

Drug Information Update

September 2022



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NEWLY AVAILABLE GENERICS

Generic Name/ Dosage Form	Brand Name	Manufacturer	Indication
Dabigatran 150 mg oral capsule	Pradaxa	Boehringer Ingelheim	 To reduce the risk of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation For the treatment of deep venous thrombosis (DVT) and pulmonary embolism (PE) in adult patients who have been treated with a parenteral anticoagulant for 5-10 days To reduce the risk of recurrence of DVT and PE in adult patients who have been previously treated For the prophylaxis of DVT and PE in adult patients who have undergone hip replacement surgery For the treatment of venous thromboembolic events (VTE) in pediatric patients 8 to less than 18 years of age who have been treated with a parenteral anticoagulant for at least 5 days To reduce the risk of recurrence of VTE in pediatric patients 8 to less than 18 years of age who have been previously treated
PEG-3350 and electrolytes	Gavilyte-C	Lupin	For bowel cleansing prior to colonoscopy or barium enema X-ray examination
Tolvaptan 15 mg oral tablet	Samsca	Otsuka	For the treatment of clinically significant hypervolemic and euvolemic hyponatremia (serum sodium <125 mEq/L or less marked hyponatremia that is symptomatic and has resisted correction with fluid restriction), including patients with heart failure and Syndrome of Inappropriate Antidiuretic Hormone (SIADH)
Lenalidomide 2.5, 20 mg oral capsules	Revlimid	Celgene	 For the treatment of adult patients with: Multiple myeloma (MM), in combination with dexamethasone MM, as maintenance following autologous hematopoietic stem cell transplantation (auto-HSCT) Transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndromes (MDS) associated with a deletion 5q abnormality with or without additional cytogenetic abnormalities



Generic Name/ Dosage Form	Brand Name	Manufacturer	Indication
			 Mantle cell lymphoma (MCL) whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib Previously treated follicular lymphoma (FL), in combination with a rituximab product Previously treated marginal zone lymphoma (MZL), in combination with a rituximab product
Tazarotene 0.05%, 0.1% topical gel	Tazorac	Allergan	 For the topical treatment of plaque psoriasis of up to 20% body surface area involvement. For the topical treatment of mild to moderate facial acne vulgaris
Timolol preservative- free 0.25% ophthalmic solution dropperette	Timoptic in Ocudose	Bausch and Lomb	Treatment of elevated intraocular pressure in patients with ocular hypertension or openangle glaucoma
Icosapent ethyl 0.5 g oral capsule	Vascepa	Amarin	 As an adjunct to maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, coronary revascularization, and unstable angina requiring hospitalization in adult patients with elevated triglyceride (TG) levels (≥ 150 mg/dL) and established cardiovascular disease or diabetes mellitus and 2 or more additional risk factors for cardiovascular disease As an adjunct to diet to reduce TG levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia



NEW DRUG ENTITIES/STRENGTHS/COMBINATIONS

Drug Name	Generic Name	Description	Comments
Zynteglo 2x to 20x10 ⁶ cell/mL intravenous suspension	betibeglogene autotemcel	One-time gene therapy indicated for and acts as a functional cure for beta-thalassemia. Zynteglo adds functional copies of the beta-globin gene into a patient's own hematopoietic stem cells and then gets readministered as a one-time hospital inpatient infusion. The estimated price will be \$2.8 million.	New Entity
Ryaltris 665 mcg-25 mcg/spray nasal spray	olopatadine HCI/mometasone	Combination of olopatadine and mometasone nasal spray indicated for treatment of symptoms of seasonal allergic rhinitis in adult and pediatric patients 12 years of age or older.	New Combination
Cytalux 3.2 mg/1.6 mL intravenous solution	pafolacianine sodium	Optical imaging agent indicated in adult patients with ovarian cancer as an adjunct for intraoperative identification of malignant lesions.	New Entity
Imbruvica 70 mg/mL oral suspension	ibrutinib	New suspension dosage form produced because of the new indication for pediatric patients age 1 year and older with chronic graft versus host disease (cGVHD) after trial of one or more therapies.	New Dosage Form
Pheburane 483 mg/gram oral granules	sodium phenylbutyrate	New oral granules dosage form and strength of sodium phenylbutyrate, which is indicated for urea cycle disorders (UCDs), involving deficiencies of arbamylphosphate synthetase (CPS), ornithine transcarbamylase (OTC) or argininosuccinic acid synthetase (AS). This new dosage form is likely for pediatric patients. The cost at the maximum dose is \$64,700 per month based on weight.	New Dosage Form and Strength
Doryx MPC 60 mg delayed release tablet	doxycycline hyclate	New strength of Doryx MPC, a formulation of doxycycline that minimizes doxycycline exposure in the upper GI tract, including the esophagus and	New Strength



Drug Name	Generic Name	Description	Comments
		stomach by delaying drug release by approximately 15 to 20 minutes farther into the GI tract.	
Pfizer COVID-19 Bivalent Booster (12y up)(PF) 30 mcg/0.3 mL intramuscular suspension	Covid-19 vaccine, bivalent (pfizer)/pf	New bivalent COVID-19 booster authorized for patients 12 years and older. Booster doses of either vaccine should be administered at least 2 months after completion of primary vaccination or receipt of a booster dose of any authorized or approved monovalent COVID-19 vaccine.	New Entity
Pfizer COVID-19 Bivalent Booster (5-11yr)(PF) 10 mcg/0.2 mL intramuscular suspension	Covid-19 vaccine, bivalent (pfizer)/pf	New bivalent COVID-19 booster intended for patients between 5 to 11 years. This product is not yet authorized.	New Entity
Moderna COVID-19 Bivalent Booster (18y up)(PF) 50 mcg/0.5 mL intramuscular suspension	Covid-19 vaccine, bivalent (moderna)/pf	New bivalent COVID-19 booster authorized for patients 18 year and older. Booster doses of either vaccine should be administered at least 2 months after completion of primary vaccination or receipt of a booster dose of any authorized or approved monovalent COVID-19 vaccine.	New Entity
Zonisade 100 mg/5 mL oral suspension	zonisamide	New oral suspension	New Dosage Form
bortezomib 2.5 mg/mL intravenous solution	bortezomib	New dosage form as a smaller 2.5 mg/mL IV vial	New Dosage Form
Xenpozyme 20 mg intravenous solution	Olipudase alfa-rpcp	Hydrolytic lysosomal sphingomyelin-specific enzyme indicated for treatment of non–central nervous system manifestations of acid sphingomyelinase deficiency (ASMD) in adult and pediatric patients. ASMD, also called Neimann-Pick disease, is a rare, progressive, genetic disorder resulting in the deficiency of sphingomyelinase, which is required to metabolize sphyingomyelin. This deficiency leads to	New Entity



Drug Name	Generic Name	Description	Comments
		the accumulation of sphingomyelin results in profound loss of neurologic function and sometimes death by the age of 2 or 3 years, depending on the severity of the disease. Xenpozyme provides an exogenous source of sphingomyelinase.	
Spevigo 60 mg/mL intravenous solution	Spesolimab-sbzo	Interleukin (IL)-36 receptor antagonist indicated for the treatment of generalized pustular psoriasis (GPP) flares in adults. GPP is a rare form of psoriasis that results in the widespread eruption of pustules and erythematous plaques, often accompanied by fever and malaise.	New Entity
CNJ-016 (National Stockpile) 50,000 unit intravenous solution	vaccinia immune globulin human	Vaccinia Immune Globulin Intravenous (VIVIG) indicated for the treatment of eczema vaccinatum, progressive vaccinia, severe generalized vaccinia, vaccinia infections in individuals who have skin conditions such as burns, impetigo, varicellazoster, or poison ivy; or in individuals who have eczematous skin lesions because of either the activity or extensiveness of such lesions, and aberrant infections induced by vaccinia virus that include its accidental implantation in eyes (except in cases of isolated keratitis), mouth, or other areas where vaccinia infection would constitute a special hazard.	New Entity
Bludigo 8 mg/mL (0.8 %) intravenous solution	Indigotindisulfonate sodium	Diagnostic dye indicated for use as a visualization aid used in the cystoscopic assessment of the integrity of the ureters in adults following urological and gynecological open, robotic, or endoscopic surgical procedures.	New Route
Orkambi 75 mg-94 mg oral granules in packet	Lumacaftor/ivacaftor	New oral granule strength due to the expanded indication to patients one year of age or older with	New Strength



Drug Name	Generic Name	Description	Comments
		cystic fibrosis who are homozygous for the F508del mutation in the CFTR gene. It was previously only indicated in ages two years and older.	
Sotyktu 6 mg tablet	Deucravacitinib	First-in-class selective tyrosine kinase 2 (TYK2) inhibitor indicated for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.	New Entity
xenon-133 in air 370 MBq (10 mCi), 740 MBq (20 mCi) gas for inhalation	xenon 133 in air	New formulation of a diagnostic agent used for the evaluation of pulmonary function.	New Formulation



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†
Pemazyre	pemigatinib 4.5, 9, 13.5 mg oral tablets	Incyte	 For the treatment of adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s). For the treatment of adults with relapsed or refractory myeloid/lymphoid neoplasms (MLNs) with FGFR1 rearrangement
Imbruvica	ibrutinib 70 mg/mL oral suspension; ibrutinib 70, 140, 280, 420, 560 mg oral tablets	Pharmacyclics	 Kinase inhibitor indicated for the treatment of: Adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s). Adult patients with chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL) Adult patients with chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL) with 17p deletion Adult patients with Waldenström's macroglobulinemia (WM) Adult patients with marginal zone lymphoma (MZL) who require systemic therapy and have received at least one prior anti-CD20-based therapy



Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication†
			 This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s). Adult and pediatric patients age 1 year and older with chronic graft versus host disease (cGVHD) after failure of one or more lines of systemic therapy
Lynparza	olaparib 100, 150 oral tablet	AstraZeneca	Poly (ADP ribose) polymerase (PARP) inhibitor indicated for the treatment of adult patients with deleterious or suspected deleterious germline BRCA mutated advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy (product withdrawn from market)
Imfinzi	durvalumab 120 mg/2.4 mL, 500 mg/10 mL IV vial	AstraZeneca	 Programmed death-ligand 1 (PD-L1) blocking antibody indicated: For the treatment of adult patients with unresectable, Stage III non-small cell lung cancer (NSCLC) whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy In combination with etoposide and either carboplatin or cisplatin, as first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC) In combination with gemcitabine and cisplatin, as treatment of adult patients with locally advanced or metastatic biliary tract cancer (BTC).
Zonisade	zonisamide 100 mg/5 mL oral suspension	Azurity	Adjunctive therapy for the treatment of partial onset seizures in adults and pediatric patients 16 years of age and older
Orkambi	lumacaftor/ivacaftor 75 mg/94 mg, 100 mg/125 mg, 150 mg/188 mg oral granule packet	Vertex	For the treatment of cystic fibrosis (CF) in patients aged 1 2-years and older who are homozygous for the F508del mutation in the CFTR gene



RECALLS

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
MILK OF MAGNESIA USP, 2400 mg/30 mL, Magnesium Hydroxide, 30 mL cup, packaged in 10 cups per tray, 10 trays per carton, For Institutional Use Only, Major Pharmaceuticals, 17177 N Laurel Park Dr., Suite 233, Livonia, MI 48152, NDC 0904-6846-73.	Class I	Drugs	Lot# 20071A, EXP Jul. 2022	Microbial Contamination of Non- Sterile Products	Plastikon Healthcare LLC
MILK OF MAGNESIA USP, 2400 mg/10 mL, Magnesium Hydroxide, 30 mL cup, packaged in 10 cups per tray, 10 trays per carton, For Institutional Use Only, Major Pharmaceuticals, 17177 N Laurel Park Dr., Suite 233, Livonia, MI 48152, NDC 0904-6840-72.	Class I	Drugs	Lot # 20074A, EXP Jul. 2022	Microbial Contamination of Non- Sterile Products.	Plastikon Healthcare LLC
Magnesium Hydroxide 1200 mg, Aluminum Hydroxide 1200 mg, Simethicone 120 mg per 30 mL, 30 mL cup, packaged in 10 cups per tray, 10 trays per carton, For Institutional Use Only, Major Pharmaceuticals, 17177 N Laurel Park Dr., Suite 233, Livonia, MI 48152, NDC 0904-6838-73	Class I	Drugs	Lot# 20076A, EXP Jul. 2022, 20079A, 20081A, EXP Aug. 2022; 21096A, EXP Oct. 2022; 21115A, 21103A, EXP Sep. 2022.	Microbial Contamination of Non- Sterile Products.	Plastikon Healthcare LLC
Magnesium Hydroxide 2400 mg, Aluminum Hydroxide 2400 mg, Simethicone 240 mg MAX, per 30 mL Oral Suspension, 30 mL cup, packaged in 10 cups per tray, 10 trays per carton, For Institutional Use Only, Major Pharmaceuticals, 17177 N Laurel Park Dr.,	Class I	Drugs	Lot #: 20051A, EXP Aug. 2022; 20088A, EXP Sep. 2022.	Microbial Contamination of Non- Sterile Products.	Plastikon Healthcare LLC



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Suite 233, Livonia, MI 48152, NDC 0904- 6839-73					
CVS Health, Magnesium Citrate SALINE LAXATIVE, Oral Solution, (1.745 g/fl oz), Lemon Flavor, 10 FL OZ (296 mL), a) UPC 0 50428 30594 2; b) UPC 0 50428 33517 8; Distributed by: CVS Pharmacy, Inc., One CVS Drive, Woonsocket, RI 02895.	Class I	Drugs	Lot# (a) 0556808, EXP 12/8/2023; 0563095, EXP 2/18/2024; 0562243, EXP 2/17/2024; 0557622, EXP 1/12/2024; (b) 0498395, EXP 8/8/2022	Microbial contamination of non- sterile products.	Vi-Jon, LLC
equate Magnesium Citrate, SALINE LAXATIVE, (1.745g/fl oz) 10 FL OZ (296mL), Grape Flavor, Distributed By: Walmart, Inc. Bentonville, AR 72716; NDC 49035-592-38 UPC 6 81131 28715 9	Class I	Drugs	Lot# 0525509, EXP 3/6/2023	Microbial contamination of non- sterile products.	Vi-Jon, LLC
EQUALINE magnesium citrate saline laxative, oral solution, (1.745 g/fl oz), DYE FREE lemon flavor, 10 FL OZ (296 mL), Distributed by Supervalu Inc. Eden Prairie, MN 55344 USA, or Distributed By UNFI Providence, RI 02908, NDC 41163-769-38 UPC 0 41163 50068 6	Class I	Drugs	Lot # 0511629, EXP 12/4/2022	Microbial contamination of non- sterile products.	Vi-Jon, LLC
Kroger, Magnesium Citrate SALINE LAXATIVE, Oral Solution, 1.745 g, Lemon Flavor, 10 FL OZ (296 mL), Distributed By The Kroger CO Cincinnati, Ohio 45202; NDC 30142-899-38 UPC 0 41260 00182 6	Class I	Drugs	Lot# 0557622, EXP 1/12/2024	Microbial contamination of non- sterile products.	Vi-Jon, LLC
meijer, magnesium citrate Saline Laxative, Oral Solution, (1.745 g/fl oz), Lemon Flavor, 10 FL OZ (296 mL), Dist. By Meijer Distribution, Inc. Grand Rapids, MI 49544; NDC 41250-708-38 UPC 7 13733 45945 7	Class I	Drugs	Lot# 0557622, EXP 1/12/2024	Microbial contamination of non- sterile products.	Vi-Jon, LLC



