PERFORMRx℠

Drug Information Update

January 2024

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NEWLY AVAILABLE GENERICS

Generic Name/ Dosage Form	Brand Name	Manufacturer	Indication
oxaprozin 300 mg oral capsules	Coxanto	Ayurax	• Relief of signs and symptoms of Osteoarthritis (OA) • Relief of signs and symptoms of Rheumatoid Arthritis (RA) • Relief of signs and symptoms of Juvenile Rheumatoid Arthritis (JRA)
dextroamphetamine sulfate 2.5 mg, 7.5 mg oral tablets	Zenzedi	Winder Laboratories	• Narcolepsy • Attention Deficit Disorder with Hyperactivity
dapagliflozin 5 mg, 10 mg oral tablets	Farxiga	Prasco Laboratories	• To reduce the risk of sustained eGFR decline, end stage kidney disease, cardiovascular death, and hospitalization for heart failure in adults with chronic kidney disease at risk of progression • To reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visit in adults with heart failure • To reduce the risk of hospitalization for heart failure in adults with type 2 diabetes mellitus and either established cardiovascular disease or multiple cardiovascular risk factors To be used as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus
Dapagliflozin/metformin 5 mg-1000 mg, 10 mg-1000 mg extended-release oral tablets	Xigduo	Prasco Laboratories	• To be used as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus Dapagliflozin is also indicated to reduce: o The risk of hospitalization for heart failure in adults with type 2 diabetes mellitus and established cardiovascular disease or multiple cardiovascular risk factors o The risk of cardiovascular death and hospitalization for heart failure in adults with heart failure (NYHA class II-IV) with reduced ejection fraction The risk of sustained eGFR decline, end-stage kidney disease, cardiovascular death and hospitalization for heart failure in adults with chronic kidney disease at risk of progression
insulin glargine 300 units/ml subcutaneous pen	Toujeo SoloStar	Winthrop US	• To improve glycemic control in adults and pediatric patients 6 years and older with diabetes mellitus
insulin glargine 300 units/ml subcutaneous pen	Toujeo Max SoloStar	Winthrop US	• To improve glycemic control in adults and pediatric patients 6 years and older with diabetes mellitus

Generic Name/ Dosage Form	Brand Name	Manufacturer	Indication
indomethacin 25 mg/5 ml oral suspension	Indocin	ANI Pharmaceuticals	• Moderate to severe rheumatoid arthritis including acute flares of chronic disease • Moderate to severe ankylosing spondylitis • Moderate to severe osteoarthritis Acute painful shoulder (bursitis and/or tendinitis) Acute gouty arthritis

NEW DRUG ENTITIES/STRENGTHS/COMBINATIONS

Drug Name	Generic Name	Description
iDose TR intraocular implant 75 mcg	Travoprost	New dosage form. Intracameral implant indicated for the reduction of intraocular pressure (IOP) in patients with open-angle glaucoma (OAG) or ocular hypertension (OHT).
Zituvio oral tablet 25 mg, 50 mg, 100 mg	Sitagliptin	New entity. 505(b)(2) approval. Same active ingredient and strength as Januvia. Has undergone quality testing for Nitrosamines and potential genotoxic impurities as per current regulatory standards.
Zoryve external foam 0.3 %	Roflumilast	New dosage form. Indicated the treatment of seborrheic dermatitis in adult and pediatric patients 9 years of age and older. Previously only available as a topical cream, which is indicated for plaque psoriasis.
Penbraya intramuscular suspension reconstituted	Meningococcal groups A, B, C, W and Y Vaccine	New entity. First FDA-approved pentavalent vaccine, including components that target the five serogroups that cause the majority of invasive meningococcal disease. These were previously provided in separate vaccines, including Trumenba (serogroup B) and Menveo (serogroups A, C, Y, and W-135). Approved for use in individuals 10 through 25 years of age.
Wainua subcutaneous solution auto-injector 45 mg/0.8ml	Eplontersen	New entity. Indicated for the treatment of adult patients with polyneuropathy of hereditary transthyretin-mediated amyloidosis (hATTR-PN). Will compete with already well-established hATTR-PN treatments, Onpattro (intravenous infusion), Amvuttra (provider-administered subcutaneous injection), and Tegsedi (provider-administered subcutaneous injection). Wainua is differentiated in this market, as it is the only product that can be self-administered.
Ixchiq intramuscular solution reconstituted	Chikungunya Vaccine, Live	New entity. First vaccine approved for the prevention of disease caused by chikungunya virus. Approved under accelerated approval based on anti-CHIKV neutralizing antibody titers. Continued approval for this indication is contingent upon verification of clinical benefit in confirmatory studies.

Drug Name	Generic Name	Description
Zenpep oral capsule delayed release particles 60000-189600 unit	Pancrelipase	New strength.
Iwilfin oral tablet 192 mg	Eflornithine	New dosage form & strength. 505(b)(2) approval. Indicated to reduce the risk of relapse in adult and pediatric patients with high-risk neuroblastoma (HRNB) who have demonstrated at least a partial response to prior multiagent, multimodality therapy, including anti-GD2 immunotherapy. First FDA-approved drug to reduce the risk of relapse in pediatric patients with HRNB. Eflornithine as a topical cream formulation has FDA approval in the U.S. for the reduction of unwanted facial hair in women, under the brand name Vaniqa, which was discontinued in Q1 2023.
Bosulif oral capsule 50 mg, 100 mg	Bosutinib	New strength & dosage form. Previously only available as 100 mg, 400 mg, 500 mg oral tablets.
Zilbrysq subcutaneous solution prefilled syringe 16.6 mg/0.416ml, 23 mg, 0.574ml, 32.4 mg/0.81ml	Zilucoplan	New entity. Indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive. First once-daily, subcutaneous, targeted peptide inhibitor of complement component 5 (C5). Will compete with several other therapies approved for the treatment of gMG such as, Vyvgart and Vyvgart Hytrulo, both FcRn antagonists, and Soliris and Ultomiris, both complement inhibitors administered as intravenous infusions. Unlike its competitors, Zilbrysq is the only treatment that can be self-administered.
Agamree oral suspension 40 mg/ml	Vamorolone	New entity. Corticosteroid indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients 2 years of age and older. Will compete with Emflaza.
Tramadol hcl oral tablet 25 mg	Tramadol	New strength
Hemlibra subcutaneous solution 300 mg/2ml	Emicizumab-kxwh	New strength. Previously only available as 30 mg/mL, 60 mg/0.4 mL, 105 mg/0.7 mL, and 150 mg/mL single-dose vials.

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†
Keytruda	pembrolizumab 100 mg/4 ml intravenous vial	Merck	• In combination with enfortumab vedotin for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma ~~who are not eligible for cisplatin-containing chemotherapy~~[1] [1]~~This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.~~ *Note: Keytruda has many other approved indications not mentioned here; see full prescribing information for details.*
Tarpeyo	budesonide 4 mg delayed release oral capsules	Calliditas Therapeutics	• To reduce ~~proteinuria~~ **the loss of kidney function** in adults with primary immunoglobulin A nephropathy (IgAN) **who are** at risk **for** ~~of rapid~~ disease progression~~, generally a urine protein-to-creatinine ratio (UPCR) ≥ 1.5 g/g~~[1] [1]~~This indication is approved under accelerated approval based on a reduction in proteinuria. It has not been established whether Tarpeyo slows kidney function decline in patients with IgAN. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory clinical trial.~~
Keytruda	pembrolizumab 100 mg/4 ml intravenous vial	Merck	• **In combination with chemoradiotherapy (CRT) for the treatment of patients with FIGO (International Federation of Gynecology and Obstetrics) 2014 Stage III-IVA cervical cancer** *Note: Keytruda has many other approved indications not mentioned here; see full prescribing information for details.*

Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication†
HyQvia	immune globulin (human) w/recombinant human hyaluronidase 2.5 g/25 ml, 5 g/50 ml, 10 g/100 ml, 20 g/200 ml, 30 g/300 ml subcutaneous kit	Takeda Pharmaceuticals	• Treatment of primary immunodeficiency (PI) in adults and pediatric patients two years of age and older • **Maintenance therapy in adults with chronic inflammatory demyelinating polyneuropathy (CIDP)**
Balversa	erdafitinib 3 mg, 4 mg, 5 mg oral tablets	Janssen	• Treatment of adult patients with locally advanced or metastatic urothelial carcinoma (mUC) ~~that has~~ **with** susceptible FGFR3 ~~or FGFR2~~ genetic alterations ~~and~~ **whose disease has** progressed **on** ~~during or following~~ at least one line of prior ~~platinum-containing chemotherapy including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy~~ **systemic therapy** ~~This indication is approved under accelerated approval based on tumor response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.~~

FDA DRUG SAFETY COMMUNICATIONS

[1/11/2024] Update on FDA's ongoing evaluation of reports of suicidal thoughts or actions in patients taking a certain type of medicines approved for type 2 diabetes and obesity

The U.S. Food and Drug Administration (FDA) has been evaluating reports of suicidal thoughts or actions in patients treated with a class of medicines called glucagon-like peptide-1 receptor agonists (GLP-1 Ras). These medicines are used to treat people with type 2 diabetes or to help those with obesity or overweight to lose weight. Our preliminary evaluation has not found evidence that use of these medicines causes suicidal thoughts or actions.

Over the last several months, we have conducted detailed reviews of reports of suicidal thoughts or actions received in the FDA Adverse Event Reporting System (FAERS). Because the information provided was often limited and because these events can be influenced by other potential factors, we determined that the information in these reports did not demonstrate a clear relationship with the use of GLP-1 RAs. Similarly, our reviews of the clinical trials, including large outcome studies and observational studies, did not find an association between use of GLP-1 RAs and the occurrence of suicidal thoughts or actions. However, because of the small number of suicidal thoughts or actions observed in both people using GLP-1 RAs and in the comparative control groups, we cannot definitively rule out that a small risk may exist; therefore, FDA is continuing to look into this issue.

Additional evaluations include a meta-analysis of clinical trials across all GLP-1 RA products and an analysis of postmarketing data in the Sentinel System External Link Disclaimer. A meta-analysis is a large, combined analysis of findings from clinical trials. Sentinel is a very large data network that contains health insurance claims and patient health records that can be used to investigate safety questions about FDA-regulated products. We will communicate our final conclusions and recommendations after we complete our review or have more information to share.

Patients **s**hould not stop taking GLP-1 RAs without first consulting your health care professional, as stopping these medicines may worsen your condition. Talk to your health care professional if you have questions or concerns. Tell your health care professional if you experience new or worsening depression, suicidal thoughts, or any unusual changes in mood or behavior. Call or text 988 or go to the website at https://988lifeline.org/External Link Disclaimer, which provides free support for people in distress 24 hours a day, 7 days a week.

The current prescribing information for the GLP-1 RAs approved to treat patients with obesity or overweight contains information about the risk of suicidal thoughts and actions. This information is also included in the labels of other types of weight loss medicines and is based on reports of such events observed with a variety of older medicines used or tested for weight loss.

Consistent with the prescribing information for these medications, health care professionals **s**hould monitor for and advise patients using GLP-1 RAs to report new or worsening depression, suicidal thoughts, or any unusual changes in mood or behavior. Health care professionals should consult the prescribing information when treating patients with these medications.

[1/19/2024] FDA adds Boxed Warning for increased risk of severe hypocalcemia in patients with advanced chronic kidney disease taking osteoporosis medicine Prolia (denosumab)

Based on a completed U.S. Food and Drug Administration (FDA) review of available information, we have concluded that the osteoporosis medicine Prolia (denosumab) increases the risk of severe hypocalcemia, very low blood calcium levels, in patients with advanced chronic kidney disease (CKD), particularly patients on dialysis. Severe hypocalcemia appears to be more common in patients with CKD who also have a condition known as mineral and bone disorder (CKD-MBD). In patients with advanced CKD taking Prolia, severe hypocalcemia resulted in serious harm, including hospitalization, life-threatening events, and death. As a result, we are revising the Prolia prescribing information to include a new *Boxed Warning*, FDA's most prominent warning, communicating this increased risk.

Severe hypocalcemia can be asymptomatic or may present with symptoms that include confusion; seizures; irregular heart rhythm; fainting; face twitching; uncontrolled muscle spasms; or weakness, tingling, or numbness in parts of the body.

RECALLS

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Odor-Eaters Spray Powder, Tolnaftate 1% Antifungal, packaged in a) 4 oz. aerosol cans (UPC 0 41388 0041 2, NDC 10157-4645-1) and b) 5.3 oz. aerosol cans (UPC 0 41388 00411 2, NDC 10157-4645-2) Blistex P.O. Box 5392, Oak Brook, IL 60522-5392.	Class I	Drugs	a) Lot #: D19K22, D19K23, Exp. Date 10/21; D19M24, D19M25, D19M26, D19M27, Exp. Date 12/21; D20C01, D20C02, D20C03, D20C04, Exp. Date 3/22; D20F08, D20F09, Exp. Date 6/22; LD20H10, D20H11, Exp. Date 8/22; D20K13, D20K14, Exp. Date 10/22 D21B01, Exp. Date 2/23; D21D03, Exp. Date 4/23; D21E04, D21F04, Exp. Date 5/23; D21F05, Exp. Date 6/23; D21G01, D21G02, Exp. Date 7/23; D21H03, D21H04, D21H05, Exp. Date 8/23. b) Lot #: D19M27, D19M28, D19M29, D19M30,	Chemical contamination: Presence of benzene	Blistex Inc

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			Exp. Date 12/21; D20E05, D20E06, D20E07, Exp. Date 5/22; D20M15, D20M16, Exp. Date 12/22; D21B02, Exp. Date 2/23		
Phenytoin Oral Suspension, USP, 100 mg/4 mL, packaged in packaged in 4 mL unit dose cups (NDC 0904-7079-24), 50 per case (NDC 0904-7079-57), Rx only, Major Pharmaceuticals Livonia, MI 48152	Class I	Drugs	Lot# C00099, C00115 Exp. date: 07/31/2024; C00079 Exp. date: 12/31/2023	Failed Content Uniformity Specifications	The Harvard Drug Group LLC dba Major Pharmaceuticals and Rugby Laboratories
THE ROCK, Male Sexual Performance Enhancement Capsules, 1200 mg, 1 count blister card, Distributed by Steele Productions: Hallandale, FL 33008 UPC 6 61799 95052 7	Class I	Drugs	Lot# 03032021 Exp: 12/31/2027	Marketed Without an Approved NDA/ANDA: FDA analysis found the product to be tainted with Sildenafil an ingredient found in an FDA approved product for the treatment of male sexual enhancement, making this an unapproved drug.	Noah's Wholesale LLC
TING 2% Miconazole Nitrate Athlete's Foot Spray Antifungal Spray Powder, NET WT 4.5 oz (128 g) cans, Distributed by: Insight Pharmaceuticals LLC, a Prestige Consumer Healthcare company, Tarrytown, NY 10591, UPC 363736532611.	Class I	Drugs	Lot #s: 0H88645, Exp 07/31/2024; 0B88345, Exp 02/29/2024.	Chemical Contamination; presence of benzene.	Insight Pharmaceuticals Corporation

