PERFORMRx℠

Drug Information Update

May 2021

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NEWLY AVAILABLE GENERICS

Generic Name/ Dosage Form	Brand Name	Manufacturer	Indication
isotretinoin 10 mg, 20 mg, 25 mg, 30 mg, 35 mg, 40 mg capsules	Fabior	Sun Pharmaceutical Industries	For the treatment of severe recalcitrant nodular acne in non-pregnant patients 12 years of age and older with multiple inflammatory nodules with a diameter of 5 mm or greater. Because of significant adverse reactions associated with its use, Absorica and Absorica LD are reserved for patients with severe nodular acne who are unresponsive to conventional therapy, including systemic antibiotics.
sodium fluoride 0.2% solution	Prevident Rinse	Colgate	A dental caries preventive, for weekly self-applied topical use. Weekly rinsing with a neutral 0.2% sodium fluoride solution protects against dental caries in adults and pediatric patients. PreviDent Rinse provides a ready-to-use preparation for convenient administration and favorable compliance. May be used in areas where drinking water is fluoridated since topical fluoride cannot produce fluorosis.
calcitonin salmon, synthetic 200 unit/mL vial	Miacalcin	Mylan	• Treatment of symptomatic Paget's disease of bone when alternative treatments are not suitable • Treatment of hypercalcemia • Treatment of postmenopausal osteoporosis when alternative treatments are not suitable. Fracture reduction efficacy has not been demonstrated
tiopronin 100 mg tablet	Thiola	Mission Pharma	A reducing and complexing thiol indicated, in combination with high fluid intake, alkali, and diet modification, for the prevention of cystine stone formation in adults and pediatric patients 20 kg and greater with severe homozygous cystinuria, who are not responsive to these measures alone.

NEW DRUG ENTITIES/STRENGTHS/COMBINATIONS

Drug Name	Generic Name	Description	Comments
Qelbree 100 mg, 150 mg, 200 mg capsule, extended release	viloxazine HCl	A selective norepinephrine reuptake inhibitor indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in pediatric patients 6 to 17 years of age	New Entity
artesunate 110 mg intravenous solution	artesunate	For the initial treatment of severe malaria in adult and pediatric patients. Cost is approximately $100,000 for a 3 day course of therapy for a 70 kg adult. This drug is the preferred treatment for severe malaria.	New Entity
labetalol 1 mg/mL in sodium chloride (iso) intravenous solution	labetalol in NaCl, iso-osmotic	New formulation of generic IV labetalol	New Formulation
labetalol 1 mg/mL in dextrose (iso-osmotic) intravenous solution	labetalol in dextrose, iso-osm	New formulation of generic IV labetalol	New Formulation
Nextstellis 3 mg-14.2 mg (28) tablet	drospirenone/ estetrol	505(b)2 combination of drospirenone, a progestin, and estetrol, an estrogen, indicated for use by females of reproductive potential to prevent pregnancy	New Entity
Xpovio 40 mg/week (40 mg x 1), twice week (40 mg x 2), 60 mg/week (60 mg x 1), 80 mg/week (40 mg x 2), 100 mg/week (50 mg x 2) tablet	selinexor	New strength/package size	New Strength/ Package Size
Zynlonta 10 mg intravenous solution	loncastuximab tesirine-lpyl	A CD19-directed antibody and alkylating agent conjugate indicated for the treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy,	New Entity

