PERFORMRx℠

Drug Information Update

November 2023

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NEWLY AVAILABLE GENERICS

Generic Name/ Dosage Form	Brand Name	Manufacturer	Indication
Baclofen 10 mg/5 ml oral solution	Ozobax DS	TruPharma	Treatment of spasticity resulting from multiple sclerosis, particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity. May also be of some value in patients with spinal cord injuries and other spinal cord diseases.
Fluticasone propionate 50 mcg, 100 mcg, 250 mcg dry powder inhaler	Flovent Diskus	Prasco Laboratories	Maintenance treatment of asthma as prophylactic therapy in patients aged 4 years and older.
Pitavastatin 1 mg, 2 mg, 4 mg oral tablets	Livalo	Multiple manufacturers	To be used as an adjunct to diet to reduce low-density lipoprotein cholesterol (LDL-C) in adults with primary hyperlipidemia, and adult and pediatric patients aged 8 years and older with heterozygous familial hypercholesterolemia (HeFH).

NEW DRUG ENTITIES/STRENGTHS/COMBINATIONS

Drug Name	Generic Name	Description
Velsipity oral tablet 2 mg	etrasimod	New entity. Sphingosine-1-phosphate (S1P) receptor modulator for adults with moderately to severely active ulcerative colitis (UC). Second S1P receptor modulator to be approved for UC and will directly compete with Zeposia (ozanimod), which was approved for UC in 2021. Similar to Zeposia, assessments are required prior to initiating Velsipity, including a complete blood count, an electrocardiogram, liver function tests, and an ophthalmic exam. However, unlike Zeposia, Velsipity does not require dose titration with initiation.
Abrilada subcutaneous auto-injector kit 40 mg/0.8ml; subcutaneous prefilled syringe kit 40 mg/0.8ml; subcutaneous prefilled syringe kit 20 mg/0.4ml	adalimumab-afzb	Humira biosimilar. Only available in low concentration strengths. Has interchangeable designation.
Bimzelx subcutaneous solution prefilled syringe 160 mg/ml; subcutaneous solution auto-injector 160 mg/ml	bimekizumab-bkzx	New entity. Interleukin (IL)-17A and -17F antagonist indicated for the treatment of moderate to severe plaque psoriasis (PsO) in adults who are candidates for systemic therapy or phototherapy. Will compete with several other biologics approved to treat moderate to severe PsO, including Cosentyx and Taltz, which both target IL-17A. Showed superior efficacy to Stelara, Humira, and Cosentyx in the BE VIVID, BE SURE, and BE RADIANT trials, respectively. Dosed every 8 weeks for maintenance treatment.
Ozobax ds oral solution 10 mg/5ml	baclofen	New strength. Previously only available as a 5 mg/ml oral solution.
Altuviiio intravenous solution reconstituted 750 unit	efanesoctocog alfa	New strength. Previously available as 250 unit, 500 unit, 1000 unit, 2000 unit, 3000 unit, and 4000 unit vials.
Omvoh intravenous solution 300 mg/15ml; subcutaneous solution auto-injector 100 mg/ml	mirikizumab-mrkz	New entity. Interleukin-23p19 (IL-23p19) antagonist indicated for the treatment of adults with moderately to severely active ulcerative colitis (UC). First UC treatment that selectively targets the p19 subunit of IL-23, which plays a role in inflammation related to UC. Consists of

