDPE bottle (NDC 65862-833-30), b) 500-count HDPE bottle (NDC 65862-833-05), Rx Only, Distributed by: Aurobindo Pharma USA, Inc. 279 Princeton-Hightstown Road, East Windsor,	Class II	Drugs	Lot #: a) CFSC23001A, CFSC23001B, Exp 03/31/2025; b) P2300195, Exp 12/31/2024	cGMP Deviations: Presence of N-nitroso Cinacalcet impurity above FDA recommended interim limit	Aurobindo Pharma USA Inc

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
NJ 08520, Made in India. 90 mg - 30 Tablets - NDC 65862-833-30 90 mg - 500 Tablets - NDC 65862-833-05					
Levothyroxine Sodium Tablets, USP, 75 mcg (0.075 mg), 1000-count bottle, Rx Only, Manufactured for: Accord Healthcare, Inc., Durham, NC 27703, Manufactured by: Intas Pharmaceuticals Limited, Camp Road, Selaqui, Dehradun-248 197, INDIA, NDC 16729-449-17	Class II	Drugs	Lot #: D2300191, Exp 12/31/2025	Subpotent drug	ACCORD HEALTHCARE, INC.
Duloxetine Delayed-Release Capsules USP, 20 mg, 60 count bottles, Rx only, Distributed by: Rising Pharma Holdings, Inc., East Brunswick, NJ NDC 57237-017-60	Class II	Drugs	a) Lot # DT2022023A, DT2022024A, DT2022025A, DT2022026A, DT2022027A, exp. date Nov-24 DT2023001B, DT2023004A, DT2023005A, DT2023006A, exp. date Jan-25	CGMP Deviations: Presence of N-nitroso-duloxetine impurity above recommended interim limit	Rising Pharma Holding, Inc.
Duloxetine Delayed-Release Capsules USP, 30 mg, a) 30 count (NDC 57237-018-30), b) 90 count (NDC 57237-018-90) and c) 1000 count (NDC 57237-018-99) bottles, Rx only, Distributed by: Rising Pharma Holdings, Inc., East Brunswick, NJ	Class II	Drugs	a) 30s; DT3023019A, exp. date Jan-25 DT3023050A, exp. date Apr-25; b) 90s; DT3023022A, exp. date Jan-25; c) 1000s; DT3022108A, DT3022107A, DT3022106A, DT3022111A, DT3022109A, exp. date Nov-24, DT3023001A, DT3023003A, exp. date Dec-24, DT3023024A, DT3023020B, exp. date Jan-25 DT3023027A, DT3023028A, exp. date Feb-25, DT3023034A, exp. date Mar-25, DT3023049A, exp.	CGMP Deviations: Presence of N-nitroso-duloxetine impurity above recommended interim limit	Rising Pharma Holding, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			date Apr-25, DT3023095A, exp. date Jul-25		
Duloxetine DR Capsules USP 60 mg, a) 30 count (NDC 57237-019-30), b) 90 count NDC 57237-019-90 and c) 1000 count (NDC 57237-019-99) bottles, Distributed by: Rising Pharmaceuticals, Inc., East Brunswick, NJ	Class II	Drugs	a) 30s; DT6023059A, DT6023060A, DT6023065A, DT6023069A, DT6023070A, exp. date Jan-25, DT6023080A, exp. date Feb-25, DT6023093A, exp. date Mar-25, DTC24012A, exp. date Dec-25; b) 90s; DT6023108A, exp. date Apr-25, DTC23201A, exp. date Aug-25; c) 1000s; DT6022160A, DT6022165A, DT6022162A, DT6022164A, DT6022163A, DT6022171A, DT6022169A, DT6022170A, DT6022173A, exp. date Nov-24, DT6023009A, DT6023007A, DT6023008A, DT6023011A, DT6023034B, exp. date Dec-24, DT6023067C, exp. date Jan-25, DT6023114A, exp. date Apr-25, DTC23243A, exp. date Oct-25, DTC24040A, exp. date Dec-25	CGMP Deviations: Presence of N-nitroso-duloxetine impurity above recommended interim limit	Rising Pharma Holding, Inc.
10 Irregular Pigmentation, Accelerator, Pigment Fading Activator, Only Your Rx, Nature + Science, 1 fl. oz., 30 mL Bottle, For Professional Use Only, Only YourRx Inc., Chatsworth, CA 91311, Made in USA, Onlyyourrx.com.	Class II	Drugs	Lot #: 2400017, Exp: 4/30/2026	CGMP Deviations: Inconsistency in the water systems.	Generitech Corporation