Drug Name	Generic Name	Description	Comments
		including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, DLBCL arising from low grade lymphoma, and high-grade B-cell lymphoma	
Jemperli 50 mg/mL intravenous solution	dostarlimab-gxly	A programmed death receptor-1 (PD-1)–blocking antibody indicated for the treatment of adult patients with mismatch repair deficient (dMMR) recurrent or advanced endometrial cancer, as determined by an FDA-approved test, that has progressed on or following prior treatment with a platinum-containing regimen	New Entity
Accrufer 30 mg capsule	ferric maltol	Oral iron therapy for iron deficiency in adults. Demonstrated non-inferior to IV iron.	New Entity
Xcopri Maintenance Pack 250mg/day (150 mg x 1 and 100 mg x 1) tablets	cenobamate	Anticonvulsant for partial onset seizures. New combination of 150 mg x 1 and 100 mg x 1.	New Strength Combination in Maintenance Pack
Ingrezza 60 mg capsule	valbenazine tosylate	New strength	New Strength
Exservan 50 mg oral film	riluzole	New dosage form - film formulation of riluzole	New Dosage Form
Skyrizi 150 mg/mL subcutaneous syringe, pen injector	risankizumab-rzaa	New pen formulation and package size (single syringe)	New Dosage Form
Zynrelef 200 mg-6 mg/7 mL, 400 mg-12 mg/14 mL surgical site instillation soln, ER	bupivacaine/ meloxicam	505(b)2. Indicated in adults for soft tissue or periarticular instillation to produce postsurgical analgesia for up to 72 hours after bunionectomy, open inguinal herniorrhaphy and total knee arthroplasty.	New Combination

Drug Name	Generic Name	Description	Comments
Empaveli 1,080 mg/20 mL subcutaneous solution	pegcetacoplan	Subcutaneous C3 complement inhibitor for the treatment of adult patients with paroxysmal nocturnal hemoglobinuria (PNH). Soliris and Ultomiris are the other options for this disease - both are IV and both target C5. C3 is a more proximal target in the complement cascade. Thereby, pegcetacoplan offers broader control (intravascular and extravascular hemolysis) and was demonstrated superior to Soliris in trials.	New Entity

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†
Opdivo	Nivolumab injection, 40 mg/4 mL, 100 mg/10 mL, 240 mg/24 mL solution in single-dose vials	Bristol Myers Squibb	**Gastric Cancer, Gastroesophageal Junction Cancer, and Esophageal Adenocarcinoma** • **For the treatment of patients with advanced or metastatic gastric cancer, gastroesophageal junction cancer, and esophageal adenocarcinoma in combination with fluoropyrimidine- and platinum-containing chemotherapy.** *Note: Opdivo has many other indications not presented here because there were no changes.*
Diovan	valsartan tablets, 40 mg, 80 mg, 160 mg, 320 mg	Novartis	An angiotensin II receptor blocker (ARB) indicated for: • Hypertension, to lower blood pressure in adults **and children 1 year and older**. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions • Heart failure (NYHA class II-IV), to reduce hospitalization for heart failure in adults • Post-myocardial infarction, for the reduction of cardiovascular mortality in clinically stable patients with left ventricular failure or left ventricular dysfunction following myocardial infarction in adults
Ragwitek	short ragweed pollen allergen extract tablets, 12 amb a 1-unit	Alk-Abello	An allergen extract indicated as immunotherapy for the treatment of short ragweed pollen-induced allergic rhinitis, with or without conjunctivitis, confirmed by positive skin test or in vitro testing for pollen-specific IgE

Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication†
			antibodies for short ragweed pollen. Ragwitek is approved for use in persons **5** ~~18~~ through 65 years of age.
Natroba	spinosad suspension, 9 mg spinosad/g	Parapro	• A pediculicide indicated for the topical treatment of head lice infestations in adult and pediatric patients 6 months of age and older • **A scabicide indicated for the topical treatment of scabies infestations in adult and pediatric patients 4 years of age and older**
Ferriprox	deferiprone oral solution, 100 mg/mL	Chiesi	For the treatment of transfusional iron overload in adult **and pediatric patients 3 years of age and older**: • With thalassemia syndromes ~~when current chelation therapy is inadequate~~. • **With sickle cell disease or other anemias.**
Ferriprox	deferiprone oral tablets, 500 mg, 1 g	Chiesi	For the treatment of transfusional iron overload in adult **and pediatric patients 8 years of age and older**: • With thalassemia syndromes ~~when current chelation therapy is inadequate~~. • **With sickle cell disease or other anemias.**
Farxiga	dapagliflozin tablets, 5 mg, 10 mg	AstraZeneca	• As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. • To reduce the risk of hospitalization for heart failure in adults with type 2 diabetes mellitus and either established cardiovascular disease or multiple cardiovascular risk factors. • To reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure (NYHA class II-IV) with reduced ejection fraction. • **To reduce the risk of sustained eGFR decline, end-stage kidney disease, cardiovascular death, and hospitalization for heart failure in adults with chronic kidney disease at risk of progression.**

Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication†
Keytruda	pembrolizumab injection, 100 mg/4 mL solution in a single-dose vial	Merck Sharp Dohme	Gastric Cancer: **in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy, for the first-line treatment of patients with locally advanced unresectable or metastatic HER2-positive gastric or gastroesophageal junction (GEJ) adenocarcinoma.** *Note: Keytruda has many other indications not presented here because there were no changes.*
Daptomycin	daptomycin for injection, 350 mg lyophilized powder in a single-dose vial	Xellia	Complicated skin and skin structure infections (cSSSI) in adult **and pediatric patients (1 to 17 years of age)** Staphylococcus aureus bloodstream infections (bacteremia), in adult patients including those with right-sided infective endocarditis **Staphylococcus aureus bloodstream infections (bacteremia) in pediatric patients (1 to 17 years of age).** *Note: This product is listed in Orange Book as the Reference Listed Drug with no therapeutic equivalents.*
Yescarta	axicabtagene ciloleucel 2 × 10^8 CAR-positive viable T cells in approximately 68 mL	Kite Pharma	a CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of: • Adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma. Limitations of Use: YESCARTA is not indicated for the 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. Continued approval for this**

Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication†
			indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

RECALLS

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
BD ChloraPrep Clear, 2% w/v chlorhexidine gluconate (CHG) and 70% v/v isopropyl alcohol (IPA) Sterile Solution, 0.10 fl. oz. (3 ml) each, 25 Applicators in carton, applicator is sterile if package is intact. CareFusion 213, LLC, El Paso, TX 79912, subsidiary of Becton, Dickinson and Co, NDC 54365-400-32 REF 930400	Class I	Drugs	Lot and Exp Date: 0065386, 2/28/2023; 0085419, 3/31/2023; 0091666, 3/31/2023; 0149328, 4/30/2023; 0151977, 5/31/2023; 0161217, 5/31/2023; 0175874, 6/30/2023; 0176660, 6/30/2023; 0188805, 6/30/2023; 0211068, 7/31/2023;	Non-sterility. Product is being recalled because at labeled storage conditions of 30*C/75% Relative Humidity, growth of Aspergillus penicillioides, a type of fungus, resulted in a breach of the package integrity.	CareFusion 213, LLC
BD ChloraPrep Hi-Lite Orange 2% w/v chlorhexidine gluconate (CHG) and 70% v/v isopropyl alcohol (IPA), Sterile	Class I	Drugs	Lot and Exp Date: 0107872, 4/30/2023; 0108556, 4/30/2023; 0148278, 4/30/2023; 0151978, 5/31/2023; 0155534, 5/31/2023; 0157085, 5/31/2023; 0160618, 5/31/2023; 0167907, 5/31/2023;	Non-sterility. Product is being recalled because at labeled storage conditions of	CareFusion 213, LLC

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
Solution, 0.10 fl. oz. (3 ml) each, 25 Applicators in carton, applicator is sterile if package is intact. CareFusion El Paso, TX 79912, subsidiary of Becton, Dickinson and Co., NDC 54365-400-33 REF 930415				30*C/75% Relative Humidity, growth of Aspergillus penicillioides, a type of fungus, resulted in a breach of the package integrity.	
ChloraPrep One-Step 2% w/v chlorhexidine gluconate (CHG) and 70% v/v isopropyl alcohol (IPA) Non-Sterile Solution - Clear, 0.10 fl. oz. (3ml) each, 25 applicators per carton, applicator is sterile if package is intact. CareFusion El	Class I	Drugs	Lot and Exp Date: 0008777, 12/31/2022; 0016325, 12/31/2022; 0021072, 1/31/2023; 0027041, 1/31/2023; 0030959, 1/31/2023; 0031090, 1/31/2023; 0044735, 1/31/2023; 0048062, 2/28/2023; 0052110, 2/28/2023; 0056365, 2/28/2023; 0086148, 2/28/2023; 0104864, 3/31/2023; 0192894, 6/30/2023; 8081571, 3/31/2021; 8086851, 3/31/2021; 8087784, 3/31/2021; 8095620, 3/31/2021; 8106737, 4/30/2021; 8107819, 4/30/2021; 8124917, 4/30/2021; 8130509, 4/30/2021; 8131816, 4/30/2021; 8135646, 5/31/2021; 8141808, 5/31/2021; 8149992, 5/31/2021; 8155991, 5/31/2021; 8162912, 5/31/2021; 8163900, 5/31/2021; 8165721, 6/30/2021; 8176743, 6/30/2021; 8187644, 6/30/2021; 8194993,	Microbial Contamination of Non-Sterile Product. Product is being recalled because at labeled storage conditions of 30*C/75% Relative Humidity, growth of	CareFusion 213, LLC