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Magnum XXL 9800, 2000 mg per capsule, 1 capsule per blister pack, Distributed by Magnum Los Angelas CA. UPC 6 45759 99300 7. Amazon's ASIN# B07P7ZH797, B07P94J3ZT, B07P6VK6N3, B076HNPZZZ	Class I	Drugs	All Lots	Marketed without an approved NDA/ANDA: Magnum XXL found to contain undeclared active pharmaceutical ingredient (API) - Sildenafil.	Meta Herbal
Vigabatrin for Oral Solution, USP 500 mg per packet, 50 packets per box, Rx Only, Manufactured by: InvaGen Pharmaceuticals, Inc., (a subsidiary of Cipla Ltd.), Hauppauge, NY, 11788, Manufactured for: Cipla USA, Inc., Warren, NJ 07059, NDC 69097-964-53	Class I	Drugs	Lot #: NB301030, Exp. Date 03/31/2025	Defective Container: powder may leak out of the pouch	InvaGen Pharmaceuticals, Inc.
Old Spice, PURE SPORT, (Aluminum Chlorohydrate 23.5%), Anti-Perspirant & Deodorant Spray, Topical spray can, Net WT 6.0 OZ (170g), Distributed by Procter & Gamble, Cincinnati, OH 45202. NDC: 37000-199-60, UPC 0 12044 00191 2	Class I	Drugs	Lot #: 11661458SM, 11681458SB, Exp 5/31/23; 12621458SV, 12631458SB, Exp 08/31/23	Chemical contamination: presence of benzene	The Procter & Gamble Company
Old Spice, SWEAT DEFENSE PURE SPORT PLUS, Dry Spray, (Aluminum Chlorohydrate 23.5%), Anti-Perspirant, Topical spray can, Net WT 3.8 oz (107 g) cans, Distr. by: Procter & Gamble, Cincinnati, OH 45202. NDC: 69423-387-10, UPC 0 37000 72974 7	Class I	Drugs	Lot #: 12081458SB, Exp 6/30/2021; 92181458FA, Exp 7/31/21;	Chemical contamination: presence of benzene	The Procter & Gamble Company
Old Spice, SWEAT DEFENSE ULTIMATE CAPTAIN, Aluminum Chlorohydrate 23.5%, Anti-Perspirant, Topical spray can 3.8 OZ (107 g), Distr. by: Procter & Gamble, Cincinnati, OH	Class I	Drugs	Lot #: 03581458SA, Exp 11/30/2022; 10251458SU, 10261458SA, Exp 12/31/2022;	Chemical contamination: presence of benzene	The Procter & Gamble Company

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
45202. NDC: 69423-385-10, UPC 0 37000 74947 9					
Secret, powder fresh, Aluminum chlorohydrate 24%, Anti-Perspirant/Deodorant, Topical spray can Net Wt., (a) 4OZ (113g), NDC 37000-134-11, UPC 0 37000 71109 4, (b) 6OZ (170g), NDC 37000-134-17, UPC 0 37000 71108 7; (c) twin pack-2 each can Net Wt. 6OZ (170g), NDC: 37000-134-01, UPC 0 37000 58690 6; Distr. by: Procter & Gamble, Cincinnati, OH 45202	Class I	Drugs	Lot #: (a &b) 00701458SJ, 00861458SA, 00871458SA, Exp 1/28/2022; 00921458SK, Exp 3/31/2022; 01701458SJ, 01711458SE, Exp 5/31/2022; 03431458SA, 03441458SA, 03531458SM, Exp 11/30/2022; 10681458SJ, 10691458SA, 10701458SA, 10781458SE, 10811458SJ, Exp 2/28/2023; 11701458SH, 11711458SH, 11721458SG, Exp 5/31/2023; 12181458SD, Exp 7/31/23; 12631458SH,12641458SB, 12651458SE,	Chemical contamination: presence of benzene	The Procter & Gamble Company

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			Exp 8/31/23; 10301458SA,Exp 12/31/22; 10921458SJ, 10931458SA, 11191458SJ, Exp 3/31/23; 11251458SB, 11421458SM, 11431458SB, Exp 4/30/2023; 11701458SH, 11711458SB, Exp 5/31/2023; 12101458SJ, 12121458SJ, Exp 6/30/2023 (c) 11711458SB, Exp 5/31/2023		
Secret, Dry Spray, (Aluminum chlorohydrate 23.5%), Antiperspirant, Waterlily, Topical Spray Can, Net Wt 3.8 oz (107 g), Dist. by: Procter & Gamble, Cincinnati, OH 45202. NDC: 69423-381-10; UPC 0 37000 72372 1; 12/pack UPC 0 37000 72991 4	Class I	Drugs	Lot #: 92191458FB, Exp 7/31/2021; 00091458SA, Exp 12/31/2021; 00091458SA, 11821458SB, Exp 6/30/2023.	Chemical contamination: presence of benzene	The Procter & Gamble Company
Secret, Dry Spray, Aluminum chlorohydrate 23.5%, Antiperspirant, Lavender, Topical spray can Net Wt 3.8 oz (107 g), Dist. by: Procter &	Class I	Drugs	Lot #: 00221458SU, 00231458SA, Exp 12/31/2021;	Chemical contamination: presence of benzene	The Procter & Gamble Company

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Gamble, Cincinnati, OH 45202. NDC: 69423-383-10, UPC: 0 37000 72986 0			10271458SR, Exp 12/31/2022.		
Secret, Dry Spray, Aluminum chlorohydrate 23.5%, Antiperspirant, Rose, Topical spray can Net Wt 3.8 oz (107 g), Dist. by: Procter & Gamble, Cincinnati, OH 45202. NDC: 69423-380-10, UPC 0 37000 79884 2	Class I	Drugs	Lot #: 12001458SF, Exp 06/30/2023.	Chemical contamination: presence of benzene	The Procter & Gamble Company
4.2% Sodium Bicarbonate Injection, USP 5 mEq/10 mL (0.5 mEq/mL), Glass ABBOJECT Unit of Use Syringe, For Intravenous Use, Rx Only, 10 mL Syringe per Carton, Hospira, Inc., Lake Forst, IL 60045, NDC 0409-5534-24 (carton), 0409-5534-14 (case).	Class I	Drugs	Lot GX1542, Exp. 01/01/2025	Presence of Particulate Matter; identified as glass	Pfizer Inc.
8.4 % Sodium Bicarbonate Injection, USP 50 mEq/50 mL (1 mEq/mL), Lifeshield, Glass ABBOJECT Unit of Use Syringe, Rx Only, 50 mL Syringe per Carton, Hospira, Inc., Lake Forest, IL 60045, NDC 0409-6637-24 (carton), 0409-6637-14 (case).	Class I	Drugs	Lot HA7295, EXP 03/01/2025	Presence of Particulate Matter; identified as glass	Pfizer Inc.
Atropine Sulfate Injection, USP 1 mg/10 mL (0.1 mg/mL), Lifeshield, Glass ABBOJECT Unit of Use Syringe, Rx Only, 10 mL Syringe per Carton, Hospira, Inc., Lake FOrest, IL 60045, NDC 0409-4911-11 (carton), 0409-4911-34 (case).	Class I	Drugs	Lot GY2496, Exp 02/01/2025	Presence of Particulate Matter; identified as glass	Pfizer Inc.
Americaine, (benzocaine 20%) Benzocaine Topical Anesthetic Spray, Aerosol Can 2 oz (57 G), Dist. by Insight Pharmaceuticals Corp. Tarrytown, NY 10591, USA, A Prestige Consumer Healthcare company. Made in India.	Class I	Drugs	Lot # 1A16420, exp. date 01/31/2025	Chemical Contamination: presence of benzene	Insight Pharmaceuticals LLC, a Prestige Consumer Healthcare company