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
MAXIM Assure Antibacterial, Chloroxylenol 0.1%, Net Contents: One U.S. Gallon (3.78 L), For Industrial and Institutional Use Only, MIDLAB 140 Private Brand Way, Athens, TN 37303	Class II	Drugs	Lot 0711241	cGMP Deviations: Out of specification results for micro in hand soap products.	Midlab Incorporated
boardwalk ANTIBACTERIAL HANDSOAP REFILL, Chloroxylenol 0.1%, 1 gal. (3.78 L), Manufactured for Essendant Co., One Parkway North, Deerfield, IL 60015	Class II	Drugs	Lot 0711241	cGMP Deviations: Out of specification results for micro in hand soap products.	Midlab Incorporated
Array Liquid Antiseptic Handwash, Chloroxylenol 0.1%, NET CONTENTS: 128 FL OZ (1 GAL) 3.785 L, FOR DISTRIBUTION EXCLUSIVELY BY GORDON FOOD SERVICE, WYOMING, MI 49509	Class II	Drugs	Lot 0711241	cGMP Deviations: Out of specification results for micro in hand soap products.	Midlab Incorporated
ROYALAB Germ Away Antibacterial Hand Soap, Chloroxylenol 0.1%, NET CONTENTS: ONE U.S. GALLON (3.78 L), Royal Papers, 2701 Hereford St., St. Louis, MO 63139	Class II	Drugs	Lot 0711241	cGMP Deviations: Out of specification results for micro in hand soap products.	Midlab Incorporated
Genuine Joe Antibacterial Lotion Soap , Chloroxylenol 0.1%, 1 GALLON (3.78L), Manufactured in the U.S.A. for S.P. Richards Co., Atlanta, GA 30339	Class II	Drugs	Lot 0711241	cGMP Deviations: Out of specification results for micro in hand soap products.	Midlab Incorporated
Compliance Dishwashing Liquid & Antibacterial Soap, PCMX 0.1%, Net Contents: 1 Gallon, 128 Ounces, 3.785 Liters, Royal Corporation, 10232 Palm Drive, Santa Fe Springs, CA 90670	Class II	Drugs	Lot 0711241	cGMP Deviations: Out of specification results for micro in hand soap products.	Midlab Incorporated
Duloxetine Delayed-Release Capsules, USP, 20 mg, Rx only, 60 count bottles, Manufactured by: Aurobindo Pharma Limited, Hyderabad-500 090, India, For BluePoint Laboratories NDC 68001-413-06	Class II	Drugs	Lots: DT2023001A, DT2023009A, exp date Jan 31, 2025	CGMP Deviations: Presence of N-nitroso-duloxetine impurity above the recommended interim limit	Amerisource Health Services LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Duloxetine Delayed-Release Capsules, USP, 30 mg, Rx only, a) 30 count (NDC 68001-414-04) and b) 1,000 count (NDC 68001-414-08) bottles, Manufactured by: Aurobindo Pharma Limited, Hyderabad-500 090, India, For BluePoint Laboratories	Class II	Drugs	a) 30 count; Lot, expiry: DT3023019B, DT3023020A, exp 01/31/2025 b) 1000 count; Lot, expiry: DTB23098A, exp 08/31/2025	CGMP Deviations: Presence of N-nitroso-duloxetine impurity above the recommended interim limit	Amerisource Health Services LLC
Duloxetine Delayed-Release Capsules, USP, 60 mg, Rx only, 1,000 count bottle, Manufactured by: Aurobindo Pharma Limited, Hyderabad-500 090, India, For BluePoint Laboratories NDC 68001-415-08	Class II	Drugs	Lot, expiry: DT6022159A, DT6022167A, DT6022168A, exp 11/30/2024; Lot DT6023034A, 12/31/2024; Lots DT6023050A, DT6023051A, DT6023063A, DT6023067A, exp 01/31/2025; Lots DT6023073A, DT6023072A, exp 02/28/2025	CGMP Deviations: Presence of N-nitroso-duloxetine impurity above the recommended interim limit	Amerisource Health Services LLC
Cinacalcet Tablets, 30 mg, 30-count bottle, Rx only, Manufactured for: AvKARE, Pulaski, TN 38478, NDC 42291-459-30	Class II	Drugs	Lot#: 44378, 44597, 45804, Exp 12/31/2024	CGMP deviations: Presence of Nitrosamine Drug Substance Related Impurity (NDSRI), N-Nitroso-Cinacalcet above acceptable intake limit.	AvKARE
Cinacalcet Tablets, 60 mg, 30-count bottle, Rx only, Manufactured for: AvKARE, Pulaski, TN 38478, NDC 42291-460-30	Class II	Drugs	Lot # 44550, Exp 12/31/2024	CGMP deviations: Presence of Nitrosamine Drug Substance Related Impurity (NDSRI), N-Nitroso-Cinacalcet above acceptable intake limit.	AvKARE
Cinacalcet Tablets, 90 mg, 30-count bottle, Rx only, Manufactured for: AvKARE, Pulaski, TN 38478, NDC 42291-461-30	Class II	Drugs	Lot #: 44405, Exp 12/31/2024	CGMP deviations: Presence of Nitrosamine Drug Substance Related Impurity (NDSRI), N-Nitroso-Cinacalcet above acceptable intake limit.	AvKARE