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
P, magnesium citrate SALINE LAXATIVE, Oral Solution, (1.745 g/fl oz), Lemon Flavor, 10 FL OZ (296 mL), Distributed By Publix Super Markets, Inc. 3300 Publix Corporate Parkway, Lakeland, FL 33811; NDC 56062-266-38 UPC 0 41415 50673 2	Class I	Drugs	Lot # 0562243, EXP 2/17/2024	Microbial contamination of non- sterile products.	Vi-Jon, LLC
Rexall, Magnesium Citrate Saline Laxative, Oral Solution, (1.745 g/fl oz), Lemon Flavor, 10 FL OZ (296 mL), Distributed By Dolgencorp. LLC 100 Mission Ridge, Goodlettsville, TN 37072 or Distributed By Old East Main Co. 100 Mission Ridge Goodlettsville, TN 37072; NDC 55910-183- 38, UPC 0 72785 13418 8	Class I	Drugs	Lot # 0511629, EXP 12/4/2022; 0562243, EXP 2/17/2024	Microbial contamination of non- sterile products.	Vi-Jon, LLC
SWAN, Citroma MAGNESIUM CITRATE, Saline Laxative, Oral Solution, (1.745 g/fl oz), Lemony Flavor, 10 FL OZ (296 mL), Distributed by: Vi-Jon, Inc. One Swan Drive Smyrna, TN 37167; NDC 0869-0166-38 UPC 0 72785 13405 8	Class I	Drugs	Lot # 0562243, EXP 2/17/2024	Microbial contamination of non- sterile products.	Vi-Jon, LLC
Topcare health, Magnesium Citrate, SALINE LAXATIVE, Oral Solution, (1.745 g/fl oz), Cherry Flavor, 10 FL OZ (296 mL), Distributed By Topco Associates LLC Elk Grove Village, IL 60007; NDC 36800-164-38 UPC 0 36800 45530 6	Class I	Drugs	Lot # 0546394, EXP 9/29/2023	Microbial contamination of non- sterile products.	Vi-Jon, LLC
Walgreens, Dye-Free, Magnesium Citrate, SALINE LAXATIVE, Oral Solution, (1.745 g/fl oz), Lemon Flavor, 10 FL OZ (296 mL), Distributed By: Walgreen Co. 200 Wilmot	Class I	Drugs	Lot # 0505266, EXP 10/17/2022	Microbial contamination of non- sterile products.	Vi-Jon, LLC



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Rd., Deerfield, IL 60015, NDC 0363-8166-38 UPC 3 11917 20160 3 (green label)					
Walgreens, Dye-Free, Magnesium Citrate, SALINE LAXATIVE, Oral Solution, (1.745 g/fl oz), Grape Flavor, 10 FL OZ (296 mL), Distributed By: Walgreen Co., 200 Wilmot RD., Deerfield, IL 60015; NDC 0363-7162-38 UPC 3 11917 20159 7 (purple label).	Class I	Drugs	Lot # 0506255, EXP 10/24/2022	Microbial contamination of non- sterile products.	Vi-Jon, LLC
PROPOFOL Injectable Emulsion, 1 g/100 mL (10 mg/mL), packaged in 100 mL glass fliptop vial (NDC 0409-4699-54) further packaged in a tray of 10 vials (NDC Carton: 0409-4699-24), Rx only, Distributed by Hospira, Inc., Lake Forest, IL 60045 USA	Class I	Drugs	Lot#: EA7470, Exp 6/1/2023	Presence of particulate matter	Pfizer Inc.
Novelty Hand Sanitizer with Silicone Wrap SKU 998890 Novelty Hand Sanitizer Assorted SKU 999330 Purell Hand Sanitizer Essentials 1 FL OZ SKU 2006819 Luxury Hand Sanitizer 16.9 FL OZ SKU 2007723 Suave Hand Sanitizer Lotion 3 FL OZ SKU 2096469 Purell Hand Sanitizer Original 6.5 FL OZ SKU 2095985 Purell Hand Sanitizer Soothing Aloe 6.5 Fluid Ounces SKU 2095986 distributed to specific Family Dollar Stores 04/30/2022 through 06/10/2022.	Class II	Drugs	SKUs: 998890; 999330; 2006819; 2007723; 2096469; 2095985; 2095986	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.
AMBI Skin Cream for normal skin 2 OZ SKU 2024219 AMBI Skin Cream for oily skin 2 OZ SKU 2024222. distributed to specific Family Dollar Stores 04/30/2022 through 06/10/2022.	Class II	Drugs	SKUs: 2024219; 2024222	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
BANANA BOAT SPRT CLR SPRY SPF50 6 FL OZ SKU 2007524 SUNTONE SPORT SPRAY SPF 50 5.5 OZ SKU 2096102 HAWAIIAN TROPIC TANNING OIL SPRAY PUMP SPF 25 8 FL OZ SKU 2096111 BANANA BOAT SPORT ULTRAMIST SPRAY SPF 65 6 OZ SKU 2096117 COPPERTONE WATERBABIES LOTION SPF 50 8 FL OZ SKU 2097635 COPPERTONE SPORT SPRAY SPF 50 5.5 OZ SKU 2097636 BANANA BOAT SPRT LTION SPF 50 8 FL OZ SKU 2099592 HAWAIIAN TROPIC SHEER TOUCH LOTION SPF 30 8 FL OZ SKU 2006432 BB KIDS SUN SCREEN MIST SPRAY SPF 100 6 OZ SKU 2007523 SUNTONE KIDS SPRAY SPF 50 6 OZ SKU 2096096 NEUTROGENA BCH DFNSE SPR SPF 70 SKU 2097632 BANANA BOAT KDS SPRT SPRY SPF50 6FL OZ SKU 2097655 BANANA BOAT DRY OIL MST SPRY 15 SPF 6 OZ SKU 2097794 BANANA BOAT TAN DRY OIL MIST 4 SPF 6 OZ SKU 2097144 COPPERTONE GLOW SPRAY SPF 50 5OZ SKU 2096124 COPPERTONE SPORT LOTION SPF 50 8.75 FLOZ SKU 2096130 NEUTROGENA ULTRA SHEER LOTN SPF 55 3 FL OZ SKU 2097637 SUNTONE KIDS LOTION SPF 50 6 FL OZ SKU 2096101 BANANA BOAT SPORT ULTRA MIST 30 SPF 6 OZ SKU 2097141 COPPERTONE SPORT SPRAY SPF 30 5.5 OZ SKU 2097083 SUNTONE SPORT SPRAY SPF 70 5.5 OZ SKU 2008234 SUNTONE SPORT	Class II	Drugs	SKUs: 2007524, 2096102, 2096111, 2096117, 2097635, 2097636, 2099592, 2007523, 2096096, 2097632, 2097655, 2097794, 2097144, 2096130, 2097637, 2096101, 2097141, 2097083, 2008234, 2096099, 2097084; 2006432	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
LOTION SPF 50 6 FL OZ SKU 2096099 COPPERTONE KIDS SPRAY SPF 50 5.5 OZ SKU 2097084 distributed to specific Family Dollar Stores 04/30/2022 through 06/10/2022.					
Dermasil Dry Skin Treatment 10 OZ SKU 2098068 Aveeno Daily Moisturizing Lotion 5 OZ SKU 2005444 Aveeno Baby Daily Moistue Lotion 8 OZ SKU 900016 Vaseline Mens Extra Strength Body and Face Lotion 10 OZ SKU 2003674 distributed to specific Family Dollar Stores 04/30/2022 through 06/10/2022.	Class II	Drugs	SKUs: 2098068, 2005444, 900016, 2003674	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.
COLGATE MAX FRESH CLEAN MINT 1.90Z SKU 900596 COLGATE CAVITY PROTECTION 60Z 3PK SKU 900734 SENSODYNE REPAIR AND PROTCT WHITNG 3.4 OZ SKU 901003 COLGATE BSPW PASTE BRISK MINT 6 OZ 2PK SKU 901658 COLGATE MAX FRESH COOL MINT 60Z 2PK SKU 901785 COLGATE BSPW PASTE 6 OZ 3PK SKU 902143 CREST CMPLT SCOPE OUTLST PSTE 5.40Z 2 PK SKU 902701 COLGATE TOTAL WHITENING TP 4.8 OZ SKU 902967 CREST 3D WHITE BRILLIANCE CHARCOAL 3.9 OZ SKU 903463 COLGATE BSPW GEL FROSTY MINT 6 OZ SKU 905026 ARM & HAMMER COMPLETE CARE BKS PRX TP 6 OZ SKU 905028 COLGATE BSPW PASTE BRISK MINT 2.5 OZ SKU 905703 COLGATE BSPW PASTE BRISK MINT 6 OZ SKU 907121	Class II	Drugs	SKUs: 900596, 900734, 901003, 901658, 901785, 902143, 902701, 902967, 903463, 905026, 905028, 905703, 907121, 907125, 907151, 907766, 907839, 907872, 998200, 998278, 998881, 998902, 999286, 999318, 999498, 999633, 999750, 999916, 900353, 903152, 907327, 999760, 999910, 907160, 900791, 901677, 907170, 998277, 999282, 999937, 907165, 907220, 902966, 906406, 907329, 998257, 999723, 900592, 907865, 901243,	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
CREST BS N PX WHTE TUBE FRESH MINT 5.7			905045, 998741, 902134,		
OZ SKU 907125 COLGATE SPARKLING			900728, 901784, 902124,		
WHITE MINT ZING 2.5 OZ SKU 907151 ARM			902840, 905517, 907136,		
& HAMMERADV WHITE TP 4.3 FL OZ SKU			907781, 998268, 998397,		
907766 COLGATE MAX FRESH COOL MINT			998730, 999099, 999285,		
TP 6 OZ SKU 907839 CREST COMPLETE			902363, 903245, 903453		
SCOPE OUTLAST TP 5.4 OZ SKU 907872					
COLG MAX FRESH COOL MINT TP 6.3 OZ 3PK					
SKU 998200 COLGATE OW STAIN FIGHTR					
TOOTHPASTE 4.2 OZ SKU 998278 COLGATE					
MAX FRESH WHTNING CHRCOAL TP 6 OZ					
SKU 998881 COLGATE CHARCOAL TP 2.2 OZ					
SKU 998902 CREST 3D WHITE STAIN					
ERASER 3.10Z TWN PK SKU 999286					
COLGATE ESSENTIALS CHARCOAL PASTE 4.6					
OZ SKU 999318 COLGATE TOTAL					
CLEANMINT TOOTHPASTE 4.8 OZ SKU					
999498 COLGATE OW					
STAINFIGHTERCLEANMNT4.2OZ 2PK SKU					
999633 COLGATE OW STAIN FIGHTER					
CLEAN MNT 4.2 OZ SKU 999750 COLGATE					
DEEP CLEAN GEL TOOTHPASTE 2.5 OZ SKU					
999916 CREST TARTAR PROTECTION PASTE					
5.7 OZ SKU 900353 COLGATE TOTAL					
WHITENING GEL 4.80Z 2 PK SKU 903152					
CREST CAVITY PROTECTION PASTE 5.7 OZ					
SKU 907327 CREST PRO HEALTH					
WHITENING GEL TP 4.6 OZ SKU 999760 AIM					
CAVITY PRTCT MINT GEL 4.5 OZ SKU 999910					
CREST 3D WHITE RADIANT MINT 2.7 OZ SKU					



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
907160 CR FRESH WHT PEP GIM 2.4 OZ					
SKU 900791 COLGATE SENSITIVE					
WHITENING PASTE 6 OZ SKU 901677					
COLGATE TRIPLE ACTION 2.5 OZ SKU					
907170 COLGATE OW STAIN PREVENTION					
TP 2.1 OZ SKU 998277 CREST 3D WHITE					
CHARCOAL 2.7 OZ SKU 999282 ARM &					
HAMMER PEROXICARE MINT PASTE 6 OZ					
SKU 999937 CREST ANTI CAVITY PASTE 2.4					
OZ SKU 907165 CLOSE UP CINN RED GEL TP					
4 OZ SKU 907220 COLGATE BSPW GEL TP					
6OZ 3PK; SKU 902966 COLGATE TOTAL					
WHTN GEL TP 4.8 OZ SKU 906406 COLGATE					
CAVITY PROTECTION 6 OZ SKU 907329					
COLGATE MAX FRSH ADV WHTN CLN MNT					
TP 6 OZ SKU 998257 CG OW SF MINT PASTE					
2.0 OZ SKU 999723 COLGATE KIDS JUNIOR					
BUBBLE FRUIT 3.5 OZ SKU 900592 CREST					
BKING SDA PEROXIDE WHTNG TP 2.4 OZ SKU					
907865 CREST KIDS SPRKL TPST 2.2 OZ SKU					
901243 CREST 3D WHITE ARTIC FRESH 2.7					
OZ SKU 905045 COLGATE RENEWAL GUM					
REVITALIZE TP 3 OZ SKU 998741 ULTRA					
BRITE ADV WHITENING TP 6 OZ SKU 902134					
COLGATE BASE DEEP CLEAN GEL 6 OZ SKU					
900728 COLGATE TOTAL WHTN PASTE TP					
4.8OZ 2PK SKU 901784 SENSODYNE PRO					
NAMELGENTLE WHT 2.7 OZ SKU 902124					
SWAN ULTRA CLEAN ARCTIC MINT 33.8 FL					
OZ SKU 902840 CREST 3DW ULTRA WHITE 3					



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
OZ SKU 903453 COLGATE KIDS TP ASRTD CHARACTERS 4.6 OZ SKU 905517 PEPSODENT ORIGINAL TP 4.5 OZ SKU 907136 SENSODYNE EXTRA WHTEN TP 2.7 OZ SKU 907781 CREST PSTE DNSIFY DAILY WHITENING 4.1 OZ SKU 998268 ORAJEL PP FLUORIDE TOOTHPASTE 4.2 OZ SKU 998397 CREST 3D WHITE BRILLIANCE THPASTE 2.7 OZ SKU 998730 TOM'S KIDS STRAWBERRY ANTICAVITY 5.1 OZ SKU 999099 CREST 3D WHITE STNERSR ICY CLN MNT 3.1 OZ SKU 999285 SENSODYNE COMPLETE FRESH PASTE 3.4 OZ SKU 902363 CREST PRO HEALTH DEEP CLEAN TP 3.5 OZ SKU 903245 distributed to specific Family Dollar Stores 04/30/2022 through 06/10/2022.					
Listerine Cool mint Mouthwash 250 mL SKU 900733 Crest Scope Outlast Mint Mouthwash 1 Liter SKU 902704 Swan Mouthwash Green Mint 1 LTR SKU 908114 Colgate Peroxyl Antiseptic Mouth Sore Rinse 8.4 FL OZ SKU 998273 Listerine Cool Mint Mouthwash 50.72 FL OZ SKU 999050 Swan Spring Mint Antiseptic Mouth Rinse 8.5 OZ SKU 900273 Swan Original Antiseptic Mouth Rinse 8.5 OZ SKU 900938 Colgate Optic White Mouthwash 16 FL OZ SKU 999043 Crest Scope Classic Original Min Mouthwash 1 Ltr SKU 908109 Listerine Cool Mint Mouthwash 500 mL SKU 908223 Act Kids	Class II	Drugs	SKUs: 900733; 902704; 908114; 998273; 999050; 900273; 900938; 999043; 908109; 908223; 999935; 903150; 908466; 908123; 903156; 900980; 901904; 903159; 908004; 908005; 908465; 998269; 999752; 999762	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Bubble Gum Blowout Mouthwash 16.9 Fl OZ					
SKU 999935 Swan Ice Mint Antiseptic					
Mouth Rinse 8.5 OZ SKU 903150 Swan					
Mouthwash Cool Mint 1 Liter SKU 908466					
Crest Mouthwash Pro Health Multi					
Protection Mint 1 Liter SKU 908123, Colgate					
Mouthwash Total Advanced Peppermint					
Blast 1 Liter SKU 903156 Listerine Total Care					
Freshmine 1 Liter SKU 900980 Listerine					
Ultra Clean Cool Mint 1 Liter SKU 901904					
Listerine Mouthwash Freshburst 1 Liter SKU					
903159 Listerine Mouthwas Original Amber					
1 Liter SKU 908004 Listerine Mouthwash					
Coolmint 1 Liter SKU 908005 Swan					
Antiseptic Rinse Amber 1 Liter SKU 908465					
Crest Scope Mouthwash All Day 1 Liter SKU					
998269 Listerine Mouthwash Coolmint 95					
Milliliters SKU 999752 Swan Fresh Mint					
Mouthwash 1 Liter SKU 999762 distributed					
to specific Family Dollar Stores 04/30/2022					
through 06/10/2022.					
Hydrogen Peroxide 16 fl. oz. and 32 oz.				CGMP Deviations: product held	Family Dollar
bottles distributed to specific Family Dollar	Class II	Drugs	SKUs: 909221, 901675	outside appropriate storage	Stores, Llc.
Stores 04/30/2022 through 06/10/2022.				temperature conditions.	Stores, Lic.
SUAVE INV SLD PWDR 1.2 OZ SKU2004504			SKUs: 2098901; 2005211;		
SUAVE AP INV SOLID SWEET PEA 1.2 OZ SKU			2004504; 2004622;	CCMP Doviations: product hold	
2004622 LADY SPEED STICK AP WILD	Class II	Druge	2005184; 2028126;	CGMP Deviations: product held	Family Dollar
FREESSIA 1.4OZ SKU 2005184 SUAVE AP	Class II	Drugs	2028363; 2028365;	outside appropriate storage	Stores, Llc.
DEOD POWDER 2.6 OZ 2PK SKU 2028126			2028378; 2028538;	temperature conditions.	
SCRT IN SLD PWDR FRSH 2.10Z 2PK SKU			2028544; 2095889;		