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
NDC 63736-378-02, Can UPC 3 63736 37882 0; Case UPC 1 03 63736 37882 7					
NYSTATIN 5BU, Activity (as is): 6482 Units/mg, bulk powder container, Rx Only, For Prescription Compounding, Fagron, Inc. - 2400 Pilot Knob Rd. St Paul, MN 55120. NDC 51552-0041-5 Bar code 3 51552 00415 3	Class II	Drugs	Lot#: 230308-U46196, Exp. date 04/30/2025	Labeling: Label Error on Declared Strength: Assay value on the label is incorrect.	Fagron, Inc
NYSTATIN 500 MU, Activity (as is): 6482 Units/mg, bulk powder container, Rx Only, For Prescription Compounding, Fagron, Inc. - 2400 Pilot Knob Rd. St Paul, MN 55120. NDC 51552-0041-3, Bar code 3 51552 00413 9	Class II	Drugs	Lot #: 230308-U46225, Exp. date 04/30/2025, 221031-U42110, Exp. date 04/30/2025	Labeling: Label Error on Declared Strength: Assay value on the label is incorrect.	Fagron, Inc
NYSTATIN 2 BU, Activity (as is): 6482 Units/mg, bulk powder container, Rx Only, For Prescription Compounding, Fagron, Inc. - 2400 Pilot Knob Rd. St Paul, MN 55120. NDC 51552-0041-4, Bar code 3 51552 00414 6	Class II	Drugs	Lot #: 230308-U46224, Exp. date 04/30/2025, 221031-U42105, Exp. date 04/30/2025	Labeling: Label Error on Declared Strength: Assay value on the label is incorrect.	Fagron, Inc
NYSTATIN 150 MU, Activity (as is): 6482 Units/mg, bulk powder container, Rx Only, For Prescription Compounding, Fagron, Inc. - 2400 Pilot Knob Rd. St Paul, MN 55120. NDC 51552-0041-1, Bar code 3 51552 00411 5	Class II	Drugs	Lot #: 221031-U42104, Exp. date 04/30/2025	Labeling: Label Error on Declared Strength: Assay value on the label is incorrect.	Fagron, Inc
Selenium Sulfide 2.25% Shampoo, 180mL bottle, Rx Only, Manufactured for: Bi-Coastal Pharma Int. LLC, Shrewsbury, NJ 07702, NDC 42582-900-06.	Class II	Drugs	Lot #220551, Exp: 2/28/2025	CGMP Deviations: Stability data does not support expiry date.	Private Label Partners, Inc.
Ipratropium Bromide and Albuterol Sulfate Inhalation Solution (0.5 mg/3 mg per 3 mL), 60 x 3 mL Sterile Unit-Dose Vials (2 pouches of 30 - 3 mL vials each), Manufactured By: The Ritedose	Class II	Drugs	Batch 21C56	CGMP Deviations: Products were exposed to temperatures outside	CARDINAL HEALTHCARE

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Corporation, Columbia, SC 29203; Distributed By: Cipla USA Inc., 10 Independence Boulevard, Suite 300, Warren, NJ 07059. NDC: 69097-840-64				of the products labeled storage conditions.	
ALBUTEROL SULFATE HFA Inhalation Aerosol, 90MCG per actuation, 200 Metered Inhalations, Net Wt. 18 g, Rx Only, Manufactured for: Prasco Laboratories, Mason, OH 45040 USA. NDC: 66993-019-68	Class II	Drugs	Batch MY7E	CGMP Deviations: Products were exposed to temperatures outside of the products labeled storage conditions.	CARDINAL HEALTHCARE
ALBUTEROL SULFATE IN 90MCG per actuation, 200 Metered Inhalations, Rx Only, 8.5 g Net Contents, Manufactured for: Lupin Pharmaceuticals, Inc., Baltimore, Maryland 21202; Manufactured by: Lupin Limited, Pithampur (M.P.) 454 775, India. NDC: 68180-963-01	Class II	Drugs	Batch K100715	CGMP Deviations: Products were exposed to temperatures outside of the products labeled storage conditions.	CARDINAL HEALTHCARE
ALLOPURINOL Tablets, USP 300 MG 500 count Tablets per bottle, Rx only, Manufactured By: Dr. Reddy's Laboratories LA LLC, Shreveport, LA 71106. NDC: 55111-730-05	Class II	Drugs	Batch L100813	CGMP Deviations: Products were exposed to temperatures outside of the products labeled storage conditions.	CARDINAL HEALTHCARE
AMOXICILLIN for Oral Suspension USP, 400MG/5ML, 100ML (when reconstituted), Manufactured In Canada By: TEVA CANA LIMITED, Toronto, Canada M1B 2K9; Manufactured For: TEVA PHARMACEUTICALS USA, INC., North Wales, PA 19454. NDC: 0093-4161-73	Class II	Drugs	Batch 35447184A	CGMP Deviations: Products were exposed to temperatures outside of the products labeled storage conditions.	CARDINAL HEALTHCARE
AMOXICILLIN Tablets, USP, 875MG, 20 Tablets, Rx Only, Manufactured by Sandoz GmbH for	Class II	Drugs	Batch LJ9004	CGMP Deviations: Products were exposed	CARDINAL HEALTHCARE

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Sandoz Inc., Princeton, NJ 08540. NDC: 0781-5060-20				to temperatures outside of the products labeled storage conditions.	
Aripiprazole Tablets, USP, 5 mg, 30 Tablets per bottle, Distributed by: Amneal Pharmaceuticals LLC, Bridgewater, NJ 08807. NDC: 65162-897-03	Class II	Drugs	Batch AR202318	CGMP Deviations: Products were exposed to temperatures outside of the products labeled storage conditions.	CARDINAL HEALTHCARE
ARMOUR THYROID (thyroid tablets, USP), 2 GRAIN (120 mg), 100 Tablets, Rx Only, Distributed by: Allergan US, INc., Madison, NJ 07940. NDC: 0456-0461-01	Class II	Drugs	Batch W05543	CGMP Deviations: Products were exposed to temperatures outside of the products labeled storage conditions.	CARDINAL HEALTHCARE
Asmanex Twisthaler (mometasone furoate inhalation powder, 220 mcg per actuation), 120 Metered Doses, Rx only, Manufactured for: Organon LLC, a subsidiary of Organon & Co., Jersey City, NJ 07302; Manufactured by: MSD International GmbH (Singapore Branch) Singapore 638030, Singapore. NDC: 78206-114-01	Class II	Drugs	Batch U027458	CGMP Deviations: Products were exposed to temperatures outside of the products labeled storage conditions.	CARDINAL HEALTHCARE
Low Dose ASPIRIN, 81 mg, 120 Enteric Coated Tablets, Distributed by: Rugby Lavoratories, 17177 N Laurel Park Drive, Suite 233, Livonia, MI 48152. NDC: 0536-1234-41	Class II	Drugs	Batch P126201	CGMP Deviations: Products were exposed to temperatures outside of the products labeled storage conditions.	CARDINAL HEALTHCARE
Bumetanide Tablets, USP, 2 mg, 100 Tablets per bottle, Rx only, Manufactured by: Amneal Pharmaceuticals Pvt. Ltd., Ahmedabad 382213	Class II	Drugs	Batch AM211171	CGMP Deviations: Products were exposed to temperatures outside	CARDINAL HEALTHCARE

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
India; Distributed by: Amneal Pharmaceuticals LLC, Bridgewater, NJ 08807				of the products labeled storage conditions.	
CHLORTHALIDONE Tablets, USP, 25MG, 1000 Tablets, Rx only, Manufactured by: Appco Pharma LLC, Piscataway, NJ 08854 USA; Manufactured For: Dr. Reddy's Laboratories Inc., Princeton, NJ 08540 USA. NDC: 43598-719-10	Class II	Drugs	Batch 2107329UM	CGMP Deviations: Products were exposed to temperatures outside of the products labeled storage conditions.	CARDINAL HEALTHCARE
CITALOPRAM Tablets, USP, 20MG, 100 Tablets, Rx only, Manufactured for: Mylan Pharmaceuticals Inc., Morgantown, WV 26505 USA. NDC: 0378-6232-01	Class II	Drugs	Batch 3131748	CGMP Deviations: Products were exposed to temperatures outside of the products labeled storage conditions.	CARDINAL HEALTHCARE
Colgate Total SF Toothpaste, Net Wt 4.8 oz (136 g), Stannous Fluoride 0.454%, Clean Mint, Dist. by: COLGATE-PALMOLIVE CO., New York, NY 10022 USA	Class II	Drugs	Batch 1293US561C	CGMP Deviations: Products were exposed to temperatures outside of the products labeled storage conditions.	CARDINAL HEALTHCARE
Dicyclomine Hydrochloride Tablets, USP 20 mg, 100 Tablets, Rx only, Manufactured For: Teva Pharmaceuticals USA, Parsippany, NJ 07054. NDC: 0591-0795-01	Class II	Drugs	Batch 3197790	CGMP Deviations: Products were exposed to temperatures outside of the products labeled storage conditions.	CARDINAL HEALTHCARE
Donepezil HCl Tablets, 10 mg, 90 Tablets, Rx only, Distributed by: Solco Healthcare U.S. LLC, Hurracao, Puerto Rico 00791. NDC: 43547-276-09	Class II	Drugs	Batch 17616	CGMP Deviations: Products were exposed to temperatures outside of the products labeled storage conditions.	CARDINAL HEALTHCARE
Donepezil HCl Tablets, 5 mg, 90 Tablets, Rx only, Distributed by: Solco Healthcare U.S. LLC,	Class II	Drugs	Batch 17605	CGMP Deviations: Products were exposed	CARDINAL HEALTHCARE