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Levothyroxine Sodium Tablets USP, 125 mcg, packaged in a) 90-count bottles (NDC 0378-1813-77) and b) 1000-count bottles (NDC 0378-1813-10), Rx only, Manufactured for: Mylan Pharmaceuticals Inc. Morgantown, WV 26505 U.S.A.	Class II	Drugs	Lot #: a) 3182797, Exp. Date Nov 2024; 8177587, b) 3199816, Exp. Date Jun 2025	Superpotent Drug and Subpotent Drug: potency failures obtained	Viatris Inc
Levothyroxine Sodium Tablets USP, 137 mcg, packaged in a) 90-count bottles (NDC 0378-1823-77) and b) 1000-count bottles (NDC 0378-1823-10), Rx only, Manufactured for: Mylan Pharmaceuticals Inc. Morgantown, WV 26505 U.S.A.	Class II	Drugs	Lot #: a) 8165919, Exp. Date Dec 2024; 8172050, Exp. Date Mar 2025; 8183251, Exp. Date Sept 2025 b) 3185542, Exp. date Dec 2024; 3192838, Exp. Date Mar 2025; 3208172, Exp. Date Sept 2025	Superpotent Drug and Subpotent Drug: potency failures obtained	Viatris Inc
Levothyroxine Sodium Tablets USP, 150 mcg, packaged in a) 90-count bottles (NDC 0378-1815-77) and b) 1000-count bottles (NDC 0378-1815-10), Rx only, Manufactured for: Mylan Pharmaceuticals Inc. Morgantown, WV 26505 U.S.A.	Class II	Drugs	Lot #: a) 8177720, Exp. Date Jun 2025; b) 3200218, Exp. Date Jun 2025	Superpotent Drug and Subpotent Drug: potency failures obtained	Viatris Inc
Levothyroxine Sodium Tablets USP, 175 mcg, packaged in a) 90-count bottles (NDC 0378-1817-77) and b) 1000-count bottles (NDC 0378-1817-10), Rx only, Manufactured for: Mylan Pharmaceuticals Inc. Morgantown, WV 26505 U.S.A.	Class II	Drugs	Lot #: a) 3192915, 8172108, Exp. Date Mar 2025; b) 3208680, Exp. Date Sep 2025	Superpotent Drug and Subpotent Drug: potency failures obtained	Viatris Inc
Levothyroxine Sodium Tablets USP, 200 mcg, packaged in a) 90-count bottles (NDC 0378-1819-77) and b) 1000-count bottles (NDC 0378-1819-10), Rx only, Manufactured for: Mylan Pharmaceuticals Inc. Morgantown, WV 26505 U.S.A.	Class II	Drugs	Lot #: a)8179847, Exp. Date July 2025; b) 3203518, Exp. Date July 2025	Superpotent Drug and Subpotent Drug: potency failures obtained	Viatris Inc

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Levothyroxine Sodium Tablets USP, 25 mcg, packaged in a) 90-count bottles (NDC 0378-1800-77) and b) 1000-count bottles (NDC 0378-1800-10), Rx only, Manufactured for: Mylan Pharmaceuticals Inc. Morgantown, WV 26505 U.S.A.	Class II	Drugs	Lot #: a) 8181875, Exp. Date Aug 2025; 8174497, Exp. Date April 2025 b) 3209099, Exp. Date Sep 2025; 3206534, Exp. Date Aug 2025; 3196137, Exp. Date April 2025	Superpotent Drug and Subpotent Drug: potency failures obtained	Viatris Inc
Levothyroxine Sodium Tablets USP, 50 mcg, packaged in a) 90-count bottles (NDC 0378-1803-77) and b) 1000-count bottles (NDC 0378-1803-10), Rx only, Manufactured for: Mylan Pharmaceuticals Inc. Morgantown, WV 26505 U.S.A.	Class II	Drugs	Lot #: a) 8174701, Exp. Date April 2025; 8182228, Exp. Date Aug 2025 b)3193984, Exp. Date Mar 2025; 3206790, Exp. Date Aug 2025	Superpotent Drug and Subpotent Drug: potency failures obtained	Viatris Inc
Levothyroxine Sodium Tablets USP, 75 mcg, packaged in a) 90-count bottles (NDC 0378-1805-77) and b) 1000-count bottles (NDC 0378-1805-10), Rx only, Manufactured for: Mylan Pharmaceuticals Inc. Morgantown, WV 26505 U.S.A.	Class II	Drugs	Lot #: a) 8177078, Exp. Date May 2025; 8168596, Exp. Date Jan 2025 b) 3199313, Exp. Date May 2025; 3194118, Exp. Date Mar 2025; 3186238, Exp. Date Dec 2024; 3209590, Exp. Date Sep 2025; 3199317, Exp. Date May 2025; 3188733, Exp. Date Jan 2025	Superpotent Drug and Subpotent Drug: potency failures obtained	Viatris Inc
Levothyroxine Sodium Tablets USP, 88 mcg, packaged in a) 90-count bottles (NDC 0378-1807-77) and b) 1000-count bottles (NDC 0378-1807-10), Rx only, Manufactured for: Mylan Pharmaceuticals Inc. Morgantown, WV 26505 U.S.A.	Class II	Drugs	Lot # a) 8180781, Exp. Date Aug 2025; b)3191628, Exp. Date Feb 2025; 3197139, Exp. Date Apr 2025; 3188976, Exp. Date Jan 2025; 3184929, Exp. Date Dec 2024; 3204909, Exp. Date Aug 2025	Superpotent Drug and Subpotent Drug: potency failures obtained	Viatris Inc
Levothyroxine Sodium Tablets USP, 100 mcg, packaged in a) 90-count bottles (NDC 0378-1809-77) and b) 1000-count bottles (NDC 0378-1809-10), Rx only,	Class II	Drugs	Lot #: a) 8171269, Exp. Date Feb 2025; 8179579, Exp. Date July 2025 b)3183815, Exp. Date Nov 2024; 3189147, Exp.	Superpotent Drug and Subpotent Drug: potency failures obtained	Viatris Inc

