

Drug Information Update

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NEWLY AVAILABLE GENERICS

Generic Name/ Dosage Form	Brand Name	Manufacturer	Indication		
Vimpat	Lacosamide 10 mg/mL solution	UCB Pharma	• Partial-onset seizures in patients 1 month of age and older Adjunctive therapy in the treatment of primary generalized tonic-clonic seizures in patients 4 years of age and older.		
Breo Ellipta	fluticasone/vilanterol 100 mcg-25 mcg/dose, 200 mcg- 25 mcg/dose blister w/device	GSK	 Once-daily treatment of asthma in patients aged 18 years and older. Breo Ellipta 100/25 is indicated for the long-term, once-daily, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema. Breo Ellipta 100/25 is also indicated to reduce exacerbations of COPD in patients with a history of exacerbations. Breo Ellipta 100/25 once daily is the only strength indicated for the treatment of COPD. 		
Clenia Plus	sulfacetamide sodium/sulfur 9%- 4.25% suspension	Scite Pharma	Topical control of acne vulgaris, acne rosacea and seborrheic dermatitis.		
Flovent HFA	fluticasone propionate 44 mcg, 110 mcg, 220 mcg/actuation aerosol	GSK	Maintenance treatment of asthma as prophylactic therapy in adult and pediatric patients aged 4 years and older.		
Targretin	bexarotene 1% gel	Bausch Health	Topical treatment of cutaneous lesions in patients with CTCL (Stage IA and IB) who have refractory or persistent disease after other therapies or who have not tolerated other therapies.		
Alimta	Pemetrexed disodium 100 mg, 500 mg vial	Eli Lilly	 Non-Squamous Non-Small Cell Lung Cancer (NSCLC): in combination with pembrolizumab and platinum chemotherapy, for the initial treatment of patients with metastatic non-squamous NSCLC, with no EGFR or ALK genomic tumor aberrations. in combination with cisplatin for the initial treatment of patients with locally advanced or metastatic, non-squamous, non-small cell lung cancer (NSCLC). 		



Generic Name/ Dosage Form	Brand Name	Manufacturer	Indication
			 as a single agent for the maintenance treatment of patients with locally advanced or metastatic, non-squamous NSCLC whose disease has not progressed after four cycles of platinum-based first-line chemotherapy. as a single agent for the treatment of patients with recurrent, metastatic non-squamous, NSCLC after prior chemotherapy. Mesothelioma: in combination with cisplatin, for the initial treatment of patients with malignant pleural mesothelioma whose disease is unresectable or who are otherwise not candidates for curative surgery.
Viibryd	Vilazodone 10 mg, 20 mg, 40 mg tablet	Allergan	Treatment of major depressive disorder (MDD) in adults.
Nexavar	Sorafenib tosylate 200 mg tablet	Bayer	 Hepatocellular Carcinoma Nexavar is indicated for the treatment of patients with unresectable hepatocellular carcinoma (HCC). Renal Cell Carcinoma Nexavar is indicated for the treatment of patients with advanced renal cell carcinoma (RCC). Differentiated Thyroid Carcinoma Nexavar is indicated for the treatment of patients with locally recurrent or metastatic, progressive, differentiated thyroid carcinoma (DTC) that is refractory to radioactive iodine treatment.
Pemfexy	Pemetrexed 25 mg/mL vial	Eagle	 In combination with cisplatin for the initial treatment of patients with locally advanced or metastatic non-squamous, non-small cell lung cancer (NSCLC). As a single agent for the maintenance treatment of patients with locally advanced or metastatic non-squamous NSCLC whose disease has not progressed after four cycles of platinum-based first-line chemotherapy. As a single agent for the treatment of patients with recurrent, metastatic non-squamous NSCLC after prior chemotherapy. Limitations of Use: PEMFEXY is not indicated for the treatment of patients with squamous cell non-small cell lung cancer.



Generic Name/ Dosage Form	Brand Name	Manufacturer	Indication	
			In combination with cisplatin for the initial treatment, of patients with malignant pleural mesothelioma whose disease is unresectable or who are otherwise not candidates for curative surgery.	



NEW DRUG ENTITIES/STRENGTHS/COMBINATIONS

Drug Name	Generic Name	Description	Comments
Voquezna Dual Pak 20 mg (28)-500 mg (84) oral pack	vonoprazan/amoxicillin	Combination of products indicated for treatment of Helicobacter pylori (H. pylori) infection in adults. Vonoprazan is a novel, first-in-class potassium- competitive acid blocker (PCAB).	New Entity and New Combination
Voquezna Triple Pak 20 mg- 500 mg-500 mg oral pack	vonoprazan/amoxicillin/ clarith	Combination of products indicated for treatment of Helicobacter pylori (H. pylori) infection in adults. Vonoprazan is a novel, first-in-class potassium- competitive acid blocker (PCAB).	New Entity and New Combination
metformin 625 mg tablet	metformin hcl	generic new strength	New Strength
Vtama 1 % topical cream	tapinarof	Novel aryl hydrocarbon receptor agonist, indicated for the topical treatment of plaque psoriasis in adults.	New Entity
pemetrexed disodium 750, 1,000 mg intravenous solution	pemetrexed disodium	New strength not offered by brand Alimta	New Strength
pemetrexed disodium 25 mg/mL intravenous solution	pemetrexed disodium	505(b)(2) drug approval for various uses in NSCLC and mesothelioma.	New Formulation and Strength
pemetrexed 100, 500, 1000 mg intravenous powder for solution	pemetrexed	505(b)(2) drug approval for various uses in NSCLC and mesothelioma. Not yet priced.	New Dosage Form (lyophilized powder)
Beovu 6 mg/0.05 mL intravitreal syringe	brolucizumab-dbll	New syringe form	New Dosage Form
Posimir 132 mg/mL intra- subacromial injection soln	bupivacaine	To produce post-surgical analgesia for up to 72 hours following arthroscopic subacromial decompression	New Strength
Adlarity 5 mg/24 hour, 10 mg/24 hr transdermal patch	donepezil hcl	Once weekly transdermal patch for treatment of patients with mild, moderate, or severe dementia of the Alzheimer's type. 505(b)(2) approval.	New Route and Dosage Form



Drug Name	Generic Name	Description	Comments	
Alymsys 25 mg/mL intravenous solution	bevacizumab-maly	New Avastin biosimilar	Biosimilar to Avastin	
RoxyBond 5, 15, 30 mg tablet, oral ONLY (not feeding tubes)	oxycodone hcl	Obsolete since 9/24/2019. Reintroduced under a different manufacturer – Protega Pharmaceuticals	Obsolete since 9/24/2019. Reintroduced under a different manufacturer – Protega Pharmaceuticals	
Byooviz 0.5 mg/0.05 mL intravitreal solution	ranibizumab-nuna	First FDA approved Lucentis biosimilar; not classified as interchangeable. Approved for the treatment of neovascular (wet) age-related macular degeneration (AMD), macular edema following retinal vein occlusion (RVO), and myopic choroidal neovascularization (mCNV).	Biosimilar to Lucentis	
Tyvaso DPI 16, 32, 48, 64 mcg cartridge with inhaler	treprostinil	Treprostinil in a dry powder inhaler formulation for treatment of PAH and pulmonary hypertension associated with interstitial lung disease.	New Dosage Form and Strength	
Tyvaso DPI 16 mcg (112)-32 mcg (84) cartridge, 16 (112)- 32 (112)-48 (28) mcg with inhaler titration kits	treprostinil	Treprostinil in a dry powder inhaler formulation for treatment of PAH and pulmonary hypertension associated with interstitial lung disease.	New Dosage Form and Strength	
Tyvaso DPI 32 mcg-48 mcg cartridge with inhaler maintenance kit	treprostinil	Treprostinil in a dry powder inhaler formulation for treatment of PAH and pulmonary hypertension associated with interstitial lung disease.	New Dosage Form and Strength	
Priorix (PF) 10exp3.4-4.2-3.3 CCID50/0.5mL subcutaneous solution	measles, mumps, rubella vacc/pf	Alternative MMR vaccine approved for ages 12 months and older	New Formulation	
Olumiant 4 mg tablet	baricitinib	New strength tablet due to approval for COVID-19 treatment and alopecia areata	New Strength	
Ztalmy 50 mg/mL oral ganaxolone		Oral suspension for the treatment of seizures associated with cyclin-dependent kinase-like 5 deficiency disorder (CDD), a rare form of genetic epilepsy, in patients two years of age and older.	New Entity	



Drug Name	Generic Name	Description	Comments
Nucala 40 mg/0.4 mL subcutaneous syringe	mepolizumab	New strength in prefilled syringe	New Strength

PERFORM

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 ⁺
Vidaza	Azacitidine for injection, lyophilized powder in 100 mg single dose vials	Celgene/BMS	 Adult patients with the following FAB myelodysplastic syndrome (MDS) subtypes: Refractory anemia (RA) or refractory anemia with ringed sideroblasts (RARS) (if accompanied by neutropenia or thrombocytopenia or requiring transfusions), refractory anemia with excess blasts (RAEB), refractory anemia with excess blasts in transformation (RAEB-T), and chronic myelomonocytic leukemia (CMMoL). Pediatric patients aged 1 month and older with newly diagnosed Juvenile Myelomonocytic Leukemia (JMML).
Dupixent	Dupilumab injection, 100 mg/0.67 mL, 200 mg/1.14 mL, and 300 mg/2 mL syringes; 200 mg/1.14 mL and 300 mg/2 mL pens	Sanofi-Aventis	 For the treatment of adult and pediatric patients aged 6 years and older aged 6 months and older with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. DUPIXENT can be used with or without topical corticosteroids. As an add-on maintenance treatment of adult and pediatric patients aged 6 years and older with moderate-to-severe asthma characterized by an eosinophilic phenotype or with oral corticosteroid dependent asthma. Limitations of Use: Not for the relief of acute bronchospasm or status asthmaticus. As an add-on maintenance treatment in adult patients with inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP). For the treatment of adult and pediatric patients aged 12 years and older, weighing at least 40 kg, with eosinophilic esophagitis (EoE).
Tibsovo	Ivosidenib tablets, 250 mg	Servier Pharmaceuticals	 In combination with azacitidine or as monotherapy for the treatment of newly diagnosed AML in adults 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy For the treatment of adult patients with relapsed or refractory AML For the treatment of adult patients with locally advanced or metastatic cholangiocarcinoma who have been previously treated



Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication ⁺
Yervoy	Ipilimumab injection, 50 mg/10 mL and 200 mg/40 mL in single-dose vials	Bristol Myers Squibb	Yervoy, in combination with nivolumab, is indicated for the first-line treatment of patients with unresectable advanced or metastatic esophageal squamous cell carcinoma. Note: Yervoy has many other indications not presented here because there were no changes
Opdivo	Nivolumab injection, 40 mg/4 mL, 100 mg/10 mL, 120 mg/12 mL, and 240 mg/24 mL solution in single- dose vials	Bristol Myers Squibb	OPDIVO, in combination with fluoropyrimidine- and platinum-based chemotherapy, is indicated for the first-line treatment of patients with unresectable advanced or metastatic esophageal squamous cell carcinoma. Note: Opdivo has many other indications not presented here because there were no changes
Beovu	brolucizumab-dbll injection, 6 mg/0.05 mL in single-dose prefilled syringes and vials	Novartis	 Neovascular (Wet) Age-Related Macular Degeneration (AMD) Diabetic Macular Edema (DME)
Kymriah	Tisagenlecleucel infusion bags, 0.6 to 6.0 X 108 CAR- positive viable T cells	Novartis	 Patients up to 25 years of age with B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse. Adult patients with relapsed or refractory (r/r) large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, high grade B-cell lymphoma and DLBCL arising from follicular lymphoma. Limitations of Use: KYMRIAH is not indicated for treatment of patients with primary central nervous system lymphoma. Adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy. This indication is approved under accelerated approval based on response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).
Evrysdi	Risdiplam for oral solution, 60 mg of risdiplam to provide 0.75 mg/mL solution	Genentech	 Treatment of spinal muscular atrophy (SMA) in patients 2 months of age and older. pediatric and adult patients.



Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication ⁺
Riabni	rituximab-arrx injection, 100 mg/10 mL and 500 mg/50 mL solution in single-dose vials	Amgen	 Adult patients with non-Hodgkin's Lymphoma Relapsed or refractory, low grade or follicular, CD20-positive B-cell NHL as a single agent. Previously untreated follicular, CD20-positive, B-cell NHL in combination with first line chemotherapy and, in patients achieving a complete or partial response to a rituximab product in combination with chemotherapy, as single-agent maintenance therapy.o Non-progressing (including stable disease), low-grade, CD20-positive, B-cell NHL as a single agent after first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy. Previously untreated diffuse large B-cell, CD20-positive NHL in combination with cyclophosphamide, doxorubicin, vincristine, and prednisone (CHOP) or other anthracycline-based chemotherapy regimens. Adult patients with Chronic Lymphocytic Leukemia (CLL) Previously untreated and previously treated CD20-positive CLL in combination with fludarabine and cyclophosphamide (FC). Rheumatoid Arthritis (RA) in combination with methotrexate in adult patients with moderately-to severely-active RA who have inadequate response to one or more TNF antagonist therapies Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis
CellCept	mycophenolate mofetil capsules, 250 mg; tablets 500 mg; for oral suspension, 200 mg/mL upon reconstitution; for injection;	Genentech	Prophylaxis of organ rejection in adult and pediatric recipients 3 months of age and older of allogeneic kidney, heart or liver transplants, in combination with other immunosuppressants. (previously adults only for heart and liver transplant)



Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication ⁺
	500 mg in a single-dose vial for reconstitution		
Olumiant	baricitinib oral tablets; 1 mg, 2 mg, 4 mg	Eli Lilly	 The treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more TNF blockers For the treatment of COVID-19 in hospitalized adults requiring supplemental oxygen, noninvasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO). For the treatment of adult patients with severe alopecia areata.