Drug Name	Generic Name	Description
		intravenous infusions every month for 12 weeks to start, followed by subcutaneous injections very month for maintenance treatment.
Zepbound subcutaneous solution auto-injector 15 mg/0.5ml, 12.5 mg/0.5ml, 10 mg/0.5ml, 7.5 mg/0.5ml, 5 mg/0.5ml, 2.5 mg/0.5ml	tirzepatide	New weight loss indication for tirzepatide. Indicated for chronic weight management, in addition to a reduced calorie diet and increased physical activity, in adults with a body mass index (BMI) of ≥30 kg/m2 (obesity) or ≥27 kg/m2 (overweight) with at least one weight-related condition (such as hypertension, type 2 diabetes [T2D], or hypercholesterolemia). Tirzepatide was originally approved in May 2022 under the brand name Mounjaro, for use in adults with type 2 diabetes. In clinical trials, patients experienced an average weight loss of 20.9%. In a clinical trial for Wegovy (semaglutide), the current market leader, in a similar population, patients experienced an average weight loss of 14.9% at the recommended maintenance dose.
Rozlytrek oral packet 50 mg	entrectinib	New dosage form & strength. Intended for use in pediatric patients. Previously only available as oral capsules.
Fruzaqla oral capsule 1 mg, 5 mg	fruquintinib	New entity. Indicated or the treatment of adult patients with metastatic colorectal cancer (mCRC) who have been previously treated with chemotherapy (fluoropyrimidine-, oxaliplatin-, and irinotecan-based regimens), an anti-vascular endothelial growth factor (VEGF) therapy, and (if patients have RAS wild-type mCRC and the treatment is medically appropriate) an anti-epidermal growth factor receptor (EGFR) therapy.
Zurzuvae oral capsule 20 mg, 25 mg, 30 mg	zuranolone	New entity. Indicated for the treatment of postpartum depression (PPD) in adults. First FDA-approved oral treatment for PPD and the second treatment to receive approval specifically for postpartum use after Zulresso (brexanolone), which is administered intravenously. Classified as a Schedule IV drug. Treatment consists of a 14-day course.
Inpefa oral tablet 400 mg	sotagliflozin	New strength. Previously only available as 200 mg tablets. Indicated to reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visit in adults with heart failure or type 2 diabetes mellitus, chronic kidney disease, and other cardiovascular risk factors.

Drug Name	Generic Name	Description
Xphozah oral tablet 20 mg, 30 mg	tenapanor	New entity. First-in-class phosphate absorption inhibitor indicated to reduce serum phosphorus in adults with chronic kidney disease (CKD) on dialysis as add-on therapy in patients who have an inadequate response to phosphate binders or who are intolerant of any dose of phosphate binder therapy. Tenapanor is also available under the brand name Ibsrela, which is approved for use in irritable bowel syndrome with constipation (IBS-C).
Voquezna oral tablet 10 mg, 20 mg	vonoprazan	New formulation & indication. Indicated for the healing of all grades of erosive esophagitis (EE), to maintain healing of all grades of EE, and for relief of heartburn associated with EE. Provides an alternative for patients with EE who do not respond to treatment with lower-cost, generic proton pump inhibitors (PPIs), particularly for patients with more moderate to severe EE. In clinical trials, Voquezna was shown to be noninferior to lansoprazole. Previously available as Voquezna Triple Pak (vonoprazan, amoxicillin, clarithromycin) and Voquezna Dual Pak (vonoprazan, amoxicillin) for the treatment of *Helicobacter pylori* (*H. pylori*) infection in adults.

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†
Tibsovo	ivosidenib 250 mg oral tablets	Servier Pharmaceuticals	• In combination with azacitidine or as monotherapy for the treatment of newly diagnosed acute myeloid leukemia (AML) in adults 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy • Treatment of adult patients with relapsed or refractory AML • **Treatment of adult patients with relapsed or refractory myelodysplastic syndromes (MDS)** • Treatment of adult patients with locally advanced or metastatic cholangiocarcinoma who have been previously treated
Vabysmo	faricimab-svoa 6 mg mg/0.05 ml intravitreal vial	Genentech	• Treatment of patients with neovascular (wet) age-related macular degeneration (nAMD) • Treatment of patients with diabetic macular edema (DME) • **Treatment of patients with macular edema following retinal vein occlusion (RVO)**
Cosentyx	secukinumab 150 mg/ml, 300 mg/2 ml subcutaneous syringe; 150 mg/ml, 300 mg/2 ml subcutaneous auto-injector	Novartis	Interleukin-17A antagonist indicated for the treatment of: • Moderate to severe plaque psoriasis (PsO) in patients 6 years and older who are candidates for systemic therapy or phototherapy • Active psoriatic arthritis (PsA) in patients 2 years of age and older • Adults with active ankylosing spondylitis (AS) • Adults with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation • Active enthesitis-related arthritis (ERA) in patients 4 years of age and older • **Adults with moderate to severe hidradenitis suppurativa (HS)**

Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication†
Keytruda	pembrolizumab 100 mg/4 ml intravenous vial	Merck	• **In combination with gemcitabine and cisplatin for the treatment of patients with locally advanced unresectable or metastatic biliary tract cancer (BTC)** • *Note: Keytruda has many other approved indications not mentioned here; see full prescribing information for details.*
Exparel	bupivacaine liposome 133 mg/10 ml, 266 mg/20 ml injection vials	Pacira Pharmaceuticals	An amide local anesthetic indicated to produce postsurgical: • Local analgesia via infiltration in patients aged 6 years and older • Regional analgesia via: o An interscalene brachial plexus nerve block in adults o **A sciatic nerve block in the popliteal fossa in adults** o **An adductor canal block in adults**
Xtandi	enzalutamide 40 mg, 80 mg oral tablets; 40 mg oral capsules	Astellas Pharma US, Inc.	Androgen receptor inhibitor indicated for the treatment of patients with: • Castration-resistant prostate cancer • Metastatic castration-sensitive prostate cancer • **Non-metastatic castration-sensitive prostate cancer with biochemical recurrence at high risk for metastasis**