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Hurracao, Puerto Rico 00791. NDC: 43547-275-09				to temperatures outside of the products labeled storage conditions.	
Doxycycline Capsules, USP 100 mg, 50 Capsules, Rx Only, Manufactured for: Lupin Pharmaceuticals, Inc., Baltimore, Maryland 21202 Unite States; Manufactured by: Lupin Limited, Nagpur - 441 108, INDIA. NDC 68180-652-08	Class II	Drugs	Batch G104819	CGMP Deviations: Products were exposed to temperatures outside of the products labeled storage conditions.	CARDINAL HEALTHCARE
Enoxaparin Sodium Injection, USP, 150MG/ML Single-Dose Syringes with Automatic Safety Device, For Subcutaneous Injection, Ten 1 mL Syringes per box, Rx Only, Sandoz Inc, Princeton, NJ 08540. NDC: 0781-3299-69	Class II	Drugs	Batch SAH06821A	CGMP Deviations: Products were exposed to temperatures outside of the products labeled storage conditions.	CARDINAL HEALTHCARE
ESTRADIOL TABLETS USP, 0.5MG 100 Tablets, Tx Only, Teva Pharmaceuticals USA, Inc., North Wales, PA 19454. NDC: 0555-0899-02	Class II	Drugs	Batch 100023687	CGMP Deviations: Products were exposed to temperatures outside of the products labeled storage conditions.	CARDINAL HEALTHCARE
FIRST LANSOPRAZOLE PT 3MG/ML, 300ML, Rx Only, Distributed By: CutisPharma, Inc., Woburn, MA 01801. NDC: 65628-080-10	Class II	Drugs	Batch 21025A	CGMP Deviations: Products were exposed to temperatures outside of the products labeled storage conditions.	CARDINAL HEALTHCARE
Fluticasone Propionate Nasal Spray USP, 50MCG per spray, 16 g net fill weight, 120 Metered Sprays, For Intranasal Use Only, Rx Only, Manufactured for: Apotext Corp., Weston, FL 33326. NDC: 60505-0829-1	Class II	Drugs	Batch TE9159, TE8156	CGMP Deviations: Products were exposed to temperatures outside of the products labeled storage conditions.	CARDINAL HEALTHCARE

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
FOLIC ACID TABLETS, USP, 1MG, 100 Tablets per bottle, Rx Only, Manufactured by: Leading Pharma, LLC, Fairfield, NJ 07004. NDC: 69315-127-10	Class II	Drugs	Batch H08221	CGMP Deviations: Products were exposed to temperatures outside of the products labeled storage conditions.	CARDINAL HEALTHCARE
HydrALAZINE Hydrochloride Tablets, USP, 25 mg, 100 Tablets per bottle, Rx only, Distributed by: Avet Pharmaceuticals Inc., East Brunswick, NJ 08816. NDC: 23155-002-01	Class II	Drugs	Batch G210553, G210551	CGMP Deviations: Products were exposed to temperatures outside of the products labeled storage conditions.	CARDINAL HEALTHCARE
Jardiance (empagliflozin tablets), 25 mg, 30 tablets (3 blister cards with 10 tablets each), Rx only, Distributed by: Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT 06877. NDC: 0597-0153-37	Class II	Drugs	Batch D41919	CGMP Deviations: Products were exposed to temperatures outside of the products labeled storage conditions.	CARDINAL HEALTHCARE
Leader Nasal Decongestant PE (Phenylephrine HCl 10 mg), 18 Tablets per cartons, Distributed By Cardinal Health, Dublin, Ohio 43017. NDC: 70000-0126-1	Class II	Drugs	Batch P125514	CGMP Deviations: Products were exposed to temperatures outside of the products labeled storage conditions.	CARDINAL HEALTHCARE
Lillow (Levonorgestrel and Ethinyl Estradiol Tablets, USP), 0.15 mg/0.03 mg, 1 Blister Pack Containing 28 Tablets, Rx only, Distributed by: Amneal Pharmaceuticals LLC, Bridgewater, NJ 08807. NDC 69238-1554-6	Class II	Drugs	Batch A5921	CGMP Deviations: Products were exposed to temperatures outside of the products labeled storage conditions.	CARDINAL HEALTHCARE
Lisinopril and Hydrochlorothiazide Tablets USP, 10mg/12.5mg, Rx only, 100 Tablets per bottles, Manufactured for: Lupin Pharmaceuticals, Inc., Baltimore, Maryland 21202; Manufactured by:	Class II	Drugs	Batch Q101699, Q101981	CGMP Deviations: Products were exposed to temperatures outside of the products labeled storage conditions.	CARDINAL HEALTHCARE

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Lupin Limited, Nagpur-441 108, India. NDC: 68180-518-01					
Lithium Carbonate Extended-Release Tablets, USP, 300 mg, 100 Tablets per bottle, Rx only, Manufactured for: Mylan Pharmaceuticals Inc., Morgantown, WV 26505. NDC: 0378-1300-01	Class II	Drugs	Batch 3138326	CGMP Deviations: Products were exposed to temperatures outside of the products labeled storage conditions.	CARDINAL HEALTHCARE
Meloxicam Tablets, USP, 15 mg, 1000 Tablets per bottle, Rx Only, Manufactured by: Cipla Ltd., Kurkumbh, India; Manufactured for: Cipla USA, Inc., 9100 S. Dadeland Blvd., Suite 1500 Miami, FL 33156. NDC: 69097-159-15	Class II	Drugs	Batch KA11489	CGMP Deviations: Products were exposed to temperatures outside of the products labeled storage conditions.	CARDINAL HEALTHCARE
Metoprolol Succinate Extended-Release Tablets, USP, 50 mg, 1000 Tablets, Rx Only, Teva Pharmaceuticals USA, Inc., North Wales, PA 19454. NDC: 45963-676-96	Class II	Drugs	Batch 2447J211	CGMP Deviations: Products were exposed to temperatures outside of the products labeled storage conditions.	CARDINAL HEALTHCARE
Nyamyc, 100,000 USP units per gram, 60 grams, Rx only, Topical Use Only, Manufactured by: Upsher-Smith Laboratories, Inc, Minneapolis, MN 55447.	Class II	Drugs	Batch 400454	CGMP Deviations: Products were exposed to temperatures outside of the products labeled storage conditions.	CARDINAL HEALTHCARE
PredniSONE Tablets, USP, 20 mg, 100 Tablets per bottle, Rx Only, Manufactured by: Jubilant Cadista Pharmaceuticals Inc., Salisbury, MD 21801. NDC: 59746-175-06	Class II	Drugs	Batch 21P0659	CGMP Deviations: Products were exposed to temperatures outside of the products labeled storage conditions.	CARDINAL HEALTHCARE
Propranolol Hydrochloride Tablets, 20 mg, 100 Tablets per bottle, Rx only, Manufactured by: Amneal Pharmaceuticals Pvt. Ltd., Ahmedabad	Class II	Drugs	Batch 100023596	CGMP Deviations: Products were exposed to temperatures outside	CARDINAL HEALTHCARE