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
2028363 LADY SPD STK AP INV PWDR			2095896; 2099968;		
1.4OZ SKU 2028365 DEGREE INV SLD XBLST			2005168; 2007730;		
2.7 OZ 2PK SKU 2028378 SECRET DEO INV			2098900; 2099254;		
SHWR FRSH 2.1 OZ SKU 2028538 SUAVE			2003472; 2005214;		
DEO TRPCL PARADISE 1.2 OZ SKU 2028544			2007898; 2001333;		
SECRET DS WHTE PECH ARGN OIL SPRY 4.1			2002557; 2004512;		
OZ SKU 2095889 SECRET DS WILD ROSE OIL			2028253; 2096622;		
SPRAY 4.1 OZ SKU 2095896 DOVE			2003471; 2001309;		
ADVANCED COOL ESSENTIALS 2.60Z SKU			2028310; 2006902;		
2099968 OLD SPICE RED ZONE DEO			2098479; 2001336;		
SWAGGER 30Z SKU 2005168 OLD SPICE HE			2028566; 2004735;		
FRESH DEO 2.4OZ 2PK SKU 2007730			2044343; 2097527;		
SECRET OUTLAST CLEAN LVNDR GEL 2.60Z			2098905; 2028222;		
SKU 2098900 OLD SPICE WC IS BEARGLOVE			2006098; 2001311;		
2.60Z SKU 2099254 DEGREE FMAL BLCK			2004835; 2005220;		
WHT PURERN DRYSPRY3.80Z SKU 2003471			2028194; 2028249;		
DEGREE EXTREME BLAST IS 2.7 OZ SKU			2028255; 2028257;		
2005214 SECRET FRESH IS COCOA BUTTER			2028315; 2044190;		
2.60Z SKU 2007898 SECRET OUTLAST IS			2097528; 2097534;		
COMPLETELY CLEAN 2.60Z SKU 2001333			2028218; 2004752;		
DEGREE ML INVIS SLD COOL RUSH 1.70Z			2028258; 2098472		
SKU 2002557 OLD SPICE RZ SWAGGER 2.6					
OZ SKU 2004512 DOVE AP INV SLD FRESH					
1.6 OZ SKU 2028253 DEGREE FOR WOMEN					
IS BW PURE RAIN 2.6 OZ SKU 2096622					
DEGREE BLCK WHIT PURE CLN DRY SPRY 3.8					
OZ SKU 2003471 DEGREE MEN INV SLD					
SPORT TWIN 2.7 OZ 2PK SKU 2001309					
SECRET INVS SLD PWDR FRSH 2.1 OZ SKU					
2028310 DOVE ADVANCED CARE IS					



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
COCONUT 2.6 OZ SKU 2006902 SECRET					
FRESH EXP PARIS ROSE GEL 2.6 OZ SKU					
2098479 OLD SPICE FIJI 2.6OZ SKU 2001336					
SECRET AP STICK FRSH PWD 1.70Z SKU					
2028566 DOVE MEN AP INV SLD XTRA FRSH					
2.7 OZ SKU SECRET OUTLAST CLR GEL PWDR					
PROTEC 2.60Z SKU 2044343 DOVE CARING					
COCONUT DRY SPRAY 3.80Z SKU 2097527					
DOVE CLR FNSH 100 CLRS DRY SPR 3.8FLOZ					
SKU 2098905 AXE AP INV SLD DK TEMPT					
2.70Z SKU 2028222 DOVE DRY SPRAY COOL					
ESSENTIALS 3.8 OZ L2 SKU 2006098					
DEGREE FMLE INV SLD TWN PWDR 2.6 OZ					
2PK SKU 2001311 OLD SPICE HE					
PLAYMAKER 2.4 OZ SKU 2004835 GIL CLEAR					
GEL COOL WAVE 2.85 OZ 2PK SKU 2005220					
DEGREE WMNS SEXY INTRIGUE 2.6 OZ SKU					
2028194 MENNEN SPEED STCK AP INV SLD					
FRSH 1.8 OZ SKU 2028249 DOVE INV SLD					
POWDER 1.6 OZ SKU 2028255 DEGREE AP					
INV SLD XBLAST 1.7 OZ SKU 2028257 AH					
ULTRAMAX INV SLD FRSH SCT 1 OZ SKU					
2028315 POWER STICK LADY AP POWDER					
FRESH 1.7 OZ SKU 2044190 DOVE MENS					
INV SOLID CLEAN COMFORT 1.7 OZ SKU					
2097528 AXE APOLLO INV SOLID					
DEODORANT 1.7 OZ SKU 2097534 DEGREE					
AP INV SLD FRESH 2.6OZ SKU 2028218					
SUAVE AP INV SLD TRPCL PARDSE 2.6 OZ					
SKU 2004752 DEGREE AP INV SLD SHOWR					



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
1.6 OZ SKU 2028258 SUAVE MENS ACTIVE SPORT 2.7OZ SKU 2098472 OLD SPICE INV SLD KRAKENGARD 2.6OZ SKU 2098901 AXE ANARCHY INVISIBLE SOLID 2.7 OZ SKU 2005211 distributed to specific Family Dollar Stores 04/30/2022 through 06/10/2022.					
SOFTSOAP ANTI BACTRIAL LQ SOAP 11.25 FLOZ SKU 2005090 DIAL LHS WHITE TEA AND VITAMIN E 7.5FLOZ SKU 2007700 SOFTSOAP LHS CC ANTIBAC ORANGE 50 FL OZ SKU 2007708 SPA SOAP ANTIBAC GLD LHS PUMP 20.2 FL OZ SKU 2097440 DIAL FOAMING LHS POWER BERRIES 7.5 FL OZ SKU 2044098 SOFTSOAP LIQUID HAND SOAP FERSH CITRUS AB 11.25 FL OZ SKU 2005088 SPA SOAP HNDSP ANTBCTRL ULTR2X GLD 64 FL OZ SKU 2008290 DIAL FOAMING LHS SPRING WATER 7.5 FL OZ SKU 2044177 DAWN ULTRA ANTIBAC APL BLOSSOM 21.6 FLOZ SKU 1498425 DAWN ULTRA APPLE 15.5 FL OZ SKU 1414227 distributed to specific Family Dollar Stores 04/30/2022 through 06/10/2022.	Class II	Drugs	SKUs: 1498425; 1414227; 2005090; 2007700; 2007708; 2097440; 2044098; 2005088; 2008290; 2044177	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.
Ready in case ACETAMINOPHEN PM CAPLETS 24 CT SKU 900559; TYLENOL CHILD GRAPE 4 FL OZ SKU 901600 TYLENOL CHILD ORAL SUSPENSION CHERRY 4 FO 913104 TYLENOL INFANTS DROPS DF CHERRY 1OZ SKU 999108 TYLENOL PM CAPLET 24 CT	Class II	Drugs	SKUs:900559; 901600; 913104; 999108; 900603; 916986; 901155	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
SKU 900603 TYLENOL EXTRA STRENGTH CAPLET 24 CT SKU 916986 TYLENOL 8HR MSL ACHE PAIN RD CAPLET 24 CT SKU 901155 distributed to specific Family Dollar Stores 04/30/2022 through 06/10/2022. MOTRIN IB CAPLETS 24CT SKU999394; GOOD SENSE IBUPROFEN 200MG TABLETS 24CT SKU 900556;GOOD SENSE IBUPROFEN 200MG CAPLET 50 CT SKU 902333 MOTRIN CHILDREN'S BUBBLEGUM 4 FL OZ SKU 903048 GOOD SENSE IBUPROFEN REGULAR SOFTGELS 160CT SKU 999373 GOOD SENSE IBUPROFEN 200 MG CAPLET 100 CT SKU 902359 MOTRIN IB CAPLET 50 CT SKU 900604 GOOD SENSE IBUPROFEN IB CAPLET 100 CT SKU 913989 GOOD SENSE IBUPROFEN 200 MG SOFTGEL 20CT SKU 916994 ADVIL LIQUID GEL 40 CT SKU 916071 GOOD SENSE IBUPROFEN PM 200 MG 20 CT SKU 917004 ADVIL PM CAPLET 20CT SKU 913010 GOOD SENSE IBUPROFEN TABLET 100 CT SKU 913991 distributed to specific Family Dollar Stores 04/30/2022 through 06/10/2022. Specifically:	Class II	Drugs	SKUs: 999394; 900556; 902333; 903048; 999373; 902359; 900604 913989; 916994; 916071; 917004; 913010; 913991	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.
FS CLOTRIMAZOLE ANTI FUNGAL CREAM .5 OZ distributed to specific Family Dollar Stores 04/30/2022 through 06/10/2022.	Class II	Drugs	SKU: 910334	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.
DR SCHOLLS ANTI FUNGAL SPRAY PWDER 4.7 OZ SKU 998250 PREMIER ANTFGL TLNFTT LQ SPRY 5.3 FL OZ SKU 911077	Class II	Drugs	SKUs: 998250; 911077	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
distributed to specific Family Dollar Stores 04/30/2022 through 06/10/2022.					
ALEVE ANALGESIC BACK MUSCLE 24 CT SKU 999787 ALEVE PM CAPLETS 20 CT SKU 900442 ALEVE CAPLET 50 CT SKU 916980 distributed to specific Family Dollar Stores 04/30/2022 through 06/10/2022.	Class II	Drugs	SKUs: 999787; 900442; 916980	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.
DIAL MENS EUCALYPTUS AB BODY WASH 20 FLOZ SKU 2096030 distributed to specific Family Dollar Stores 04/30/2022 through 06/10/2022.	Class II	Drugs	SKU: 2096030	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.
DISNEY LICENSED ANTI BAC WIPES 20 CT SKU 998908; ANTIBACTERIAL WIPES 40CT SKU 2007538 distributed to specific Family Dollar Stores 04/30/2022 through 06/10/2022.	Class II	Drugs	SKUs: 998908; 2007538	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.
DOCTOR DANDRUF 2N1 SHAMP CLN APL 13.5FLOZ SKU 2005726 SUAVE 2N1 MENS CC ANTI DNDRF SHMP 28 FLOZSKU 2006512 MANE N TAIL 2 IN 1 ANTI DANDRUFF 12 FL OZ SKU 2024652 HEAD AND SOULDERS 2N1 SMOOTH SILKY 12.8 FL OZ SKU 2097272 DOCTOR MED DANDRUFF TREAT 11 FL OZ SKU 2005531 HEAD AND SOULDERS CLASSIC CLEAN SH 13.5 OZ SKU 2099110 DOCTOR DANDRUF 2IN1 SHAM DRYSCLP 13.5FL OZ SKU 2038805 HEAD AND SOULDERS 2IN 1 DRY SCALP 13.5 FL OZ SKU 2038366 HEAD AND SOULDERS 2IN 1 DRY SCALP SHAMPOO 23.7 FLOZ SKU 2005504	Class II	Drugs	SKUs: 2005726; 2006512; 2024652; 2097272; 2005531; 2099110; 2038805; 2038366; 2005504; 2038806; 2038935; 2005121	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
DOCTOR DANDRUFF 2N1 SHAMPOO 13.5FL					
OZ SKU 2038806 DOCTOR SHAMPOO T GEL					
8.5 FL OZ SKU 2038935 DOCTOR 2N1					
DANDRUFF CLSC 23.7FLOZ SKU 2005121					
distributed to specific Family Dollar Stores					
04/30/2022 through 06/10/2022.					
Orajel Cold Sore Pain Cream 1.25 fl. oz.				CGMP Deviations: product held	Family Dollar
distributed to specific Family Dollar Stores	Class II	Drugs	SKU: 906766	outside appropriate storage	Stores, Llc.
04/30/2022 through 06/10/2022.				temperature conditions.	300.00, 2.0.
ORAJEL GUM PAIN RELIEF GEL 0.125OZ SKU					
903432 GOOD SENSE ORAL PAIN RELIEF					
0.50Z SKU 999543 ORAJEL ORAL PAIN		Drugs	SKUs: 903432; 999543; 912968; 999075	CGMP Deviations: product held outside appropriate storage	Family Dollar
0.125 FL OZ SKU 912968 ORAJEL MOUTH	Class II				Stores, Llc.
SORE GEL 0.125 OZ SKU 999075 distributed			312300, 333073	temperature conditions.	Stores, Lie.
to specific Family Dollar Stores 04/30/2022					
through 06/10/2022.					
ORAJEL NON MED TEETHING GEL 0.125 OZ				CGMP Deviations: product held	Family Dollar
distributed to specific Family Dollar Stores	Class II	Drugs	SKU: 999093	outside appropriate storage	Stores, Llc.
04/30/2022 through 06/10/2022.				temperature conditions.	Stores, Etc.
NPX TRIPLE ANTIBIOTIC OINTMENT 1 OZ SKU					
910320 NPX PAIN ITCH SCAR ANTIBAC				CGMP Deviations: product held	
OINTMENT 1 OZ SKU 999855 NPX TRPL	Class II	Drugs	SKUs: 910320; 999855;	outside appropriate storage	Family Dollar
ANTIBIOTIC PLS PAIN OINMNT 1 OZ SKU	Class II	Diugs	901498	temperature conditions.	Stores, Llc.
901498 distributed to specific Family Dollar				temperature conditions.	
Stores 04/30/2022 through 06/10/2022.					
FS HYDROCORTISONE CREAM 1 OZ SKU				CGMP Deviations: product held	
910321 CORTIZONE 10 CREME 0.5 OZ SKU	Class II	Drugs	SKUs: 910321; 910167	outside appropriate storage temperature conditions.	Family Dollar
910167 distributed to specific Family Dollar	Ciass II	Diugs	3803. 910321, 91010/		Stores, Llc.
Stores 04/30/2022 through 06/10/2022.				temperature conditions.	



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
BENADRYL EXTRA STRENGTH CREAM 1 OZ distributed to specific Family Dollar Stores	Class II	Drugs	SKU: 902163	CGMP Deviations: product held outside appropriate storage	Family Dollar
04/30/2022 through 06/10/2022.	0.000	2.083	51(0) 502205	temperature conditions.	Stores, Llc.
DESITIN CREAMY OINTMENT 2 FL OZ SKU				·	
912976 BABY LOVE OINTMENT CREAM 4				CGMP Deviations: product held	
OZ SKU 902617 DESITIN MAXIMUM	Class II	Drugs	SKUs: 912976; 902617;	outside appropriate storage	Family Dollar
STRENGTH PASTE 4 OZ SKU 903097 distributed to specific Family Dollar Stores			903097	temperature conditions.	Stores, Llc.
04/30/2022 through 06/10/2022.					
AD PREV OINT ORIG 4 OZ distributed to				CGMP Deviations: product held	5 11 5 11
specific Family Dollar Stores 04/30/2022	Class II	Drugs	SKUs: 900018	outside appropriate storage	Family Dollar
through 06/10/2022.				temperature conditions.	Stores, Llc.
BC ARTHRITIS PAIN FAST PAIN RELIEF 24CT					
SKU 999839 GOOD SENSE ARTHRITIS	Clara II	D	CVII- 000000 04.4774	CGMP Deviations: product held	Family Dollar
CAPLET 24 CT SKU 914771 distributed to specific Family Dollar Stores 04/30/2022	Class II	Drugs	SKUs: 999839; 914771	outside appropriate storage temperature conditions.	Stores, Llc.
through 06/10/2022.				temperature conditions.	
LIDOCAINE ARTHRITIS AND SPORT WNTGRN				CGMP Deviations: product held	
16 FLOZ distributed to specific Family Dollar	Class II	Drugs	SKU: 902929	outside appropriate storage	Family Dollar
Stores 04/30/2022 through 06/10/2022.				temperature conditions.	Stores, Llc.
READY IN CASE RUBBING ALCHL 50 PCT				CGMP Deviations: product held	
WNTRGRN 16 FLOZ distributed to specific	Class II	Drugs	SKU:900535	outside appropriate storage	Family Dollar
Family Dollar Stores 04/30/2022 through 06/10/2022.				temperature conditions.	Stores, Llc.
BC POWDER 50 CT SKU 901588 BC					
POWDER 18 CT SKU 913228 GOODYS				CGMP Deviations: product held	
POWDER 50 CT SKU 901589 distributed to	Class II	Drugs	SKUs: 901588; 913228;	outside appropriate storage	Family Dollar
specific Family Dollar Stores 04/30/2022		_	901589	temperature conditions.	Stores, Llc.
through 06/10/2022.					