RECALLS

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
ION*Sinus Spray, 1 fl oz/ 30 mL, Manufactured by: ION* Biome Charlottesville, VA	Class I	Drugs	All lots within expiry.	Microbial contamination of Non-Sterile Products	Biomic Sciences, LLC dba ION Intelligence of Nature
4.2% Sodium Bicarbonate Injection, USP 5 mEq/10 mL (0.5mEq/mL), Glass ABBOJECT Unit of Use Syringe, packaged as 1 vial and injector per carton, Rx only, Hospira Inc., Lake Forest, IL 60045, NDC 0409-5534-24	Class I	Drugs	Lot#: GJ5007, Exp. 8/1/2024	Presence of Particulate Matter: identified as glass.	Pfizer Inc.
1% Lidocaine HCl Injection, USP, 50mg/5mL(10mg/mL), Glass ABBOJECT Unit of Use Syringe, packaged as 1 vial and injector per carton, Rx only, Distributed by Hospira Inc., Lake Forest, IL 60045, NDC 0409-4904-11	Class I	Drugs	Lot#: 42290DK, Exp. 6/1/2024	Presence of Particulate Matter: identified as glass.	Pfizer Inc.
2% Lidocaine HCl Injection, USP, 100mg/5mL(20mg/mL), Glass ABBOJECT Unit of Use Syringe, packaged as 1 vial and injector per carton, Rx only, Distributed by Hospira Inc., Lake Forest, IL 60045, NDC 0409-4903-11	Class I	Drugs	Lot#: GH6567, Exp. 7/1/2024	Presence of Particulate Matter: identified as glass.	Pfizer Inc.
ION* Sinus Support Nasal Spray, 1 fl oz/30 ml bottles, Manufactured by: ION* Intelligence of Nature Charlottesville, VA	Class II	Drugs	All lots within expiry.	Microbial contamination of Non-Sterile Products	Biomic Sciences, LLC dba ION Intelligence of Nature
Restore Sinus Spray, Manufactured by: Biomic Sciences, LLC Charlottesville, VA	Class II	Drugs	All lots within expiry.	Microbial contamination of Non-Sterile Products	Biomic Sciences, LLC dba ION Intelligence of Nature