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
382213, India; Distributed by: Amneal Pharmaceuticals LLC, Bridgewater, NJ 08807. NDC: 69238-2078-1				of the products labeled storage conditions.	
Ricola CherryHoney Herb Throat Drops (menthol, 1.8 mg), 10 Drops per roll, Manufacturer: Ricola Ltd., 4242 Laufen, Switzerland; Distributed by: Ricola USA Inc., 6 Campus Drive, 2nd Floor South, Parsippany, NJ 07054. NDC: 54305-507-10	Class II	Drugs	Batch 2000058693	CGMP Deviations: Products were exposed to temperatures outside of the products labeled storage conditions.	CARDINAL HEALTHCARE
RIVASTIGMINE TRANSDERMAL SYSTEM, Delivers 4.6 mg/24 hours, 30 systems per box, Rx Only, Distributed by: Alvogen, Inc., Morristown, NJ 07960. NDC 47781-304-03	Class II	Drugs	Batch P0248AL0AT	CGMP Deviations: Products were exposed to temperatures outside of the products labeled storage conditions.	CARDINAL HEALTHCARE
SPIRIVA HANDIHALER (tiotropium bromide inhalation powder) 18 mcg/Capsule, 30 capsules, 3 blister cards, each card contains 10 capsules, Rx only, For oral inhalation only, Distributed by: Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT 06877 USA. NDC: 0597-0075-41	Class II	Drugs	Batch 104440	CGMP Deviations: Products were exposed to temperatures outside of the products labeled storage conditions.	CARDINAL HEALTHCARE
Terconazole Vaginal Suppositories, 80 mg, 3 Suppositories with Vaginal Applicator, Rx only, Manufactured by: Cosette Pharmaceuticals, Inc., 111 Coolidge Street, South Plainfield, NJ 07080. NDC: 0713-0552-73	Class II	Drugs	Batch 1014228A	CGMP Deviations: Products were exposed to temperatures outside of the products labeled storage conditions.	CARDINAL HEALTHCARE
Triamterene and Hydrochlorothiazide Capsules, USP, 37.5 mg/25 mg, 100 capsules per bottle, Rx Only, Distributed by: Lannett Company, Inc, Philadelphia, PA 19136. NDC 0527-1632-01	Class II	Drugs	Batch 21000279A, 21000280A	CGMP Deviations: Products were exposed to temperatures outside	CARDINAL HEALTHCARE

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
				of the products labeled storage conditions.	
Warfarin Sodium Tablets, USP, 2.5 mg, 100 Tablets per bottle, Rx only, Manufactured For: Teva Pharmaceuticals, Parsippany, NJ 07054. NDC: 0093-1714-01	Class II	Drugs	Batch 2169041	CGMP Deviations: Products were exposed to temperatures outside of the products labeled storage conditions.	CARDINAL HEALTHCARE
Warfarin Sodium Tablets, USP, 5 mg, 100 Tablets per bottle, Rx Only, Manufactured for: Teva Pharmaceuticals, Parsippany, NJ 07054. NDC: 0093-1721-01	Class II	Drugs	Batch 2323041	CGMP Deviations: Products were exposed to temperatures outside of the products labeled storage conditions.	CARDINAL HEALTHCARE
Inhub Wixela (fluticasone propionate and salmeterol inhalation powder, USP) 500/50MCG, 60 Doses of Inhalation Powder, Manufactured for: Mylan Pharmaceuticals Inc., Morgantown, WV 26505. NDC: 0378-9320-32	Class II	Drugs	Batch 62002532	CGMP Deviations: Products were exposed to temperatures outside of the products labeled storage conditions.	CARDINAL HEALTHCARE
B-Complex, Thiamine HCl / Riboflavin / Niacinamide / Dexpanthenol / Pyridoxine HCl injection, 74/2/75/2/2 MG/ML, 30ML Sterile Multiple-Dose Vial, Rx only, AnazaoHealth, 7465 W Sunset Rd #1200, Las Vegas, NV 89113, NDC 72682-2230-3	Class II	Drugs	Lots: 505075, Exp: 02/05/24; 505596, Exp: 02/06/24; 506155, Exp: 02/07/24; 508103, Exp: 02/13/24; 510837, Exp: 02/19/24; 512411, Exp: 02/20/24; 514856, Exp: 02/25/24; 515642, Exp: 02/28/24; 518309, Exp:	Presence of Particulate Matter.	AnazaoHealth Corporation