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
READY IN CASE PAIN RELIEVER PM CAPLET 100 CT SKU 902381 GOOD SENSE PAIN RELIEVER APAP 500MG CAPLET 250CT SKU 902332 READY IN CASE PM PAIN RELIEVER CAPLET 50 CT SKU 913982 GOOD SENSE PAIN RELIEVER APAP ES 500 CT SKU 999029 GOOD SENSE PAIN RELIEVER CAPLET 100 CT SKU 913890 distributed to specific Family Dollar Stores 04/30/2022 through 06/10/2022.	Class II	Drugs	SKUs: 902381; 902332; 913982; 999029; 913890	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.
READY IN CASESLEEP AID SOFT GEL 32 CT SKU 901457 READY IN CASE SLEEP AID 64 CT SKU 999026 ZZZQUIL WARMING BERRY 12FL OZ SKU 999811 GOOD SENSESLEEP AID CAPLET 100 CT SKU 901496 GOOD SENSESLEEP AID CAPLET 24 CT SKU 913985 GOOD SENSE EZ NITE SLEEP BERRY 12FL OZSKU 999789 distributed to specific Family Dollar Stores 04/30/2022 through 06/10/2022.	Class II	Drugs	SKUs: 901457; 999026; 999811; 901496; 913985; 999789	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.
VICKS VAPORUB 1.76 OZ SKU 919667 VICKS VAPOR RUB LAVENDER 1.76 OZ 999813 SWAN MEDICATED CHEST RUB 3.53 OZ SKU 920611 distributed to specific Family Dollar Stores 04/30/2022 through 06/10/2022.	Class II	Drugs	SKUs: 919667; 999813; 920611	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.
QP MOTION SICKNESS TABLET 8 CT distributed to specific Family Dollar Stores 04/30/2022 through 06/10/2022.	Class II	Drugs	SKU: 901583	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
PREFERRED URINRY PN RLF MAX STRNGTH 12 CT distributed to specific Family Dollar Stores 04/30/2022 through 06/10/2022.	Class II	Drugs	SKU: 900754	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.
READY IN CASE MICON 7 DAY 1.59 OZ SKU 939212 READY IN CASE MICON 3 DAY COMBO PACK SKU 902373 distributed to specific Family Dollar Stores 04/30/2022 through 06/10/2022.	Class II	Drugs	SKUs: 939212; 902373	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.
AZO YEAST PLUS 20 CT distributed to specific Family Dollar Stores 04/30/2022 through 06/10/2022.	Class II	Drugs	SKU: 902787	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.
VICKS VAPOCOOL DROPS SEVERE 18 CT SKU 999488 BEST HEALTH HONEY LEMON COUGH DROP 80 CT SKU 998844 distributed to specific Family Dollar Stores 04/30/2022 through 06/10/2022.	Class II	Drugs	SKUs: 999488; 998844	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.
ZZZQUIL NIGHT PAIN BERRY 12 FL OZ distributed to specific Family Dollar Stores 04/30/2022 through 06/10/2022.	Class II	Drugs	SKU: 903452	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.
JET ALERT TABLET 30 CT distributed to specific Family Dollar Stores 04/30/2022 through 06/10/2022.	Class II	Drugs	SKU: 914001	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.
SWAN PETROLEUM JELLY 7.5 OZ SKU 910721 BABY LOVE PETROLEUM JELLY 13 OZ SKU 910726 VASELINE PETROLEUM JELLY ORIGINAL 7.5 OZ 2099273 distributed to specific Family Dollar Stores 04/30/2022 through 06/10/2022.	Class II	Drugs	SKUs: 910721; 910726; 2099273	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
MY CHOICE LEVONORGESTREL TABLET distributed to specific Family Dollar Stores 04/30/2022 through 06/10/2022.	Class II	Drugs	SKU: 998211	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.
DR SCHOLLS CLR AWAY LIQ WART REMVR 20CT SKU 998384 DR SCHOLLS CALLUS REMOVER PADS 4CT SKU 998431 DR SCHOLLS CORN REMOVERS 9CT SKU 998403 distributed to specific Family Dollar Stores 04/30/2022 through 06/10/2022.	Class II	Drugs	SKUs: 998384; 998431; 998403	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.
ZARBEES NTRL CHLD COUGH MUCUS GRP 4 FL OZ distributed to specific Family Dollar Stores 04/30/2022 through 06/10/2022.	Class II	Drugs	SKU: 999983	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.
ZARBEES NTRLS BABY CGH MUCUS GRP 2 FL OZ distributed to specific Family Dollar Stores 04/30/2022 through 06/10/2022.	Class II	Drugs	SKU: 999984	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.
GOOD SENSE HEMORRHOID OINTMENT 2 OZ SKU 910325 GOOD SENSE HEMORRHOIDAL WIPES 48 CT SKU 902260 distributed to specific Family Dollar Stores 04/30/2022 through 06/10/2022.	Class II	Drugs	SKUs: 910325; 902260	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.
TN DICKINSON WITCH HAZEL 16 FL OZ distributed to specific Family Dollar Stores 04/30/2022 through 06/10/2022.	Class II	Drugs	SKU: 900911	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.
DOCTOR TEALS PURE EPSOM SALT UNSCENTED 6 LBS SKU 999355 Ready in case EPSOM SALTS 2 LB SKU 909223 distributed to specific Family Dollar Stores 04/30/2022 through 06/10/2022.	Class II	Drugs	SKUs: 999355; 909223	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
SWAN POVIDONE 4 FL OZ distributed to specific Family Dollar Stores 04/30/2022 through 06/10/2022.	Class II	Drugs	SKU: 999843	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.
SWAN CALAMINE LOTION 6 FL OZ distributed to specific Family Dollar Stores 04/30/2022 through 06/10/2022.	Class II	Drugs	SKU: 901469	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.
GOOD SENSE SORE THROAT SPRAY CHERRY 6 FL OZ distributed to specific Family Dollar Stores 04/30/2022 through 06/10/2022.	Class II	Drugs	SKU: 913018	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.
VASELINE ECZEMA CALMING THERPY CRM 6.8 OZ distributed to specific Family Dollar Stores 04/30/2022 through 06/10/2022.	Class II	Drugs	SKU: 2098741	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.
GUARDIAN ANTACID EX STRGTH TBLT FRT 96CT SKU 901379 GUARDIAN CHWABLE SMTHIES BRRY FSION 60CT SKU 999845 GS EFFERVESCENT ANTACID TABLET 36 CT SKU 913102 GUARDIAN ANTCD TBLT XTRA STGTH BRY 96 CT SKU 914109 GUARDIAN ANTCID TBLT REG STTH FRT 150 CT SKU 914726 GC ANTACID SUPREME CHERRY 12 FL OZ SKU 914112 GUARDIAN ANTD ULTR STRGTH 1000 FRT 72 CT SKU 902322 distributed to specific Family Dollar Stores 04/30/2022 through 06/10/2022.	Class II	Drugs	SKUs: 901379; 999845; 913102; 914109; 914726; 914112; 902322	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.
ALKA SELTZER EXTRA STRENGTH 24 CT distributed to specific Family Dollar Stores 04/30/2022 through 06/10/2022.	Class II	Drugs	SKU: 903323	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.
MYLANTA MAX STRENGTH CLASSIC FLVR 12 FLOZ distributed to specific Family Dollar Stores 04/30/2022 through 06/10/2022.	Class II	Drugs	SKU: 999844	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
GOOD SENSE OMEPRAZOLE TABLET 14CT SKU 900055 PRILOSEC OTC TABLET 14 CT SKU914128 distributed to specific Family Dollar Stores 04/30/2022 through 06/10/2022.	Class II	Drugs	SKUs: 900055; 914128	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.
GOOD SENSE ESOMEPRAZOLE ACID REDUCER 20MG 42CT distributed to specific Family Dollar Stores 04/30/2022 through 06/10/2022.	Class II	Drugs	SKU: 999850	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.
PEPCID COMPLETE CHEWABLE TAB BERRY 8CT SKU 903365 PEPCID AC MAXIMUM STRENGTH TABLET 25 CT SKU 902063 PEPCID AC MAXIMUM STRENGTH TABLET 8 CT SKU 914773 distributed to specific Family Dollar Stores 04/30/2022 through 06/10/2022.	Class II	Drugs	SKUs: 903365; 902063; 914773	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.
PREVACID 24HR LANSOPRAZOLE 15MG CAP 14CT distributed to specific Family Dollar Stores 04/30/2022 through 06/10/2022.	Class II	Drugs	SKU: 903449	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.
RIC STOOL SOFTENER SOFTGEL 100 CT SKU 917000 RIC STOOL SOFTNER 100 CT SKU 902493 distributed to specific Family Dollar Stores 04/30/2022 through 06/10/2022.	Class II	Drugs	SKUs: 917000; 902493	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.
READY IN CASE RUBBING ALCOHOL 91 PCT 16 FL OZ SKU 902270 READY IN CASE 70 PCT ISOPROPYL ALCOHOL 32 FL OZ SKU 999747 READY IN CASE 91PCT ISOPROPYL ALCOHOL 32 FL OZ SKU 999742 READY IN CASE 70PCT ISOPROPYL ALCOHOL 16 FL OZ SKU 999743 distributed to specific Family	Class II	Drugs	SKUs: 902270; 999747; 999742; 999743	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Dollar Stores 04/30/2022 through 06/10/2022.					
DRX FIBER CAPSULES 100 CT distributed to specific Family Dollar Stores 04/30/2022 through 06/10/2022.	Class II	Drugs	SKU: 998899	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.
FW ASPIRIN CHEWABLE TABLET 36CT SKU 913990 GS ENTERIC ASPIRIN TABLET 120 CT SKU 913724 BAYER BACK BODY EX STRGTH CAPLETS 24CT SKU 900438 BAYER LOW DOSE 81 MG TABLET 120 CT SKU 916070 BAYER ASPIRIN 325MG TABLET 24CT SKU 913996 BAYER LOW DOSE TABLET 32CT SKU 915641 BAYER 81MG CHEWABLE TABLET 36 CT SKU 916078 distributed to specific Family Dollar Stores 04/30/2022 through 06/10/2022.	Class II	Drugs	SKUs: 913990; 913724; 900438; 916070; 913996; 915641; 916078	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.
QP LAXATIVE BISACODYL 5 MG TABLET 50 CT SKU 902449 QP WOMEN LAXATIVE BISCODYL TABLET 25 CT SKU 915221 distributed to specific Family Dollar Stores 04/30/2022 through 06/10/2022.	Class II	Drugs	SKUs: 902449; 915221	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.
GC MILK OF MAGNESIA CHERRY 12 FL OZ SKU 915000 GC MILK OF MAGNESIA MINT 12 FL OZ SKU 915623 distributed to specific Family Dollar Stores 04/30/2022 through 06/10/2022.	Class II	Drugs	SKUs: 915000; 915623	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.
DULCOLAX 5 MG TABLET 25 CT distributed to specific Family Dollar Stores 04/30/2022 through 06/10/2022.	Class II	Drugs	SKU: 916079	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
FLEET GLYCERIN SUPPOSITORIES 50 CT distributed to specific Family Dollar Stores 04/30/2022 through 06/10/2022.	Class II	Drugs	SKU: 917001	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.
MIRALAX 8.3 OZ distributed to specific Family Dollar Stores 04/30/2022 through 06/10/2022.	Class II	Drugs	SKU: 902219	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.
MEDIC EYE DROPS MAX REDNESS SKU 998920 CLR EYS MX RDNS RLIF 0.5 FL OZ SKU 901844 SYSTANE ULTRA HIGH PRFRM LUB DRPS 0.14 FLOZ SKU 901961 LUMIFY REDNESS REL EYE DROPS 2.5 FL OZ SKU 998300 FC EYE DROPS ADVANCED 0.5 OZ SKU 902280 distributed to specific Family Dollar Stores 04/30/2022 through 06/10/2022.	Class II	Drugs	SKUs: 998920; 901844; 901961; 998300; 902280	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.
ST IVES BLKHD CLRNG GREEN TEA SCRUB 6 OZ SKU 2007787 AMBI EXFOLIATING WASH 5 OZ SKU 2097153 CC BLACKHEAD SCRUB 5 OZ SKU 2032021 distributed to specific Family Dollar Stores 04/30/2022 through 06/10/2022.	Class II	Drugs	SKUs: 2007787; 2097153; 2032021	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.
AMBI NRSHNG DAILY FACIAL MSTURZER 1.7 OZ distributed to specific Family Dollar Stores 04/30/2022 through 06/10/2022.	Class II	Drugs	SKU: 2096628	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.
ACNE FREE ADAPALENE GL ACN TRTMT 0.5 OZ SKU 2096518 ACNE FREE TRMINTR 10 SPOT TRTMT 1 OZ SKU 2096507 distributed to specific Family Dollar Stores 04/30/2022 through 06/10/2022.	Class II	Drugs	SKUs: 2096518; 2096507	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
VOLTAREN ARTHRITIS PAIN GEL 20G distributed to specific Family Dollar Stores 04/30/2022 through 06/10/2022.	Class II	Drugs	SKU: 998708	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.
ARTHRITIS HOT CREME 3 OZ SKU 901452 ICY HOT PATCH 1 CT SKU 911030 ICY HOT MUSCLE RUB 1.25 OZ SKU 920205 ICY HOT NO MESS 1.5 OZ SKU 998751 distributed to specific Family Dollar Stores 04/30/2022 through 06/10/2022.	Class II	Drugs	SKUs: 901452; 911030; 920205; 998751	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.
ASPERCREME WITH LIDOCAINE CREME 1.75 OZ SKU 999852 ICY HOT LIDOCAINE CREAM 1.75 OZ SKU 999853 distributed to specific Family Dollar Stores 04/30/2022 through 06/10/2022.	Class II	Drugs	SKUs: 999852; 999853	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.
BLISTEX LIP MEDEX 0.25OZ SKU 906120 BLISTEX LIP MEDEX POT 0.38 OZ SKU 998852 distributed to specific Family Dollar Stores 04/30/2022 through 06/10/2022.	Class II	Drugs	SKUs: 906120; 998852	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.
CARMEX DAILY CARE CHERRY SPF 15 0.35 OZ SKU 901842 CARMEX LIP BALM JAR 0.25OZ SKU 903284 CARMEX STRWBRRY STCK W SPF 15 0.15OZ SKU 905760 distributed to specific Family Dollar Stores 04/30/2022 through 06/10/2022.	Class II	Drugs	SKUs: 901842; 903284; 905760	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.
MIDOL COMPLETE CAPLET 16 CT SKU 913028 QP MENSTRUAL RELIEF COMPLETE CAPLET 16CT SKU 999982 QP PMS FORMULA CAPLET 32 CT SKU 913232 distributed to specific Family Dollar Stores 04/30/2022 through 06/10/2022.	Class II	Drugs	SKUs: 913028; 999982; SKUs: 913232; 999982; 913028	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
NPX ENEMA 4.5 FL OZ 2 PK distributed to specific Family Dollar Stores 04/30/2022 through 06/10/2022.	Class II	Drugs	SKU: 915626	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.
STYE EYE OINTMENT 0.125 OZ distributed to specific Family Dollar Stores 04/30/2022 through 06/10/2022.	Class II	Drugs	SKU: 998301	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.
MYLICON INFANT GAS DROPS 0.5 OZ distributed to specific Family Dollar Stores 04/30/2022 through 06/10/2022.	Class II	Drugs	SKU:999109	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.
GOOD SENSE LICE SHAMPOO 6FL OZ distributed to specific Family Dollar Stores 04/30/2022 through 06/10/2022.	Class II	Drugs	SKU: 902311	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.
AFRIN NO DRIP SEVERE CONGESTION 0.5FL OZ distributed to specific Family Dollar Stores 04/30/2022 through 06/10/2022.	Class II	Drugs	SKU: 902045	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.
NICORETTE GUM WHITE ICE MINT 4 MG 20 CT distributed to specific Family Dollar Stores 04/30/2022 through 06/10/2022.	Class II	Drugs	SKU: 902014	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.
EXCEDRIN MIGRAINE CAPLET 24 CT distributed to specific Family Dollar Stores 04/30/2022 through 06/10/2022.	Class II	Drugs	SKU: 913722	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.
JOHNSONS BABY FIRST TOUCH GIFT SET 4PC distributed to specific Family Dollar Stores 04/30/2022 through 06/10/2022.	Class II	Drugs	SKU: 999553	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.
GUARDIAN BISMUTH CHWBLE CHRY TABS 30 CTSKU 902321 RIC BISMUTH MAXIMUM STRENGTH 8 FL OZ SKU 914325 PEPTO BISMOL ORIGINAL 8 FL OZ SKU 914324 RIC BISMUTH REG STRENGTH CHERRY 8 FL OZ SKU 914781 PEPTO BISMOL CHERRY 8 FL	Class II	Drugs	SKUs: 902321; 914325; 914324; 914781; 916063; 999812	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
OZ SKU 916063 PEPTO B LIQUID ORIGINAL TRAVEL 3.4 FL OZ SKU 999812 distributed to specific Family Dollar Stores 04/30/2022 through 06/10/2022.					
GS ANTI DIARRHEAL LOPERAMIDE CAPLET 12 CT SKU 915632 IMODIUM AD MINT 4 OZ SKU 902080 IMODIUM AD CAPLET 6 CT SKU 915628 distributed to specific Family Dollar Stores 04/30/2022 through 06/10/2022.	Class II	Drugs	SKUs: 915632 ; 902080; 915628	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.
QP DPHNHDRME ALRGY MIN TBLT 12 CT SKU 900449 QP ALLERGY DIPHENHYDRAMINE 25 MG 48 CT SKU 916003 QP ALLERGY MULTI SYMPTOM CAPLET 24CT SKU 916918 BENADRYL D CHILD ALLERGY SINUS GRAPE 4FO SKU 901738 GOOD SENSE CHILD ALLERGY CHERRY 4 FL OZ SKU 916917 BENADRYL ALLERGY CONGESTN ULTRA TAB 24CT SKU 999834 BENADRYL ALLERGY ULTRATAB 24CT SKU 902217 BENADRYL ALLERGY LIQUIDGELS 24 CT SKU 916715 distributed to specific Family Dollar Stores 04/30/2022 through 06/10/2022.	Class II	Drugs	SKUs: 900449; 916003; 916918; 901738; 916917; 999834; 902217; 916715	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.
CLARITIN ALLERGY LIQ CHLDRNS GRAPE 2 FLOZ SKU 900834 CLARITIN ALLERGY 10MG TABLETS 5 CT SKU 916116 GS ALLERGY LORATADINE TABLET 30 CT SKU 916114 CLARITIN ALLERGY 10 MG TABLET 10 CT SKU	Class II	Drugs	SKUs: 900834; 916116; 916114; 901655	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
901655 distributed to specific Family Dollar					
Stores 04/30/2022 through 06/10/2022.					
READY IN CASE CTRZNE ALRGY ALL DY TBLT					
5 CT SKU 900448 ZYRTEC CHILDRENS					
GRAPE 4 FL OZ SKU 999368 GOOD SENSE			SKUs: 900448; 999368;	CGMP Deviations: product held	Family Dollar
ALLERGY CETIRIZINE 10 MG TABLET 14 CT	Class II	Drugs	916897	outside appropriate storage	Stores, Llc.
SKU 916897 distributed to specific Family				temperature conditions.	
Dollar Stores 04/30/2022 through					
06/10/2022. ROBITUSSIN COUGH N CHEST CONGESTION					
4 FL OZ SKU 919471 DELSYM ORANGE 3 FL				CCNAD Devicationer and deat hold	
OZ SKU 901880 distributed to specific	Class II	Drugs	SKUs: 919471 ; 901880	CGMP Deviations: product held outside appropriate storage	Family Dollar
Family Dollar Stores 04/30/2022 through	Class II	Drugs	3803. 919471 , 901880	temperature conditions.	Stores, Llc.
06/10/2022.				temperature conditions.	
DAYQUIL COLD FLU LQD 12 FL OZ SKU					
900205 RIC NIGHT TIME CLD FLU RLF SOFT					
GELS 8 CT SKU 900523 ALKA SELTZER PLUS					
DAY NIGHT LGEL 20 CT SKU 902012 GS					
COLD FLU RELIEF NGHTTIME CHRY12FL OZ					
SKU 917523 RIC COLD FLU DAY TIME			CVII. 000205 000522		
LIQUID CAP 16 CT SKU 903037 ASP SEVERE			SKUs: 900205; 900523;	CCMD De l'all'ann ann de de la la	
COLD COUGH CITRUS 20CT SKU 902906	Class II	Drugs	902012; 917523; 903037;	CGMP Deviations: product held	Family Dollar
ASP SEVERE COLD ORANGE ZEST 20CT SKU	Class II	Drugs	902906; 902908; 903333; 903335; 999542; 903334;	outside appropriate storage	Stores, Llc.
902908 ALKA SELTZER PLUS SEVERE COLD			900576; 903759; 900207	temperature conditions.	
ORIG 20CT SKU 903333 AS PLUS SINUS			900376, 903739, 900207		
ALLERGY N COUGH PMAX 16CT SKU 903335					
NYQUIL SEVERE VAPOCOOL LIQUID 8 FL OZ					
SKU 999542 AS PLUS MAX STRNGTH SINUS					
CONG N PN 20CT SKU 903334 GS DAYTIME					
COLD FLU RLF ORANGE 12FL OZ SKU 900576					