RECALLS

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
MILK OF MAGNESIA USP, (Magnesium Hydroxide), 2400 mg/30 mL, 30 mL cup, packaged in 10 cups per tray, 10 trays per carton, For Institutional Use Only, Distributed by Major Pharmaceuticals, Livonia, MI 48152, NDC 0904-6846-73.	Class I	Drugs	Lot: 20024A, 20025A, EXP Mar 2022	Microbial Contamination of Non- Sterile Products	Plastikon Healthcare LLC
Magnesium Hydroxide 1200mg, Aluminum Hydroxide 1200mg, Simethicone 120mg, 30 mL cup, packaged in 10 cups per tray, 10 trays per carton, For Institutional Use Only, Distribute by Major Pharmaceuticals, Livonia, MI 48152, NDC: 0904-6838-73.	Class I	Drugs	Lot: 21067A, EXP Jun 2023	Microbial Contamination of Non- Sterile Products	Plastikon Healthcare LLC
Humalog KwikPen, Insulin lispro injection, U- 100, 100 units per mL, 5x3 mL Prefilled Pens per box, Marketed by Lilly USA, LLC, Indianapolis, IN 46285, Box NDC 0002-8799- 59, Pen NDC 002-7516-59	Class I	Drugs	Unknown	TEMPERATURE ABUSE: Products were exposed to temperatures outside of the products labeled storage conditions due to inclement weather.	Cardinal Health Inc.
Benzonatate capsules, 100mg, repackaged in 30-count bottles, Distributed by Calvin Scott & Co., Inc, Albuq., NM. 87123, NDC 67877-0573-05	Class I	Drugs	CSI Lot: CS-20180W-004, Exp 3/22	Labeling: Label Mix-up: Bottle labeled as Benzonatate 100 mg capsules contained Benzphetamine 50 mg tablets and a bottle labeled as Benzphetamine 50 mg tablets contained Benzonatate 100 mg capsules.	Calvin Scott & Company, Inc.
Anagrelide Capsules USP, 0.5 mg, 100-count bottles, Rx Only, Manufactured in India For: TEVA PHARMACEUTICALS USA, Inc., North Wales, PA 19454. NDC 0172-5241-60.	Class I	Drugs	Lot # GD01090, Exp 05/2022	Failed Dissolution Specifications- Low Out-Of-Specification results obtained during stability testing.	Teva Pharmaceutic als USA Inc



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Acetaminophen Oral Solution, USP 650mg/ 20.3 mL cup, packaged in 10 cups per tray, 10 trays per carton, For Institutional Use Only, Distributed by Major Pharmaceuticals, Livonia, MI 48152, NDC: 0904-6820-76.	Class II	Drugs	Lot: 20040A, EXP May 2022	CGMP Deviations: Failure to properly investigate failed microbial testing.	Plastikon Healthcare LLC
MILK OF MAGNESIA USP, (Magnesium Hydroxide), 2400 mg/30 mL, 30 mL cup, packaged in 10 cups per tray, 10 trays per carton, For Institutional Use Only, Distributed by Major Pharmaceuticals, Livonia, MI 48152, NDC 0904-6846-73.	Class II	Drugs	Lot: 20041A, EXP May 2022	CGMP Deviations: Failure to properly investigate failed microbial testing.	Plastikon Healthcare LLC
Magnesium Hydroxide 1200mg, Aluminum Hydroxide 1200mg, Simethicone 120mg, 30 mL cup, packaged in 10 cups per tray, 10 trays per carton, For Institutional Use Only, Distributed by Major Pharmaceuticals, Livonia, MI 48152, NDC: 0904-6838-73.	Class II	Drugs	Lot: 20042A, 20043A, 20045A, 20046A, 20047A, EXP May 2022	CGMP Deviations: Failure to properly investigate failed microbial testing.	Plastikon Healthcare LLC
Trulicity (dulaglutide) injection, 1.5 mg/0.5mL once weekly, 4 Single-Dose Pens, Rx only, Eli Lilly and Company, Indianapolis, IN 46285, NDC 00002-1434-80	Class II	Drugs	Lot #: D482749A, Exp: 10/15/2023.	TEMPERATURE ABUSE: Products were exposed to temperatures outside of the products labeled storage conditions due to inclement weather.	Cardinal Health Inc.
Trulicity (dulaglutide) injection, 0.75 mg/0.5mL once weekly, 4 Single-Dose Pens, Rx only, Eli Lilly and Company, Indianapolis, IN 46285, NDC 00002-1433-80	Class II	Drugs	Lot #: D484557A, Exp: 10/25/2023.	TEMPERATURE ABUSE: Products were exposed to temperatures outside of the products labeled storage conditions	Cardinal Health Inc.
Accupril (Quinapril HCl Tablets) 10 mg, 90 Tablets Rx only NDC 0071-0530-23 Distributed by: Parke-Davis Division of Pfizer Inc. NY, NY 10017	Class II	Drugs	Lot: DR9639 Exp. MAR 31 2023	CGMP Deviations: Contains N- nitrosoquinapril above the acceptable limits.	Pfizer Inc.



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Accupril (Quinapril HCl Tablets) 20 mg, 90 Tablets, Rx only NDC 0071-0532-23 Distributed by: Parke-Davis Division of Pfizer Inc. NY, NY 10017	Class II	Drugs	Lots: DX8682 Exp. MAR 31 2023; DG1188 Exp. MAR 31 2022	CGMP Deviations: Contains N- nitrosoquinapril above the acceptable limits.	Pfizer Inc.
Accupril (Quinapril HCl Tablets) 40 mg, 90 Tablets, Rx only NDC 0071-0535-23 Distributed by: Parke-Davis Division of Pfizer Inc. NY, NY 10017	Class II	Drugs	Lots: DX6031 Exp. MAR 31 2023; CK6260 Exp. MAY 31 2022	CGMP Deviations: Contains N- nitrosoquinapril above the acceptable limits.	Pfizer Inc.
GaviLyte -C (Polyethylene Glycol 3350, 240 g) and electrolytes for Oral Solution, USP with flavor pack NDC# 43386-060-19	Class II	Drugs	Lot # S001132, exp. date July 2022 NDC # 43386- 060-19	Failed Stability Specification	Lupin Pharmaceutic als Inc.
Losartan HCTZ 100/25 mg, 90 count bottles NDC# 70518-2578-00 Repackaged NDC Original NDC # 68180-0217-09	Class II	Drugs	Lot # B1329507-082921, exp. date 08/31/2022 B1348363-091421, exp. date 09/30/2022 B1387286-101021, exp. date 10/31/2022 B1390974-101221, exp. date 10/31/2022 B1426010-110521, exp. date 11/30/2022	CGMP Deviations- AZIDO Impurity levels observed to be above acceptable limits.	RemedyRepac k Inc.
Losartan HCTZ 100/12.5 mg, 90 count bottles NDC# 70518-2564-00 Repackaged NDC Original NDC # 68180-0216-09	Class II	Drugs	Lot # B1364261-092721, exp. date 09/30/2022 B1377667-100521, exp. date 10/31/2022 B1412576-102621, exp. date 10/31/2022 B1436925-111321, exp. date 11/30/2022	CGMP Deviations- AZIDO Impurity levels observed to be above acceptable limits.	RemedyRepac k Inc.



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Losartan HCTZ 50/12.5 mg, 90 count bottle Original NDC# 33342-0050-10 Repackaged NDC# 70518-3231-00	Class II	Drugs	Lot # B1377711-100521, exp. date 10/31/2022 B1412137-102621, exp. date 10/31/2022	CGMP Deviations- AZIDO Impurity levels observed to be above acceptable limits	RemedyRepac k Inc.
Losartan Potassium & HCTZ Tablets 50mg/12.5 mg, hydrochlorothiazide USP 12.5, Pkg Size: 90, NDC: 68788-7758-09.	Class II	Drugs	Lot: K1721D, EXP: 4/30/2023, NDC: 68788- 7758-09; Lot: K1021E, EXP: 7/31/2023, NDC: 68788-7758-09.	CGMP Deviations- AZIDO Impurity levels observed to be above acceptable limits	Preferred Pharmaceutic als, Inc.
Losartan Potassium & HCTZ Tablets 50mg/12.5 mg, hydrochlorothiazide USP 12.5 mg, Pkg Size: 30, NDC: 68788-7758-03.	Class II	Drugs	Lot: K1721E, EXP: 4/30/2023, NDC: 68788- 7758-03; Lot: H3021Q, EXP: 2/28/2023, NDC: 68788-7758-03.	CGMP Deviations- AZIDO Impurity levels observed to be above acceptable limits	Preferred Pharmaceutic als, Inc.
Daytrana (methylphenidate transdermal system) Delivers 10 mg over 9 hours (1.1 mg/hr) Contains: 30 Patches, Rx only, Manufactured for Noven Therapeutics, LLC, Miami, FL 33186, By Noven Pharmaceuticals, Inc., Miami, FL, 33186, NDC 68968-5552-3	Class II	Drugs	Lot: 90764 Exp. 08/2022	Defective Delivery System: customer complaints exceeded respective action limits.	Noven Pharmaceutic als Inc
Losartan Pot/HCTZ 100/12.5 mg 90 Tabs NDC 72189-290-90 Packaged and Distributed By: Direct Rx Dawsonville, GA 30534 Mfg. For Macleods Pharma USA, Inc. Plainsboro, NJ 08540	Class II	Drugs	Lot: 250C2116 Exp. 5/31/23	CGMP Deviations- AZIDO Impurity levels observed to be above acceptable limits .	Direct Rx
Losartan Pot/HCTZ 50/12.5 mg 90 Tabs NDC 72189-297-90 Packaged and Distributed By: Direct Rx Dawsonville, GA 30534 Mfg. For Macleods Pharma USA, Inc. Plainsboro, NJ 08540	Class II	Drugs	Lots: 19NO2108 Exp. 1/31/25; 19NO2114 Exp. 1/31/25; 22NO2126 Exp. 1/31/25	CGMP Deviations- AZIDO Impurity levels observed to be above acceptable limits .	Direct Rx



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Losartan Pot/HCTZ 100/25 mg 90 Tabs NDC 72189-289-90 Packaged and Distributed By: Direct Rx Dawsonville, GA 30534 Mfg. For Macleods Pharma USA, Inc. Plainsboro, NJ 08540	Class II	Drugs	Lots: 08NO2102 Exp. 1/31/25; 17NO2118 Exp. 1/31/25; 18NO2123 Exp. 1/31/25; 25OC2114 Exp. 1/31/25; 22NO2105 Exp. 1/31/25	CGMP Deviations- AZIDO Impurity levels observed to be above acceptable limits .	Direct Rx
QM-4 Papaverine 30 mg/mL Phentolamine 3 mg/mL Alprostadil 300 mcg/mL Atropine 0.2 mg/mL, Multi-Dose 10 mL vial, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835, NDC 73198- 0020-10	Class II	Drugs	Lot: L24F08 BUD: 12/8/2022	Lack of assurance of sterility.	Olympia Compounding Pharmacy dba Olympia Pharmacy
RE-1 Papaverine 30 mg/mL Phentolamine 3 mg/mL Alprostadil 200 mcg/mL, packaged as a) 2.5 mL Multi Dose vial, NDC 73198-0015- 03; b) 10 mL Multi Dose vial, NDC 73198- 0015-10; Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835	Class II	Drugs	Lots: B24E09-22 BUD: 02/09/2023; B24F09-22 BUD: 02/09/2023	Lack of assurance of sterility.	Olympia Compounding Pharmacy dba Olympia Pharmacy
RE-2 Papaverine 30 mg/mL Phentolamine 3 mg/mL Alprostadil 300 mcg/mL, Packaged as a) 2.5 mL Multi Dose vial, NDC 73198-0016- 03; b) 10 mL Multi Dose vial, NDC 73198- 0016-10; Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835	Class II	Drugs	Lots: K24B09, K24C09 BUD: 11/09/2022	Lack of assurance of sterility.	Olympia Compounding Pharmacy dba Olympia Pharmacy
SB-5 Papaverine 30 mg/mL Phentolamine 3 mg/mL PGE 50 mcg/mL, Multi-Dose 10 mL vial, Rx Only, Olympia Pharmaceuticals 6700 Conroy Rd., Ste. 155 Orlando, FL 32835, NDC 73198-0024-10	Class II	Drugs	Lot: B24D02-22 BUD: 02/02/2023	Lack of assurance of sterility.	Olympia Compounding Pharmacy dba Olympia Pharmacy



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
SB-6 Papaverine 30 mg/mL Phentolamine 3 mg/mL PGE 60 mcg/mL, Packaged in a) 5 mL Multi-Dose vial, NDC 73198-0025-05; b) 10 mL, Multi-Dose vial, NDC 73198-0025-10; Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835	Class II	Drugs	Lots: L24D14, L24C14 BUD: 12/14/2022	Lack of assurance of sterility.	Olympia Compounding Pharmacy dba Olympia Pharmacy
Sermorelin Acetate Lyophilized powder for reconstitution 9 mg Per Multi-Dose Vial, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835, NDC 73198-0059-00	Class II	Drugs	Lots: L24115 BUD: 12/15/2022; A24203 BUD: 01/03/2023; A24106 BUD: 01/06/2023	Lack of assurance of sterility.	Olympia Compounding Pharmacy dba Olympia Pharmacy
Diluent for Reconstitution Multi-Dose 10 mL vial, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835, NDC 73198-0113-10	Class II	Drugs	Lots: J24125, J24025 BUD: 10/25/2022; K24002 BUD: 11/2/2022; L24013, L24213 BUD: 12/13/2022; A24003 BUD: 1/3/2023; A24404 BUD: 1/4/2023; A24031-22 BUD: 1/31/2023; B24001-22 BUD: 2/1/2023	Lack of assurance of sterility.	Olympia Compounding Pharmacy dba Olympia Pharmacy
Sodium Bicarbonate 8.4% MDV Injection, Multi-Dose 30 mL vial, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835, NDC 73198-0101-30	Class II	Drugs	Lot: L41002 BUD: 6/2/2022	Lack of assurance of sterility.	Olympia Compounding Pharmacy dba Olympia Pharmacy
Sodium Selenite 200 mg/mL, Multi-Dose 30 mL vial, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835, NDC 73198-0074-30	Class II	Drugs	Lots: L24014 BUD: 6/14/2022; B24024-22 BUD: 8/24/2022	Lack of assurance of sterility.	Olympia Compounding Pharmacy dba Olympia Pharmacy



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Sodium Tetradecyl Sulfate 0.3% Injection, Multi-Dose 30 mL vial, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835, NDC 73198-0121-30	Class II	Drugs	Lot: B24309-22 BUD: 8/9/2022	Lack of assurance of sterility.	Olympia Compounding Pharmacy dba Olympia Pharmacy
Sodium Tetradecyl Sulfate 1.5% MDV Injection, Multi-Dose 30 mL vial, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835, NDC 73198- 0122-30	Class II	Drugs	Lot: B24308-22 BUD: 8/8/2022	Lack of assurance of sterility.	Olympia Compounding Pharmacy dba Olympia Pharmacy
Sodium Tetradecyl Sulfate 5% MDV Injection, Multi-Dose 5 mL vial, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835, NDC 73198- 0102-05	Class II	Drugs	Lot: L24306 BUD: 6/6/2022	Lack of assurance of sterility.	Olympia Compounding Pharmacy dba Olympia Pharmacy
T-105 Papaverine 30 mg/mL Phentolamine 1 mg/mL PGE 10 mcg/mL, Packaged as a) 2.5 mL Multi-Dose vial NDC 73198-0005-03; b) 5 mL Multi Dose vial, NDC 73198-0005-05, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835	Class II	Drugs	Lots: K41J09, K41I09 BUD: 11/9/2022; B24B22-22 BUD: 2/22/2023	Lack of assurance of sterility.	Olympia Compounding Pharmacy dba Olympia Pharmacy
T-106 Papaverine 30 mg/mL Phentolamine 1 mg/mL Alprostadil 25 mcg/mL, Packaged as a) 5 mL Multi-Dose vial NDC 73198-0013-05; b) 10 mL Multi-Dose vial NDC 73198-0013- 10, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835	Class II	Drugs	Lot: K24F09 BUD: 11/9/2022	Lack of assurance of sterility.	Olympia Compounding Pharmacy dba Olympia Pharmacy
Testosterone Cypionate 200 mg/mL in Grapeseed Oil, Multi-Dose 10 mL vial, Rx Only, Olympia Pharmaceuticals, 6700	Class II	Drugs	Lots: J48011, J42011 BUD: 10/11/2022; J24C12 BUD: 10/12/2022;	Lack of assurance of sterility.	Olympia Compounding Pharmacy dba