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			03/05/24; 524262, 524266, Exp: 03/12/24; 524909, Exp: 03/13/24; 526526, Exp: 03/16/24; 529204, Exp: 03/18/24; 530858, Exp: 03/20/24; 535766, Exp: 03/30/24		
Thiamine HCl/Pyridoxine HCl 20 mg/mL /100mg/ml Injection Solution, 30mL Amber Glass Vial, Rx only, AnazaoHealth, 7465 W. Sunset Road, Las Vegas, NV, NDC 72682-8721-3.	Class II	Drugs	Lots: 508029, Exp: 12/14/23; 513191, Exp: 12/22/23; 524670, Exp: 01/12/24; 526254, Exp: 01/13/24; 530738, Exp: 01/19/23; 533570, Exp: 01/25/24; 538736, Exp: 02/03/24; 543220, Exp:02/16/24; 543508, Exp: 02/17/24; 545675, Exp: 02/22/24	Presence of Particulate Matter.	AnazaoHealth Corporation
Sertraline Tablets, USP 100 mg, 30 tablets per bottle, Distributed by: Wal-Mart, Bentonville, AR 72716, Manufactured for: Cipla USA, Inc., Warren, NJ 07059, Packaged by: Legacy	Class II	Drugs	Lot #: 222033, exp. date 08/31/2024	CGMP Deviations: Inadequate line clearance which may result in a potential comingling of product.	Legacy Pharmaceutical Packaging LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Pharmaceutical Packaging LLC., Earth City, MO 63045, NDC# 68645-523-54					
DELFLEX Peritoneal Dialysis Solution in Biofine container 1.5% Dextrose, packaged in 6000mL bags, Rx only, Fresenius Medical Care NA Waltham, MA 02451, NDC 49230-206-62.	Class II	Drugs	Part Number: 077-60621, Lot #: 23JK02010, Exp. Date 1/31/2025	Lack of Sterility Assurance	Fresenius Medical Care Holdings, Inc.
Nasal Spray Original No Drip Oxymetazoline HCl Nasal Solution, 12 Hour Pump Mist, 1 FL oz. (30 mL) bottle, a) Quality Choice, Distributed by C.D.M.A. Inc., 43157 W 9 Mile Rd, Novi, MI 48375, NDC# 63868-607-01, UPC 6-35515-98843-9, b) Premier Value, Distributed by: Pharmacy Value Alliance, LLC, 407 East Lancaster Avenue, Wayne, PA 19087 UPC 8-40986-03509-8.	Class II	Drugs	Lot # SD23032, Exp 04/30/2026	CGMP Deviations: Firm reported possible microbial contamination in the purified water used in the manufacturing of the products. No contamination was found in the final products.	Seaway Pharma Inc.
Premier Value Tussin Cough DM, Dextromethorphan HBr...Cough Suppressant, Guaifenesin...Expectorant, Alcohol Free, 8 FL OZ (237 mL) bottle, Distributed by: Pharmacy Value Alliance, LLC, 407 East Lancaster Avenue, Wayne PA 19087, UPC 8-40986-03789-4.	Class II	Drugs	Lot # SD23033, Exp 04/30/2025	CGMP Deviations: Firm reported possible microbial contamination in the purified water used in the manufacturing of the products. No contamination was found in the final products.	Seaway Pharma Inc.
Quality Choice No Drip Extra Moisturizing Nasal Pump Mist Oxymetazoline hydrochloride 0.05%, 12 Hour Nasal Decongestant, 1 fl oz (30 mL) bottle, Distributed by C.D.M.A, Inc. 43157 W 9	Class II	Drugs	Lot # SE23034, Exp 05/31/2026	CGMP Deviations: Firm reported possible microbial contamination in the purified water	Seaway Pharma Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Mile Rd. Novi, MI 48375, NDC# 63868-676-01, UPC 6-35515-98847-7.				used in the manufacturing of the products. No contamination was found in the final products.	
Quality Choice No Drip Severe Congestion Nasal Pump Mist, Oxymetazoline hydrochloride 0.05%, Nasal Decongestant, 12 Hours, 1 fl. oz. bottle, Distributed by C.D.M.A., Inc., 43157 W 9 Mile Rd., Novi, MI 48375, NDC 63868-608-01, UPC 6-35515-98846-0	Class II	Drugs	Lot # SE23035, Exp 05/31/2026	CGMP Deviations: Firm reported possible microbial contamination in the purified water used in the manufacturing of the products. No contamination was found in the final products.	Seaway Pharma Inc.
Tacrolimus Capsules, USP 1mg, 100-Count Bottles, Rx Only, Manufactured by: Dr. Reddy's Laboratories Limited, Bachupally, 500 090, INDIA, NDC 55111-526-01	Class II	Drugs	Lot# C2307275; Exp. January 2026	Presence of Foreign Tablets/Capsules: One 0.5 mg Tacrolimus capsule found in a bottle of 1 mg Tacrolimus capsules.	Dr. Reddy's Laboratories, Inc.
Desloratadine Tablets USP 5mg a) 100 count (NDC 68180-153-01) and b) 500 count (NDC 68180-153-02) bottles, Rx Only, Manufactured for: Lupin Pharmaceuticals, Inc. Baltimore, Maryland 21202.	Class II	Drugs	Lot # G201822, exp. date Jan 2024, 100 count G201823, exp. date Jan 2024, 100 count G201824, exp. date Jan 2024, 500 count	CGMP Deviations: N-Nitroso Desloratadine impurity result exceeded the acceptable intake limit.	Lupin Pharmaceuticals Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
buPROPion Hydrochloride Extended-Release Tablets, USP (XL) 150mg, 30-count bottles, Rx Only, Manufactured for: Rising Pharma Holdings, Inc. East Brunswick, NJ 08816 Manufactured by: Graviti Pharmaceuticals Pvt. Ltd. Telangana - 502307, INDIA, NDC 16571-862-03	Class II	Drugs	Lot #: BPA123098A, Exp. Date 06/2025	Presence of Foreign Tablets/Capsules	Rising Pharma Holding, Inc.
Tizanidine Tablets, USP 4mg, 150-count bottle, Rx only, Mfd. By: Dr. Reddy's Laboratories Limited, Srikakulam - 532 409 INDIA, NDC 55111-180-15	Class II	Drugs	Lot #: T2304007, Exp 7/31/2026	Presence of Foreign tablets/capsules - identified as tizanidine 2 mg tablets.	Dr. Reddy's Laboratories, Inc.
Old Spice, SWEAT DEFENSE, STRONGER SWAGGER, Dry Spray, 48 Hour, (Aluminum Chlorohydrate 23.5%), Anti-Perspirant, Topical Spray Can, Net WT 3.8 oz (107 g), Distr. by: Procter & Gamble, Cincinnati, OH 45202. NDC 69423-386-10, UPC 0 37000 73034 7 OR UPC 0 12044 04475 9 (12 Pack, older label)	Class II	Drugs	All lots with expiry through September 2023,	CGMP Deviation; manufactured at the same facility where other lots were found to be contaminated with benzene	The Procter & Gamble Company
Secret, Dry Spray, (Aluminum chlorohydrate 23.5%), Antiperspirant, Light Essentials, Topical spray can Net Wt 3.8 oz (107 g), Dist. by: Procter & Gamble, Cincinnati, OH 45202. NDC: 69423-382-10, UPC 0 37000 72992 1	Class II	Drugs	All lots with expiry through September 2023	CGMP Deviation; manufactured at the same facility where other lots were found to be contaminated with benzene	The Procter & Gamble Company
Secret, OUTLAST, Dry Spray, (Aluminum chlorohydrate 23.5%), Antiperspirant, Completely Clean, Topical spray can 3.8 oz (107 g), Dist. by: Procter & Gamble, Cincinnati, OH 45202. NDC: 69423-384-10, UPC 0 37000 74764 2	Class II	Drugs	All lots with expiry through September 2023	CGMP Deviation; manufactured at the same facility where other lots were found to be contaminated with benzene	The Procter & Gamble Company

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Secret OUTLAST Dry Spray, (Aluminum chlorohydrate 23.5%), Antiperspirant, Protecting Powder, Topical spray can 3.8 oz (107 g), Dist. by: Procter & Gamble, Cincinnati, OH 45202. NDC: 69423-478-10, UPC 0 37000 74772 7	Class II	Drugs	All lots with expiry through September, 2023	CGMP Deviation; manufactured at the same facility where other lots were found to be contaminated with benzene	The Procter & Gamble Company
Old Spice Pure Sport 2021 Gift Set, Contains: Old Spice Pure Sport Body Wash 18 Fl Oz (532 mL), 2-in-1 Shampoo & Conditioner 13.5 Fl Oz (400 mL), and Old Spice, SWEAT DEFENSE PURE SPORT PLUS, Dry Spray, (Aluminum Chlorohydrate 23.5%), Anti-Perspirant, Topical spray can, Net WT 3.8 oz (107 g). Dist. by: Procter & Gamble, Cincinnati, OH 45202. Gift Set NDC 69423-590-01, UPC 12044 04853 5	Class II	Drugs	All lots with expiry through September 2023	CGMP Deviation; manufactured at the same facility where other lots were found to be contaminated with benzene	The Procter & Gamble Company
Old Spice, PURE SPORT, (Aluminum Chlorohydrate 23.5%), Anti-Perspirant & Deodorant Spray, Topical spray can, Net WT 6.0 OZ (170g), Distributed by Procter & Gamble, Cincinnati, OH 45202. NDC: 37000-199-60, UPC 0 12044 00191 2	Class II	Drugs	All lots with expiry through September 2023	CGMP Deviation; manufactured at the same facility where other lots were found to be contaminated with benzene	The Procter & Gamble Company
Old Spice, SWEAT DEFENSE PURE SPORT PLUS, (Aluminum Chlorohydrate 23.5%), Anti-Perspirant, Topical spray can, Net WT 3.8 oz (107 g) cans, Distr. by: Procter & Gamble, Cincinnati, OH 45202. NDC: 69423-387-10, UPC 0 37000 72974 7	Class II	Drugs	All lots with expiry through September 2023	CGMP Deviation; manufactured at the same facility where other lots were found to be contaminated with benzene	The Procter & Gamble Company
Old Spice, SWEAT DEFENSE ULTIMATE CAPTAIN, Aluminum Chlorohydrate 23.5%, Anti-Perspirant, Topical spray can 3.8 OZ (107 g),	Class II	Drugs	All lots with expiry through September 2023	CGMP Deviation; manufactured at the same facility where	The Procter & Gamble Company