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
NYQUIL SEVERE COLD FLU BERRY 8 FL OZ					
SKU 903759 NYQUIL ORGNL COLD AND FLU					
LQD 12FL OZ SKU 900207 distributed to					
specific Family Dollar Stores 04/30/2022					
through 06/10/2022.					
QP SUDFEDRINE PE MAX STRENGTH TBLT 24				CGMP Deviations: product held	Family Dollar
CT distributed to specific Family Dollar	Class II	Drugs	SKU: 916001	outside appropriate storage	Stores, Llc.
Stores 04/30/2022 through 06/10/2022.				temperature conditions.	300103) 2.01
REFENESEN MUCUS RELIEF TABLET 30 CT					
SKU 917531 MUCINEX DM MAX STRENGTH					
7CT SKU 900854 RIC MUCUS RLF DM MAX			SKUs: 917531; 900854;	CGMP Deviations: product held	Family Dollar
STNGTH CHRY 6FL OZ SKU 999559 VICKS	Class II	Drugs	999559; 998933	outside appropriate storage	Stores, Llc.
JARABE COUGH CONGESTION 8FLOZ SKU			,	temperature conditions.	
998933 distributed to specific Family Dollar					
Stores 04/30/2022 through 06/10/2022.					
MUCINEX FASTMAX CAPLETS COLD FLU 4CT				CGMP Deviations: product held	Family Dollar
distributed to specific Family Dollar Stores	Class II	Drugs	SKU: 903372	outside appropriate storage	Stores, Llc.
04/30/2022 through 06/10/2022.				temperature conditions.	, ,
HYLANDS 4KIDS COLD N MUCUS RELIEF 4 FL				CGMP Deviations: product held	Family Dollar
OZ distributed to specific Family Dollar	Class II	Drugs	SKU: 999246	outside appropriate storage	Stores, Llc.
Stores 04/30/2022 through 06/10/2022.				temperature conditions.	
QP COLD MULTI SYMPTM DAY NITE CPLT 24				CGMP Deviations: product held	Family Dollar
CT distributed to specific Family Dollar	Class II	Drugs	SKU: 916058	outside appropriate storage	Stores, Llc.
Stores 04/30/2022 through 06/10/2022.				temperature conditions.	000.00, 2.0.
MUCINEX SE MAX STRENGTH 7CT				CGMP Deviations: product held	Family Dollar
distributed to specific Family Dollar Stores	Class II	Drugs	SKU: 900844	outside appropriate storage	Stores, Llc.
04/30/2022 through 06/10/2022.				temperature conditions.	000.00, 2.0.
QP COUGH COLD TABLET 16 CT distributed				CGMP Deviations: product held	Family Dollar
to specific Family Dollar Stores 04/30/2022	Class II	Drugs	SKU: 916922	outside appropriate storage	Stores, Llc.
through 06/10/2022.				temperature conditions.	200.00, 210.



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
VICKS DAYQUIL NYQUIL LIQ COMB PK 6 FLOZ distributed to specific Family Dollar Stores 04/30/2022 through 06/10/2022.	Class II	Drugs	SKU: 903367	CGMP Deviations: product held outside appropriate storage temperature conditions.	Family Dollar Stores, Llc.
Divalproex Sodium Extended Release Tablets, USP, 250 mg, packaged in 100-count bottle, Rx only, Manufactured by: Amneal Pharmaceuticals, India, Distributed by: Amneal Pharmaceuticals, Bridgewater, NJ, NDC 65162-755-10	Class II	Drugs	Lot #: AR210705, Exp 04/2024	Failed dissolution specifications.	Amneal Pharmaceutic als of New York, LLC
Maxim Instant Foam Hand Sanitizer (benzalkonium chloride 0.1%) packaged in a) 1 U.S. Gallon (3.78 Liters) drums UPC 7 61841 02502 6 and b) 55 U.S. Gallon drums (208 Liters) UPC 0 07 61841 02504 0, Midlab 140 Private Brand Way, Athens, TN 37303	Class II	Drugs	Lot #: a) 03292022-1, 05092022-1, 02012022-1, 06172022-1, 12132021-1, 07272022-1, and b) 06252022-1	CGMP Deviations: Product manufactured using expired active ingredient, Benzalkonium chloride.	Midlab Incorporated
Corsair Personal Care 99X Instant Foam Hand Sanitizer (benzalkonium chloride 0.1%)128 Fl. Oz. (1 Gal.) 3.78 liters bottles, Southern Products & Services, Inc. 2515 Jake Drive Ste B, Cumming, GA 30028	Class II	Drugs	Lot #: 06172022-1	CGMP Deviations: Product manufactured using expired active ingredient, Benzalkonium chloride.	Midlab Incorporated
Luxury 70% Isopropyl Alcohol, 16 FL. OZ. (1 PT) 473 ML, Distributed by: TSM Brands LLC, 540 Equinox Ln, Manalapan, NJ 07726, UPC 868275965734.	Class II	Drugs	Lot # 235, 236, 237, 238, 239, 240, 241, 242, 243, 244, 245, 246, 247, 248, 249, 250, 251, 252, 253, 254, 255, 256, 257, 258, 259, 260, 261, 262, 263, 264, 265, 266, 267, 268, 269, 270, 271, 272, 273, 274, 275, 276, 277, 278, 279, 280, 281, 282, 283,	Labeling: Product Contains Undeclared API - product contains undeclared ethyl alcohol	Tsm Brands LLC



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			284, 285, 286, 287, 288, 289, 290, 291, 292, 293, 294, 295, 296, 297, 298, 299, 300, 301, 302, 303, 304, 305, 306, 307, 308, 309, 310, 311, 312, 313, 314, 315, 316, 317, 318, 319, 320, 321, 322, 323, 324, 325, 326, 327, 328, 329, 330, 331, 332, 333, 334, 335, 336, 337, 338.		
Luxury 70% Isopropyl Alcohol, First Aid Antiseptic with Wintergreem12 FL. OZ. (1 PT) 355 ML, Distributed by: TSM Brands LLC, 540 Equinox Ln, Manalapan, NJ 07726, UPC 868275965765.	Class II	Drugs	Lot # 015, 016, 017, 018, 018, 019, 020, 021, 022, 023, 024, 025, 026, 027, 028, 029, 030, 031, 032, 033, 034, 035, 036, 037, 038.	Labeling: Product Contains Undeclared API - product contains undeclared ethyl alcohol	Tsm Brands LLC
Colgate Anticavity Fluoride Toothpaste, OPTIC WHITE PRO SERIES, Stain Prevention, 5% Hydrogen Peroxide, Net Wt. 2.1 OZ. (59 g) UPC 0 35000 99658 9. Dist. by: Colgate- Palmolive Company New York, NY 10022 U.S.A.	Class II	Drugs	SKUs 998277 distributed to Family Dollar retail stores in AZ, CA, GA, ID, IN, MT, NM, NV, OR, TX, UT	cGMP deviation: Product held outside of appropriate temperature storage conditions.	Family Dollar Stores, Llc.
Colgate Anticavity Fluoride Toothpaste, OPTIC WHITTE RENEWAL, 3% Hydrogen Peroxide, High Impact White, Net Wt. 3.0 OZ. (85 g) UPC 0 35000 97008 4. Dist. by: Colgate-Palmolive Company New York, NY 10022 U.S.A.	Class II	Drugs	SKUs 999088 distributed to Family Dollar retail stores in AZ, CA, GA, ID, IN, MT, NM, NV, OR, TX, UT	cGMP deviation: Product held outside of appropriate temperature storage conditions.	Family Dollar Stores, Llc.



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Colgate Anticavity Fluoride Toothpaste, OPTIC WHITE ADVANCED ICY FRESH, Net Wt. 3.2 OZ. (90 g) UPC 0 35000 97159 3. Dist. by: Colgate-Palmolive Company New York, NY 10022 U.S.A.	Class II	Drugs	SKUs 999749 distributed to Family Dollar retail stores in AZ, CA, GA, ID, IN, MT, NM, NV, OR, TX, UT	cGMP deviation: Product held outside of appropriate temperature storage conditions.	Family Dollar Stores, Llc.
Colgate Anticavity Fluoride Toothpaste, OPTIC WHITE with CHARCOAL COOL MINT PASTE, Net Wt. 4.2 OZ. UPC 0 35000 97872 1. Dist. by: Colgate-Palmolive Company New York, NY 10022 U.S.A.	Class II	Drugs	SKUs 998909 distributed to Family Dollar retail stores in AZ, CA, GA, ID, IN, MT, NM, NV, OR, TX, UT	cGMP deviation: Product held outside of appropriate temperature storage conditions.	Family Dollar Stores, Llc.
Colgate Anticavity Fluoride Toothpaste OPTIC WHITE STAIN FIGHTER CLEAN MINT PASTE. Net Wt. 4.2 OZ. (119 g) UPC 0 35000 45836 0. Dist. by: Colgate-Palmolive Company New York, NY 10022 U.S.A.	Class II	Drugs	SKUs 999750 distributed to Family Dollar retail stores in AZ, CA, GA, ID, IN, MT, NM, NV, OR, TX, UT	cGMP deviation: Product held outside of appropriate temperature storage conditions.	Family Dollar Stores, Llc.
Colgate Whitening Mouthwash, OPTIC WHITE ICY FRESH MINT. 16 fl. OZ. (1 pt) 473 mL UPC 0 35000 67111 0. Dist. by: Colgate-Palmolive Co. New York, NY 10022 U.S.A.	Class II	Drugs	SKUs 999043 distributed to Family Dollar retail stores in AZ, CA, GA, ID, IN, MT, NM, NV, OR, TX, UT	cGMP deviation: Product held outside of appropriate temperature storage conditions.	Family Dollar Stores, Llc.
Triamcinolone Acetonide Cream USP, 0.1%, 80 g tube, Rx Only, Manufactured By Perrigo, Bronx, NY 10457, Distributed By Perrigo, Allegan, MI 49010, NDC 45802-064-36.	Class II	Drugs	Lot 2CT0486 , Exp 02/29/2024	CGMP Deviations: Product complaints reporting the product to have a gritty texture and lack of effectiveness.	Padagis US LLC
Neomycin Sulfate Tablets, USP 500 mg, 100-count bottles, Rx only, Distributed by: TEVA PHARMACEUTICALS USA, INC North Wales, PA 19454, NDC 0093-1177-01	Class II	Drugs	Lot #: 3007830, 3007746, 3007829, Exp. Date 10/2024	CGMP Deviations: A foreign matter identified as teflon was found in the Active Pharmaceutical Ingredient (API) used in the manufacture of	Teva Pharmaceutic als USA Inc