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Conroy Rd., Ste. 155 Orlando, FL 32835, NDC 73198-0054-10					Olympia Pharmacy
Testosterone Cypionate 200 mg/mL in Sesame Oil, Packaged in a) 5 mL Multi-Dose vial NDC, 73198-0055-05; b) 10 mL Multi- Dose vial NDC 73198-0055-10; Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835.	Class II	Drugs	Lot: J24B13 BUD: 10/13/2022	Lack of assurance of sterility.	Olympia Compounding Pharmacy dba Olympia Pharmacy
Tri-Immune Boost Glutathione 200 mg/mL Ascorbic Acid 200 mg/mL Zinc Sulfate 2.5 mg/mL Multi-Dose 30 mL vial, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835, NDC 73198- 0104-30	Class II	Drugs	Lots: B24D01-22, B24C01- 22 BUD: 6/1/2022	Lack of assurance of sterility.	Olympia Compounding Pharmacy dba Olympia Pharmacy
Ultratest Testosterone Cypionate 160 mg/mL Testosterone Propionate 40 mg/mL, Multi-Dose 10 mL vial, Rx Only, Olympia Pharmaceuticals 6700 Conroy Rd., Ste. 155 Orlando, FL 32835, NDC 73198-0058-10	Class II	Drugs	Lots: J24014, J24114 BUD: 10/14/2022	Lack of assurance of sterility.	Olympia Compounding Pharmacy dba Olympia Pharmacy
Vitamin D3 (50,000 IU/mL)Multi-Dose 30 mL vial, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835, NDC 73198-0075-30	Class II	Drugs	Lots: L24009 BUD: 6/9/2022; L24028 BUD: 6/28/2022	Lack of assurance of sterility.	Olympia Compounding Pharmacy dba Olympia Pharmacy
Zinc Chloride (0.5 mg/mL), Multi-Dose 30 mL vial, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835, NDC 73198-0071-30	Class II	Drugs	Lot: K24024 BUD: 5/24/2022	Lack of assurance of sterility.	Olympia Compounding Pharmacy dba Olympia Pharmacy



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Alpha Lipoic Acid 25 mg/mL, Multi-Dose 30 mL vial, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835, NDC 73198-0076-30	Class II	Drugs	Lots: L24C06, L24B06 BUD: 6/6/2022; B41023- 22 BUD: 8/23/2022	Lack of assurance of sterility.	Olympia Compounding Pharmacy dba Olympia Pharmacy
Preserved Ascorbic Acid 500 mg/mL, Multi- Dose 30 mL vial, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835 NDC 73198-0079-30	Class II	Drugs	Lots: A24B2022, A24C05 BUD: 7/5/2022; A24C12- 22 BUD 7/12/2022; A24C18-22 BUD: 7/18/2022; A24C20-22 BUD: 7/20/2022	Lack of assurance of sterility.	Olympia Compounding Pharmacy dba Olympia Pharmacy
AT-6 Papaverine 40 mg/mL Phentolamine 4 mg/mL Atropine 0.3 mg/mL, Multi-Dose 10 mL vial, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835 NDC 73198-0040-10	Class II	Drugs	Lot: K24409 BUD: 11/9/2022	Lack of assurance of sterility.	Olympia Compounding Pharmacy dba Olympia Pharmacy
Bimix-3 Papaverine 30 mg/mL Phentolamine 3 mg/mL, Packaged as a) 2.5 mL Multi-Dose Vial, NDC73198-0027-03; b) 10 mL Multi- Dose Vial, NDC 73198-0027-10; Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835	Class II	Drugs	Lots: J24F20, J24E20 BUD: 10/20/2022, B24G22-22, B24F22-22 BUD: 2/22/2023	Lack of assurance of sterility.	Olympia Compounding Pharmacy dba Olympia Pharmacy
Calcium Chloride 10% (100 mg/mL), Multi- Dose 30 mL vial, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835 NDC 73198-0064-30	Class II	Drugs	Lots: B24C21-22 BUD: 8/21/2022, B24B21-22 BUD: 8/21/2022, A24010- 22 BUD: 7/10/2022, A24110-22 BUD: 7/10/2022	Lack of assurance of sterility.	Olympia Compounding Pharmacy dba Olympia Pharmacy



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Cyanocobalamin 2 mg/mL, Multi-Dose 10 mL vial, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835, NDC 73198-0115-10	Class II	Drugs	Lots: B24115-22 BUD: 8/15/2022; L24001 BUD: 6/1/2022	Lack of assurance of sterility.	Olympia Compounding Pharmacy dba Olympia Pharmacy
Pyridoxine 100 mg/mL, Multi-Dose 30 mL vial, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835, NDC 73198-0066-30	Class II	Drugs	Lot: A24018-22 BUD: 7/18/2022	Lack of assurance of sterility.	Olympia Compounding Pharmacy dba Olympia Pharmacy
Dexpanthenol 250 mg/mL Multi-Dose 30 mL Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835, NDC 73198-0070-30	Class II	Drugs	Lot: L24016 BUD: 6/16/2022	Lack of assurance of sterility.	Olympia Compounding Pharmacy dba Olympia Pharmacy
FA Papaverine 20 mg/mL Phentolamine 2 mg/mL Alprostadil 20 mcg/mL Atropine 0.2 mg/mL, Multi-Dose 10 mL vial, Rx Only, 6700 Olympia Pharmaceuticals, Conroy Rd., Ste. 155 Orlando, FL 32835, NDC 73198-0006-10	Class II	Drugs	Lot: B41C22-22 BUD: 2/22/2023	Lack of assurance of sterility.	Olympia Compounding Pharmacy dba Olympia Pharmacy
Folic Acid 1 mg/mL Hydroxocobalamin 1 mg/mL, Multi-Dose 30 mL vial, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835, NDC 73198- 0112-30	Class II	Drugs	Lots: L24007 BUD: 6/7/2022; B24017-22 BUD: 8/17/2022	Lack of assurance of sterility.	Olympia Compounding Pharmacy dba Olympia Pharmacy
Formula F1 Papaverine 1.8 mg/mL Phentolamine 0.2 mg/mL Alprostadil 18 mcg/mL Atropine 0.02 mg/mL, Packaged as a)2.5 mL Multi-Dose vial, NDC 73198-0001- 03; b) 10 mL Multi-Dose vial, NDC 73198-	Class II	Drugs	Lots: K41C09, K41B09 BUD: 11/9/2022, and A24C19-22 BUD: 1/19/2023	Lack of assurance of sterility.	Olympia Compounding Pharmacy dba Olympia Pharmacy



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
0001-10; Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835					
Formula F2 Papaverine 9 mg/mL Phentolamine 1 mg/mL Alprostadil 10 mcg/mL Atropine 0.1 mg/mL, Multi-Dose 10 mL vial, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835, NDC 73198-0002-10	Class II	Drugs	Lot: A24F19-22 BUD: 1/19/2023	Lack of assurance of sterility.	Olympia Compounding Pharmacy dba Olympia Pharmacy
Formula F9 Papaverine 0.9 mg/mL Phentolamine 0.1 mg/mL PGE 20 mcg/mL Atropine 0.01 mg/mL, Multi-Dose 10 mL vial, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835, NDC 73198-0004-10	Class II	Drugs	Lot: B24G02-22 BUD: 2/2/2023	Lack of assurance of sterility.	Olympia Compounding Pharmacy dba Olympia Pharmacy
Lidocaine 2% (20 mg/mL), Multi-Dose 30 mL vial , Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835, NDC 73198-0097-30	Class II	Drugs	Lots: L246022 BUD: 6/22/2022; B24208-22 BUD: 8/8/2022	Lack of assurance of sterility.	Olympia Compounding Pharmacy dba Olympia Pharmacy
Lidocaine 1%/Epinephrine 1:100,000/mL, Multi-Dose 30 mL vial, Rx Only, Olympia Pharmaceuticals 6700 Conroy Rd., Ste. 155 Orlando, FL 32835, NDC 73198-0099-30	Class II	Drugs	Lot: K41023 BUD: 5/23/2022	Lack of assurance of sterility.	Olympia Compounding Pharmacy dba Olympia Pharmacy
Lipo-Mino-Mix Pyridoxine HCL (B6) 2 mg/mL Methionine 12.4 mg/mL Inositol 25 mg/mL Choline Chloride 25 mg/mL Thiamine HCL (B1) 50 mg/mL Riboflavin5P04 (B2) 5 mg/mL, Packaged as a) 10 mL Multi-Dose vial, NDC 73198-0130-10; b) 30 mL Multi-	Class II	Drugs	Lots: A24103 BUD: 7/3/2022; B41B01-22 BUD: 8/1/2022	Lack of assurance of sterility.	Olympia Compounding Pharmacy dba Olympia Pharmacy



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Dose vial, NDC 73198-0130-30; Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835					
Lipostat-Plus Methionine 25 mg/mL Inositol 50 mg/mL Choline Chloride 50 mg/mL Cyanocobalamin 1 mg/mL Pyridoxine HCL 175 mcg/mL, Multi-Dose 30 mL vial, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835. NDC 73198- 0047-30.	Class II	Drugs	Lots: A24H26-22, A24G26- 22 BUD: 7/26/2022, K24130 BUD: 5/30/2022	Lack of assurance of sterility.	Olympia Compounding Pharmacy dba Olympia Pharmacy
Lipostat Plus SF Inositol 50 mg/mL Choline Chloride 50 mg/mL Cyanocobalamin 1 mg/mL Pyridoxine HCL 175 mcg/mL Multi- Dose 30 mL vial, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835. NDC 73198-0048-30	Class II	Drugs	Lot: K24030 BUD: 5/30/2022	Lack of assurance of sterility.	Olympia Compounding Pharmacy dba Olympia Pharmacy
Magnesium Chloride, 200 mg/mL, Multi- Dose 30 mL vial, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835. NDC 73198-0072-30.	Class II	Drugs	Lot: A24012-22 BUD: 7/12/2022	Lack of assurance of sterility.	Olympia Compounding Pharmacy dba Olympia Pharmacy
Methylcobalamin 5 mg/mL, Packaged as a) Multi-Dose 10mL vial, NDC 73198-0051-10; b) Multi-Dose 30mL vial, NDC 73198-0051- 30, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835	Class II	Drugs	Lots: L24122, L24C22, L24B22 BUD: 6/22/2022, A24124-22 BUD: 7/24/2022, A24225-22 BUD: 7/25/2022, A24026- 22 BUD: 7/26/2022, A24027-22 BUD: 7/27/2022, A24C31-22,	Lack of assurance of sterility.	Olympia Compounding Pharmacy dba Olympia Pharmacy



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			A24B31-22 BUD: 7/31/2022		
 MICC, Methionine 25 mg/mL Inositol 50 mg/mL Choline Chloride 50 mg/mL Cyanobalamin 330 mcg/mL, Packaged as a) Multi-Dose 10 mL vial, NDC 73198-0052-10; b) Multi-Dose 30 mL vial, NDC 73198-0052-30, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835 	Class II	Drugs	Lots: K41F17, K41B17, K41C17, K41E17 BUD: 5/17/2022	Lack of assurance of sterility.	Olympia Compounding Pharmacy dba Olympia Pharmacy
Myers Cocktail, Magnesium Chloride 9.65 mg/mL Dexpanthenol 4.07 mg/mL Thiamine HCL 1.62 mg/mL Riboflavin-5-Phosphate 3.23 mg/mL Pyridoxine HCL 1.63 mg/mL Niacinamide 1.62 mg/mL Calcium Gluconate 4.07 mg/mL Ascorbic Acid 64.4 mg/mL, Single-Dose 10 mL vial, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835. NDC 73198-0088-10.	Class II	Drugs	Lots: L24029 BUD: 6/29/2022, A24125-22 BUD: 7/25/2022, A24331- 22 BUD: 7/31/2022	Lack of assurance of sterility.	Olympia Compounding Pharmacy dba Olympia Pharmacy
NAD+ Nicotinamide Adenine Dinucleotide, Lyophilized powder for reconstitution, Multi-Dose 500 mg per vial, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835. NDC 73198- 0083-00.	Class II	Drugs	Lots: A2401422 BUD: 1/14/2023, K41001 BUD: 11/1/2022, K41130 BUD: 11/30/2022, L24113 BUD: 12/13/2022, L41102 BUD: 12/2/2022	Lack of assurance of sterility.	Olympia Compounding Pharmacy dba Olympia Pharmacy
NB-343 Papaverine 30 mg/mL Phentolamine 3 mg/mL PGE 30 mcg/mL, Multi-Dose 10 mL vial, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835. NDC 73198-0010-10.	Class II	Drugs	Lot: L24C08 BUD: 12/8/2022	Lack of assurance of sterility.	Olympia Compounding Pharmacy dba Olympia Pharmacy



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Olympia Mineral Blend Magnesium Chloride 80 mg/mL Zinc Sulfate 1 mg/mL Manganese Sulfate 20 mcg/mL Copper Gluconate 0.2 mg/mL Sodium Selenite 18 mcg/mL, Multi- Dose 30 mL vial, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835. NDC 73198-0061-30.	Class II	Drugs	Lots: L24B1 BUD: 6/16/2022, L24D16 BUDL 6/16/2022, A24C24-22, A24E24-22 BUDL 7/24/2022	Lack of assurance of sterility.	Olympia Compounding Pharmacy dba Olympia Pharmacy
Olympia Vita-Complex Thiamine HCL (B1) 100 mg/mL Niacinamide (B3) 100 mg/mL Riboflavin 5 P04 (B2) 2 mg/mL Dexpanthenol (B5) 2 mg/mL Pyridoxine HCL (B6) 2 mg/mL Multi-Dose 30 mL vial, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835. NDC 73198-0063-30.	Class II	Drugs	Lots: B24B1422, B24E1422 BUD: 8/14/2022, B24B1522 BUD: 8/15/2022, L24B15, L24C15, L24D15 BUD: 6/15/2022	Lack of assurance of sterility.	Olympia Compounding Pharmacy dba Olympia Pharmacy
Ondansetron Hydrochloride, 1 mg/mL, Multi-Dose 30 mL vial, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835. NDC 73198-0127-30.	Class II	Drugs	Lot: B24015-22 BUD: 8/15/2022	Lack of assurance of sterility.	Olympia Compounding Pharmacy dba Olympia Pharmacy
PGE-3 Alprostadil 150 mcg/mL, Multi-Dose 10 mL vial, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835. NDC 73198-0030-10.	Class II	Drugs	Lot: L24508 BUD: 12/8/2022	Lack of assurance of sterility.	Olympia Compounding Pharmacy dba Olympia Pharmacy
Phenylephrine 1 mg/mL, Multi-Dose 5 mL vial, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835. NDC 73198-0021-05.	Class II	Drugs	Lots: K41016 BUD: 11/16/2022 and A24025- 22 BUD: 1/25/2023	Lack of assurance of sterility.	Olympia Compounding Pharmacy dba Olympia Pharmacy