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Manufactured for: Mylan Pharmaceuticals Inc. Morgantown, WV 26505 U.S.A.			Date Jan 2025; 3192027, Exp. Date Feb 2025; 3202894, Exp. Date Jul 2025; 3192026, Exp. Date Feb 2025; 3199781, Exp. Date Jun 2025. 3192028, exp. date Feb 2025 3202895, exp. date July 2025		
Levothyroxine Sodium Tablets USP, 112 mcg, packaged in a) 90-count bottles (NDC 0378-1811-77) and b) 1000-count bottles (NDC 0378-1811-10), Rx only, Manufactured for: Mylan Pharmaceuticals Inc. Morgantown, WV 26505 U.S.A.	Class II	Drugs	Lot #: a) 8171623, Exp. Date Feb 2025; 8164486, Exp. Date Nov 2024 b)3205462, Exp. Date Aug 2025; 3192428, Exp. Date Feb 2025; 3184096, Exp. Date Nov 2024	Superpotent Drug and Subpotent Drug: potency failures obtained	Viatris Inc
Kirkland Severe Cold & Flu Plus Congestion: Day - 112 coated caplets blister pack; (Acetaminophen 325mg, Dextromethorphan HBr 10 mg, Guaifenesin 200 mg, Phenylephrine HCl 5 mg); Night - 56 coated caplets blister pack; (Acetaminophen 325mg, Dextromethorphan HBr 10 mg, Doxylamine succinate 6.25 mg, Phenylephrine HCl 5 mg); Manufactured BY: LNK International, Inc. FOR: Costco Wholesale Corporation. NDC# 63981-795-81	Class II	Drugs	Lot # P139953, exp. date 2026/AUG Lot # P139815, exp. date 2026/AUG	CGMP Deviations: Released product should have been rejected.	LNK International, Inc.
Levothyroxine Sodium Tablets, USP, 100 mcg (0.1 mg), 100 Tablets per carton (10 unit dose blister cards of 10 tablets each), Rx only, Manufactured for: Mylan Pharmaceuticals Inc., Morgantown, WV 26505 USA. NDC: 51079-442-20	Class II	Drugs	Lot #: 3115936, Exp. Date 07/2025	Subpotent and Superpotent Drug	Mylan Institutional, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Levothyroxine Sodium Tablets, USP, 112 mcg (0.112 mg), 100 Tablets per carton (10 unit dose blister cards of 10 tablets each), Rx only, Manufactured for: Mylan Pharmaceuticals Inc., Morgantown, WV 26505 USA. NDC: 42292-039-20	Class II	Drugs	Lot #: 3115707, Exp. Date 02/2025	Subpotent and Superpotent Drug	Mylan Institutional, Inc.
Levothyroxine Sodium Tablets, USP, 125 mcg (0.125 mg), 100 Tablets per carton (10 unit dose blister cards of 10 tablets each), Rx only, Manufactured for: Mylan Pharmaceuticals Inc., Morgantown, WV 26505 USA. NDC: 51079-443-20	Class II	Drugs	Lot #: 3115893, Exp. Date 6/2025	Subpotent and Superpotent Drug	Mylan Institutional, Inc.
Levothyroxine Sodium Tablets, USP, 137 mcg (0.137 mg), 100 Tablets per carton (10 unit dose blister cards of 10 tablets each), Rx only, Manufactured for: Mylan Pharmaceuticals Inc., Morgantown, WV 26505 USA. NDC: 42292-041-20	Class II	Drugs	Lot #: 3115448, Exp. Date 12/31/2024;3115732, Exp. Date 3/31/2025; 3116024, Exp. Date 9/30/2025	Subpotent and Superpotent Drug	Mylan Institutional, Inc.
Levothyroxine Sodium Tablets, USP, 150 mcg (0.150 mg), 100 Tablets per carton (10 unit dose blister cards of 10 tablets each), Rx only, Manufactured for: Mylan Pharmaceuticals Inc., Morgantown, WV 26505 USA. NDC: 51079-445-20	Class II	Drugs	Lot #: 3115924, Exp. Date 06/2025	Subpotent and Superpotent Drug	Mylan Institutional, Inc.
Levothyroxine Sodium Tablets, USP, 175 mcg (0.175 mg), 100 Tablets per carton (10 unit dose blister cards of 10 tablets each), Rx only, Manufactured for: Mylan Pharmaceuticals Inc., Morgantown, WV 26505 USA. NDC: 42292-040-20	Class II	Drugs	Lot #: 3115869, Exp. Date 03/2025	Subpotent and Superpotent Drug	Mylan Institutional, Inc.
Hylenex recombinant (hyaluronidase) injection, 150 USP units/mL, 4x1 mL Single Dose Vials, Rx only, Manufactured for and	Class II	Drugs	Serial # 100000831961 100000820688	cGMP Deviations: Temperature excursion	Mckesson Medical-Surgical Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
marketed by Halozyme, Inc., 12390 El Camino Real San Diego California 92130, Distributed by Antares Pharma, Inc., Ewing, NJ NDC 18657-117-04			100000820689 100000820515		Corporate Office
Dabigatran Etexilate, 75 mg capsules, 60-count bottles, Rx Only, Manufactured by: Alkem Laboratories Ltd., INDIA, Distributed by: Ascend Laboratories, LLC Parsippany, NJ 07054 NDC 67877-474-60	Class II	Drugs	Lot #: 24142328, 24142329, 24142330, Exp. Date May 31, 2026.	CGMP Deviations: Presence of N-nitroso-Dabigatran impurity above recommended interim limit	Ascend Laboratories, LLC
Dabigatran Etexilate, 150mg capsules, 60-count bottles, Rx Only, Manufactured by: Alkem Laboratories Ltd., INDIA, Distributed by: Ascend Laboratories, LLC Parsippany, NJ 07054 NDC 67877-475-60	Class II	Drugs	Lot #: 24142192, 24142193, 24142194, Exp. Date April 30, 2026; 24142463, Exp. Date May 31, 2026;	CGMP Deviations: Presence of N-nitroso-Dabigatran impurity above recommended interim limit	Ascend Laboratories, LLC
Timolol Maleate Ophthalmic Solution USP, 0.25%, Sterile, 15mL bottles, Rx only, Manufactured by: FDC Limited, Waluj, Aurangabad, Maharashtra, India, Distributed by: Rising Pharmaceuticals Inc, New Jersey, NDC 64980-513-15.	Class II	Drugs	Lot #: 083I006, Exp 08/31/2025	Defective Container: Unable to get the solution out of the bottle as the spike of the cap was lodged in the nozzle of the product bottle.	FDC Limited
Dihydroergotamine Mesylate Injection, solution for injection, USP, 1 mg/mL Ampules, Rx Only, Distributed by: Provepharm Inc. 100 Springhouse Drive Suite 105, Collegeville, PA 19426, NDC 81284-411-05	Class II	Drugs	Lot #: F9026F01, F9026F02, Exp. Date 12/2025	Discoloration	Provepharm Inc.
VCF, Vaginal Contraceptive Gel, Birth Control, 10 Pre-filled Applicators, Net Wt. 0.09 oz (2.55g) Each, Distributed By: Apothecus Pharmaceutical Corp., Ronkonkoma, NY 11779, NDC 52925-512-10	Class II	Drugs	Lot: 3A001/3A001A, Exp: 07/25	CGMP deviations: out of specifications for assay	Apothecus Pharmaceutical Corp.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Olanzapine Tablets, USP 2.5 mg, 30-count bottle, Rx Only, Manufactured for: Macleods Pharma USA, Inc. Princeton, NJ 08540, Manufactured for: Macleods Pharma USA Inc. Princeton, NJ,08540: Manufactured by: Macleods Pharmaceuticals, Ltd. Baddi Himachal Pradesh, INDIA, NDC 33342-067-07.	Class II	Drugs	Lot# BOB12318A Exp 07/31/2027	Failed Impurities/Degradation Specifications	Macleods Pharmaceuticals Ltd
Gelato, Benzocaine 20% Topical Gel Anesthetic Gel, Net Wt. 1 oz. (30ml), Manufactured by Keystone Industries 480 S. Democrat Rd., Gibbstown, NJ 08027, NDC# 68400-352-30.	Class II	Drugs	Lot: BNZ-001646, Exp Date: 11/26/2026, Keystone item No. 03-02319	CGMP deviations: the bulk product was rejected by the Quality Unit after routine inspection of the mixing vessel showed scratches on the sides and bottom of the mixing vessel. Product was to be rejected but was inadvertently released and shipped to customers.	Keystone Industries
M&S Dental Supply Co LLC., Topical Anesthetic Gel, Benzocaine 20%, Net Wt. 1 oz. (30ml), Manufactured for: M&S Dental Supply Co LL, 105-30 101 Avenue, Ozone Park, NY 11416.	Class II	Drugs	Lot: BNZ-001646, Exp Date: 11/26/2026, Keystone Item No: 03-09619	CGMP deviations: the bulk product was rejected by the Quality Unit after routine inspection of the mixing vessel showed scratches on the sides and bottom of the mixing vessel. Product was to be rejected but was inadvertently released and shipped to customers.	Keystone Industries
Primo, Topical Anesthetic gel, Benzocaine 20%, Net Content: 1 oz. (30g), Gluten Free, Manufactured for: Primo Dental Products, 845 Third Avenue, 6th Floor, New York, NY 10022.	Class II	Drugs	Lot: BNZ-001646, Exp Date: 11/26/2026, Keystone Item No. 03-13119	CGMP deviations: the bulk product was rejected by the Quality Unit after routine inspection of the mixing vessel showed scratches on the sides and bottom of the mixing vessel. Product was to be rejected but	Keystone Industries