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
				Neomycin Sulfate Tablets, USP 500 mg.	
MILK OF MAGNESIA USP, 2400 mg/30 mL, Magnesium Hydroxide, 30 mL cup, packaged in 10 cups per tray, 10 trays per carton, For Institutional Use Only, Major Pharmaceuticals, 17177 N Laurel Park Dr., Suite 233, Livonia, MI 48152, NDC 0904- 6846-73.	Class II	Drugs	Lot # 20072A, 20075A, EXP Jul. 2022; 20087A, EXP Aug. 2022; 20089A, 20090A, EXP Sep. 2022; 20100A, 20102A, EXP Oct. 2022; 20106A, 20107A EXP Nov. 2022; 20109A, EXP Dec. 2022; 21010A, EXP Jan. 2023; 21028A, 21030A, 21032A, EXP Mar. 2023; 21045A, 21046A, EXP Apr. 2023; 21054A, EXP May. 2023; 21078A, 21079A, 21085A, EXP Jul. 2023; 21088A, EXP Aug. 2023	CGMP Deviations: products manufactured under conditions which reflect manufacturing processes that were not adequately controlled.	Plastikon Healthcare LLC
MILK OF MAGNESIA USP, 2400 mg/10 mL, Magnesium Hydroxide, 30 mL cup, packaged in 10 cups per tray, 10 trays per carton, For Institutional Use Only, Major Pharmaceuticals, 17177 N Laurel Park Dr., Suite 233, Livonia, MI 48152, NDC 0904-6840-72.	Class II	Drugs	Lot # 20085A, EXP Aug. 2022; 20099A, EXP Oct. 2022; 21039A, 21052A, EXP May. 2023; 21114A, EXP Oct. 2023; 21130A, 21132A, EXP Dec. 2023.	CGMP Deviations: products manufactured under conditions which reflect manufacturing processes that were not adequately controlled.	Plastikon Healthcare LLC
Magnesium Hydroxide 1200 mg, Aluminum Hydroxide 1200 mg, Simethicone 120 mg per 30 mL, 30 mL cup, packaged in 10 cups per tray, 10 trays per carton, For Institutional Use Only, Major	Class II	Drugs	Lot # 20077A, 20080A, 20082A, EXP Aug. 2022; 21016A, EXP Feb. 2023; 21026A, EXP Mar. 2023; 21042A, 21047A, 21050A,	CGMP Deviations: products manufactured under conditions which reflect manufacturing processes that were not adequately controlled.	Plastikon Healthcare LLC



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Pharmaceuticals, 17177 N Laurel Park Dr., Suite 233, Livonia, MI 48152, NDC 0904- 6838-73			EXP Apr. 2023; 21057A, 21059A, 21060A,EXP May. 2023; 21061A, 21067A, 21070A, 21072A, EXP Jun. 2023; 21095A, 21097A, 21099A, EXP Sep. 2023; 21107A, 21109A, 21111A, 21113A, EXP Oct. 2023; 21138A, EXP Dec. 2023; 22002A, 22004A, 22005A, EXP Jan. 2024		
Magnesium Hydroxide 2400 mg, Aluminum Hydroxide 2400 mg, Simethicone 240 mg MAX, per 30 mL Oral Suspension, 30 mL cup, packaged in 10 cups per tray, 10 trays per carton, For Institutional Use Only, Major Pharmaceuticals, 17177 N Laurel Park Dr., Suite 233, Livonia, MI 48152, NDC 0904-6839-73	Class II	Drugs	Lot # 20084A, 20086A, EXP Aug. 2022; 21074A, 21077A, EXP Jul. 2023	CGMP Deviations: products manufactured under conditions which reflect manufacturing processes that were not adequately controlled.	Plastikon Healthcare LLC
Acetaminophen Oral Solution 160 mg / 5 mL, 5 mL cup, packaged in 10 cups per tray, 10 trays per carton, For Institutional Use Only, Major Pharmaceuticals, 17177 N Laurel Park Dr., Suite 233, Livonia, MI 48152, NDC 0904-6738-70	Class II	Drugs	Lot# 20078A, 20083A EXP Aug. 2022; 20092A, EXP Sep. 2022; 21058A, 21048C, EXP May. 2023; 21063C, EXP Jun. 2023; 21093B, EXP Sep. 2023; 22001C, EXP Jan. 2024; 22017A, EXP Mar. 2024.	CGMP Deviations: products manufactured under conditions which reflect manufacturing processes that were not adequately controlled.	Plastikon Healthcare LLC
Acetaminophen Oral Solution, 325 mg / 10.15 mL, 10.15 mL cup, packaged in 10 cups per tray, 10 trays per carton, For	Class II	Drugs	Lot # 20062A, 20067A, EXP Jun. 2022; 20092A, 20093A, EXP Sep. 2022;	CGMP Deviations: products manufactured under conditions which reflect manufacturing	Plastikon Healthcare LLC



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Institutional Use Only, Major Pharmaceuticals, 17177 N Laurel Park Dr. Suite 233, Livonia, MI 48152, NDC 0904- 6739-71			20101A, 21110A, EXP Oct. 2022; 20108A, EXP Nov. 2022; 21012A, EXP Jan. 2023; 21044A, 21048B, EXP Apr. 2023; 21053A, EXP May. 2023; 21063B, 21068B, EXP Jun. 2023; 21084B, EXP Jul. 2023; 21090A, EXP Aug. 2023; 21119A, EXP Nov. 2023; 21122B, EXP Dec. 2023; 22001B, 22006A, EXP Jan. 2024; 22017B, EXP Mar.	processes that were not adequately controlled.	
Acetaminophen Oral Solution 650 mg / 20.3 mL, 20.3 mL cup, packaged in 10 cups per tray, 10 trays per carton, For Institutional Use Only, Major Pharmaceuticals, 17177 N Laurel Park Dr. Suite 233, Livonia, MI 48152, NDC 0904-6820-76	Class II	Drugs	Lot # 20064A, 20066A, EXP Jun. 2022; 20069A, 20073A, EXP Jul. 2022; 20094A, 20094B, 20095A, 20095B, EXP Sep. 2022; 20103A, EXP Oct. 2022; 20105A, EXP Nov. 2022; 20111A, 20111B, EXP Dec. 2022; 21005A, 21005B, EXP Jan. 2023; 21019A, 21019B, EXP Feb. 2023; 21035A, 21035B, 21038A, EXP Mar. 2023; 21048A, 21048D, EXP Apr. 2023; 21058B, EXP May. 2023; 21063A, 21068A, EXP Jun.	CGMP Deviations: products manufactured under conditions which reflect manufacturing processes that were not adequately controlled.	Plastikon Healthcare LLC



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			2023; 21084A, EXP Jul. 2023; 21090B, EXP Aug. 2023; 21093A, EXP Sep. 2023; 21124A, 21126A, EXP Nov. 2023; 21136A,20112A, 21122A,21122C, 20112B, EXP Dec. 2023; 22001A, 22001D, 22006B, 22006C, EXP Jan. 2024; 22010A, 22011A, 22011B, EXP Feb. 2024; 22014A, 22015A, 22021A, EXP Mar. 2024.		
CALCIUM CARBONATE ORAL SUSPENSION, 1250 mg/5 mL, 5 mL cup, packaged in 10 cups per tray, 4 trays per carton, For Institutional Use Only, Major Pharmaceuticals, 17177 N Laurel Park Dr. Suite 233, Livonia, MI 48152, NDC 0904- 7098-94	Class II	Drugs	Lot # 21021A, 21023A, 21024A, EXP Feb. 2023; 21064A, EXP Jun. 2023; 21073A, 21075A, EXP Jul. 2023; 21100A, EXP Sep. 2023; 21118A, 21120A, EXP Nov. 2023; 21128A, 21129A, 21131A, 21135A, EXP Dec. 2023; 22019A, EXP Mar. 2024.	CGMP Deviations: products manufactured under conditions which reflect manufacturing processes that were not adequately controlled.	Plastikon Healthcare LLC
Diphenhydramine HCl Oral Solution 12.5 mg / 5 mL, 5 mL cup, packaged in 10 cups per tray, 10 trays per carton, For Institutional Use Only, Major Pharmaceuticals, 17177 N Laurel Park Dr. Suite 233, Livonia, MI 48152, NDC 0904-6740-70	Class II	Drugs	Lot # 20063A, EXP Jun. 2022; 20098A, EXP Oct. 2022; 21055B, EXP May. 2023; 21066A, EXP Jun. 2023; 21083B, EXP Jul. 2023; 21112B, EXP Oct.	CGMP Deviations: products manufactured under conditions which reflect manufacturing processes that were not adequately controlled.	Plastikon Healthcare LLC



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			2023; 22009A, EXP Feb. 2024.		
Diphenhydramine HCl Oral Solution, 25 mg / 10 mL, 10 mL cup, packaged in 10 cups per tray, 10 trays per carton, For Institutional Use Only, Major Pharmaceuticals, 17177 N Laurel Park Dr. Suite 233, Livonia, MI 48152, NDC 0904-6741-72	Class II	Drugs	Lot # 20065A, EXP Jun. 2022; 20068A, 20070A, EXP Jul. 2022; 20097A, 20098A, EXP Oct. 2022; 21055A, EXP May. 2023; 21083A, EXP Jul. 2023; 21091A, EXP Aug. 2023; 21112A, EXP Oct. 2023	CGMP Deviations: products manufactured under conditions which reflect manufacturing processes that were not adequately controlled.	Plastikon Healthcare LLC
GUAIFENESIN AND DEXTROMETHORPHAN 100 mg-10 mg/5 mL, 5 mL cup, packaged in 10 cups per tray, 10 trays per carton, For Institutional Use Only, Major Pharmaceuticals, 17177 N Laurel Park Dr. Suite 233, Livonia, MI 48152. NDC 0904- 6844-70	Class II	Drugs	Lot # 20091A, EXP Sep. 2022; 20104A, EXP Nov. 2022; 21013A, EXP Feb. 2023; 21041A, EXP Apr. 2023; 21102A, EXP Sep. 2023; 21121A, 21127A, EXP Nov. 2023; 22003A, 22007A, EXP Jan. 2024; 22016A, EXP Mar. 2024	CGMP Deviations: products manufactured under conditions which reflect manufacturing processes that were not adequately controlled.	Plastikon Healthcare LLC
GUAIFENESIN AND DEXTROMETHORPHAN 200-20 mg/10 mL, 10 mL cup, packaged in 10 cups per tray, 10 trays per carton, For Institutional Use Only, Major Pharmaceuticals, 17177 N Laurel Park Dr. Suite 233, Livonia, MI 48152, NDC 0904-6980-72	Class II	Drugs	Lot # 20091A, EXP Sep. 2022; 20104A, EXP Nov. 2022; 21017A, EXP Feb. 2023; 21034A, 21036A EXP Mar. 2023; 21092A, EXP Aug. 2023; 21105A, 21106A, EXP Oct. 2023; 21134A, EXP Dec. 2023; 22007B, EXP Jan. 2024; 22012A, EXP Feb. 2024; 22016B, EXP Mar. 2024	CGMP Deviations: products manufactured under conditions which reflect manufacturing processes that were not adequately controlled.	Plastikon Healthcare LLC



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
CORRECTDOSE Children's ALLERGY RELIEF (Diphenhydramine HCl 12.5 mg per 5 mL), 2.04 FL. OZ (60 mL) packaged in 12-5mL individual doses, Distributed by Correct Dose Inc, Braintree MA 02184. NDC 62320-302-05 UPC 8 60003 67144 3	Class II	Drugs	Lot # 21011A, EXP Jan. 2023	CGMP Deviations: products manufactured under conditions which reflect manufacturing processes that were not adequately controlled.	Plastikon Healthcare LLC
CORRECTDOSE Children's PAIN RELIEF & Fever Reducer, Cherry, (Acetaminophen 160 mg per 5 mL), 2.04 FL.OZ (60mL), packaged in 12-5mL individual doses, Distributed by Correct Dose Inc, Braintree MA 02184. NDC 62320-311-05 UPC 8 60003 67145 0	Class II	Drugs	Lot # 20096A, EXP Oct. 2022	CGMP Deviations: products manufactured under conditions which reflect manufacturing processes that were not adequately controlled.	Plastikon Healthcare LLC
CORRECTDOSE Children's COUGH & CHEST CONGESTION DM (Guaifenesin 100 mg / Dextromethorphan 5 mg per 5 mL) 2.04FL. OZ (60mL), packaged in 12-5 individual doses, Distributed by Correct Dose Inc, Braintree MA 02184. NDC 62320-321-05 UPC 8 60003 67146 7	Class II	Drugs	Lot # 21014A, EXP Feb. 2023	CGMP Deviations: products manufactured under conditions which reflect manufacturing processes that were not adequately controlled.	Plastikon Healthcare LLC
Difluprednate Ophthalmic Emulsion, 0.05%, 5 mL bottle, RX only, Manufactured for Exelan Pharmecuticals, Inc., Boca Raton, FL 33432, NDC 76282-708-50.	Class II	Drugs	Lot # DEG5BD2, Exp 07/2023	Lack of Assurance of Sterility: customer complaint for defective container where breakage of the protective cap exposes tip of eye drop which could compromise sterility.	CIPLA
Difluprednate Ophthalmic Emulsion, 0.05%, 5 mL bottle, RX only, Manufactured by Cipla Ltd., India, Manufactured for: Cipla USA, Inc., NJ 07059, NDC 69097-341-35.	Class II	Drugs	Lot #: DEG1HC2, DEG2HC2, DEG3HC2, DEG4HC2, DEG5HC2, DEG6HC2, Exp 01/2023; DEG1IC2, DEG2IC2,	Lack of Assurance of Sterility: customer complaint for defective container where breakage of the protective cap exposes tip of eye	CIPLA



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			DEG3IC2, DEG4IC2, Exp 02/2023; DEG1LC2, DEG2LC2, Exp 05/2023; DEG1BD2, DEG2BD2, DEG3BD2, Exp 07/2023	drop which could compromise sterility.	
Lidocaine Hydrochloride Jelly USP, 2%, Sterile, 30mL tube, Rx only, Manufactured by: Akorn, Inc., Lake Forest, IL 60045, NDC 17478-711-31	Class II	Drugs	Lot # 9J36A, 9J36B, 9J39A, 9J39B, 9J39C, 9J39D, 9J39E, 9J42B, 9J42C, Exp 8/31/2022; 9K62A, 9K62B, 9K62C, Exp 9/30/2022; 9M04A, 9M04B, Exp 11/30/2022	cGMP Deviations: Turbidity discovered in Artificial Tears Ointment during sterility testing. Scope expanded to include other lots and products which potentially share the same root cause.	Akorn, Inc.
Sodium Chloride Ophthalmic Ointment USP, 5%, Sterile, Net Wt 3.5 g (1/8 oz) tube, Mfg by: Akorn, Inc., Lake Forest , IL 600405, NDC 17478-622-35	Class II	Drugs	Lot#: 9J58A, 9J58B, Exp 8/31/2022	cGMP Deviations: Turbidity discovered in Artificial Tears Ointment during sterility testing. Scope expanded to include other lots and products which potentially share the same root cause.	Akorn, Inc.
Magnesium Citrate SALINE LAXATIVE, Oral Solution, 1.745 g, Lemon Flavor, 10 FL OZ (296 mL), a) CVS Health UPC 0 50428 33517 8 or UPC 0 50428 30594 2 Distributed by: CVS Pharmacy, Inc., One CVS Drive, Woonsocket, RI 02895; b) Best Choice UPC 0 70038 20049 9 Proudly Distributed By: Valu Merchandisers, Co. 5000 Kansas Ave Kansas City, KS 66106; c) Care One UPC 3 41520 31322 6 Distributed By: Foodhold U.S.A., LLC, Landover, MD 20785 or Distributed By:	Class II	Drugs	All lots remaining within expiry.	CGMP Deviations	Vi-Jon, LLC



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Adusa Distribution, LLC Salisbury, NC 28147;					
d) Cariba UPC 6 46702 05701 2 Distributed					
by: Cariba International P.O. Box 1208 Safety					
Harbor, Florida 34595; e) Cruz Blanca UPC 3					
0869-7403-08 2 or 3 08697 40308 2					
Fabricado por Vi-Jon Inc. Smyrna, TN 37167					
U.S.A. Dist.; f) Discount Drug Mart UPC 0					
93351 02820 5 Distributed By: Discount					
Drug Mart 211 Commerce Drive, Medina,					
Ohio 44256; g) Equaline NDC 41163-709-38					
UPC 0 41163 50067 9 Distributed by					
SUPERVALU INC. Eden Prairie, MN 55344					
USA or Distributed By UNFI Providence, RI					
02908 USA; h) Equate NDC 49035-506-38					
UPC 6 81131 28714 2 Distributed By:					
Walmart Inc., Bentonville, AR 72716; i)					
Exchange Select 6 14299 40420 5					
Manufactured For Your Military Exchanges					
By: Vi-Jon Inc. 8515 Page Avenue, St. Louis,					
MO 63114; j) Family Wellness UPC 0 32251					
58082 6 Distributed By: Midwood Brands,					
LLC 500 Volvo Parkway Chesapeake, VA					
23330; k) Good Sense NDC 50804-166-38					
UPC 8 46036 00737 4 Distributed By: Geiss,					
Destin & Dunn, Inc. Peachtree City, GA					
30269 or Distributed by: Perrigo Direct, Inc.					
Peachtree City, GA 30269; I) Harris Teeter					
UPC 0 72036 72612 4 Proudly Distributed					
By: Harris Teeter, LLC Matthews, NC 28105;					
m) HEB UPC 0 41220 51086 3 Made With					