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Pneumococcal 15-valent Conjugate Vaccine	Class II	Biologics	Lots: W027275, W036242, W037992, W039033, X004289, X005583, X011328, X011332, X011735, X012044	Merck Sharp & Dohme LLC became aware of Vaxneuvance breaking at the syringe flange and/or hub resulting in injury (e.g., skin laceration) during administration. Additionally, breakages were identified by healthcare professionals before administration, while securing the needle to the syringe, during vaccine administration or during post-administration (e.g., when activating a needle safety mechanism). Merck is expanding the scope of the existing recall to include all remaining lots manufactured prior to Corrective and Preventative Action (CAPA) implementation. The recall of the remaining pre-CAPA lots will be made to the	Merck Sharp & Dohme LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
				wholesale level including CDC.	
Gynazole-1, (Butoconazole Nitrate) Vaginal Cream USP, 2%, Net Wt 5.8 g per pre-filled applicator, packaged in 1 prefilled applicator per carton, Rx Only, Manufactured By Padagis, Yeruham, Israel; Distributed By: Padagis, Allegan, MI 49010. NDC: 45802-396-01	Class II	Drugs	Lot#: 164185, Exp. Date 4/2024	Incorrect Product Formulation: Hydrophilic Colloidal Silica was used to manufacture the product rather than Hydrophobic Colloidal Silica as required by the manufacturing process.	Padagis US LLC
Strong Iodine Solution U.S.P. (Lugol's Solution) (Iodine 5%), 14 mL Glass Dropper bottle in box, RX only, Safecor Health, LLC, Woburn, MA 01801. NDC# 48433-230-15	Class II	Drugs	Lot # 21A0073, Exp 11/30/2023; 21A0091, Exp. 12/31/2023; 21A0103, Exp 01/31/2024; 21A0135, Exp 03/31/2024; 22A0011, Exp 06/30/2024; 22A0019, Exp 07/31/2024; 22A0057, Exp 09/30/2024; 22A0083, Exp 11/30/2024; 22A0104, Exp 12/31/2024; 22A0110, Exp 01/31/2025;	CGMP Deviations: Recall due to the absence of USP CGMP compendial requirements.	Safecor Health, LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			22A0150, Exp 03/31/2025; 23A0007, Exp 06/30/2025; 23A0041, Exp 09/30/2025; 23A0045, Exp 11/30/2025; 23A0058, Exp 11/30/2025; 23A0067, Exp 11/30/2025; 23A0080, Exp 12/31/2025; 23A0090, Exp 01/31/2026		
TUMS Antacid, Calcium Carbonate USP 1000 mg, Peppermint flavor, chewable tablets, 72-count bottle, Dist. by: GSK CH, Warren, NJ 07059. NDC: 0135-0228-06, UPC 3-0766-0745-85-3	Class II	Drugs	Lot#: HB2G, Exp. Date 8/31/2027	Presence of Foreign Substance: The foreign material is primarily comprised of glass mineral wool.	GlaxoSmithKline Consumer Healthcare Holdings LLC
TUMS Antacid, Calcium Carbonate USP 1000 mg, Peppermint flavor, chewable tablets, packaged in 12-count roll, Dist. by: GSK CH, Warren, NJ 07059. NDC: 0135-0228-01, UPC 3-0766-0746-80-5	Class II	Drugs	Lot #: HA7G, Exp. Date 8/31/2027	Presence of Foreign Substance: The foreign material is primarily comprised of glass mineral wool.	GlaxoSmithKline Consumer Healthcare Holdings LLC
TUMS Antacid, Calcium Carbonate USP 1000 mg, Assorted Fruit flavor, Chewable Tablets, packaged in 160-count bottles, Dist. by: GSK CH,	Class II	Drugs	Lot #: HV6B, Exp. Date 9/30/2027	Presence of Foreign Substance: The foreign material is primarily	GlaxoSmithKline Consumer Healthcare Holdings LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Warren, NJ 07059. NDC: 0135-0118-14, UPC 3-0766-0746-10-2				comprised of glass mineral wool.	
TUMS Antacid, Calcium Carbonate USP 1000 mg, Assorted Berries flavor, Chewable Tablets, packaged in 72-count bottles, Dist. by: GSK CH, Warren, NJ 07059. NDC: 135-0181-02, UPC 3-0766-0746-50-8	Class II	Drugs	Lot #: HR5W, Exp. Date 09/30/2027	Presence of Foreign Substance: The foreign material is primarily comprised of glass mineral wool.	GlaxoSmithKline Consumer Healthcare Holdings LLC
TUMS Antacid, Calcium Carbonate USP 1000 mg, Assorted Berries flavor, Chewable Tablets, packaged in 12-count roll, Dist. by: GSK CH, Warren, NJ 07059. NDC: 135-0181-03, UPC 3-0766-0746-70-6	Class II	Drugs	Lot#: HR6A, Exp. Date 09/30/2027	Presence of Foreign Substance: The foreign material is primarily comprised of glass mineral wool.	GlaxoSmithKline Consumer Healthcare Holdings LLC
TUMS Antacid, Calcium Carbonate USP 1000 mg, Assorted Berries flavor, Chewable Tablets, packaged in 265-count bottle, Dist. by: GSK CH, Warren, NJ 07059. NDC: 135-0181-05, UPC 3-0766-3072-14-7	Class II	Drugs	Lot #: J96X,J96W, Exp. Date 09/30/2027	Presence of Foreign Substance: The foreign material is primarily comprised of glass mineral wool.	GlaxoSmithKline Consumer Healthcare Holdings LLC
TUMS Antacid, Calcium Carbonate USP 1000 mg, Assorted Berries flavor, chewable tablets, 72-count bottle, Dist. by: GSK CH, Warren, NJ 07059. NDC: 0135-0118-83, UPC 3-0766-0746-50-8	Class II	Drugs	Lot#: KH5L, Exp. Date 09/30/2027	Presence of Foreign Substance: The foreign material is primarily comprised of glass mineral wool.	GlaxoSmithKline Consumer Healthcare Holdings LLC
Liothyronine Sodium Tablets, USP, 5 mcg, 100-count bottles, Rx only, Distributed by: Sun Pharmaceutical Industries, Inc.Cranbury, NJ 08512, Manufactured by: Sun Pharmaceutical Industries Ltd. Survey No. 259/15, Dadra-396 191,(U.T. of D & NH), India. NDC 62756-589-88	Class II	Drugs	Lot #: DND0058A, Exp. Date 12/2023	Failed Impurities/Degradation Specifications.	SUN PHARMACEUTICAL INDUSTRIES INC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Liothyronine Sodium Tablets, USP, 25 mcg, 100-count bottles, Rx only, Distributed by: Sun Pharmaceutical Industries, Inc.Cranbury, NJ 08512, Manufactured by: Sun Pharmaceutical Industries Ltd. Survey No. 259/15, Dadra-396 191,(U.T. of D & NH), India. NDC 62756-590-88	Class II	Drugs	Lot #: DNC2204A, Exp. Date 11/2023	Failed Impurities/Degradation Specifications.	SUN PHARMACEUTICAL INDUSTRIES INC
Buprenorphine HCl, Injection, 0.3mg/mL, For Intramuscular or Intravenous Use, Rx Only, 1mL Single Dose Vial, (supplied in packages of 5 vials) Distributed by Par Pharmaceutical, Chestnut Ridge, NY 10977, NDC: 42023-179-05	Class II	Drugs	Lot No: 343716, Exp. Date: 11/2021; Lot No: 350565, Exp. Date: 07/2022; Lot No: 26921, Exp. Date: 07/2022; Lot No: 36227, Exp. Date: 02/2023	Crystallization: presence of white, crystalline product agglomeration observed in 2 vials during annual inspection of retain samples.	PAR Sterile Products LLC
Deferasirox Tablets for Oral Suspension, 500mg, 30-count bottle, Rx only, Manufactured for: Glenmark Pharmaceuticals Inc., USA, Mahwah, NJ 07430, Product of India, NDC 68462-496-30	Class II	Drugs	Lot #: 17220063, Exp 12/2023; 17220396, 17220397, Exp 01/2024; 17220965, Exp 04/2024; 17221187, 17221523, Exp 07/2024; 17221793, 17221794, 17221801, Exp 08/2024	Failed Dissolution Specifications	Glenmark Pharmaceuticals Inc., USA
Montelukast Sodium Tablets, USP 10 mg, Rx Only, 1000 count bottle, Distributed by: Dr. Reddy's Laboratories., Princeton, NJ 08540, Made in India, NDC# 55111-725-10.	Class II	Drugs	Lot # C2305569, Exp. date 03/31/2026	Presence of Foreign Tablet(s)/Capsule(s): A foreign tablet was found in a bottle of Montelukast Sodium Tablets, USP 10mg,	Dr. Reddy's Laboratories, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
				identified as metoprolol 25 mg.	
Clinical TREAT Antifungal Powder, Vanilla Scent, 3 OZ (85 g) tube, Active Ingredient: Miconazole Nitrate 2.0% w/w Antifungal, Manufactured for Medline Industries, LP, Three Lakes Drive, Northfield, IL 60093 USA, NDC: 53329-169-79	Class II	Drugs	Lot 007782, Exp 08/31/2024	CGMP deviations: the product was shipped from the Manufacturer to a Medline warehouse and released to stock while it was still under investigation for low assay results on the active ingredient miconazole nitrate.	MEDLINE INDUSTRIES, LP - Northfield
Oxybutynin Chloride Extended-Release Tablet USP, 5 mg, 100 count bottles, Rx Only, Manufactured by: Cadila Healthcare Ltd, Baddi, India. Distributed by: Zydus Pharmaceuticals (USA) Inc. NDC # 68382-255-01	Class II	Drugs	M212749, exp. date 11/2024; M214477, exp. date 11/2024; M214478, exp. date 11/2024; M214479, exp. date 11/2024; M214480, exp. date 11/2024	Failed Dissolution Specifications-out-of-specification (OOS) test results observed for dissolution at the 6 month long term time point.	Zydus Pharmaceuticals (USA) Inc
Oxybutynin Chloride Extended-Release Tablet USP, 10 mg, 100 count bottles Rx Only, Manufactured by: Cadila Healthcare Ltd, Baddi, India. Distributed by: Zydus Pharmaceuticals (USA) Inc. NDC # 68382-256-01.	Class II	Drugs	M213318, exp. date 11/2024; M213314, exp. date 11/2024; M213315, exp. date 11/2024; M214436, exp. date 11/2024; M214437, exp. date 11/2024; M214438, exp. date 11/2024; M300653, exp. date	Failed Dissolution Specifications-out-of-specification (OOS) test results observed for dissolution at the 6 month long term time point.	Zydus Pharmaceuticals (USA) Inc