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
				was inadvertently released and shipped to customers.	
Dental City, Topical Anesthetic Gel, Benzocaine 20%, Net Content: 1 oz. (30 ml), Gluten Free, Manufactured for: Dental City, Green Bay, WI 54311, dentalcity.com.	Class II	Drugs	Lot: BNZ-001646, Exp Date: 11/26/2026, Keystone Item No. 03-25119	CGMP deviations: the bulk product was rejected by the Quality Unit after routine inspection of the mixing vessel showed scratches on the sides and bottom of the mixing vessel. Product was to be rejected but was inadvertently released and shipped to customers.	Keystone Industries
Patterson Dental, Patterson Topical Anesthetic Gel, Benzocaiine, 1 oz. (30 ml), Manufactured for (Fabrique pour): Patterson Dental Supply, Inc. 1031 Mendota Heights Road, Saint Paul, MN 55120, NDC 50227-1002-3.	Class II	Drugs	Lot: BNZ-001646, Exp Date: 11/26/2026, Keystone Item No. 03-27119	CGMP deviations: the bulk product was rejected by the Quality Unit after routine inspection of the mixing vessel showed scratches on the sides and bottom of the mixing vessel. Product was to be rejected but was inadvertently released and shipped to customers.	Keystone Industries
Health-Tec, Topical Anesthetic Gel, Benzocaine 20%, Made in USA, 1 FL. OZ (29.6 ml), NDC 69634-021-30.	Class II	Drugs	Lot: BNZ-001646, Exp Date: 11/26/2026, Keystone Item No. 03-28119	CGMP deviations: the bulk product was rejected by the Quality Unit after routine inspection of the mixing vessel showed scratches on the sides and bottom of the mixing vessel. Product was to be rejected but was inadvertently released and shipped to customers.	Keystone Industries
Burkhart, Topical Anesthetic Gel, Benzocaine 20%, Gluten Free, 1 FL. OZ (30 ml), Manufactured for Burkhart Dental Supply, Tacoma, Washington 98409.	Class II	Drugs	Lot: BNZ-001646, Exp Date: 11/26/2026, Keystone Item No. 03-29119	CGMP deviations: the bulk product was rejected by the Quality Unit after routine inspection of the mixing vessel	Keystone Industries