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Pride & Care For H-E-B San Antonio, TX					
78204; n) Health Mart NDC 62011-0380-1					
UPC 0 52569 14215 8 Distributed by					
McKesson One Post Street, San Francisco,					
CA 94104; o) Kroger NDC 30142-899-38 UPC					
0 41260 00182 6 Distributed By The Kroger					
CO Cincinnati, Ohio 45202; p) Leader Sugar-					
Free NDC 70000-0424-1 UPC 0 96295 13554					
1 Distributed By Cardinal Health Dublin, OH					
43017; q) Major NDC 0904-6787-44 UPC 3					
09046 78744 0 Distributed By: Major					
Pharmaceuticals 17177 N Laurel Park Drive,					
Suite 233 Livonia, MI 48152; r) Meijer NDC					
41250-708-38 UPC 7 13733 45945 7 Dist. By					
Meijer Distribution, Inc. Grand Rapids, MI					
49544; s) Premier Value UPC 8 40986 03530					
2 Distributed by: Pharmacy Value Alliance					
LLC. 407 East Lancaster Avenue, Wayne, PA					
19087; t) Publix NDC 56062-266-38 UPC 0					
41415 50673 2 Distributed By Publix Super					
Markets, Inc. 3300 Publix Corporate					
Parkway, Lakeland, FL 33811; u) Quality					
Choice UPC 6 35515 90125 4 Distributed by					
C.D.M.A., Inc. 43157 W 9 Mile Rd Novi, MI					
48375; v) Rexall UPC 0 72785 13418 8					
Distributed By Dolgencorp. LLC 100 Mission					
Ridge Goodlettsville, TN 37072 or					
Distributed By Old East Main Co. 100					
Mission Ridge Goodlettsville, TN 37072; w)					
Rite Aid NDC 11822-4330-2 UPC 0 11822					



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
43300 6 Distributed By: Rite Aid 30 Hunter					
Lane Camp Hill, PA 1701; x) Signature Care					
NDC 21130-709-38 UPC 3 21130 77915 5					
Distributed By: Better Living Brands LLC P.O.					
Box 99, Pleasanton, CA 94566-0009; y)					
Sound Body UPC 0 72785 11479 1					
Manufactured for Big Lots by: Vi-Jon, Inc.					
8515 Page Avenue; St. Louis, MO 63114; z)					
Sunmark NDC 70677-0051-1 UPC 0 10939					
90844 5 Distributed By McKesson One Post					
Street, San Francisco, CA 94104 or					
Distributed by McKesson Corp., via Strategic					
Sourcing Services LLC, Memphis, TN 38141;					
aa) Swan NDC 0869-0166-38 UPC 0 72785					
13405 8 Distributed by: Vi-Jon, Inc. One					
Swan Drive Smyrna, TN 37167; bb) Topcare					
health UPC 0 36800 45529 0 Distributed By					
Topco Associates, LLC. Elk Grove Village, IL					
60007; cc) Up & Up NDC 11673-708-38 or					
NDC 11673-666-38 UPC 0 72785 12883 5					
Dist. by Target Corp., Mpls., MN 55403; dd)					
Walgreens NDC 0363-8166-38 UPC 3 11917					
20160 3 Distributed By: Walgreen Co. 200					
Wilmot Rd., Deerfield, IL 60015					
Magnesium Citrate SALINE LAXATIVE, Oral					
Solution, 1.745 g, Cherry Flavor, 10 FL OZ					
(296 mL), a) Best Choice UPC 0 70038 58790	Class II	Drugs	All lots remaining within	CCMP Dovictions	Vi lon II.C
3 Proudly Distributed By: Valu	Ciass II	Drugs	expiry.	CGMP Deviations	Vi-Jon, LLC
Merchandises, Co. 5000 Kansas Ave. Kansas					
City, KS 66106; b) Careone UPC 3 41520					



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
00055 3 Distributed By: Foodhold U.S.A.,					
LLC, Landover, MD 20785, Careone UPC 3					
41520 00055 3 Distributed By: Adusa					
Distribution, LLC Salisbury, NC 28147; c) CVS					
Health UPC 0 50428 29733 9 Distributed by:					
CVS Pharmacy, Inc. One CVS Drive,					
Woonsocket, RI 02895, CVS Health UPC 0					
50428 28515 2 Distributed by: CVS					
Pharmacy, Inc. One CVS Drive, Woonsocket,					
RI 02895; d) Equaline NDC 41163-769-38					
UPC 0 41163 50068 6 Distributed by					
Supervalu Inc. Eden Prairie, MN 55344 USA,					
Equaline NDC: 41163-769-38 UPC 0 41163					
50068 6 Distributed By UNFI Providence, RI					
02908; Equate NDC 49035-593-38 UPC 6					
81131 28716 6 Distributed By: Walmart Inc.,					
Bentonville, AR 72716; Family Wellness NDC					
56319-164-38 UPC 0 32251 57788 8; e)					
GoodSense NDC 50804-164-38 UPC 8 46036					
00739 8 Distributed By: Geiss, Destin &					
Dunn, Inc. Peachtree City, GA 30269,					
GoodSense NDC 508-164-38 UPC 8 46036					
00739 8 Distributed by: Geiss, Destin &					
Dunn, Inc. A Perrigo Company, Peachtree					
City, GA 30269; f) HEB UPC 0 41220 51087 0					
Made with Pride & Care For H-E-B San					
Antonio, TX 78204; g) Health Mart NDC					
62011-0381-1 UPC 0 52569 14216 5					
Distributed by McKesson One Post Street,					
San Francisco, CA 94104, Health Mart NDC					



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
62011-0381-1 NDC 0 52569 14216 5					
Distributed by McKesson Corp., via Strategic					
Sourcing Services LLC, Memphis, TN 38141;					
h) Leader Sugar-Free NDC 70000-0575-1					
UPC 0 96295 14106 1 Distributed By					
Cardinal Health Dublin, Ohio 43017, Leader					
Sugar-Free NDC 70000-0576-1 UPC 0 96295					
14105 4 Distributed By Cardinal Health					
Dublin, Ohio 43017; i) Meijer Sugar Free					
Low Sodium NDC 41250-769-38 UPC 7					
13733 45944 0 Dist. By Meijer Distribution,					
Inc. Grand Rapids, MI 49544; j) Premier					
Value UPC 8 40986 03529 6 Distributed by:					
Pharmacy Value Alliance LLC 407 East					
Lancaster Avenue, Wayne, PA 19087; k) P					
NDC 56062-264-38 UPC 0 41415 50573 5					
Distributed By Publix Super Markets, Inc.					
3300 Publix Corporation Parkway, Lakeland,					
FL 33811; I) Quality Choice UPC 6 35515					
90111 7 Distributed by C.D.M.A., Inc. 43157					
W 9 Mile Rd Novi, MI 48375; Rexall UPC 0					
72785 13416 4 Distributed By Dolgencorp,					
LLC 100 Mission Ridge Goodlettsville, TN					
37072 USA, Rexall UPC 0 72785 13416 4					
Distributed By Old East Main Co. 100					
Mission Ridge Goodlettsville, TN 37072; m)					
Rite Aid NDC 11822-4303-2 UPC 0 11822					
43303 7 Distributed By: Rite Aid 30 Hunter					
Lane Camp Hill, PA 17011; Signature Care					
NDC 21130-165-38 UPC 3 21130 78971 0					

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Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Distributed By Better Living Brands LLC P.O.					
Box 99, Pleasanton, CA 94566; n) Sunmark					
NDC 70677-0053-1 UPC 0 10939 91044 8					
Distributed By McKesson One Post Street,					
San Francisco, CA 94104; o) Swan Very Low					
Sodium NDC 0869-0164-38 UPC 3 08690					
69338 1 Distributed by: Vi-Jon, Inc. One					
Swan Drive Smyrna, TN 37167; p) TopCare					
Health NDC 36800-164-38 UPC 0 36800					
45530 6 Distributed By Topco Associates LLC					
Elk Grove Village, IL 60007; q) Walgreens					
NDC 0363-8164-38 UPC 3 11917 20158 0					
Distributed By: Walgreen Co., 200 Wilmot					
RD., Deerfield, IL 60015 (red label),					
Walgreens NDC 0363-8164-38 UPC 3 11917					
20158 0 Distributed By: Walgreen Co. 200					
Wilmot RD., Deerfield, IL 60015					
Magnesium Citrate SALINE LAXATIVE, Oral					
Solution, 1.745 g, Grape Flavor, 10 FL OZ					
(296 mL), a) Best Choice UPC 0 70038 66220					
4 Proudly Distributed By: Valu					
Merchandisers, Co. 5000 Kansas Ave Kansas					
City, KS 66106; b) CVS Health UPC 0 50428			All lots remaining within		
30745 8 Distributed by: CVS Pharmacy, Inc.	Class II	Drugs	•	CGMP Deviations;	Vi-Jon, LLC
One CVS Drive, Woonsocket, RI 02895, CVS			expiry.		
Health UPC 0 50428 32503 2 Distributed by:					
CVS Pharmacy, Inc. One CVS Drive,					
Woonsocket, RI 02895; c) Equate NDC					
49035-592-38 UPC 6 81131 28715 9					
Distributed By: Walmart, Inc. Bentonville, AR					



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
72716; d) HEB UPC 0 41220 51088 7 Made With Pride & Care For H-E-B San Antonio, TX 78204; Kroger UPC 0 41260 00871 9 Distributed By The Kroger Co. Cincinnati, Ohio 45202; e) Leader NDC 70000-0576-1 UPC 0 96295 14105 4 Distributed By Cardinal Health Dublin, Ohio 43017; f) Rexall UPC 0 72785 13417 1 Distributed By Dolgencorp, LLC 100 Mission Ridge Goodlettsville, TN 37072 USA, Rexall UPC 0 72785 13417 1 Distributed By Old East Main Co. 100 Mission Ridge Goodlettsville, TN 37072; g) Walgreens NDC 0363-7162-38 UPC 3 11917 20159 7 Distributed By: Walgreen Co., 200 Wilmot RD., Deerfield, IL 60015 (purple label), Walgreens NDC 0363-7162-38 UPC 3 11917 20159 7 Distributed					
By: Walgreen Co. 200 Wilmot RD., Deerfield, IL 60015 (blue label)					
L-Carnitine 500 mg/mL Injectable, 10 ML vial, Rx only, Carolina Infusion LLC, 95 Bees Creek Road, Ridgeland, SC 29936.	Class II	Drugs	Lot: 06132022@17; BUD: 02/15/2023	Lack of Assurance of Sterility	Carolina Infusion
MIC/B12 25/50/50/1 MG/ML Injectable, 10 ML vial, Rx only, Carolina Infusion LLC, 95 Bees Creek Road, Ridgeland, SC 29936.	Class II	Drugs	Lots: 08012022@4 BUD: 01/28/2023; 08082022@12 BUD: 02/04/2023	Lack of Assurance of Sterility	Carolina Infusion
MIC/B12/L-Carn (HD) 35/35/35/1/35 MG/ML Injectable, 10 ML vial, Rx only, Carolina Infusion LLC, 95 Bees Creek Road, Ridgeland, SC 29936.	Class II	Drugs	Lots: 05042022@4 BUD: 10/31/2022; 062920222@9 BUD:	Lack of Assurance of Sterility	Carolina Infusion



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			12/26/2022; 07262022@3 BUD: 01/22/2023		
Sermorelin Acetate 1 MG/ML Injectable, 9 ML syringes, Carolina Infusion LLC, 95 Bees Creek Road, Ridgeland, SC 29936.	Class II	Drugs	Lots: 08012022@14 BUD: 08/31/2022; 08192022@7 BUD: 09/23/2022	Lack of Assurance of Sterility	Carolina Infusion
Semaglutide/Cyanocobalamin 5/2 MG/ML Injectable, 0.2 ML syringe, Rx only, Carolina Infusion LLC, 95 Bees Creek Road, Ridgeland, SC 29936.	Class II	Drugs	Lots: 08122022@8 BUD: 09/11/2022; 08162022@3 BUD: 09/15/2022	Lack of Assurance of Sterility	Carolina Infusion
Semaglutide/Cyanocobalamin 10/2 MG/ML Injectable, 0.4 ML syringe, Rx only, Carolina Infusion LLC, 95 Bees Creek Road, Ridgeland, SC 29936.	Class II	Drugs	Lot: 08152022@14 BUD: 09/14/2022	Lack of Assurance of Sterility	Carolina Infusion
Semaglutide/Cyanocobalamin 24/2 MG/ML Injectable, 0.4 ML syringe, Rx only, Carolina Infusion LLC, 95 Bees Creek Road, Ridgeland, SC 29936.	Class II	Drugs	Lot: 08172022@1 BUD: 09/16/2022	Lack of Assurance of Sterility	Carolina Infusion
TEST CYP (Grapeseed) 200 MG/ML Injectable, 10 ML vial, Rx only, Carolina Infusion LLC, 95 Bees Creek Road, Ridgeland, SC 29936.	Class II	Drugs	Lots: 06132022@5 BUD: 09/11/2022; 08082022@17 BUD: 11/06/2022	Lack of Assurance of Sterility	Carolina Infusion
TEST CYP/DHEA (Sesame Oil) 100 MG/2.5 MG/ML Injection, 3 ML and 6 ML vials, Rx only, Carolina Infusion LLC, 95 Bees Creek Road, Ridgeland, SC 29936.	Class II	Drugs	Lots: 07182022@9 BUD: 10/16/2022; 07272022@15 BUD: 10/25/2022	Lack of Assurance of Sterility	Carolina Infusion
TEST CYP/DHEA (Sesame) 200 MG/2.5 MG/ML Injectable, 10 ML vial, Carolina Infusion LLC, 95 Bees Creek Road, Ridgeland, SC 29936.	Class II	Drugs	Lots: 06012022@1, 06012022@2 BUD: 08/30/2022; 06032022@1, 06032022@2,	Lack of Assurance of Sterility	Carolina Infusion



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			06032022@13 BUD:		
			09/01/2022;		
			06062022@7, BUD:		
			09/04/2022;		
			06072022@3,		
			06072022@4 BUD:		
			09/05/2022;		
			06082022@1,		
			06082022@2,		
			06082022@4 BUD:		
			09/06/2022;		
			06102022@8, BUD:		
			09/08/2022; 09/11/2022;		
			06132022@1,		
			06132022@7,		
			06132022@14,		
			06132022@15, BUD:		
			09/11/2022;		
			06142022@7,		
			06142022@8,		
			06142022@15, BUD:		
			09/12/2022;		
			06152022@2, BUD:		
			09/13/2022;		
			06172022@4, BUD:		
			09/15/2022;		
			06202022@9,		
			06202022@10,		
			06202022@23, BUD:		
			09/18/2022;		



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			06212022@2, BUD:		
			09/19/2022;		
			06222022@2,		
			06222022@3, BUD:		
			09/20/2022;		
			06242022@4,		
			06242022@5, BUD:		
			09/22/2022;		
			06272022@3, BUD:		
			09/25/2022;		
			06292022@5,		
			06292022@6, BUD:		
			09/27/2022;		
			07012022@11,		
			07012022@12, BUD:		
			09/29/2022;		
			07052022@3,		
			07052022@4, BUD:		
			10/03/2022;		
			07062022@4,		
			07062022@5,		
			07062022@10, BUD:		
			10/04/2022;07082022@4,		
			07082022@5, BUD:		
			10/06/2022;		
			07092022@12,		
			07092022@13, BUD:		
			10/07/2022;		
			07112022@16,		
			07112022@17, BUD:		