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Pyridoxine HCL 100 mg/mL, Multi-Dose 30 mL vial, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835. NDC 73198-0066-30.	Class II	Drugs	Lot: A24018-22 BUD: 7/18/2022	Lack of assurance of sterility.	Olympia Compounding Pharmacy dba Olympia Pharmacy
QM-2 Papaverine 30 mg/mL Phentolamine 3 mg/mL Alprostadil 60 mcg/mL Atropine 0.2 mg/mL Multi-Dose 10 mL Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835. NDC 73198-0018-10.	Class II	Drugs	Lot: K24D15 BUD: 11/15/2022	Lack of assurance of sterility.	Olympia Compounding Pharmacy dba Olympia Pharmacy
QM-3 Papaverine 30 mg/mL Phentolamine 3 mg/mL Alprostadil 150 mcg/mL Atropine 0.2 mg/mL, Multi-Dose 10 mL vial, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835. NDC 73198- 0019-10.	Class II	Drugs	Lot: A24505 BUD: 1/5/2023	Lack of assurance of sterility.	Olympia Compounding Pharmacy dba Olympia Pharmacy
Amino Blend Glutamine 30 mg/mL Ornithine HCL 50 mg/mL Arginine HCL 100 mg/mL Lysine HCL 50 mg/mL Citrulline 50 mg/mL, Multi-Dose 30 mL vial, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155 Orlando, FL 32835.NDC 73198-0129-30.	Class II	Drugs	Lots: A24104, A24304 BUD: 7/4/2022; A24303 BUD: 7/3/2022; B2422322, B24123-22 BUD: 8/22/2022	Lack of assurance of sterility.	Olympia Compounding Pharmacy dba Olympia Pharmacy
Zonisamide Capsules USP, 100 mg, 90-count bottle, Rx Only, Packaged and Distributed By: Direct Rx Dawsonville, GA 30534, Manufactured for: Glenmark Pharmaceuticals Inc., USA Mahwah, NJ 07430, NDC 61919-775-90	Class II	Drugs	Lot: 23JY2124 Exp. 6/30/23	CGMP Deviations: Gaps in the quality system in the Quality Control microbiology laboratory.	Direct Rx
Equate Tartar Control Plus (Eucalyptol 0.092%, Menthol 0.042%, Methyl salicylate	Class II	Drugs	Lots: 0559696, 0563041, Exp. 02/2024	Superpotent Drug: product complaint for milky blue	Vi-Jon, LLC



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
0.060%, Thymol 0.064%) Antiseptic Mouthrise Plus, Antigingivitis/Antiplaque, Blue Mint, 1.5 Liter (50.7 FL OZ) bottle, Distributed By: Wal-Mart Stores, Inc., Bentonville, AR 72716, UPC 6 81131 14800 9				appearance and consistency, further investigation by the firm found the recalled lots out of specification for the four active ingredients.	
Losartan Pot./HCTZ 100/12.5 mg Packaged and Distributed By: Direct Rx Dawsonville, GA 30534 Mfg For: Lupin Pharmaceuticals, Inc. Baltimore, MD 21202 a) 30 Tabs NDC 72189-167-30; b) 90 Tabs NDC 72189-167- 90	Class II	Drugs	a) 30-count bottles- Lot: 11MY2103 Exp. 11/30/22 Lot: 05JA2106 Exp. 6/30/22 b) 90-count bottles- Lot: 20MY2115 Exp. 11/30/22 Lot: 22JU2118 Exp. 12/31/22 Lot: 29JY2113 Exp. 12/31/22 Lot: 13SE2113 Exp. 2/28/23 Lot: 05JA2106 Exp. 6/30/22	CGMP Deviations- AZIDO Impurity levels observed to be above acceptable limits	Direct Rx
8.4% Sodium Bicarbonate Injection, USP, 1 mEq/mL, 4.2 g/50 mL (84 mg/mL), 1 x 50 mL Pre-Filled Syringe, packaged in a) 10 x 1 syringe carton, b) 30 x 1 syringe carton, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-214-50	Class II	Drugs	Lots: SB2001A, Exp. 1/2/2023; SB2005B, SB2005C, Exp. 3/8/2023; SB2006A, SB2006B, SB2006C, Exp. 3/16/2023	Lack of Assurance of Sterility	Nephron Sterile Compounding Center LLC
Calcium Gluconate Injection, USP 10%, 0.465 mEq Ca++/mL, 1 g/10 mL (100 mg/mL), 10 mL Pre-Filled Syringe, 5 x 10 Pre-filled Syringes, 6 x 5 Syringe Carton, Rx Only, Nephron 503B outsourcing facility, 4500	Class II	Drugs	Lots: CG1003A, Exp. 12/3/2022; CG2001A, Exp. 2/10/2023	Lack of Assurance of Sterility	Nephron Sterile Compounding Center LLC



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
12th St. Extension, West Columbia, SC 29172, NDC: 69374-950-10					
EPINEPHrine Injection, USP, 0.1 mg/10 mL (10 mcg/mL), 10 mL Pre-Filled Syringe, 5 x 10 mL Pre-filled Syringes, 6 x 5 Syringe Carton, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-544-10	Class II	Drugs	Lots: EN2005A, Exp. 7/25/2022; EN2009A, Exp. 8/20/2022; EN2010A, Exp. 9/13/2022	Lack of Assurance of Sterility	Nephron Sterile Compounding Center LLC
Epinephrine Injection, USP, 1 mg/10 mL (100 mcg/mL), 10 mL Pre-Filled Syringe, 5 x 10 mL Pre-Filled Syringes, 6 x 5 Syringe Carton, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-925-10	Class II	Drugs	Lots: EN1047A, Exp. 6/7/2022; EN2002A, Exp. 7/7/2022; EN2006A, Exp. 7/19/2022; EN2011A, Exp. 9/1/2022	Lack of Assurance of Sterility	Nephron Sterile Compounding Center LLC
Fentanyl Citrate in 0.9% Sodium Chloride Injection, USP, 2500 mcg/250 mL (10 mcg/mL), 150 mL IV Bag, 10 x 1 IV Bag, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-523-21	Class II	Drugs	Lots: FN1088A, Exp. 6/21/2022; FN1089A, Exp. 6/26/2022	Lack of Assurance of Sterility	Nephron Sterile Compounding Center LLC
Glycopyrrolate Injection, USP, 1 mg/5 mL (0.2 mg/mL), Preservative Free, 5 mL Pre- Filled Syringe, 5 x 5 mL Pre-Filled Syringes, 6 x 5 Syringe Carton, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-903- 05	Class II	Drugs	Lot: GL2002B Exp. 8/13/2022	Lack of Assurance of Sterility	Nephron Sterile Compounding Center LLC
Glycopyrrolate Injection, USP, 0.6 mg/3 mL (0.2 mg/mL), Preservative Free, 3 mL Pre- Filled Syringe, 5 x 3 mL Pre-Filled Syringes, 6	Class II	Drugs	Lot: GL2002A, Exp. 8/13/2022	Lack of Assurance of Sterility	Nephron Sterile



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
x 5 Syringe Carton, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-903- 03					Compounding Center LLC
Hydromorphone HCl Injection, USP, 50 mg/50 mL (1 mg/mL), 50 mL Pre-Filled Syringe, 5 x 50 mL Pre-Filled Syringes, 6 x 5 Syringe Carton, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-559- 50	Class II	Drugs	Lot: HN2005A, Exp. 9/17/2022	Lack of Assurance of Sterility	Nephron Sterile Compounding Center LLC
Hydromorphone HCl Injection, USP, 6 mg/30 mL (0.2 mg/mL), 30 mL Pre-Filled Syringe, 5 x 30 mL Pre-Filled Syringes, 6 x 5 Syringe Carton, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-529-30	Class II	Drugs	Lot: HH2008A, Exp. 9/5/2022	Lack of Assurance of Sterility	Nephron Sterile Compounding Center LLC
Ketamine Hydrochloride Injection, USP, 30 mg/3 mL (10 mg/mL), 3 mL Pre-Filled Syringe, 5 x 3 mL Pre-Filled Syringes, 6 x 5 Syringe Carton, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-982- 33	Class II	Drugs	Lot: KH2008A, Exp. 8/8/2022	Lack of Assurance of Sterility	Nephron Sterile Compounding Center LLC
Ketamine Hydrochloride Injection, USP, 50 mg/5 mL (10 mg/mL), 5 mL Pre-Filled Syringe, 5 x 5 mL Pre-Filled Syringes, 6 x 5 Syringe Carton, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension,	Class II	Drugs	Lots: KH1086A, Exp. 6/24/2022; KH2002B, Exp. 7/5/2022; KH2008B, Exp. 8/8/2022; KH2012A, Exp. 8/23/2022	Lack of Assurance of Sterility	Nephron Sterile Compounding Center LLC



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
West Columbia, SC 29172, NDC: 69374-982- 55					
Labetalol HCl Injection, USP, 20 mg/4 mL (5 mg/mL), Preservative Free, 4 mL Pre-Filled Syringe, 5 x 4 mL Pre-Filled Syringes, 6 x 5 Syringe Carton, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-946-04	Class II	Drugs	Lots: LB1020A, LB1022A Exp. 5/21/2022; LB2003A, Exp. 8/5/2022; LB2007A, Exp. 9/20/2022	Lack of Assurance of Sterility	Nephron Sterile Compounding Center LLC
Lidocaine HCI Injection, USP, 2%, 100 mg/5 mL (20 mg/mL), Preservative Free, 5 mL Pre- Filled Syringe, 5 x 5 mL Pre-FIlled Syringes, 6 x 5 Syringe Carton, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-949- 05	Class II	Drugs	Lot: LI2001A, Exp. 6/8/2022	Lack of Assurance of Sterility	Nephron Sterile Compounding Center LLC
Neostigmine Methylsulfate Injection, USP, 5 mg/5 mL (1 mg/mL), Preservative Free, 5 mL Pre-Filled Syringe, 5 x 5 mL Pre-Filled Syringes, 6 x 5 Syringe Carton, Rx Only Nephron 503B outsourcing facility 4500 12th St. Extension West Columbia, SC 29172 NDC: 69374-902-05	Class II	Drugs	Lots: NE2001A, Exp. 6/30/2022; NE2009B, Exp. 8/27/2022	Lack of Assurance of Sterility	Nephron Sterile Compounding Center LLC
Oxytocin 30 Units/500 mL (0.06 Units/mL) in 0.9% Sodium Chloride Injection, USP, 500 mL Single-Dose Container Bag, 10 x 1 IV Bag, Rx Only Nephron 503B outsourcing facility 4500 12th St. Extension West Columbia, SC 29172 NDC: 69374-543-50	Class II	Drugs	Lots: OX2008C, Exp. 5/27/2022; OX2010C, Exp. 6/17/2022; OX2011C, OX2011D, Exp. 6/24/2022	Lack of Assurance of Sterility	Nephron Sterile Compounding Center LLC



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Phenylephrine HCI Injection, USP, 0.4 mg/10 mL (40 mcg/mL), 10 mL Pre-Filled Syringe, 5 x 10 mL Pre-Filled Syringes, 6 x 5 Syringe Carton, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-955-10	Class II	Drugs	Lots: PE1108A, Exp. 5/27/2022; PE2006A, Exp. 8/3/2022; PE2010A, Exp. 8/12/2022	Lack of Assurance of Sterility	Nephron Sterile Compounding Center LLC
Phenylephrine HCl Injection, USP, 0.8 mg/10 mL (80 mcg/mL), 10 mL Pre-Filled Syringes, 5 x 10 mL Pre-Filled Syringes, 6 x 5 Syringe Carton, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-956-10	Class II	Drugs	Lots: PE1107A, Exp. 5/22/2022; PE1123A, Exp. 6/21/2022; PE2007A, Exp. 8/4/2022; PE2012A, Exp. 8/28/2022	Lack of Assurance of Sterility	Nephron Sterile Compounding Center LLC
Phenylephrine HCl Injection, USP, 1 mg/10 mL (100 mcg/mL), 10 mL Pre-Filled Syringe, 5 x 10 mL Pre-Filled Syringes, 6 x 5 Syringe Carton, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-957-10	Class II	Drugs	Lots: PE1115B, PE1115C, Exp. 5/31/2022; PE1122A, Exp. 6/19/2022; PE2004B, PE2004C, Exp. 7/11/2022; PE2011A, PE2011C, Exp. 8/22/2022; PE2015A, PE2015B, PE2015C, Exp. 9/5/2022; PE2016A, PE2016B, PE2016C, Exp. 9/13/2022	Lack of Assurance of Sterility	Nephron Sterile Compounding Center LLC
Rocuronium Bromide Injection, 50 mg/5 mL (10 mg/mL), Preservative Free, 5 mL Pre- Filled Syringe, 5 x 5 mL Pre-Filled Syringes, 6 x 5 Syringe Carton, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-924- 05	Class II	Drugs	Lots: RC1050A, Exp. 5/30/2022; RC1051B, Exp. 6/6/2022; RC1053A, Exp. 6/27/2022; RC2001A, Exp. 7/19/2022; RC2002A, Exp. 8/13/2022; RC2003A, Exp. 8/28/2022; RC2004A, Exp. 9/8/2022	Lack of Assurance of Sterility	Nephron Sterile Compounding Center LLC



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Succinylcholine Chloride Injection, USP, 100 mg/5 mL (20 mg/mL), Preservative Free, 5 mL Pre-Filled Syringe, 5 x 5 mL Pre-Filled Syringes, 6 x 5 Syringe Carton, Rx Only, Nephron 503B outsourcing facility, 4500 12th St. Extension, West Columbia, SC 29172, NDC: 69374-920-05	Class II	Drugs	Lots: SU2004A, Exp. 5/18/2022; SU2007A, Exp. 6/2/2022	Lack of Assurance of Sterility	Nephron Sterile Compounding Center LLC
Losartan Potassium Tablets, USP 25 mg, Rx only, Manufactured by: Vivimed Life Sciences Private Limited, Plot No., 101, 102, 107 & 108, SIDCO Pharmaceutical Complex, Alathur, Kanchipuram - 603 110, Tamilnadu, India, Distributed by: Strides Pharma Inc., East Brunswick, NJ 08816. 90 film coated tablets NDC 64380-933-05 1000 film coated tablets NDC 64380-933-08	Class II	Drugs	NDC 64380-933-05 Lot 7901007A, Exp Date Jun- 22; Lot 7901144A, 7901178A & 7901179A, Exp Date Sep-22; Lots 7901246A & 7901247A, Exp Date Oct-22; Lot 7901343A, Exp Date Dec- 22. NDC 64380-933-08 Lot 7901006A, Exp Date Jun-22; Lot 7901145A & 7901180A, Exp Date Sep- 22; Lot 7901181A, Exp Date Oct-22.	CGMP Deviations- AZIDO Impurity levels observed to be above acceptable limits	Strides Pharma Inc.
Losartan Potassium Tablets, USP, 50 mg, Rx Only, Manufactured by: Vivimed Life Sciences Private Limited, Plot No., 101, 102, 107 & 108, SIDCO Pharmaceutical Complex, Alathur, Kanchipuram - 603 110, Tamilnadu, India, Distributed by: Strides Pharma Inc., East Brunswick, NJ 08816. 90 film coated tablets NDC 64380-934-05 1000 film coated tablets NDC 64380-934-08	Class II	Drugs	NDC 64380-934-05 Lot 7901146A, 7901147A, 7901148A & 7901149A, Exp Date Sep-22; Lot 7901279A, 7901280A, 7901281A, 7901282A, 7901283A & 7901284A, Exp Date Nov-22; Lot 7901359A, 7901360A &	CGMP Deviations- AZIDO Impurity levels observed to be above acceptable limits	Strides Pharma Inc.