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
				showed scratches on the sides and bottom of the mixing vessel. Product was to be rejected but was inadvertently released and shipped to customers.	
Pearson Quality, Topical Anesthetic Gel, 20% Benzocaine, For Professional Use Only, Net Contents: 1 oz (30 g), Manufactured for Pearson Dental Supply Inc., Sylmar, CA 91342 USA.	Class II	Drugs	Lot: BNZ-001646, Exp Date: 11/26/2026, Keystone Item No. 03-30619	CGMP deviations: the bulk product was rejected by the Quality Unit after routine inspection of the mixing vessel showed scratches on the sides and bottom of the mixing vessel. Product was to be rejected but was inadvertently released and shipped to customers.	Keystone Industries
safco, SensiCaine Ultra, Topical Anesthetic Gel, Contains 20% Benzocaine, 1 oz (29.6 mL), Cherry, NDC 67239-0219-1, Gluten Free, Distributed by: Safco Dental Supply Co., Buffalo Grove, IL 60089, Made in USA, For Professional Use Only.	Class II	Drugs	Lot: BNZ-001646, Exp Date: 11/26/2026, Keystone Item No. 03-64119	CGMP deviations: the bulk product was rejected by the Quality Unit after routine inspection of the mixing vessel showed scratches on the sides and bottom of the mixing vessel. Product was to be rejected but was inadvertently released and shipped to customers.	Keystone Industries
Quala Dental Products, Topical Anesthetic Gel, Contains 20% Benzocaine, Net Contents: 1 oz (30g), Gluten Free, Quala Dental Products, Made in USA for: NDC, Inc, 407 New Sanford Road, La Vergne, TN 37086, www.quala.com	Class II	Drugs	Lot No.: BNZ-001646, Exp Date: 11/26/2026, Keystone Item No. 03-64419	CGMP deviations: the bulk product was rejected by the Quality Unit after routine inspection of the mixing vessel showed scratches on the sides and bottom of the mixing vessel. Product was to be rejected but was inadvertently released and shipped to customers.	Keystone Industries