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			10/09/2022;		
			07122022@14,		
			07122022@15, BUD:		
			10/10/2022;		
			07132022@5, BUD:		
			10/11/2022;		
			07152022@11,		
			07152022@12, BUD:		
			10/13/2022;		
			07182022@2,		
			07182022@3, BUD:		
			10/16/2022;		
			07192022@10,		
			07192022@11,		
			07192022@22, BUD:		
			10/17/2022;		
			07202022@9,		
			07202022@10,		
			07202022@11, BUD:		
			10/18/2022;		
			07222022@2, BUD:		
			10/20/2022;		
			07252022@18,		
			07252022@19, BUD:		
			10/23/2022;		
			07272022@12, BUD:		
			10/25/2022;		
			07282022@5, BUD:		
			10/26/2022;		
			07292022@4,		



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			07292022@5, BUD:		
			10/27/2022;		
			08012022@6,		
			08012022@7, BUD:		
			10/30/2022;		
			08022022@1, BUD:		
			10/31/2022;		
			08032022@8,		
			08032022@12,		
			08032022@13, BUD:		
			11/01/2022;		
			08052022@5,		
			08052022@6, BUD:		
			11/03/2022;		
			08082022@9,		
			08082022@15,		
			08082022@16, BUD:		
			11/06/2022;		
			08092022@10,		
			08092022@11, BUD:		
			11/07/2022;		
			08122022@5,		
			08122022@6, BUD:		
			11/10/2022;		
			08152022@16,		
			08152022@17,		
			08152022@20, BUD:		
			11/13/2022;		
			08192022@24,		
			08192022@5 <i>,</i>		



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			08192022@6, 08192022@25, BUD: 11/17/2022; 08222022@9, 08222022@10, BUD: 11/20/2022; 08232022@15, 08232022@18, BUD: 11/21/2022		
TEST CYP/PROP (50:50) 100 MG/100 MG/ML Injectable, 12.6 ML vial, Rx only, Carolina Infusion LLC, 95 Bees Creek Road, Ridgeland, SC 29936.	Class II	Drugs	Lot: 07052022@1 BUD: 10/08/2022	Lack of Assurance of Sterility	Carolina Infusion
TRI-MIX 30/1/10 Injectable, 10 ML vial, Rx only, Carolina Infusion LLC, 95 Bees Creek Road, Ridgeland, SC 29936.	Class II	Drugs	Lots: 06282022@1, BUD: 08/27/2022; 06292022@8, BUD: 08/28/2022; 07012022@19, BUD: 08/30/2022; 07012022@3, BUD: 08/30/2022; 07122022@8, BUD: 09/10/2022; 07132022@9, BUD: 09/11/2022; 07192022@1, BUD: 09/17/2022; 07292022@9, BUD: 09/27/2022; 08032022@10, BUD:	Lack of Assurance of Sterility	Carolina Infusion



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			10/02/2022; 08092022@2, BUD: 10/08/2022; 08102022@1, 08102022@6, 08102022@7, BUD: 10/09/2022; 08152022@5, BUD: 10/14/2022; 08192022@1, 08192022@1,		
TRI-MIX 30/1/20 Injectable, 5 ML vial, Rx only, Carolina Infusion LLC, 95 Bees Creek Road, Ridgeland, SC 29936.	Class II Dru	Drugs	10/18/2022 Lots: 06272022@6 BUD: 08/26/2022; 07212022@3 BUD: 09/19/2022; 07292022@11 BUD: 09/27/2022; 08052022@7 BUD: 10/04/2022; 08102022@5 BUD:	Lack of Assurance of Sterility	Carolina Infusion
			10/09/2022; 08122022@14 BUD: 10/11/2022; 08172022@7 BUD: 10/16/2022		
TRI-MIX 30/1/40 Injectable, 10 ML vial, Rx only, Carolina Infusion LLC, 95 Bees Creek Road, Ridgeland, SC 29936.	Class II	Drugs	Lots: 07052022@8, BUD: 09/03/2022; 07292022@10, BUD: 09/27/2022	Lack of Assurance of Sterility	Carolina Infusion
TRI-MIX 30/1/60 Injectable, 5 ML vial, Rx only, Carolina Infusion LLC, 95 Bees Creek Road, Ridgeland, SC 29936.	Class II	Drugs	Lots: 07012022@6, BUD: 09/20/2022; 07192022@16, BUD:	Lack of Assurance of Sterility	Carolina Infusion



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			09/17/2022; 07012022@4, BUD: 08/30/2022		
TRI-MIX 30/2/20 Injectable, 10 ML vial, Rx only, Carolina Infusion LLC, 95 Bees Creek Road, Ridgeland, SC 29936.	Class II	Drugs	Lots: 07052022@10, BUD: 09/03/2022; 07052022@16, BUD: 09/03/2022; 07122022@11, BUD: 09/08/2022; 07182022@17, BUD: 09/16/2022; 07202022@6, BUD: 09/18/2022; 07252022@9, BUD: 09/23/2022; 072920222@2, BUD: 09/27/2022; 07292022@13, BUD: 09/27/2022; 08122022@9, BUD: 10/11/2022; 08162022@2, BUD: 10/15/2022; 082620222@1, BUD: 10/25/2022	Lack of Assurance of Sterility	Carolina Infusion
TRI-MIX 30/2/40 Injectable, 10 ML vial, Rx only, Carolina Infusion LLC, 95 Bees Creek Road, Ridgeland, SC 29936.	Class II	Drugs	Lots: 07152022@4, BUD: 09/13/2022; 08152022@15, BUD: 10/14/2022	Lack of Assurance of Sterility	Carolina Infusion



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
TRI-MIX 50/2.5/25 Injectable, 2 ML vial, Rx only, Carolina Infusion LLC, 95 Bees Creek Road, Ridgeland, SC 29936.	Class II	Drugs	Lot: 07052022@2, BUD: 09/03/2022	Lack of Assurance of Sterility	Carolina Infusion
QUAD-MIX 30/2/60/0.15 Injectable, 5 ML vial, Rx only, Carolina Infusion LLC, 95 Bees Creek Road, Ridgeland, SC 29936.	Class II	Drugs	Lot: 08022022@12, BUD: 10/01/2022	Lack of Assurance of Sterility	Carolina Infusion
QUAD-MIX 30MG/3MG/60MCG/0.2 Injectable, 10 ML vial, Rx only, Carolina Infusion LLC, 95 Bees Creek Road, Ridgeland, SC 29936.	Class II	Drugs	Lot: 08082022@3, BUD: 10/07/2022	Lack of Assurance of Sterility	Carolina Infusion
Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate and Amphetamine Sulfate Tablets (Mixed Salts of a Single Entity Amphetamine Product), 15 mg, Rx Only, 100 tablets per bottle, Teva Pharmaceuticals USA, Inc. North Wales, PA 19454, NDC 0555-0777-02.	Class II	Drugs	Lot #: 100023340, Exp 10/2024	Labeling: Label Error on Declared Strength; A sealed 100-count bottle labeled with 15 mg actually contained 100 tablets of 20 mg strength of the drug product.	Teva Pharmaceutic als USA Inc
Synergy Hand Sanitizer, Non-Sterile Solution to help reduce bacteria that can potentially cause disease, For use when soap and water are not available, Alcohol 80% Topical Solution, Antiseptic, 8.5 oz./ 250 mL bottles, Made and Distributed by: Superior Glove Works Ltd., 36 Vimy Street, Acton, Ontario, L7J 1S1, Canada, Made in Canada, UPC: 779406201594.	Class II	Drugs	Lot # 200513TA, Exp. 05/2023.	CGMP Deviations: FDA analysis found product to contain acetaldehyde impurity and the Sum of All Impurities, above specification limits.	SUPERIOR GLOVE WORKS, LTD.
Bupivacaine HCl 0.375% w/v and Lidocaine HCl 2% w/v Solution for Retrobulbar or Peribulbar Injection; packaged in a) 10 mL	Class II	Drugs	Lot #s: a) 58366, exp. date 09/26/2022; 60247, exp. date 12/04/2022; b)	Lack of Assurance of Sterility	Pine Pharmaceutic als, LLC



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
prefilled syringe, Item# 803, barcode 6919408031; b) 5 mL prefilled syringe, Item# 933, barcode 6919409331, Rx only, Pine Pharmaceuticals, 355 Riverwalk Parkway, Tonawanda, NY 14150.			54825, exp. date 08/10/2022; 57583, exp. date 08/22/2022; 59343, exp. date 10/30/2022; 60355, exp. date 10/11/2022		
Lisinopril Tablets USP, 10 mg, 1000-count bottles, Rx Only, Manufactured for: Lupin Pharmaceuticals, Inc. Baltimore, Maryland 21202, Manufactured by: Lupin Limited, Nagpur- 441 108, India. NDC 68180-980-03	Class II	Drugs	Lot # Q201182, exp. date March 2024	Presence of Foreign Substance: Foreign material (metal piece) embedded in one tablet.	Lupin Pharmaceutic als Inc.
Triamcinolone Acetonide cream, 0.1%, 80 g tube, Rx only, Packaged and Distributed By: Direct Rx, Dawsonville, GA 30534, Dist. By Perrigo, Allegan, MI 49010, NDC 72189-330-80.	Class II	Drugs	Lot: 12JY2216, Exp. 2/29/24	CGMP Deviations: Product complaints reporting the product to have a gritty texture and lack of effectiveness.	Direct Rx
Lisinopril 10 mg tablets, 30-count Blister Card, Rx Only, MFG: Lupin Pharma, Baltimore, MD Repackaged by: RemedyRepack Inc, Indiana PA. Original NDC# 68180-0980-03, Repackaged NDC# 70518-0468-00	Class II	Drugs	Lot # J0636336-073022, J0637605-080422, Exp. date 08/31/2023	Presence of Foreign Substance: Foreign material (metal piece) embedded in one tablet.	RemedyRepac k Inc.
Nighttime Sleep-Aid (doxylamine succinate HCl) tablets, 25 mg, 48-count blisters per carton, Distributed by: CVS Pharmacy, Inc., One CVS Drive, Woonsocket, RI 02895, UPC 0 50428 34873 4.	Class III	Drugs	P121512, exp. date 08/2023; P122015, exp. date 09/2023; P122712, exp. date 11/2023; P123090, exp. date 12/2023; P123170, exp. date 12/2023; P124325, exp. date 03/2024;	Labeling: Not Elsewhere Classified: Carton incorrectly identifies product as doxylamine succinate HCl, however the product is doxylamine succinate.	LNK International, Inc.



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			P124664, exp. date 03/2024; P125165, exp. date 05/2024; P125576, exp. date 06/2024; P125577, exp. date 06/2024; P127089, exp. date 10/2024; P127090, exp. date 10/2024; P127386, exp. date 11/2024; P128572, exp. date 01/2025; P128383, exp. date 01/2025; P129536, exp. date 04/2025		
Timolol Maleate Ophthalmic Solution, USP, 0.5%, 5 x 0.3 mL Single-Dose Vials, Rx Only, Sterile, Manufactured for: Akorn, Inc., Lake Forest, IL 60045. NDC 17478-189-24	Class III	Drugs	Lot #: 9N72, EXP 09/30/2022	Identification of an unknown impurity at the 12-month stability point. Further investigation has identified the impurity as Timolol Phenol S-Oxide.	Akorn, Inc
Banana Boat Hair & Scalp Defense, Clear Sunscreen Spray SPF 30, packaged in aluminum spray can, Net Wt 6 oz., Distributed by: Edgewell Personal Care Brands, LLC, Shelton, CT 06484, UPC 0 7965604041 8	Not Yet Classified	Drugs	Lot #: 20016AF, Exp 12/22; 20084BF, Exp 2/23; 21139AF, Exp 4/24	Chemical contamination: presence of Benzene	Edgewell Personal Care Brands, LLC

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



CURRENT DRUG SHORTAGES

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

Generic Name or Active Ingredient

Amifostine Injection

Amino Acids

Amoxapine Tablets

Atropine Sulfate Injection

Azacitidine for Injection

Azithromycin (Azasite) Ophthalmic Solution 1%

Bacteriostatic 0.9% Sodium Chloride Injection

Bacteriostatic Water for Injection

Belatacept (Nulojix) Lyophilized Powder for Injection

Belladonna and Opium Suppositories

Bumetanide Injection

Bupivacaine Hydrochloride and Epinephrine Injection

Bupivacaine Hydrochloride Injection

Calcium Disodium Versenate Injection

Calcium Gluconate Injection

Cefazolin Injection

Cefixime Oral Capsules

Cefotaxime Sodium Injection

Cefotetan Disodium Injection

Chlordiazepoxide Hydrochloride Capsules

Chloroprocaine Hydrochloride Injection

Conivaptan Hydrochloride (Vaprisol) in 5% Dextrose Plastic Container

Conjugated Estrogens/Bazedoxifene (DUAVEE) Tablet, Film Coated

Cortisone Acetate Tablets

Cyclopentolate Ophthalmic Solution

Cytarabine Injection

Dacarbazine Injection

Desmopressin Acetate Nasal Spray

Dexamethasone Sodium Phosphate Injection

Dexmedetomidine Injection

Dextrose 10% Injection

Dextrose 25% Injection

Dextrose 5% Injection

Dextrose 50% Injection

Diazepam Rectal Gel

Diflunisal Tablets

Digoxin Injection

Diltiazem Hydrochloride Injection



Disopyramide Phosphate (Norpace) Capsules

Dobutamine Hydrochloride Injection

Dopamine Hydrochloride Injection

Echothiophate Iodide (Phospholine Iodide) Ophthalmic Solution

Enalaprilat Injection

Epinephrine Injection, 0.1 mg/mL

Epinephrine Injection, Auto-Injector

Erythromycin Ophthalmic Ointment

Fentanyl Citrate (Sublimaze) Injection

Floxuridine for Injection

Fludarabine Phosphate Injection

Fluorescein Injection

Flurazepam Hydrochloride Capsules

Fluvoxamine ER Capsules

Furosemide Injection

Gentamicin Sulfate Injection

Guanfacine Hydrochloride Tablets

Heparin Sodium and Sodium Chloride 0.9% Injection

Hydromorphone Hydrochloride Injection

Hydroxypropyl (Lacrisert) Cellulose Ophthalmic Insert

Ibutilide Fumarate Injection

Indigotindisulfonate Sodium Injection

Iodixanol Injection

Iohexol Injection

Iomeprol injection

Iopromide (Ultravist) Injection

Isoniazid Injection

IV Fat Emulsion

Ketamine Injection

Ketoprofen Capsules

Ketorolac Tromethamine Injection

Leucovorin Calcium Lyophilized Powder for Injection

Leuprolide Acetate Injection

Lidocaine Hydrochloride (Xylocaine) and Dextrose Injection Solution-Premix Bags

Lidocaine Hydrochloride (Xylocaine) Injection

Lidocaine Hydrochloride (Xylocaine) Injection with Epinephrine

Lithium Oral Solution

Lorazepam Injection

Mannitol Injection

Mepivacaine Hydrochloride Injection

Methyldopa Tablets

Methylprednisolone Acetate Injection

Metronidazole Injection

Midazolam Injection

Morphine Sulfate Injection

Multi-Vitamin Infusion (Adult and Pediatric)



Nizatidine Capsules

Oxytocin Injection

Paclitaxel Injection (protein-bound particles)

Pantoprazole Sodium for Injection

Parathyroid Hormone (Natpara) Injection

Pentostatin Injection

Physostigmine Salicylate Injection

Potassium Acetate Injection

Potassium Chloride Concentrate Injection

Promethazine (Phenergan) Injection

Propofol Injectable Emulsion

Protamine Sulfate Injection

Remifentanil Injection

Rifampin Capsules

Rifampin Injection

Rifapentine Tablets

Ropivacaine Hydrochloride Injection

Semaglutide (Ozempic) Injection

Semaglutide (WEGOVY®) Injection

Sincalide (Kinevac) Lyophilized Powder for Injection

Sodium Acetate Injection

Sodium Bicarbonate Injection

Sodium Chloride 0.9% Injection Bags

Sodium Chloride 14.6% Injection

Sodium Chloride 23.4% Injection

Sodium Chloride Injection USP, 0.9% Vials and Syringes

Sodium Phosphates Injection

Sterile Water for Injection

Streptozocin (Zanosar) Sterile Powder

Sufentanil Citrate Injection

Sulfasalazine Tablets

Technetium TC-99M Mebrofenin Injection

Technetium Tc99m Succimer Injection (DMSA)

Teprotumumab-trbw

Thiothixene Capsules

Triamcinolone Acetonide Injectable Suspension

Triamcinolone Hexacetonide Injectable suspension

Trimethobenzamide Hydrochloride Capsules

Valproate Sodium Injection

Vandetanib Tablets

Vecuronium Bromide for Injection