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			12/2024; M300654, exp. date 12/2024		
Oxybutynin Chloride Extended-Release Tablet USP, 15 mg, 100 count bottles, Rx Only, Manufactured by: Cadila Healthcare Ltd, Baddi, India. Distributed by: Zydus Pharmaceuticals (USA) Inc. NDC # 68382-257-01.	Class II	Drugs	M211541, exp. date 10/2024 M211542, exp. date 10/2024 M212746, exp. date 10/2024 M300660, exp. date 12/2024	Failed Dissolution Specifications-out-of-specification (OOS) test results observed for dissolution at the 6 month long term time point.	Zydus Pharmaceuticals (USA) Inc
Ranolazine Extended-Release Tablets 500mg, 60 Tablets per bottle, Rx Only, Manufactured by: Glenmark Pharmaceuticals Limited, Plot No. 2, Phase-2, Pharma Zone SEZ, Pithampur Dist - Dhar, Madhya Pradesh - 454775, India, Manufactured for: Glenmark Pharmaceuticals Inc., USA, Mahwah, NJ 07430, NDC 68462-319-60.	Class II	Drugs	Lot # 17230388, Exp. 01/31/2025	Failed Dissolution Specifications: Out of specification for dissolution.	Glenmark Pharmaceuticals Inc., USA
DOP Instant Hand Sanitizer (Ethyl Alcohol 65%) with Moisturizers, Original, 4FL OZ (118 ml) bottle, Hecho en Puerto Rico por: Omega & Delta Co., Inc. UPC 7 42699 00027 4	Class II	Drugs	Lot #s 1327034, 1328034, 1277029, 1278029, 1202015, 1203015, 0246097, 0247097, 0247099, 0248099, 0252099	Sub Potent and Super Potent Product: During an impact assessment of the DOP Hand Sanitizer product, it was identified that several lots distributed did not comply with the finished good acceptance criteria established.	Omega & Delta Co., Inc.
DOP Instant Hand Sanitizer (Ethyl Alcohol 65%) with Moisturizers, 8FL OZ (237mL) bottle, Hecho	Class II	Drugs	Lot #s 1113005, 1116005, 0237088, 0232084, 012764,	Sub Potent and Super Potent Product: During an impact assessment of	Omega & Delta Co., Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
en Puerto Rico por: Omega & Delta Co., Inc. UPC 7 42699 00030 4			012864, 0244096, 0245096.	the DOP Hand Sanitizer product, it was identified that several lots distributed did not comply with the finished good acceptance criteria established.	
Equate Hand Sanitizer (Ethyl Alcohol 62%), 7.5 FL.OZ. (221 mL) UPC 6 81131 05961 9	Class II	Drugs	Lot #s 006511	Sub Potent and Super Potent Product: During an impact assessment of the DOP Hand Sanitizer product, it was identified that several lots distributed did not comply with the finished good acceptance criteria established.	Omega & Delta Co., Inc.
Oxygen, Compressed USP, UN 1072, packaged in cylinders labeled as Size: a) C; b) D; c) E; d) H; e) M; f) M6, Rx only, Family Medical Supply, 2011 W Cumberland St. Dunn, NC 28334.	Class II	Drugs	All lots manufactured and distributed May 10, 2023, through October 31, 2023.	cGMP Deviations	Family Medical Supply Inc
Oxytocin synthetic, 30 Units added to 0.9% Sodium Chloride 500mL IV Bag (0.06 Units per mL), Rx only, Leiter Compounding Health, 13796 Compark Blvd, Englewood, CO 80112, NDC 71449-157-70	Class III	Drugs	Lot#: 2330956, Exp. 10/23/2023; 2330964, Exp. 10/24/2023; 2331014, Exp. 11/6/2023; 2331033, Exp. 11/8/2023	Labeling: Not Elsewhere Classified	Denver Solutions, LLC DBA Leiters Health