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Ipana, 20% Benzocaine Topical Gel, 28g, Maxill Inc., St Thomas ON Canada.	Class II	Drugs	Lot No.: BNZ-001646, Exp Date: 11/26/2026, Keystone Item No. 03-35119	CGMP deviations: the bulk product was rejected by the Quality Unit after routine inspection of the mixing vessel showed scratches on the sides and bottom of the mixing vessel. Product was to be rejected but was inadvertently released and shipped to customers.	Keystone Industries
Henry Schein, Benzo-Jel, Topical Anesthetic Gel, 20% Benzocaine, 1 fl. oz. (29.6 mL), Distributed by Henry Schein, Melville, NY 11747, For Professional Use Only,	Class II	Drugs	Lot: BNZ-001646, Exp Date: 11/26/2026, Keystone Item No. 03-43619	CGMP deviations: the bulk product was rejected by the Quality Unit after routine inspection of the mixing vessel showed scratches on the sides and bottom of the mixing vessel. Product was to be rejected but was inadvertently released and shipped to customers.	Keystone Industries
LITE Regener-Eyes, Ophthalmic Solution (glycerin 0.4%), 3mL bottles, Distributed by: Regener-Eyes, Tampa, FL; Manufactured by: Regenerative Processing Plant, LLC, 34176 US HWY 19N, FL, NDC 82305-006-01	Class II	Drugs	Lot #: P121322A, P121322B, Exp. Date 12/13/2024; P121422A, Exp. Date 12/14/2024; P121922A, P121922B, Exp. Date 12/19/2024; P122022A, Exp. Date 12/20/2024; P122122A, P122122B, Exp. Date 12/21/2024; P122622A, P122622B, Exp. Date 12/26/2024; P122722A, P122722B, Exp. Date 12/27/2024; P122822A, P122822B, Exp. Date 12/28/2024. P010223A, Exp.	Lack of Sterility Assurance	Regenerative Processing Plant, LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			Date 1/2/2025; P010323LV1, Exp. Date 1/3/2025; P010523A, P010523B, Exp. Date 1/5/2025; P010923A, Exp. Date 1/9/2025; P011023LV2, Exp. Date 1/10/2025, P011223A, P011223B, Exp. Date 1/12/2025; P011623A; Exp. Date 1/16/2025, P011723LV3, Exp. Date 1/17/2025; P011923A, P011923B, Exp. Date 1/19/2025; P012323A, P012323B, Exp. Date 1/23/2025; P012523A, Exp. Date 1/25/2025; P013123A, Exp. Date 1/31/2025; P020223A, Exp. Date 2/2/2025; P020623A, Exp. Date 2/6/2025,P020823A, Exp. Date 2/8/2025, P020923A, Exp. Date 2/9/2025, P021323A, Exp. Date 2/13/2025; P021523A, P021523B, Exp. Date 2/15/2025, P021623A, Exp. Date 2/16/2025, P022023A, Exp. Date 2/20/2025, P022123A, Exp. Date 2/21/2025, P022323A, Exp. Date 2/23/2025, P022723A, Exp. Date 2/27/2025, P030123A, Exp. Date		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			3/1/2025, P030223A, Exp. Date 3/2/2025, P030623A, Exp. Date 3/6/2025; P030723A, Exp. Date 3/7/2025; P030823A, Exp. Date 3/8/2025; P030923A Exp. Date 3/9/2025, P031423A, Exp. Date 3/14/2025, P032023A, Exp. Date 3/20/2025, P032123A, Exp. Date 3/21/2025; P032223A, Exp. Date 3/22/2025; P032723A, Exp. Date 3/27/2025; P040423A, Exp. Date 4/4/2025; P040523A, Exp. Date 4/5/2025; P040623A, Exp. Date 4/6/2025; P041023A, Exp. Date 4/10/2025;P041123A, Exp. Date 4/11/2025; P041223A, Exp. Date 4/12/2025; P041323A, Exp. Date 4/13/2025; P041723A, Exp. Date 4/17/2025; P041823A, Exp. Date 4/18/2025;P041923A, Exp. Date 4/19/2025; P042023A, Exp. Date 4/20/2025; P042423A, Exp. Date 4/24/2025; P042523A, Exp. Date 4/25/2025;P042623A, Exp. Date 4/26/2025;		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			P050323A, Exp. Date 5/3/2025; P050823A, Exp. Date 5/8/2025;P050923A, Exp. Date 5/9/2025;P051023A, Exp. Date 5/10/2025;P051123A, Exp. Date 5/11/2025;P051523A, Exp. Date 5/15/2025; P051623A, Exp. Date 5/16/2025; P051723A, Exp. Date 5/17/2025; P052223A, Exp.: 5/22/2025; P052323A, Exp.: 5/23/2025; P052423A, Exp. Date 5/24/2025; P052523A, Exp.: 5/25/2025; P053023A, Exp. Date 5/30/2025; P053123A, Exp. Date 5/31/2025; P060123A, Exp. Date 6/1/2025; P060223A, Exp. Date 6/2/2025; P060523A, Exp. Date 6/5/2025; P060623A, Exp. Date 6/6/2025; P060723A, Exp. Date 6/7/2025; P060823A, Exp. Date 6/8/2025; P061223A, Exp. Date 6/12/2025; P061323A, Exp. Date 6/13/2025; P061423A, Exp. Date 6/14/2025		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
PROFESSIONAL Regener-Eyes, Ophthalmic Solution (glycerin 0.5%) , 3mL bottles, Distributed by: Regener-Eyes, Tampa, FL; Manufactured by: Regenerative Processing Plant, LLC, 34176 US HWY 19N, FL, NDC 82305-003-01	Class II	Drugs	Lot #: P120522A, Exp. Date 12/5/2025, P120522B, Exp. Date 12/5/2024; P120822A, Exp. Date 12/8/2024; P1208228, Exp. Date 12/8/2024; P121222A, P1212228, Exp. Date 12/12/2024; P121922A, P121922B, Exp. Date 12/19/2024; P122222A, Exp. Date 12/22/2024; P122622A, P122622B, Exp. Date 12/26/2024; P010223A, Exp. Date 1/2/2025; P010423PV1, Exp. Date 1/4/2025; P010523A, P010523B, Exp. Date 1/5/2025; P010923A, Exp. Date 1/9/2025; P011123PV2, Exp. Date 1/11/2025; P011223A, P011223B, Exp. Date 1/12/2025; P011623A, Exp. Date 1/16/2025; P011823PV3, Exp. Date 1/18/2025; P011923A, P011923B, Exp. Date 1/19/2025; P012323A, P012323B, Exp. Date 1/23/2025; P012623A, Exp. Date 1/26/2025; P013023A, Exp. Date 1/30/2025; P020123A, Exp. Date 2/1 /2025; P020723A, Exp. Date 2/7/2025; P021423, Exp. Date	Lack of Sterility Assurance	Regenerative Processing Plant, LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			2/14/2025, P021623A, Exp. Date 2/16/2025; P022023A, Exp. Date 2/20/2025; P022223A, Exp. Date 2/22/2025; P022823A, Exp. Date 2/28/2025; P030123A, Exp. Date 3/1/2025; P050423A, Exp. Date 5/4/2025, P051823A, Exp. Date 5/18/2025, P052523A, Exp. Date 5/25/2025		
Nebivolol Tablets, 2.5. mg, 30-count bottles, Rx only, Distributed by: Aurobindo Pharma USA, Inc., 279 Princeton-Hightstown Road, East Windsor, NJ 08520. NDC: 59651-137-30	Class II	Drugs	Lot #: NB0224001A and NB0224001B, Exp. Date 04/2027	CGMP Deviations: Presence of Nitrosamine Drug Substance Related Impurity (NDSRI), N-Nitroso Nebivolol above acceptable intake (AI) limit.	Aurobindo Pharma USA Inc
Esomeprazole Magnesium for Delayed-Release Oral Suspension 40 mg, 30 Single-Dose Packets, Rx Only, Manufactured by: Zydus Lifesciences Ltd. Ahmedabad, India, Distributed by: Zydus Pharmaceuticals (USA) Inc., Pennington, NJ 08534, NDC 68382-849-94. Packaged in sachets	Class III	Drugs	Lot#: M408002, Exp 05/31/2026	Labeling: Not Elsewhere Classified - Wrong NDC number	Zydus Pharmaceuticals (USA) Inc
Javygtor (sapropterin dihydrochloride) Tablets 100mg, 120-count bottle, Rx Only, Distributor: Dr. Reddy's Laboratories Inc., Princeton, NJ 08540 Made in India, NDC 43598-096-04.	Class III	Drugs	Lot #: T2300653, Exp 01/31/2025; T2303956, T2303750, Exp 06/30/2025; T2304190, T2304987, Exp 08/31/2025; T2302026, Exp 03/31/2025; T2302526, Exp 05/31/2025.	Failed Impurities/Degradation Specifications: The observed impurity level was 0.15%, exceeding the specification limit of not more than 0.12%.	Dr. Reddy's Laboratories, Inc.
Varithena (polidocanol injectable foam)Administration Pack, Contains: 3 silicone-free syringes, 2 compression pads,	Class III	Drugs	Lot # 34067418, Exp. March 2026, 34067419, Exp. March 2026	Defective Delivery System: incorrect silicone oil-free NormJect 10 mL Luer Lock Solo	Biocompatibles UK, Ltd.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
1 Varithena Transfer Unit, 1 manometer tubing, Rx Only, Distributed by Biocompatibles Inc., a BTG International Group company. CN01114.3				syringes packaged in the pack, instead of the required silicone oil-free NormJect 10 mL Luer Solo syringes (luer slip connection).	