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			7901361A, Exp Date Dec- 22; Lot 7901362A, 7901406A, 7901407A, 7901408A & 7901409A, Exp Date Jan-23. 64380- 934-08 Lot 7901008A & 7901009A, Exp Date Jun- 22; Lot 7901150A & 7901151A, Exp Date Sep- 22; Lot 7901285B, 7901286B, 7901287A, 7901288A, 7901289A, 7901290A, 7901291A, 7901292A, 7901293A & 7901294A, Exp Date Nov- 22.		
Losartan Potassium Tablets, USP, 100 mg, Rx Only, Manufactured by: Vivimed Life Sciences Private Limited, Plot No., 101, 102, 107 & 108, SIDCO Pharmaceutical Complex, Alathur, Kanchipuram - 603 110, Tamilnadu, India, Distributed by: Strides Pharma Inc., East Brunswick, NJ 08816. 90 film coated tablets NDC 64380-935-05 1000 film coated tablets NDC 64380-935-08	Class II	Drugs	64380-935-05 Lots 7901047B, 7901048B, 7901049B & 7901050B, Exp Date Jul-22; Lots 7901185A, 7901186A, 7901187A & 7901188A, Exp Date Oct-22; Lots 7901250A, 7901251A & 7901252A, Exp Date Nov- 22. 64380-935-08 Lots 7900813B, 7900814B, 7900936A, 7900935A, 7900936A, 7900937A, 7900938A & 7900939B,	CGMP Deviations- AZIDO Impurity levels observed to be above acceptable limits	Strides Pharma Inc.



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			Exp Date May-22; Lots 7901043A, 7901044A, 7901045A & 7901046A, Exp Date Jul-22; Lots 7901158B, 7901159B, 7901160B, 7901161A, 7901182A & 7901183A, Exp Date Sep-22; Lots 7901184A, 7901189A, 7901190A, 7901191A, 7901192A, 7901193A, 7901194A & 7901195A, Exp Date Oct-22; Lots 7901295B, 7901296B, 7901297B, 7901296B, 7901297B, 7901296B, 7901297B, 7901300B, 7901301B & 7901302B, Exp Date Nov-22; Lots 7901338A, 7901339A, 7901340A, 7901341A & 7901342A, Exp Date Dec- 22; Lot 7901387A, Exp Date Jan-23		
Only At Family Dollar AMBI Skincare Even & Clear Nourishing Daily Facial Moisturizer With Broad Spectrum SPF 30 Sunscreen, Net Wt. 1.7 FL. OZ. (50 mL)	Class II	Drugs	SKUs 2096628.	cGMP deviations: product stored outside of labeled temperature requirements.	Family Dollar Stores, Llc.
AMBI Skincare Fade Cream Normal Skin, Net Wt. 2 OZ. (56g)	Class II	Drugs	SKUs 2024222	cGMP deviations: product stored outside of labeled temperature requirements.	Family Dollar Stores, Llc.



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
AMBI Skincare Fade Cream Oily Skin New & Improved, Net Wt. 2 OZ (56g)	Class II	Drugs	SKUs 2024219	cGMP deviations: product stored outside of labeled temperature requirements.	Family Dollar Stores, Llc.
AMBI Skincare Even & Clear Exfoliating Wash Salicylic Acid Acne Treatment With Oat and Sea Whip, Net Wt. 5 OZ. (141 g)	Class II	Drugs	SKUs 2097153	cGMP deviations: product stored outside of labeled temperature requirements.	Family Dollar Stores, Llc.
Luxury Hygiene Hand Sanitizer Moisturizing Formula with Vitamin E Advanced Aloe Vera, 8 FL. OZ. (236 mL), TSM Brands LLC 540 Equinox Ln Manalapan, NJ 07726, UPC 6 86275 96537 6	Class II	Drugs	SKUs 2007625	cGMP deviations: product stored outside of labeled temperature requirements.	Family Dollar Stores, Llc.
Luxury Hygiene Hand Sanitizer Moisturizing Formula with Vitamin E, 8 FL. OZ. (236 mL), TSM Brands LLC 540 Equinox Ln Manalapan, NJ 07726, UPC 6 86275 96536 9	Class II	Drugs	SKUs 2007626	cGMP deviations: product stored outside of labeled temperature requirements.	Family Dollar Stores, Llc.
Aveeno Daily Moisturizing lotion Fragrance Free with Soothing Oat & Rich Emollients, Net Wt. 5 oz (141 g), Distributed by Johnson & Johnson Consumer, Inc. Skillman, NJ 08558, UPC 3 81137-001530 7	Class II	Drugs	SKUs 2005444	cGMP deviations: product stored outside of labeled temperature requirements.	Family Dollar Stores, Llc.
EPI-PEN 2-PAK (epinephrine injection, USP), Single-Dose Auto-Injectors 0.3 mg, Rx only, Manufactured for: Mylan Specialty LP., NDC 49502-500-02	Class II	Drugs	McKesson Medical- Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			impacted product may have been shipped to the customer. The letters clearly explain that consignees should identify product received from MMS between June 1 and September 30, 2021. A consignee should be able to use its own records to determine whether it received an impacted product from MMS during that timeframe and whether it still has any of that product in inventory. The recall notification letter informs consignees that they may contact Sedgwick if they have any questions.		
Miocol-E (acetylcholine chloride intraocular solution) 20 mg/2mL (10 mg/mL), Rx only, Manufacturer: Bausch & Lomb, NDC 24208- 539-20	Class II	Drugs	(Code info for this product is same as preceding product)	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
TobraDex (tobramycin and dexamethasone), Ophthalmic Ointment, 3.5 gm, Rx only, Manufacturer: Novartis, NDC 0078-0876-01	Class II	Drugs	(Code info for this product is same as preceding product)	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc.



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
					Corporate Office
Topex (benzocaine 20%), Topical Anesthetic Gel Strawberry, 1 oz, Rx only, Manufacturer: DS Healthcare, NDC 0699-5116-01	Class II	Drugs	McKesson Medical- Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Azithromycin for Injection USP Vial, 500 mg per vial, Rx only, Manufacturer: Auromedics Pharma LLC, NDC 55150-174-10	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Bupivacaine HCI Injection, single dose vial, Preservative Free 0.5%, 10mL (25/ct), Rx only, Manufacturer: Auromedics Pharma LLC, NDC 55150-169-10	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Bupivacaine HCl Injection, single dose vial, 0.5%, 30 mL/5 mg/mL, Rx only, Manufacturer: Auromedics Pharma LLC, NDC 55150-0170-30	Class II	Drugs	(Code info for this product is same as preceding product)	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Bupivacaine HCl Injection, Multi dose vial, 0.25%, 50 mL/2.5 mg/mL, Rx only, Manufacturer: Auromedics Pharma LLC, NDC 55150-0249-50	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Bupivacaine HCl Injection, Multi dose vial, 0.50%, 50 mL/5 mg/mL, Rx only, Manufacturer: Auromedics Pharma LLC, NDC 55150-0250-50	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Bupivacaine HCl Injection, Single Dose Vial, 0.75%, 10 mL/7.5 mg/mL, Rx only, Manufacturer: Auromedics Pharma LLC, NDC 55150-0171-10	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Dexmedetomidine HCL Single Dose Vial 200 mcg per 2 mL (100mcg/mL), Rx only, Manufacturer: Auromedics Pharma LLC, NDC 55150-0209-02	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Lidocaine Patch, 5%, 30-count box, Rx only, Manufacturer: Rhodes Pharmaceuticals, NDC 42858-0118-30	Class II	Drugs	(Code info for this product is same as preceding product)	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Olanzapine single dose vial Lyophilized, 10 mg, Rx only, MFG: Auromedics Pharma LLC, NDC# 55150-0308-01	Class II	Drugs	<u>(Code info for this product</u> is same as preceding product)	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Arzol (Silver Nitrate Applicator), (Silver Nitrate 75%, Potassium Nitrate 25%), 100- count box, Rx only, Manufacturer: Arzol Chemical Co, NDC 12870-0001-02	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Sumatriptan Injection, USP, 6mg/0.5 mL, packaged in a box of 5 x 0.5 mL single-dose vials, Rx only, Manufacturer: Auromedics Pharma LLC, NDC 55150-0173-01	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Betadine 5%, Sterile Ophthalmic Prep Solution, (povidine-iodine ophthalmic solution), 1 fl. oz. (30 mL), Rx only, Mfd for: Alcon Surgical Inc., NDC 0065-0411-30	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Ampicillin for Injection, USP, 1 g per vial, 10- count box, Rx only, Distributed by: Auromedics Pharma, NDC 55150-113-10	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Epidural Tray, Nerve Block Single shot, Rx only, # 182207, MFG: Avanos Medical Sales LLC	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Dihydroergotamine Mesylate, Injection, USP, 1mg/mL, packaged in box of 5 x 1 mL ampules, Rx only, Manufactured for: Perrigo, Minneapolis, MN, NDC 0574-0850- 10	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
EPI-Pen Jr, 2-PAK, (epinephrine injection, USP) Single-Dose Auto-Injectors 0.15 mg, packaged in 2 count carton, Rx only, MFG: Mylan Pharma, NDC 49502-501-02	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Epinephrine Injection, USP, Single-Dose Auto-Injectors 0.3 mg, packaged in 2 count carton, Rx only, MFG: Mylan Pharma, NDC 49502-102-02	Class II	Drugs	(Code info for this product is same as preceding product)	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Epinephrine Injection, USP, Single-Dose Auto-Injectors 0.15 mg, packaged in 2 count carton, Rx only, MFG: Mylan Pharma NDC 49502-101-02	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Firmagon (degarelix for injection) 80 mg, Maintenance Dose (28 days), packaged in a kit, Rx only, MFG: Ferring Pharmaceuticals Inc., NDC 55566-8303-01	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Firmagon (degarelix for injection) 240 mg, Starting Dose, packaged in a kit, Rx only, MFG: Ferring Pharmaceuticals Inc., NDC 55566-8403-01	Class II	Drugs	(Code info for this product is same as preceding product)	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
GlucaGen (glucagon) for injection, 1 mg per vial, single dose kit, Rx only, Manufactured for: Boehringer Mannheim, NDC 0597-0260- 10	Class II	Drugs	<u>(Code info for this product</u> is same as preceding product)	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Albuterol Sulfate Inhalation Solution, 0.021%, 0.63 mg/3mL, packaged in 30 x 3 mL Sterile Unit-Dose Vials, Rx only, MFG: Nephron Pharma, NDC 0487-0301-01	Class II	Drugs	(Code info for this product is same as preceding product)	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Albuterol Sulfate Inhalation Solution 0.083%, 2.5 mg/3mL, packaged in 5 x 3 mL unit-dose vials, Rx only, Manufactured by: Nephron Pharma, NDC 0487-9501-03	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Albuterol Sulfate Inhalation Solution 0.083%, 2.5 mg/3mL, packaged in 25 X 3mL unit-dose vials, Rx only, MFG by: Nephron Pharma, NDC 0487-9501-25	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Adrenalin (epinephrine injection, USP) 30 mg/30 mL (1mg/mL), 30 mL multiple dose vial, Rx only, MFG: Par Pharma, NDC 42023- 168-01	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Albuterol Sulfate Inhalation Aerosol HFA with Dose Indicator, 90 mcg, 200 metered inhalations, Rx only, Manufactured for: PAR Pharmaceutical, NDC 0254-1007-52	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product</u>)	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Albuterol Sulfate Inhalation Aerosol HFA 90 mcg, with Dose Indicator, 200 metered inhalations, Rx only, Distributed by: Sandoz Inc., NDC 0781-7296-85	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Amoxicillin Capsules, USP, 500 mg, 100- count bottle, Rx only, MFG: Sandoz Pharma, NDC 0781-2613-01	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Aparaclonidine Ophthalmic Solution 0.5% as base, 0.5%, 5 mL bottle, Rx only, MFG:Sandoz Pharma, NDC 61314-665-05	Class II	Drugs	(Code info for this product is same as preceding product)	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc.



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
					Corporate Office
Aprepitant Capsule, USP, 40 mg, 1 capsule per unit dose package, Rx only, MFG: Sandoz Pharma, NDC 0781-2321-06	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Betamethasone Dipropionate Cream USP, 0.05%, 45 grams tube, Rx only, MFG: Sandoz Pharma, NDC 0168-0055-46	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Ciprofloxacin Ophthalmic Solution 0.3%, 10 mL bottle, Rx only, Manufactured by: Alcon Laboratories, Inc., NDC 61314-0656-10	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Spinal Tray (A4058-25 Spinal Tray 25G Whitacre No Epinephrine), Rx only, Manufacturer: Smiths Medical ASD, Inc., NJ	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Sterile Water for Injection USP, 2000 mL, Rx only, Baxter Healthcare Corp., NDC 0338- 0013-06	Class II	Drugs	(Code info for this product is same as preceding product)	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Doxycycline Capsules, USP, 100 mg, 50- count bottle, Rx only, Distributed by: Sun Pharmaceuticals, NDC 63304-616-50	Class II	Drugs	(Code info for this product is same as preceding product)	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc.