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
VANCOmycin HCl PF, 1.25 g added to 0.9% Sodium Chloride 250 mL IV Bag, Rx only, Leiters Compounding Health, 13796 Compark Blvd, Englewood, CO 80112, NDC 71449-028-68.	Class III	Drugs	Lot#: 2330781, Exp. 10/19/23; 2330791, Exp. 10/29/23; 2330795, Exp. 11/02/23; 2330800, Exp. 11/09/23; 2330807, Exp. 11/11/23; 2330812, Exp. 11/16/23; 2330816, Exp. 11/19/23; 2330822, 10/20/23; 2330897,11/23/23; 2330899, 11/25/23; 2330901, 11/26/23; 2330918, 11/30/23; 2330943, 01/12/24; 2331050, 01/14/24; 2331064, 01/21/24; 2331102, Exp. 01/25/24.	Labeling: Not Elsewhere Classified	Denver Solutions, LLC DBA Leiters Health
VANCOmycin HCl PF, 1.5 g added to 0.9% Sodium Chloride 250 mL IV Bag, Rx only, Leiters Compounding Health, 13796 Compark Blvd, Englewood, CO 80112, NDC 71449-029-68.	Class III	Drugs	Lot#: 2330792, Exp. 12/17/23; 2330801, Exp. 12/26/23; 2330821, 10/15/23; 2330823, Exp. 10/21/23; 2330825, Exp. 10/27/23; 2330846, Exp. 10/28/23; 2330847,	Labeling: Not Elsewhere Classified	Denver Solutions, LLC DBA Leiters Health