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
Paso, TX 79912, NDC 054365-400-01 Cat. No. 260400			6/30/2021; 8199884, 7/31/2021; 8201565, 7/31/2021; 8205560, 7/31/2021; 8206895, 7/31/2021; 8207995, 7/31/2021; 8221939, 7/31/2021; 8228634, 8/31/2021; 8235981, 8/31/2021; 8247508, 8/31/2021; 8264554, 9/30/2021; 8289654, 9/30/2021; 8299615, 10/31/2021; 8304783, 10/31/2021; 8311788, 10/31/2021; 8316776, 10/31/2021; 8332585, 11/30/2021; 8333924, 11/30/2021; 8337646, 11/30/2021; 8337647, 11/30/2021; 8338794, 11/30/2021; 8340914, 11/30/2021; 8352585, 12/31/2021; 8354835, 12/31/2021; 9007921, 12/31/2021; 9015917, 12/31/2021; 9015920, 12/31/2021; 9030934, 1/31/2022; 9043625, 1/31/2022; 9045819, 1/31/2022; 9046572, 2/28/2022; 9052554, 2/28/2022; 9059817, 2/28/2022; 9060734, 2/28/2022; 9071761, 2/28/2022; 9080812, 3/31/2022; 9087980, 3/31/2022; 9087982, 3/31/2022; 9088850, 3/31/2022; 9092575, 3/31/2022; 9100768, 3/31/2022; 9101529, 3/31/2022; 9105675, 3/31/2022; 9113528, 4/30/2022; 9123753, 4/30/2022; 9130718, 4/30/2022; 9133928, 4/30/2022; 9135816, 5/31/2022; 9149671, 5/31/2022; 9150905, 5/31/2022; 9154935, 5/31/2022; 9156866, 5/31/2022; 9165856, 5/31/2022; 9189224, 6/30/2022; 9194257, 6/30/2022; 9196196, 6/30/2022; 9198900, 6/30/2022; 9199815, 6/30/2022; 9200420, 6/30/2022; 9205441, 7/31/2022; 9206555, 7/31/2022; 9233323, 8/31/2022; 9233645, 8/31/2022;	Aspergillus penicillioides, a type of fungus, resulted in a breach of the package integrity.	