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
					Corporate Office
BSS Sterile Irrigating Solution (balanced salt solution), 15 mL bottle, Rx only, MFG: Alcon Surgical Inc, NDC 0065-0795-15	Class II	Drugs	(Code info for this product is same as preceding product)	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
BSS Sterile Irrigating Solution (balanced salt solution), 500 mL bottle, Rx only, MFG: Alcon Surgical Inc, NDC 0065-0795-50	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Isopto Atropine (atropine sulfate ophthalmic solution) 1%, 5mL bottle, MFG: Alcon Surgical, NDC 0065-0303-55	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
MIOSTAT (Carbachol Intraocular Solution, USP) 0.01%, 1.5 mL, Rx only, MFG: Alcon Surgical Inc., NDC 0065-0023-15	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Meclizine Hydrochloride Tablets, USP, 25 mg, 50-count cartons (5 x10 unit dose), 10 Tablets per card, 5 cards per carton, Rx only, MFG: Avkare Inc., NDC 50268-523-15	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Glucagen (glucagon) for injection, packaged in a 10-count box, (10 vials each containing 1	Class II	Drugs	(Code info for this product is same as preceding product)	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc.



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
mg per vial), Rx only, MFG: Boehringer Mannheim, NDC 0597-0053-45					Corporate Office
Naltrexone Hydrochloride Tablets, USP, 50 mg, 100-count bottle, Rx only, MFG: Mallinckrodt Inc., NDC 0406-1170-03	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Ipratropium Bromide Inhalation Solution, 0.02%, 0.5 mg/2.5 mL, packaged in 25-count box (25 x 2.5 mL sterile unit-dose vials), Rx only, MFG: Nephron Pharma, NDC 0487- 9801-25	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
ClomiPHENE Citrate Tablets, USP 50 mg, 30- count bottle, Rx only, MFG: PAR Pharma, NDC 49884-701-55	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Olanzapine Orally Disintegrating Tablets, USP 10 mg, 30-count box unit dose tablets (3 blister cards each containing 10 tablets), Rx only, MFG: PAR PHARMA, NDC 49884- 321-55	Class II	Drugs	(Code info for this product is same as preceding product)	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Lidocaine Patch 5%, 30-count carton, Rx only, MFG: Qualitest Products, NDC 0603- 1880-16	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Ciprofloxacin Ophthalmic Solution 0.3%, 5 mL bottle, Rx only, MFG: Sandoz Pharma, NDC 61314-656-05	Class II	Drugs	(Code info for this product is same as preceding product)	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc.



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
					Corporate Office
Hydrocortisone Ointment USP, 2.5%, NET WT 28.35 g (1 oz) tube, Rx only, MFG: Sandoz Pharma, NDC 0168-0146-30	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
HydrOXYzine Pamoate Capsules, USP, 50 mg, 100-count bottle, Rx only, MFG: Sandoz Pharma, NDC 0185-0615-01	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Lidocaine and Prilocaine Cream, 2.5%/2.5%, 5 gram tubes, Rx only, MFG: Sandoz Pharma, NDC 0168-0357-56	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Metronidazole Vaginal Gel USP, 0.75% with 5 applicators, Net Wt. 70 g tube, Rx only, MFG: Sandoz, NDC 0781-7077-87	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Nitrostat (Nitroglycerin Sublingual Tablets, USP) 0.4 mg/tablet, 25-count bottle, Rx only, Distributed by: Pfizer Parke-Davis, Division of Pfizer Inc., NDC 0071-0418-13	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Xylocaine - MPF (lidocaine HCl and epinephrine injection, USP), 1%, 300 mg/30 mL, single dose vial, 5-count box, Rx only,	Class II	Drugs	(Code info for this product is same as preceding product)	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc.



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
MFG: App Pharmaceuticals LLC, NDC 63323- 0487-31					Corporate Office
Glucagon Emergency Kit for Low Blood Sugar, Glucagon for Injection, 1 mg per vial Diluent for Glucagon, 1ml syringe, Rx only, MFG: Eli Lilly, NDC 0002-8031-01	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Xylocaine + Epinephrine, multi dose vial 1%, packaged in a) 20 mL, 25-count box (NDC 63323-482-27) b) 50 mL, 25-count box (NDC 63323-482-57), Rx only, MFG: Fresenius Kabi USA LLC	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Xylocaine + Epinephrine, multi dose vial 2%, 20 mL, 25 count box, Rx only, MFG: Fresenius Kabi USA LLC, NDC 63323-483-27	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Doxycycline Hyclate Tablets, USP, 100 mg, 50-count carton (10 tablets each blister pack x 5), Rx only, MFG: Major Pharma, NDC 0904-0430-06	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Ibuprofen Tablets USP, 400 mg, 100-count unit dose box, Rx only, MFG: Major Pharma, NDC 0904-5853-61	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Metronidazole tablets, USP 250 mg, 100- count unit dose box, Rx only, MFG: Major Pharma, NDC 0904-1453-61	Class II	Drugs	(Code info for this product is same as preceding product)	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc.



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
					Corporate Office
Promethazine HCl Tablets, USP, 25 mg, 100- count unit dose box, Rx only, MFG: Major Pharma, NDC 0904-6461-61	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Sodium Bicarbonate Tablets, 600 mg, 1000- count bottle, MFG: Major Pharma, NDC 0536-1047-10	Class II	Drugs	<u>(Code info for this product</u> is same as preceding product)	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Sulfamethoxazole and Trimethoprim Tablets, USP, 800mg/160mg, 100-count unit dose box, Rx only, MFG: Major Pharma, NDC 0904-2725-61	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Medroxyprogesterone acetate injectable suspension, 150 mg/mL, 1 mL single dose vial, Rx only, MFG: NorthStarRx/Teva Pharma USA , NDC 16714-981-01	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
MethyLPREDNISolone Acetate Injectable Suspension USP, 40 mg/mL, packaged in a) single dose vial (NDC 6714-088-01) b) 25- count box (NDC16714-088-25), Rx only, MFG: NorthstarRx/Teva Pharma USA	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
MethyLPREDNISolone Acetate Injectable Suspension, USP, 200 mg/5 mL (40 mg/mL), 5 mL Multiple Dose Vial, Rx only, MFG:	Class II	Drugs	(Code info for this product is same as preceding product) cKesson Medical-	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc.



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
NorthstarRx/Teva Pharma USA , NDC 16714- 089-01			<u>(Code info for this product</u> <u>is same as preceding</u> product)		Corporate Office
MethyLPREDNISolone Acetate Injectable Suspension, USP, 400 mg/10 mL (40 mg/mL), 10 mL Multiple Dose Vial, Rx only, MFG: NorthstarRx/Teva Pharma USA, NDC 16714- 090-01	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
MethyLPREDNISolone Acetate Injectable Suspension USP, 400 mg/5 mL (80 mg/mL), 5 mL Multiple Dose Vial, Rx only, MFG: NorthstarRx/Teva Pharma USA, NDC 16714- 473-01	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Ketoconazole Cream, 2%, Net Wt 60 grams tube, Rx only, MFG: Nycomed Inc, NDC 0168-0099-60	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Clonidine Hydrochloride Tablets, USP, 0.1 mg, 100-count bottle, Rx only, MFG: Teva/Actavis, NDC 00228-2127-10	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Levalbuterol Tartrate HFA Inhalation Aerosol, 45 mcg/actuation, 200 metered inhalations, Rx only, MFG: Teva Pharma USA, NDC 0591-2927-54	Class II	Drugs	<u>(Code info for this product</u> is same as preceding product)	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Lidocaine Patch 5%, 30-count box, Rx only, MFG: Teva Pharma USA, NDC 0591-3525-30	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Medroxyprogesterone acetate injectable suspension, USP, 150 mg/mL, 1 mL vials, packaged in a) single dose vial (NDC 0703- 6801-01), b) 25-count box single dose vials (NDC 0703-6801-04), Rx only, MFG: Teva Pharma USA	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
MethyLPREDNISolone Acetate Injectable Suspension, USP, 40 mg/mL, packaged in a) 1 mL single dose vial (NDC 0703-0031-01), b) 25-count box (NDC 0703-0031-04), Rx only, MFG: Teva Pharma USA	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
MethyLPREDNISolone Acetate Injectable Suspension, USP, 200mg/5mL (40 mg/mL), 5 mL multi-dose vial, Rx only, MFG: Teva Pharma USA, NDC 0703-0043-01	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
MethyLPREDNISolone Acetate Injectable Suspension USP, 400 mg/10 mL (40 mg/mL), 10 mL multi-dose vial, Rx only, MFG: Teva Pharma USA, NDC 0703-0045-01	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
MethyLPREDNISolone Acetate Injectable Suspension USP, 80 mg/mL, packaged in a) 1 mL single dose vial (NDC 0703-0051-01) b)	Class II	Drugs	(Code info for this product is same as preceding product)	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc.



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
25-count box (NDC 0703-0051-04), Rx only, MFG: Teva Pharma USA					Corporate Office
MethyLPREDNISolone Acetate Injectable Suspension USP, 400 mg/5mL (80 mg/mL), 5 mL multi-dose vials, Rx only, MFG: Teva Pharma USA, NDC 0703-0063-01	Class II	Drugs	(Code info for this product is same as preceding product)	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Mupirocin Ointment, USP 2%, 22 grams tube, Rx only, MFG: Teva Pharma USA, NDC 0093-1010-42, MFG: Teva Pharma USA	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Proair, HFA (albuterol sulfate) Inhalation Aerosol 90 mcg per actuation, 200 metered inhalations, Rx only, MFG: Teva Pharma USA, NDC 59310-579-22	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Propofol Injectable Emulsion, USP, 200 mg/ 20 mL (10 mg/mL), packaged in a) 50 mL vial, in packs of 20 (NDC 00591-2136-51), b) 100 mL vial, in packs of 10 (NDC 00591- 2136-68), Rx only, MFG: Teva Pharma USA	Class II	Drugs	(Code info for this product is same as preceding product)	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Propofol Injectable Emulsion, USP 200 mg per 20 mL (10 mg per mL), twenty-five 20 mL vials, Rx only, MFG: Teva Pharma USA, NDC 0591-2136-95	Class II	Drugs	(Code info for this product is same as preceding product)	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Vecuronium Bromide for Injection, 10 mg (1mg/ mL) vial, 10-count box, Rx only, MFG: Teva Pharma USA, NDC 0703-2914-03	Class II	Drugs	(Code info for this product is same as preceding product)	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc.



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
					Corporate Office
Revonto (dantrolene sodium for injection), 20 mg/vial, 6-count box, Rx only, MFG: US WorldMeds, Inc., NDC 27505-003-67	Class II	Drugs	(Code info for this product is same as preceding product)	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Revonto (dantrolene sodium for injection), 20 mg/vial, 6-count box, Rx only, MFG: US WorldMeds, Inc., NDC 78670-003-67	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Recothrom Thrombin Topical (Recombinant), 5,000 units, packaged in a box containing a 5000-unit vial of RECOTHROM with a 5-mL prefilled diluent syringe (containing sterile 0.9% sodium chloride, USP), a sterile needle-free transfer device, a 5-mL sterile empty syringe, and a pre-printed label, Rx only, MFG: Baxter, NDC# 0338-0322-01	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Transderm Scop (scopolamine) Transdermanl System, 1 mg/ 3 days, 10 (patches) transdermal Systems Multipack, Rx only, MFG: Baxter Healthcare Corp, NDC 10019-553-03	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
E-Z-HD (Barium Sulfate for Oral Suspension), 98% w/w, 340 g bottle, Rx only, MFG: Bracco Diagnostics Inc., NDC 32909-764-01	Class II	Drugs	(Code info for this product is same as preceding product)	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc.



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
					Corporate Office
E-Z-Gas II, Effervescent Granules, Net Weight: 4 g, 50 packets per box, MFG: Bracco Diagnostics Inc., NDC 0270-9020-01 (discontinued), NDC 10361-793-01 (current)	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Gastrografin (Diatrizoate Meglumine and Diatrizoate Sodium Solution USP), packaged in: Twenty-four 30 mL single dose bottles, Rx only, MFG: Bracco Diagnostics Inc., NDC 0270-0445-35	Class II	Drugs	(Code info for this product is same as preceding product)	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Kinevac (Sincalide for Injection), 5mcg per vial, 10 vials per box, Rx only, MFG: Bracco Diagnostics Inc., NDC 0270-0556-15	Class II	Drugs	(Code info for this product is same as preceding product)	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Levofloxacin Tablets, 500 mg, 100-count unit dose box, Rx only, MFG: Major Pharma, NDC 0904-6352-61	Class II	Drugs	(Code info for this product is same as preceding product)	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Celestone Soluspan (betamethasone sodium phosphate and betametasone acetate injectable suspension 6 mg/mL, 30 mg/5mL, multidose vial, Rx only, MFG: Merck Company, NDC 0085-4320-01	Class II	Drugs	(Code info for this product is same as preceding product)	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Proventil HFA, (Albuterol Sulfate Inhalation Aerosol), 200 metered inhalations, Rx only, MFG: Merck Company, NDC 0085-1132-04	Class II	Drugs	(Code info for this product is same as preceding product)	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc.



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
					Corporate Office
Duraclon (clonidine HCl injection, USP), 1000 mcg/10 mL (100 mcg/mL), 10 mL single-dose vial, Rx only, MFG: Mylan Pharma, NDC 67457-218-10	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Loperamide Hydrochloride capsules, USP, 2 mg, 100-count bottle, Rx only, MFG: Mylan Pharma, NDC 0378-2100-01	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Prazosin Hydrochloride Capsules, USP, 1 mg, 100-count bottle, Rx only, MFG: Mylan Pharma, NDC 0378-1101-01	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Labetalol Hydrochloride Tablets, USP, 100 mg, 100-count bottle, Rx only, MFG: Par Pharma, NDC 49884-122-01	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Bupivacaine Hydrochloride, USP 0.5% (5mg/mL), 25 vials x 50 mL per box, Rx only, MFG: Pfizer, NDC 0409-1163-01	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Depo-Medrol (methylprednisolone acetate injectable suspension, USP) 40 mg/mL, 1 mL	Class II	Drugs	(Code info for this product is same as preceding product)	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc.



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
single-dose vial, Rx only, MFG: Pfizer, NDC 0009-3073-03					Corporate Office
Depo-Medrol (methylprednisolone acetate injectable suspension, USP) 80mg/mL, packaged in a) 1 mL single-dose vial (NDC# 0009-3475-01), b) 25-count box (NDC 0009- 3475-03), Rx only, MFG: Pfizer	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Epinephrine, ABJT 0.1 mg/mL, 10 mL, 20GX1.5 (10 pack), Rx only, MFG: Pfizer, NDC 04094-933-01	Class II	Drugs	(Code info for this product is same as preceding product)	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Thrombin JMI, Vial 5,000IU 2/diluent, kit, Rx only, MFG: Pfizer NDC 60793-215-05	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Verapamil HCL, ampule, 2.5 mg/ML 2ML (5/pack), Rx only, MFG: Pfizer, NDC 04094- 011-01	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Diphenhydramine HCl oral solution, USP, 25 mg/10 mL UD, packaged in a) 10 mL unit dose cups (NDC 0121-0978-10), b) 100- count box (NDC 0121-0978-00), Rx only, MFG: Pharmaceutical Associates Inc.	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Neomycin and Polymyxin B Sulfates and Dexamethasone Ophthalmic Ointment, 3.5 g	Class II	Drugs	(Code info for this product is same as preceding product)	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc.