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			Exp. 11/03/23; 2330856, 11/17/23; 2330858, Exp. 12/03/23; 2330860, 12/15/23; 2330866, Exp. 12/29/23; 2331053, Exp. 01/13/24.		
Methotrexate Tablets, USP, 2.5 mg, 10x10 Unit-Dose Tablets per carton, Rx only, Distributed by: West-Ward Pharmaceuticals Corp., Eatontown, NJ 07724. NDC: 0054-8550-25	Class III	Drugs	Lot, expiry: Lot AB7486B, exp Dec 2023; Lot AB8766B, exp April 2024; Lot AB9484B, exp Aug 2024	Failed Tablet/Capsule Specifications: Tablets were observed to have an unsmooth surface with two tablets demonstrating illegible tablet identification and scoring.	West-Ward Columbus Inc
Opium Tincture, USP (Deodorized), 10 mg/mL of anhydrous morphine, packaged in 118 mL (4 Fl oz) bottles, Rx only, Manufactured for: Edenbridge Pharmaceuticals, LLC Parsippany, NJ 07054, NDC 42799-217-01	Class III	Drugs	Lot#: 23ZCP1, Exp. Date 02/22/2026;Lot #:23ZDR1, Exp. Date 03/09/2026	Subpotent Drug	Edenbridge Pharmaceuticals, LLC
Bisoprolol Fumarate and Hydrochlorothiazide Tablets, USP, 5mg/6.25mg, 100-count Bottle, RX only, Manufactured by: Glenmark Pharmaceuticals Limited, Pithampur, Madhya Pradesh 454775, India, Manufactured for: Glenmark Pharmaceuticals Inc., USA, Mahwah, NJ 07430. NDC 68462-879-01	Class III	Drugs	Lot# 17212352, Exp 11/31/2023	Failed Impurities/Degradation Specifications	Glenmark Pharmaceuticals Inc., USA
Synthroid, Levothyroxine Sodium Tablets, USP 125mcg (0.125mg), 100-count bottle, Rx Only	Class III	Drugs	Lot # 1187435 exp date: 02/2024	Labeling: Wrong Barcode- One (1) of	AbbVie Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
AbbVie Inc. North Chicago, IL 60064, U.S.A. NDC 0074-7068-11				every forty (40) unit dose blister will contain incorrect barcode information that causes a 125mcg unit dose is scanned as 200mcg unit dose.	
Oxaydo (oxycodone HCl, USP) tablets, 7.5 mg, 100 Tablets per bottle, Rx only, Distributed by: Zyla Life Sciences US Inc., Wayne, PA 19087. NDC: 69344-213-11	Class III	Drugs	Lot 22W02, Exp 01/31/2025	Sub-potent Drug: Lower potency than labeled.	Zyla Life Sciences US Inc.
Mycophenolate Mofetil for Oral Suspension, USP, 200 mg/mL, Rx Only, bottle, Manufactured for: VistaPharm, Inc., Largo, FL 33771, USA, NDC#66689-307-08.	Class III	Drugs	Lot #: M23400A, M23401A, M23402A, Exp Date. 04/30/2025; M23591A, M23592A, Exp Date. 06/30/2025.	Defective Container: The adaptor does not fit into the neck of the bottle after reconstitution with water.	VistaPharm LLC
Hydrocortisone 1% and Acetic Acid 2% Otic Solution USP, 10ml dropper bottle, RX Only, Mfd. by: Taro Pharmaceuticals Inc. Brampton, Ontario, Canada LGT 1C, Dist. by: Taro Pharmaceuticals U.S.A., Inc. Hawthorne, NY 10532. NDC 51672-3007-1	Class III	Drugs	Lot# AC86809, AC86812, Exp Date: 01/31/2024	Failed Impurities/Degradation Specifications:Out-of-Specification result for Hydrocortisone related impurity and slightly lower than the established level of the Hydrocortisone Assay obtained during stability testing.	Taro Pharmaceuticals Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
V-FORCE Homeopathic, 1 FL OZ (30 ml) per glass bottle, Distributed by: BioActive Nutritional, Inc., 1803 N. Wickham Rd., Melbourne, FL 32935	Class III	Drugs	Lot: Z65842 no exp date on product	Incorrect Product Formulation: product contains Active Ingredient Glandula Suprarenalis Suis 8X instead of Glandula Suprarenalis Bovine 8X (as stated on the product label).	Grato Holdings, Inc.