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
			9236531, 8/31/2022; 9238871, 8/31/2022; 9241929, 8/31/2022; 9242192, 8/31/2022; 9246940, 8/31/2022; 9246944, 8/31/2022; 9249460, 8/31/2022; 9251683, 8/31/2022; 9253785, 8/31/2022; 9254193, 8/31/2022; 9255899, 8/31/2022; 9257889, 8/31/2022; 9261886, 9/30/2022; 9266348, 9/30/2022; 9270894, 9/30/2022; 9278673, 9/30/2022; 9280666, 9/30/2022; 9284872, 9/30/2022; 9289666, 9/30/2022; 9291336, 10/31/2022; 9293445, 10/31/2022; 9295140, 10/31/2022; 9297772, 10/31/2022; 9304891, 10/31/2022; 9305777, 10/31/2022; 9311057, 10/31/2022; 9316346, 11/30/2022; 9325127, 11/30/2022; 9326162, 11/30/2022; 9331792, 11/30/2022; 9344775, 11/30/2022; 9345956, 11/30/2022; 9345958, 11/30/2022; 9350617, 12/31/2022; 9352330, 12/31/2022;		
ChloraPrep With Tint 2% w/v chlorhexidine gluconate (CHG) and 70% v/v isopropyl alcohol (IPA) Non-Sterile Solution - Hi-Lite Orange, 0.10 fl. oz. (3 ml) each, 25 applicators in carton, applicator is	Class I	Drugs	Lot and Exp Date: 0011737, 1/31/2023; 0020739, 1/31/2023; 0023790, 1/31/2023; 0037278, 1/31/2023; 0037279, 1/31/2023; 0038209, 1/31/2023; 0044734, 12/31/2022; 0007625, 10/31/2022; 0007630, 12/31/2022; 8095632, 3/31/2021; 8116723, 4/30/2021; 8127657, 4/30/2021; 8135651, 5/31/2021; 8137527, 5/31/2021; 8151741, 5/31/2021; 8158638, 5/31/2021; 8164530, 6/30/2021; 8178658, 6/30/2021; 8193779, 6/30/2021; 8197517, 6/30/2021; 8198765, 7/31/2021; 8212881, 7/31/2021; 8220737, 7/31/2021; 8226561, 7/31/2021; 8235991, 8/31/2021; 8249940, 8/31/2021; 8295569,	Microbial Contamination of Non-Sterile Product:. Product is being recalled because at labeled storage conditions of 30*C/75% Relative	CareFusion 213, LLC

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
sterile if package is intact. CareFusion El Paso, TX 79912, NDC 054365-400-11 Cat. No. 260415			10/31/2021; 8304501, 10/31/2021; 8304849, 10/31/2021; 8306694, 10/31/2021; 8311791, 10/31/2021; 8334983, 11/30/2021; 8347719, 11/30/2021; 9008965, 12/31/2021; 9011841, 12/31/2021; 9031893, 1/31/2022; 9037824, 1/31/2022; 9038599, 1/31/2022; 9042938, 1/31/2022; 9044573, 1/31/2022; 9045831, 2/28/2022; 9051563, 2/28/2022; 9052565, 2/28/2022; 9053560, 2/28/2022; 9058847, 2/28/2022; 9059821, 2/28/2022; 9067665, 2/28/2022; 9072856, 2/28/2022; 9086532, 3/31/2022; 9087985, 3/31/2022; 9122538, 4/30/2022; 9126562, 4/30/2022; 9126564, 4/30/2022; 9137903, 5/31/2022; 9137904, 5/31/2022; 9154908, 5/31/2022; 9168975, 6/30/2022; 9171618, 6/30/2022; 9191256, 6/30/2022; 9218464, 7/31/2022; 9218595, 7/31/2022; 9221444, 7/31/2022; 9228305, 8/31/2022; 9241932, 8/31/2022; 9247742, 8/31/2022; 9249471, 8/31/2022; 9257903, 8/31/2022; 9263093, 9/30/2022; 9267133, 9/30/2022; 9269603, 9/30/2022; 9282881, 9/30/2022; 9284875, 9/30/2022; 9284881, 9/30/2022; 9289669, 9/30/2022; 9290455, 10/31/2022; 9291279, 10/31/2022; 9295914, 10/31/2022; 9296395, 10/31/2022; 9305775, 11/30/2022; 9311076, 2/28/2023; 9316348, 10/31/2022; 9317310, 11/30/2022; 9317312, 11/30/2022; 9324565, 11/30/2022; 9337530, 11/30/2022; 9341852, 11/30/2022; 9345911, 11/30/2022; 0098528, 12/31/2022;	Humidity, growth of Aspergillus penicillioides, a type of fungus, resulted in a breach of the package integrity.	