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
tube, Rx only MFG: Sandoz, NDC 61314-631- 36					Corporate Office
Ondansetron HCL, Tab 8 mg filmcoated, 30- count bottle, Rx only, MFG: Sandoz Pharma, NDC 65862-188-30	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Pantoprazole Sodium for Injection, 40 mg/vial, 10 single-dose vials, Rx only, MFG: Sandoz Pharma, NDC 0781-3232-95	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product</u>).	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Prednisolone Acetate Ophthalmic Suspension, USP 1%, 5 mL bottle, Rx only, MFG: Sandoz Pharma, NDC 61314-637-05	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Triamcinolone Acetonide cream, USP, 0.1% ,15 grams tube, Rx only, MFG: Sandoz Pharma, NDC 0168-0004-15	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Polymyxin B Sulfate and Trimethoprim Ophthalmic Solution, USP, sterile, 0.1%, 10 mL bottle, Rx only, MFG: Sandoz Pharma, NDC 6131462810	Class II	Drugs	(Code info for this product is same as preceding product)	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Tropicamide Ophthalmic Solution, USP 1%, 3 mL bottle, Rx only, MFG: Sandoz Pharma, NDC 6131435502	Class II	Drugs	(Code info for this product is same as preceding product)	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc.



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
					Corporate Office
Pilocarpine HCL Ophthalmic Solution, USP 2%, 15 mL, Rx only, MFG: Somerset Therapeutics, Inc., NDC 7006919101	Class II	Drugs	(Code info for this product is same as preceding product)	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Metoprolol tablets 50 mg, 100-count botte, Rx only, MFG: Sun Pharmaceuticals, NDC 57664-0477-52	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Sumatriptan Succinate Tablets, 100 mg, 9 (1 x 9) Unit-of- use tablets box, Rx only, MFG: Sun Pharmaceuticals, NDC 62756-522-69	Class II	Drugs	(Code info for this product is same as preceding product)	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Geodon for injection (ziprasidone mesylate), 20 mg/mL, 1 mL single dose vial, Rx only, MFG: Viatris, NDC 0049-3920-83	Class II	Drugs	(Code info for this product is same as preceding product)	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Tetracaine Hydrochloride Ophthalmic Solution, 0.5%, 4 mL bottle, Rx only, MFG: Alcon Surgical Inc., NDC 0065-0741-14	Class II	Drugs	(Code info for this product is same as preceding product)	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Ofloxacin Otic Solution 0.3%, 5 mL bottle, Rx only, MFG: Amneal/Akyma Pharmaceuticals, NDC 69238-1615-3	Class II	Drugs	(Code info for this product is same as preceding product)	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc.



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
					Corporate Office
Diprivan (Propofol) Emulsion, 100 mg/mL, 10mL vial, Rx only, MFG: App Pharmaceutical LLC, NDC 63323-269-10	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Diprivan (Propofol) Emulsion, 200 mg per 20 mL (10mg/mL), 20 mL vial, Rx only, MFG: App Pharmaceutical LLC, NDC 63323-269-29	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Cefazolin for injection USP, and Dextrose Injection, USP, 1G, 50 ML duplex container, Rx only, MFG: B. Braun Medical Inc., NDC 0264-3103-11	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Cefazolin for injection USP, and Dextrose Injection, USP, 2 g, 50 mL duplex container, Rx only, MFG: B. Braun Medical Inc., NDC 0264-3105-11	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Intralipid (I.V. Fat emulsion), 20%, 250 mL bag, Rx only, MFG: Baxter Healthcare, NDC 0338-0519-09	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Intralipid (I.V. Fat emulsion), 20%, 100 mL bag, Rx only, MFG: Baxter Healthcare, NDC 0338-0519-58	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc.



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
					Corporate Office
Biopsy and Aspiration Tray Bone Marrow Illinois 11GX4 (10/cs) Rx CRFPED Lidocaine Hydrochloride USP, 1%, 5mL, Rx only, MFG: Becton Dickinson	Class II	Drugs	<u>(Code info for this product</u> <u>is same as preceding</u> <u>product)</u>	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Paracentesis/Thoracentises Tray (10/cs) Rx CRFPED, Lidocaine Hydrochloride USP, 1%, 5mL, Rx only, MFG: Becton Dickinson	Class II	Drugs	<u>(Code info for this product</u> is same as preceding product)	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office
Ethanol for Injection 95%, 67 mL Multi-Dose vial, Rx only, US Specialty Formulations, 1403 South Albert Street, Allentown, PA 18103, PN: 69389-06229	Class II	Drugs	Lot #: 02RP1503A, exp. date 30-Sep-22; 02RP1506A, exp. date 31- Dec-22; 02RP1516A, exp. date 30-Jun-23	Lack of Assurance of Sterility	US Specialty Formulations LLC
B-Complex + Chromic Chloride (Choline Chloride 3%, Inositol 3%, Pyridoxine HCl 2%, Niacinamide 2%, Thiamine HCl 2%, Chlorobutanol 0.5%, Riboflavin 0.05%, Chromic Chloride 0.003%), 30 mL Multi-Dose Vial, packaged in 2 x 30 mL Multi-Dose Vials per carton, US Specialty Formulations, LLC, 116 Research Drive, Bethlehem, PA 18015, P/N: 234-15523	Class II	Drugs	Lot #: 02RP1507A, exp. date 30-Jun-22; 02RP1512A, exp. date 30- Sep-22; 02RP1514A, exp. date 31-Nov-22; 02RP1515A, exp. date 31- Dec-22	Lack of Assurance of Sterility	US Specialty Formulations LLC
Homeopathic EarAche Drops, 0.33 FL OZ (10 mL) bottles, Distributed by: RITE AID, 30 Hunter Lane, Camp Hill, PA 17011. NDC 11822-3644-3	Class II	Drugs	Lot #: G11639, Exp. Date 09/24	Microbial contamination of non- sterile product.	Grato Holdings, Inc.



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Homeopathic EarAche Ear Drops, 0.33 FL OZ (10 mL) bottles, Distributed by: CVS Pharmacy, Inc., One CVS Drive, Woonsocket, RI 02895. NDC 59779-568-15	Class II	Drugs	Lot #: G11639, Exp. Date 09/24	Microbial contamination of non- sterile product.	Grato Holdings, Inc.
Earache Drops, 0.33 FL OZ (10 mL) bottles, Distributed by: Walgreen Co., 200 Wilmot Rd., Deerfield, IL 60015. NDC 0363-3233-15	Class II	Drugs	Lot #: G11639, Exp. Date 09/24	Microbial contamination of non- sterile product.	Grato Holdings, Inc.
HAND SANITIZER SAY GOODBYE TO GERMS Alcohol Antiseptic 80% Topical Non-Sterile Solution, 12 FL OZ (254 mL) bottles, Distributed by: Hand Cleansing Gel 850 Kaliste Saloom Rd. Suite 212 Lafayette, LA 70508 UPC 8 60003 62626 9	Class II	Drugs	Batch# 100620-128201, 100620-128202, 100620- 128203, 100620-128204, 100620-128205, 100620- 128206, 100620-128207, 100620-128208, 100620- 128209, 100620-128210, 100620-128211, 100620- 128212	CGMP Deviations: FDA analysis found product to contain acetaldehyde and acetal above specification limits.	Hand Sanitizer LLC
medroxyPROGESTERone Acetate Injectable Suspension, USP, 1 mL Prefilled Syringe, 150 mg/mL, Rx only, Manufactured by: Sun Pharmaceutical Industries, Ltd., Halol- Baroda Highway, Halol-389 350, Gujarat, India Distributed by: Afaxys Pharma, LLC, Charleston, SC, 29403, USA, Product of Italy, NDC 50102-591-40.	Class II	Drugs	Lots#: JKX4312A & JKX4313A, Exp 09/2022; JKX4827A, Exp 09/2023; HAC1290A & HAC2082B, Exp 06/2023;	Lack of assurance of sterility	SUN PHARMACEUT ICAL INDUSTRIES INC
medroxyPROGESTERone Acetate Injectable Suspension, USP, 1 mL Prefilled Syringe, 150 mg/mL, Rx only, Manufactured for: Northstar Rx LLC, Memphis, TN 38141, Manufactured by: Sun Pharmaceutical	Class II	Drugs	Lot#: HAC1289A, Exo 06/2023; JKX2679A, Exp 06/2022; JKX3762A, Exp 08/2022; HAC0164A, Exp 06/2023.	Lack of assurance of sterility	SUN PHARMACEUT ICAL INDUSTRIES INC



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Industries Ltd., Halol-Baroda Highway, Halol- 389 350, Gujarat, India, NDC 16714-999-01.					
medroxyPROGESTERone Acetate Injectable Suspension, USP, 1 mL Prefilled Syringe, 150 mg/mL, Rx only, Manufactured by Sun Pharmaceutical Industries Ltd., Halol-Baroda Highway, Halol-389 350, Gujarat, India, Distributed by: Sun Pharmaceutical Industries, Inc., Cranbury, NJ 08512, NDC 62756-091-40.	Class II	Drugs	Lot #: HAC1951A, Exp 06/2023	Lack of assurance of sterility	SUN PHARMACEUT ICAL INDUSTRIES INC
medroxyPROGESTERone Acetate Injectable Suspension, USP, 1 mL Single-Dose Vial, 150 mg/mL, Rx only, Manufactured for: Northstart Rx LLC, Memphis, TN, 38141, Manufactured by: Sun Pharmaceutical Industries Ltd., Halol Baroda Highway, Halol- 389 350, Gujarat India , NDC 16714-981-01.	Class II	Drugs	Lot: HAC2075A, Exp 06/2023; HAC2076A, Exp 07/2023; HAC2077A, HAC2078A, Exp 08/2023; HAC3803A, Exp 09/2023; HAC0551A, Exp 02/2023; HAC0562A, HAC1183A, Exp 03/2023; HAC1807A, Exp 06/2023; JKX6017A, JKX6018A Exp 12/2022; HAC0163A, Exp 01/2023; HAC1184A, Exp 04/2023; HAC0162A, Exp 12/2022.	Lack of assurance of sterility	SUN PHARMACEUT ICAL INDUSTRIES INC
medroxyPROGESTERone Acetate Injectable Suspension, USP, 25 x 1 mL Single-Dose Vial, 150 mg/mL, Rx only, Distributed by: Sun Pharmaceutical Industries, Inc. Cranbury, NJ 08512, Manufactured by: Sun Pharmaceutical Industries Ltd., Halol Baroda	Class II	Drugs	Lot#: HAC2074A, Exp Date 06/2023; HAC0163B, Exp Date 01/2023 & HAC1741A, Exp Date 04/2023	Lack of assurance of sterility	SUN PHARMACEUT ICAL INDUSTRIES INC



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Highway, Halol-389 350, Gujarat India , NDC 16714-090-40 packaged in 25 count carton.					
Premium Nature Instant Hand Sanitizer, (ethyl alcohol 65%), 8 oz/ 236 ML plastic bottles; Premium Nature, South Plainfield, NJ. UPC 819192028668	Class II	Drugs	all lots	Subpotent Drug: FDA analysis has revealed some bottles of these products were sub potent for ethanol.	AMS Packaging Inc
Anthracinum, Potency: 6C, 7C, 8C, 9C, 12C, 14C, 30C, 200C, 11X, 14X, 30X Liquid Pellets, OTC, Washington Homeopathic Products, 260 JR Hawvermale Way Berkeley Springs, WV 25411	Class II	Drugs	Lot # 18415, 19369, 21577, 20308, 20331	cGMP deviations	Washington Homeopathic Products, Inc.
Bacillinum Pulmo, Potency: 30C, 200C, Liquid Pellets, Rx only, Washington Homeopathic Products, 260 JR Hawvermale Way, Berkeley Springs, WV 25411	Class II	Drugs	Lot # 20308, 20331	cGMP deviations	Washington Homeopathic Products, Inc.
Candida Albicans, Potency: 9C, 10C, 12C, 13C, 14C 15C 16C, 19C, 24C, 25C, 26C, 30C, 200C, 14X, 15X, 16X, 20X, 288X, 30X, Liquid Pellets, OTC, Washington Homeopathic Products, 260 JR Hawvermale Way, Berkeley Springs, WV 25411	Class II	Drugs	Lot # 17759, 18479, 18133	cGMP deviations	Washington Homeopathic Products, Inc.
Candida Parapsilosis, Potency: 14X, 15X, 16X, 20X, 28X, 30X, 9C, 10C, 13C, 15C, 25C, 30C, 13X, 27X, 30X, Liquid Pellets, OTC, Washington Homeopathic Products, 260 JR Hawvermale Way, Berkeley Springs, WV 25411	Class II	Drugs	Lot # 22315, 26502	cGMP deviations	Washington Homeopathic Products, Inc.
Colibacillinum, Potency: 12C, 14C, 15C, 18C, 20C, 30C, Liquid Pellets, OTC, Washington	Class II	Drugs	Lot # 21881	cGMP deviations	Washington Homeopathic Products, Inc.



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Homeopathic Products, 260 JR Hawvermale Way, Berkeley Springs, WV 25411					
Diphtherinum, Potency: 14C, 30C, 200C, Liquid Pellets, Rx only, Washington Homeopathic Products, 260 JR Hawvermale Way, Berkeley Springs, WV 25411,	Class II	Drugs	Lot # 20332, 20333	cGMP deviations	Washington Homeopathic Products, Inc.
Influenzinum, Potency: 9X, 10X, 12X, 15X, 25X, 30X, 200C, 12C, 30C 1M, Liquid Pellets, OTC, Washington Homeopathic Products, 260 JR Hawvermale Way, Berkeley Springs, WV 25411	Class II	Drugs	Lot # 28960, 28962, 28961, 27415, 27464	cGMP deviations	Washington Homeopathic Products, Inc.
Medorrhinum, Potency:12C, 30C, 200C, 1M, Liquid Pellets, Rx only, Washington Homeopathic Products, 260 JR Hawvermale Way, Berkeley Springs, WV 25411	Class II	Drugs	Lot# 20211, 20543, 22709	cGMP deviations	Washington Homeopathic Products, Inc.
Morbillinum, Potency:7C, 8C, 9C, 10C 12C, 13C, 15C, 20C, 21C, 30C, 200 C,Liquid Pellets, OTC, Washington Homeopathic Products, 260 JR Hawvermale Way, Berkeley Springs, WV 25411	Class II	Drugs	Lot# 20307, 20309	cGMP deviations	Washington Homeopathic Products, Inc.
Pertussinum, Potency: 19C, 30C, 200C, 1M, Liquid Pellets, OTC, Washington Homeopathic Products, 260 JR Hawvermale Way, Berkeley Springs, WV 25411	Class II	Drugs	Lot# 18829, 20142, 25410	cGMP deviations	Washington Homeopathic Products, Inc.
Proteus, Potency: 7C, 8C, 9C, 12C, 15C, 16C, 20C, 30C, 200C, OTC, Liquid Pellets, Washington Homeopathic Products, 260 JR Hawvermale Way, Berkeley Springs, WV 25411	Class II	Drugs	Lot# 22747, 22771	cGMP deviations	Washington Homeopathic Products, Inc.