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

CURRENT DRUG SHORTAGES

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

Generic Name or Active Ingredient

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

Difluprednate Emulsion
Digoxin Injection
Diltiazem Hydrochloride Injection
Disopyramide Phosphate Capsule
Dobutamine Hydrochloride Injection
Dopamine Hydrochloride Injection
Dulaglutide Injection
Echothiophate Iodide Ophthalmic Solution
Enalaprilat Injection
Epinephrine Bitartrate, Lidocaine Hydrochloride Injection
Epinephrine Injection
Erythromycin Ointment
Etomidate Injection
Fentanyl Citrate Injection
Fluconazole Injection
Fludarabine Phosphate Injection
Fluorescein Sodium Injection
Flurazepam Hydrochloride Capsule
Furosemide Injection
Gentamicin Sulfate Injection
Heparin Sodium Injection
Hydrocortisone Sodium Succinate Injection
Hydromorphone Hydrochloride Injection
Hydroxypropyl Cellulose (1600000 Wamw) Insert
I.V. Fat Emulsion
Isoniazid Tablet
Ketamine Hydrochloride Injection
Ketorolac Tromethamine Injection
Ketorolac Tromethamine Tablet, Film Coated
Leucovorin Calcium Injection
Lidocaine Hydrochloride Injection
Lidocaine Hydrochloride Solution
Liraglutide Injection
Lisdexamfetamine Dimesylate Capsule
Lisdexamfetamine Dimesylate Tablet, Chewable
Lorazepam Injection
Mannitol Injection
Mepivacaine Hydrochloride Injection
Methamphetamine Hydrochloride Tablet
Methotrexate Sodium Injection
Methotrexate Sodium Tablet
Methyldopa Tablet, Film Coated
Methylphenidate Hydrochloride Tablet, Extended Release
Methylprednisolone Acetate Injection
Metronidazole Injection
Midazolam Hydrochloride Injection

Morphine Sulfate Injection
Multi-Vitamin Infusion (Adult and Pediatric) Injection
Neomycin Sulfate Tablet
Nitroglycerin Injectable
Nitroglycerin Injection
Nizatidine Capsule
Oxybutynin Chloride Syrup
Parathyroid Hormone Injection
Penicillin G Benzathine Injection
Potassium Acetate Injection
Potassium Chloride Injection
Promethazine Hydrochloride Injection
Propranolol Hydrochloride Injection
Quinapril Hydrochloride Tablet
Quinapril/Hydrochlorothiazide Tablet
Remifentanil Hydrochloride Injection
Rifampin Capsule
Rifampin Injection
Rifapentine Tablet, Film Coated
Rocuronium Bromide Injection
Ropivacaine Hydrochloride Injection
Semaglutide Injection
Sodium Acetate Injection
Sodium Bicarbonate Injection
Sodium Chloride 0.9% Injection
Sodium Chloride 14.6% Injection
Sodium Chloride 23.4% Injection
Sodium Chloride Injection
Sodium Chloride Irrigant
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
Tirzepatide Injection
Triamcinolone Acetonide Injection
Triamcinolone Hexacetonide Injection
Trimethobenzamide Hydrochloride Capsule
Valproate Sodium Injection
Vecuronium Bromide Injection
Vinblastine Sulfate Injection