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
Acetaminophen, Extra Strength, Aspirin Free, 500 MG Tablets, 100-count bottles, Mfr: Major Pharmaceuticals, Livonia, MI 48152; Packaged Exclusively By: A-S Medication Solutions LLC, Libertyville, IL 60048, Product # 6967-0; NDC: 50090-5350-0; contained within Health Essentials Kit, Kit Contains: 1 bottle hand sanitzer, 1 reusable face mask, 1 bottle Acetaminophen 500 mg, 1 bag cough drops, 1 digital	Class I	Drugs	Lots 323206, 323207, 323208, 335353, 335354, 335355, 335356, 335358, 335359,335360, 335361, 335362, 335395, 352116, Expiry 7/31/2022; 323209, 323210, 323211, 323212, 323213, 323214, 323215, 323216, 323218, 323219, 323220, 323222, 323223, 323224, 323238, 335363, 335364, 335365, 335366, 335367, 335368, 335369, 335370, 335371, 335372, 335373, 335374, 335375, 335376, 335377, Expiry 8/31/2022	Labeling: Label Mix-up; The bottle of over-the-counter Acetaminophen 500mg Extra Strength, 100 count, included in Health Essential Kits, labeled incorrectly with a prescription drug label instead of an OTC drug label.	A-S Medication Solutions LLC.

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
thermometer, 50 disposable gloves.					
heal the world, moisturizing original hand sanitizer, Non-Sterile Solution, Alcohol Antiseptic, 70% Topical Solution, 9.6 FL OZ. (285 mL) bottle, Heal The World, LLC, Draper, UT 84020, UPC 6 19988 44038 0.	Class I	Drugs	Lots: SAA21, SAA24, SAA27, SAA22, SAA23, SAA29, SAA26, SAA28, SAA25, SAA32, SAA55, SAA56, SAA44, SAA60, expiration 5/2022	Labeling Not Elsewhere Classified: Hand sanitizer packaged in containers resembling drinking water bottles.	PNHC, LLC.
BD ChloraPrep Hi-Lite Orange 26 mL Applicator (2% w/v chlorhexidine gluconate (CHG) and 70% v/v Isopropyl alcohol (IPA)) Sterile Solution, CareFusion 213, LLC, El Paso, TX 79912, subsidiary of Becton, Dickinson	Class I	Drugs	Lot #: 0108186, Exp. 4/30/2023; 0327867, 0327868, 0328213, 0338656, 0339071, 0328947, 0328949, 0329475, 0329477, 0330457, 0330955, 0330606 0333826, 0333852, 0333855, 0334119, 0335787, 0335792, 0335029, 0336506 0336972, 0336051, 0337245, 0337025, 0338653, 0338542, 0338852, 0339892 0339457, Exp. 11/30/2023	Defective Delivery System: An increase in complaints identified endcap being loose or falling off upon activation releasing glass shards	CareFusion 213, LLC

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
and Co, NDC 54365-400-38				containing the solution.	
Flurandrenolide Ointment USP, 0.05%, Net Wt. 60 grams, Rx Only, Teligent Pharma, Inc. Buena, New Jersey 08310 NDC 52565-017-60	Class II	Drugs	Lot #13974 EXP 7/2021	Failed Impurities/Degradation Specifications:	Teligent Pharma, Inc.
Betadine (Povidone-Iodine) 5%, 0.5mL per syringe Single Use Syringe Rx only, For Topical Ophthalmic Use (DO NOT INJECT) STERILE OPHTHALMIC SOLUTION, PRESERVATIVE FREE, Edge Pharma, LLC 856 Hercules Dr. Colchester, VT 05446 Customer	Class II	Drugs	Lot 02-2021-16@4 BUD 5/31/2021	Defective container; syringe content migrating past the seal of the plunger may cause a lack of assurance of sterility	Edge Pharma, LLC

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
Service (USA) 1-802-992-1178					
Minivelle (estradiol transdermal system) Delivers 0.075 mg/day, 8 patches/box, Rx only, Mfd. by: Noven Pharmaceuticals, Inc. Miami, Florida 33186 Dist. by: Noven Therapeutics, LLC Miami, Florida 33186, NDC 68968-6675-8	Class II	Drugs	Lot #: 88584 Exp. 03/2022	Defective Delivery System: Out of specification for release rate testing and shear, an attribute related to the adhesive properties of the transdermal patches. As a result, patients could experience patches that do not stick well to the skin.	Noven Pharmaceuticals Inc
Estradiol Transdermal System Delivers 0.0375 mg/day, 8 Systems/box, Rx	Class II	Drugs	Lot #: 88321 Exp. 02/2022	Defective Delivery System: Out of specification for release rate	Noven Pharmaceuticals Inc