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

FDA Drug Safety Communications

[Posted 12-12-2-24] Serious liver injury being observed in patients without cirrhosis taking Ocaliva (obeticholic acid) to treat primary biliary cholangitis
Monitor liver tests often for early identification of worsening liver function

Based on its review of postmarket clinical trial data, the U.S. Food and Drug Administration (FDA) identified cases of serious liver injury among patients being treated for primary biliary cholangitis (PBC) with Ocaliva (obeticholic acid) who did not have cirrhosis of the liver. We previously identified that PBC patients with advanced cirrhosis were at risk of serious liver injury when taking Ocaliva and updated the prescribing information to restrict its use in these patients. FDA's review of this required clinical trial found that some cases of liver injury in patients without cirrhosis resulted in liver transplant. This risk was notably higher for patients taking Ocaliva compared with a placebo, a pill without any active medicine.

FDA restricted the use of Ocaliva in patients who have PBC with advanced cirrhosis of the liver in 2021 because it can cause serious harm in those patients, adding a new *Contraindication* to the Ocaliva prescribing information and patient Medication Guide. However, our recent review of case reports submitted to FDA* found that some patients with PBC and advanced cirrhosis were still taking the medicine despite these restrictions.

We are notifying health care professionals and patients of this new safety information, and that frequent liver test monitoring is necessary to identify worsening liver function and ensure appropriate discontinuation of Ocaliva. The agency will continue to monitor the medicine's safety and will follow up if additional information becomes available.

Health care professionals should monitor liver tests frequently in patients being treated with Ocaliva to detect and address worsening liver function early. Based on the current data, it is not clear if this monitoring will be sufficient to address the risk of serious liver injury. Discontinue Ocaliva treatment with any evidence of liver disease progression or if efficacy is not established. Explain the signs and symptoms of worsening liver injury to patients receiving Ocaliva and direct them to contact you immediately if they develop any signs or symptoms of worsening liver injury.

Patients should talk to your health care professional about this safety risk and the benefits of continuing treatment with Ocaliva. Discuss any concerns you may have, including about possible alternative treatments. Contact your health care professional immediately if you develop any of the following symptoms, which may indicate worsening liver injury:

Any of these specific symptoms

- Swollen belly
- Yellow eyes or skin
- Bloody or black stools
- Coughing up or vomiting blood
- Mental status changes such as confusion, slurred speech, mood swings, changes in personality, or increased sleepiness or difficulty waking up

Any of these general symptoms if they are severe or do not go away after a few days

- Belly pain
- Nausea, vomiting, or diarrhea
- Loss of appetite or weight loss
- New or worsening tiredness
- Weakness
- Fever and chills
- Lightheadedness
- Less frequent urination

Ocaliva is a prescription medicine approved in May 2016 that has been shown to improve a certain liver test called alkaline phosphatase (ALP) in patients with PBC who have not responded well enough to another medicine called ursodeoxycholic acid (UDCA). The original clinical trial showed a decrease in ALP that supported FDA accelerated approval. FDA required the additional postmarket clinical trial to verify the clinical benefit of Ocaliva.

FDA evaluated liver safety in the postmarket clinical trial in patients who were appropriate for Ocaliva treatment based on the approved indication in the prescribing information. Among these patients, the risk of both liver transplant and death were higher in patients receiving Ocaliva compared with those receiving placebo. Specifically, among patients for whom Ocaliva was indicated, which were those with a lower risk of progression to liver transplant or death, 7 of 81 who received Ocaliva needed a liver transplant compared to 1 of 68 patients who received placebo. An additional four patients receiving Ocaliva died, compared to one receiving placebo. Analyses evaluating the risk of liver transplant and death resulted in a hazard ratio of 4.77 (95% confidence interval: 1.03, 22.09) for patients without advanced cirrhosis and not contraindicated from receiving the drug.

Following the addition of the contraindication for PBC patients with advanced cirrhosis in May 2021, we identified 20 cases (domestic, n=13; foreign, n=7) received by FDA* between May 26, 2021, and September 18, 2024, reporting one or more of the following events in patients treated with Ocaliva: liver transplant (n=7), evaluation or listing for liver transplant (n=8), or liver-related death (n=6). Although we were not able to assess the appropriateness of Ocaliva use for most of these cases because of limited information, we identified three U.S. cases of liver-related events that occurred in patients for whom Ocaliva should have been discontinued based on progression of their liver disease as indicated in the 2021 safety labeling changes. This shows the importance of ongoing monitoring of liver tests and prompt action to withdraw Ocaliva if there is evidence of progression towards cirrhosis.

*The cases were reported to the FDA Adverse Event Reporting System (FAERS) database.

We previously communicated about the risk of serious liver injury associated with Ocaliva in May 2021 (restriction of Ocaliva use in PBC patients with advanced cirrhosis). Additional communications about related safety issues for Ocaliva occurred in February 2018 (addition of *Boxed Warning* to highlight correct dosing of Ocaliva) and September 2017 (warning about serious liver injury with incorrect dosing).

We encourage health care professionals and patients to report side effects involving Ocaliva or other medicines to the FDA MedWatch program.

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

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

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 50% Injection

Dextrose Monohydrate 10% 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

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