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Pyrogenium, Potency: 15X, 16X, 17X, 19X, 21X, 22X, 25X, 30X, 1M, 200C, 30C, OTC, Liquid Pellets, Washington Homeopathic Products, 260 JR Hawvermale Way, Berkeley Springs, WV 25411	Class II	Drugs	Lot# 17931-1, 26684, 17528-1, 30755, 30406, 30515, 29079, 29221, 26953, 23757	cGMP deviations	Washington Homeopathic Products, Inc.
Streptococcinum, Potency: 8C, 9C, 30C, 200C, Liquid Pellets, Rx only, Washington Homeopathic Products, 260 JR Hawvermale Way, Berkeley Springs, WV 25411	Class II	Drugs	Lot# 21902, 21927	cGMP deviations	Washington Homeopathic Products, Inc.
Syphilinum, Potency: 9C, 30C, 200C, 10X, 12X, Liquid Pellets, Rx only, Washington Homeopathic Products, 260 JR Hawvermale Way, Berkeley Springs, WV 25411	Class II	Drugs	Lot# 20390, 20441, 20389	cGMP deviations	Washington Homeopathic Products, Inc.
Tuberculinum, Potency: 1X, 12X, 24X, 30X, 1M, Liquid Pellets, Rx only, Washington Homeopathic Products, 260 JR Hawvermale Way, Berkeley Springs, WV 25411	Class II	Drugs	Lot# 20388, 22728	cGMP deviations	Washington Homeopathic Products, Inc.
Tuberculinum Bovinum, Potency: 12C, 30C, 200C, Liquid Pellets, Rx only, Washington Homeopathic Products, 260 JR Hawvermale Way, Berkeley Springs, WV 25411	Class II	Drugs	Lot# 19148, 21028	cGMP deviations	Washington Homeopathic Products, Inc.
Vaccinotoxinum, Potency: 32X, 11C, 30C, Liquid Pellets, Rx only, Washington Homeopathic Products, 260 JR Hawvermale Way, Berkeley Springs, WV 25411	Class II	Drugs	Lot# 2512K, 20280	cGMP deviations	Washington Homeopathic Products, Inc.
Alcohol Antiseptic 80%, Topical Solution, Hand Sanitizer, Non-Sterile Solution, Packaged as (a) 250 U.S. gallons per tote, Product Code 9999D361-250: (b) 1 U.S. gallon, Product Code 9999D361-001: A.P.	Class II	Drugs	Lot: 54931, No Expiration date.	CGMP Deviations: FDA analysis found product to contain acetaldehyde and acetal above specification limits.	A.P. Nonweiler



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Nonweiler Co., Inc., 3321 County Road A, Oshkosh, WI 54901.					
Zileuton Extended-Release Tablets, 600 mg, 120-count bottle, Rx only, Manufactured for Lupin Pharmaceuticals, Inc., Baltimore, MD 21202 by Lupin Limited, Nagpur-441108, India, NDC 68180-169-16	Class II	Drugs	Lots: M100070, M100239, Exp. 06/22, M100312, Exp.09/22, M100366, Exp.10/22	Failed Dissolution Specifications: Out of specification test results observed in dissolution testing during long term stability study.	Lupin Pharmaceutic als Inc.
Phenobarbital Elixir, USP 20 mg/5 mL, 1 Pint (473 mL) bottles, Rx Only, Manufactured for: Westminster Pharmaceuticals, LLC Tampa, FL 33624, NDC 69367-172-16	Class III	Drugs	Lot #: 20FP1569 Exp. Date 08/2022; 21FP1674 Exp. Date 02/2023; 21FP1831 Exp. Date 08/2023	Does Not Meet USP or OTC Monograph: Product exceeds USP specification for alcohol content	Monarch PCM, LLC
Sirolimus Oral Solution, 1 mg/mL, 60 mL bottle, Rx Only, Manufactured by: Apotex Inc. Toronto, Ontario Canada M9L 1T9 Manufactured for: Apotex Corp. Weston, Florida 33326, NDC 60505-6197-2	Class III	Drugs	Lot: RZ1598, exp. date 02/2023	Failed Dissolution Specifications: Sirolimus Oral Solution recalled due to lot RZ1598 exceeded the specification limit at the 14-month timepoint.	Apotex Corp.
Open Nature Cough Drops Menthol-Cough Suppressant/Oral Anesthetic Peppermint Naturally Flavored, packaged in Bags of 30 lozenges, Distributed By Lucerne Foods, Inc. P.O. Box 99, Pleasanton, CA 96566-0009, UPC 0 79893 41266 5	Class III	Drugs	Lot #: 100010885, Exp 11/2024	Subpotent drug: Low OOS for menthol content at the three month room temperature.	Bestco LLC
Nitrofurantoin Capsules, USP (Monohydrate/Macrocrystals), 100 mg, 100 Capsules (10 x 10), 10-count blisters per card, 10 cards per carton, Unit Dose NDC 68084-446-11, Rx Only, Distributed by: American Health Packaging, Columbus, Ohio 43217, NDC: 68084-446-01	Class III	Drugs	Lot # 1003829, Exp date 1/31/23	Failed Dissolution Specifications: Nitrofurantoin Capsules recalled due to dissolution failure at 0-time of the repackaged lot. Drug release results were above specification at 0-time.	American Health Packaging



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Tivicay (dolutegravir) Tablets 50 mg, 30- count Bottle, Rx Only, Manufactured for: ViiV Healthcare RTP, NC 27709, NDC 49702- 228-13.	Class III	Drugs	Lot: 2A9E, Exp 1/2027	Labeling: incorrect or missing lot and/or expiration date. An incorrect expiration date was printed on the product labeling with an expiration date of January 2027, whereas the correct expiration date is September 2026.	GlaxoSmithKli ne LLC
Benzphetamine tablets, 50mg, CIII, repackaged in 30-count bottles, Distributed by Calvin Scott & Co., Inc, Albuq., NM. 87123, NDC 10702-0040-50	Class III	Drugs	CSI Lot: CS-20274-005, Exp 5/22	Labeling: Label Mix-up: Bottle labeled as Benzonatate 100 mg capsules contained Benzphetamine 50 mg tablets and a bottle labeled as Benzphetamine 50 mg tablets contained Benzonatate 100 mg capsules.	Calvin Scott & Company, Inc.
Higher Education Make Out Ready Vegan Lip Balm, SPF 15, Net Wt. 0.15 oz (4.25 g) per tube, Active Ingredients: Oxtinoxate (7.5%), Oxybenzone (3%); Distributed by: Higher Education Skincare, 1.833.251.0388	Class III	Drugs	Lot 93400-21200	Mislabeling: The active ingredient list on the label does not match the product's actual ingredients Specifically, the label states Octinoxate 7.5% and Oxybenzone 3%, while the product therein is made with Octinoxate 7.5%, Octisalate 5%, Octocrylene 5%, and Avobenzone 3%.	Eco Lips, Inc
Ipratropium Bromide 0.5 mg and Albuterol Sulfate 3 mg Inhalation Solution 3mL vial, packaged in a) 30-count (NDC 0487-0201- 03), b) 60-count (NDC 0487-0201-60), Rx only, MFG: Nephron Pharma	Class III	Drugs	McKesson Medical- Surgical (MMS) is not able to identify the particular lot number received by a particular consignee for the recalled prescription	cGMP deviations: Temperature abuse	Mckesson Medical- Surgical Inc. Corporate Office



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			products. Each letter includes the date it was distributed to customers and the dates that impacted product may have been shipped to the customer.		
Xiidra (lifitegrast ophthalmic solution), packaged in a) 60 Single-Use Containers: 12 pouches x 5 single-use containers (0.2 mL each vial) (NDC 0078-0911-12) and b) 5- Single-Use Containers (NDC 0078-0911-05) Rx Only, Manufactured by: The Ritedose Corporation, Columbia, SC 29203, Distributed by: Novartis Pharmaceuticals Corporation, East Hanover, NJ 07936.	Class III	Drugs	Lot #:a) and b) 20E21, 20E22, 20E53, 20E54, 20E95, 20E96, 20ED1, 20ED2, 20ED3, 20EK1 Exp. Date 4/2023; 20F27, 20F28, 20F66, 20F67,20FH6, Exp. Date 05/2023; 20G47, 20G48, 20G49, 20G57, 20G88, 20G49, 20G57, 20G88, 20GE5, 20GE6, Exp. Date 06/2023; 20M41, 20M42, 20M56, 20M66, 20M67, 20MA4, Exp. Date 07/2023; 20S20, 20S22, 20S44, 20S94, Exp. Date 10/2023; 20SA6, 20SA7, 20SE0, Exp. Date 10/2023, 20TE2, 20TG5, Exp. Date 11/2023.	Failed Impurities/Degradation Specifications.	Novartis Pharmaceutic als Corporation
Xiidra (lifitegrast ophthalmic solution) 5%, packaged in a) 60 Single-Use Containers: 12 pouches x 5 single-use containers (0.2 mL each vial) (NDC 54092-606-01) and b) 5-	Class III	Drugs	Lot #: a) and b)19E31, 19E32, 19E85, 19E86, 19EC0, 19EG8 & 19EG9, Exp. Date 05/2022; 19F13,	Failed Impurities/Degradation Specifications.	Novartis Pharmaceutic als Corporation



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Single-Use Containers (NDC 54092-606-06), Rx Only, Manufactured for: Shire US Inc., 300 Shire Way, Lexington, MA 02421.			19FB0 & 19FC5, Exp. Date 6/2022;19G33, 19G34,19GJ8, Exp. Date 07/2022;19M25, 19M26 & 19M68, Exp. Date 08/2022;19NC0, 19NC1, 19NF2,19NF3, Exp. Date 09/2022;19P26, 19P59, 19P60,19P85,19P86 19P87, Exp. Date 10/2022;19S55, 19S03, 19S04, 19S05,19S07, Exp. Date 11/2022; 19T06, 19T60, 19T61, Exp. Date 12/2022; 20A38, 20A39, 20A64, 20A65, 20AA1, 20AA2, 20AC8, 20AC9, 20AE7, Exp. Date 01/2023; 20B24, 20B25, 20B55, 20B56, 20B57 & 20B58, Exp. Date 02/2023		
Xiidra (lifitegrast ophthalmic solution) 5% PROFESSIONAL SAMPLE, packaged in a) 5 single-use containers (0.2 mL each vial) (NDC 0078-0911-95) and b) 4 pouches x 5 single- use containers (NDC 0078-0911-94), Rx Only, Manufactured by: The Ritedose Corporation Columbia, SC 29203; Distributed by: Novartis Pharmaceuticals Corporation East Hanover, NJ 07936.	Class III	Drugs	Lot #: a) and b) 20DJ3, Exp. Date 03/2023.	Failed Impurities/Degradation Specifications.	Novartis Pharmaceutic als Corporation



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Xiidra (lifitegrast ophthalmic solution) 5% PROFESSIONAL SAMPLE, packaged in a) 5 single-use containers (0.2 mL each vial) (NDC 54092-606-07) and b) 4 pouches x 5 single- use containers (NDC 54092-606-04), Rx Only, Manufactured for: Shire US Inc., 300 Shire Way, Lexington, MA 02421.	Class III	Drugs	Lot #: a) and b) 19F39, Exp. Date 06/2022; 19P27, Exp. Date 10/2022; 20CD1, Exp. Date 03/2023	Failed Impurities/Degradation Specifications.	Novartis Pharmaceutic als Corporation
Alprostadil Injection USP 500 mcg/mL, 1 mL Single Dose Vial, 5 vials per Carton, Rx Only, Carton NDC 0703-1501-02, Distributed by: Teva Pharmaceuticals USA, Inc., Parsippany, NJ 07054, Vial NDC 0703-1501-01	Class III	Drugs	Lot #:100022404, Exp Date 10/2022; Lot #:100023333, Exp Dat 12/2022	Failed Impurities/Degradation Specifications; out-of-specification results for impurities obtained during routine stability testing	Teva Pharmaceutic als USA Inc

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



FDA DRUG SAFETY COMMUNICATIONS

[6/1/2022] FDA approval of lymphoma medicine Ukoniq (umbralisib) is withdrawn due to safety concerns

Possible increased risk of death outweighs the benefits

Due to safety concerns, the U.S. Food and Drug Administration (FDA) has withdrawn its approval for the cancer medicine Ukoniq (umbralisib). Ukoniq was approved to treat two specific types of lymphoma: marginal zone lymphoma (MZL) and follicular lymphoma (FL).

Updated findings from the UNITY-CLL clinical trial continued to show a possible increased risk of death in patients receiving Ukoniq. As a result, we determined the risks of treatment with Ukoniq outweigh its benefits. Based upon this determination, the drug's manufacturer, TG Therapeutics, announced it was voluntarily withdrawing Ukoniq from the market for the approved uses in MZL and FL.

Health care professionals should stop prescribing Ukoniq and switch patients to alternative treatments. Inform patients currently taking Ukoniq of the increased risk of death seen in the clinical trial and advise them to stop taking the medicine. In limited circumstances in which a patient may be receiving benefit from Ukoniq, TG Therapeutics plans to make it available under expanded access.

Patients should talk to your health care professionals about alternative treatments and stop taking Ukoniq. It is best to dispose of unused Ukoniq using a drug take-back location such as in a pharmacy, but if one is not available, you can dispose of Ukoniq in your household trash by doing the following:

- 1. Mix the medicine with an unappealing substance such as dirt, cat litter, or used coffee grounds; do not crush them.
- 2. Place the mixture in a container such as a sealed plastic bag.
- 3. Throw away the container in your home trash.
- 4. Delete all personal information on the prescription labels of empty medicine bottles or packaging, then throw away or recycle them.

We urge health care professionals and patients to report side effects involving medicines to the FDA MedWatch program, using the information in the "Contact FDA" box at the bottom of the page.

Health care professionals, patients, and consumers can sign up for email alerts about Drug Safety Communications on medicines or medical specialties of interest to you.



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: <u>https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm</u>

Generic Name or Active Ingredient

Amifostine Injection Amino Acids Amoxapine Tablets Amphetamine Oral Suspension, Extended Release 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 **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 Continuous Renal Replacement Therapy (CRRT) Solutions **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 Fentanyl Citrate (Sublimaze) Injection Floxuridine for Injection **Fludarabine Phosphate Injection Fluorescein Injection 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 Iodixanol (Visipaque) Injection Iohexol (Omnipague) Injection Iopromide (Ultravist) Injection Isoniazid Injection **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 Lipid Injection Lithium Oral Solution Lorazepam Injection Lutetium Lu 177 Dotatate (LUTATHERA) 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** 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 Rifampin Capsules Rifampin Injection Rifapentine Tablets Ropivacaine Hydrochloride 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 Powder for Injection 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 Vecuronium Bromide for Injection