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Distr. by: Procter & Gamble, Cincinnati, OH 45202. NDC: 69423-385-10, UPC 0 37000 74947 9				other lots were found to be contaminated with benzene	
Secret, powder fresh, (Aluminum chlorohydrate 24%), Anti-Perspirant/Deodorant, Topical spray can Net Wt., (a) 4OZ (113g), NDC 37000-134-11, UPC 0 37000 71109 4, (b) 6OZ (170g), NDC 37000-134-17, UPC 0 37000 71108 7; (c) twin pack-2 Topical spray cans, each can Net Wt. 6OZ (170g), NDC: 37000-134-01, UPC 0 37000 58690 6; Dist. by: Procter & Gamble, Cincinnati, OH 45202,	Class II	Drugs	All lots with expiry through September 2023	CGMP Deviation; manufactured at the same facility where other lots were found to be contaminated with benzene	The Procter & Gamble Company
Secret, Dry Spray, Aluminum chlorohydrate 23.5% Antiperspirant, Waterlily, Topical Spray Can, Net Wt 3.8 oz (107 g), Dist. by: Procter & Gamble, Cincinnati, OH 45202. NDC: 69423-381-10; UPC 0 37000 72372 1; 12/pack UPC 0 37000 72991 4	Class II	Drugs	All lots with expiry through September 2023	CGMP Deviation; manufactured at the same facility where other lots were found to be contaminated with benzene	The Procter & Gamble Company
Secret, Dry Spray, (Aluminum chlorohydrate 23.5%), Antiperspirant, Lavender, Topical spray can Net Wt 3.8 oz (107 g), Dist. by: Procter & Gamble, Cincinnati, OH 45202. NDC: 69423-383-10, UPC: 0 37000 72986 0	Class II	Drugs	All lots with expiry through September 2023	CGMP Deviation; manufactured at the same facility where other lots were found to be contaminated with benzene	The Procter & Gamble Company
Secret Dry Spray, Aluminum chlorohydrate 23.5%, Antiperspirant, Rose, Topical spray can Net Wt 3.8 oz (107 g), Dist. by: Procter & Gamble, Cincinnati, OH 45202. NDC: 69423-380-10, UPC 0 37000 79884 2	Class II	Drugs	All lots with expiry through September 2023	CGMP Deviation; manufactured at the same facility where other lots were found to be contaminated with benzene	The Procter & Gamble Company

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Good Neighbor Pharmacy, DYE FREE, SUGAR FREE Magnesium Citrate Saline Laxative, Oral Solution, Cherry Flavor 10 fl. oz, Distributed by AmerisourceBergen, 1 West First Ave, Conshochoken, PA 19428, NDC 46122-741-38	Class II	Drugs	Lots A80673, A80742; Exp 10/31/2025	MICROBIAL CONTAMINATION OF NON-STERILE PRODUCTS - Presence of Acetobacter nitrogenifigens bacteria.	Pharma Nobis LLC
Walgreens Dye-Free Magnesium Citrate Saline Laxative/Oral Solution, Sugar Free Low Sodium, Grape flavor 10 fl. oz, Distributed by: Walgreen Co, 200 Wilmot Rd, Deerfield, IL 60015, NDC 0363-0427-98.	Class II	Drugs	Lot A80623; Exp. 11/30/2025	MICROBIAL CONTAMINATION OF NON-STERILE PRODUCTS - Presence of Acetobacter nitrogenifigens bacteria.	Pharma Nobis LLC
CVS Health Magnesium Citrate Saline Laxative Oral Solution DYE FREE Grape Flavor 10 fl. oz, Distributed by: CVS Pharmacy, Inc., One CVS Drive, Woonsocket, RI 02895, NDC 51316-881-10.	Class II	Drugs	Lot A80763; Exp. 11/2025	MICROBIAL CONTAMINATION OF NON-STERILE PRODUCTS - Presence of Acetobacter nitrogenifigens bacteria.	Pharma Nobis LLC
Freskaro refresh & revitalize Magnesium Citrate Saline Laxative Oral Solution Grape Flavor 10 fl. oz, Manufactured by: Pharma Lobis, 7400 Alumax Dr., Texarkana, TX 75501, NDC 82645-311-10.	Class II	Drugs	Lot A80553; Exp. 11/2025	MICROBIAL CONTAMINATION OF NON-STERILE PRODUCTS - Presence of Acetobacter nitrogenifigens bacteria.	Pharma Nobis LLC
Freskaro refresh & revitalize Magnesium Citrate Saline Laxative Oral Solution Cherry Flavor 10 fl. oz, Manufactured by: Pharma Lobis, 7400 Alumax Dr., Texarkana, TX 75501, NDC 82645-312-10.	Class II	Drugs	Lot A80622; Exp. 11/2025	MICROBIAL CONTAMINATION OF NON-STERILE PRODUCTS - Presence of Acetobacter nitrogenifigens bacteria.	Pharma Nobis LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Ibuprofen and Famotidine Tablets 800mg/26.6mg, Rx Only, 90 Tablets per Bottle, manufactured by: Alkem Laboratories Ltd., INDIA, Distributed by: Ascend Laboratories, LLC., Parsippany, NJ 07054, NDC 67877-626-90	Class II	Drugs	23140190, Exp. Date 12/31/2024	Presence of Foreign Tablet/Capsule: A stray Rasagiline Mesylate 1 mg tablet was discovered in an unopened bottle of Ibuprofen and Famotidine.	Ascend Laboratories, LLC
Vasostrict (vasopressin in 5% Dextrose) Injection, 20 units per 100 mL (0.2 units per mL), 100 mL x 10 Single Dose Vials per carton, Ready to Use, For Intravenous Infusion, Rx Only, Distributed by: Par Pharmaceutical, Chestnut Ridge, NY 10977. NDC: 42023-237-10	Class II	Drugs	Lot # 66702; Exp. 02/2025	Superpotent Drug: Assay from the 3-month and 6-month stability intervals exceeded the upper specification limit.	Par Sterile Products LLC
ANORO ELLIPTA (umeclidinium and vilanterol inhalation powder) 62.5 mcg/25mcg. 1 inhaler contains 30 doses (60 blisters total), Rx Only, Manufactured by GlaxoSmithKline Durham, NC 27701. NDC 0173-0869-10	Class III	Drugs	Lot #: 7Y9S. Exp June 2025	Failed Release Testing: Coarse Particle Mass for umeclidinium Out of Specification	GlaxoSmithKline LLC
Eprontia (topiramate) oral solution, 25 mg/mL, 473 mL Bottle, Rx only, Manufactured for: Azurity Pharmaceuticals, Woburn, MA 01801, NDC 52652-9001-1	Class III	Drugs	Lot #: MB22020B, Exp 12/27/2023	Failed Impurities/Degradation Specifications: Out of specification Impurity C (4,5-desisopropylidene topiramate) result observed during routine stability testing at 18 months.	Azurity Pharmaceuticals, 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
Chloroprocaine Hydrochloride Injection
Cisplatin Injection
Clindaymycin Phosphate Injection
Clonazepam Tablet
Collagenase Clostridium Histolyticum Ointment
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
Flurazepam Hydrochloride Capsule
Furosemide Injection
Gentamicin Sulfate Injection
Heparin Sodium Injection
Hydrocortisone Sodium Succinate Injection
Hydromorphone Hydrochloride Injection
Hydroxypropyl Cellulose (1600000 Wamw) Insert
Indigotindisulfonate Sodium Injection
Isoniazid Tablet
Ketamine Hydrochloride Injection
Ketorolac Tromethamine Injection
Leucovorin Calcium Injection
Lidocaine Hydrochloride Injection
Lidocaine Hydrochloride Solution
Liraglutide Injection
Lisdexamfetamine Dimesylate Capsule
Lisdexamfetamine Dimesylate Tablet, Chewable
Lorazepam Injection
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 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
Riluzole Oral Suspension
Rocuronium Bromide Injection
Ropivacaine Hydrochloride Injection
Semaglutide Injection
Sodium Acetate Injection
Sodium Bicarbonate Injection
Sodium Chloride 0.9% Injection
Sodium Chloride 0.9% Irrigation
Sodium Chloride 14.6% Injection
Sodium Chloride 23.4% Injection
Sodium Phosphate, Dibasic, Anhydrous, Sodium Phosphate, Monobasic, Monohydrate Injection, Solution
Sodium Pyrophosphate Injection
Somatropin Injection
Sterile Water Injection
Sterile Water Irrigant
Streptozocin Powder, For Solution
Sucralfate Tablet
Sufentanil Citrate Injection
Sulfasalazine Tablet
Technetium TC-99M Pyrophosphate Kit Injection
Tirzepatide Injection
Triamcinolone Acetonide Injection
Triamcinolone Hexacetonide Injection
Trimethobenzamide Hydrochloride Capsule
Valproate Sodium Injection
Vecuronium Bromide Injection
Vinblastine Sulfate Injection