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
only, Mfd. by: Noven Pharmaceuticals, Inc. Miami, Florida 33186 Dist. by: Noven Therapeutics, LLC Miami, Florida 33186, NDC 68968-3437-8				testing and shear, an attribute related to the adhesive properties of the transdermal patches. As a result, patients could experience patches that do not stick well to the skin.	
BD ChloraPrep Clear, 2% w/v chlorhexidine gluconate (CHG) and 70% v/v isopropyl alcohol (IPA) Sterile Solution, 0.10 fl. oz. (3 ml) each, 25 Applicators in carton, applicator is sterile if package is intact. CareFusion	Class II	Drugs	Lot and Exp Date: 0010759, 11/30/2022; 0025045, 11/30/2022; 0035136, 12/31/2022; 0054691, 2/28/2023; 0057018, 2/28/2023; 0058944, 2/28/2023; 0062656, 2/28/2023; 0063728, 2/28/2023; 0063740, 2/28/2023; 0064594, 2/28/2023; 0065288, 2/28/2023; 0066368, 2/28/2023; 0067288, 3/31/2023; 0069106, 3/31/2023; 0070865, 3/31/2023; 0071359, 3/31/2023; 0072872, 3/31/2023; 0073232, 3/31/2023; 0076029, 3/31/2023; 0077515, 3/31/2023; 0077519, 3/31/2023; 0078347, 3/31/2023; 0079853, 3/31/2023; 0080632, 3/31/2023; 0081061, 3/31/2023; 0081062, 3/31/2023; 0084750, 3/31/2023; 0084754, 3/31/2023; 0084758, 3/31/2023;	Lack of Assurance of Sterility: Product is being recalled because at labeled storage conditions of 30*C/75% Relative Humidity, there is the potential	CareFusion 213, LLC

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
213, LLC, El Paso, TX 79912, subsidiary of Becton, Dickinson and Co, NDC 54365-400-32 REF 930400			0085418, 3/31/2023; 0088774, 3/31/2023; 0090545, 3/31/2023; 0090949, 3/31/2023; 0091664, 3/31/2023; 0092927, 3/31/2023; 0093445, 3/31/2023; 0094039, 3/31/2023; 0005878, 3/31/2023; 0097559, 3/31/2023; 0098525, 3/31/2023; 0099419, 2/28/2023; 0099421, 3/31/2023; 0100379, 3/31/2023; 0105130, 3/31/2023; 0105985, 3/31/2023; 0106926, 4/30/2023; 0106937, 4/30/2023; 0111775, 4/30/2023; 0112982, 4/30/2023; 0113301, 4/30/2023; 0113433, 4/30/2023; 0114091, 4/30/2023; 0114101, 4/30/2023; 0115679, 4/30/2023; 0118820, 4/30/2023; 0119488, 4/30/2023; 0120668, 4/30/2023; 0121257, 4/30/2023; 0121281, 4/30/2023; 0122195, 4/30/2023; 0125774, 4/30/2023; 0126308, 4/30/2023; 0127006, 4/30/2023; 0127856, 4/30/2023; 0128820, 4/30/2023; 0129413, 4/30/2023; 0132806, 4/30/2023; 0132808, 4/30/2023; 0133318, 4/30/2023; 0135284, 4/30/2023; 0136179, 4/30/2023; 0136919, 4/30/2023; 0139776, 4/30/2023; 0139779, 4/30/2023; 0140050, 4/30/2023; 0141253, 4/30/2023; 0142167, 4/30/2023; 0143703, 4/30/2023; 0148151, 4/30/2023; 0149875, 5/31/2023; 0153587, 5/31/2023; 0154180, 5/31/2023; 0154183, 5/31/2023; 0155301, 5/31/2023; 0155611, 5/31/2023; 0156437, 5/31/2023; 0156782, 5/31/2023; 0157078, 5/31/2023; 0160601, 5/31/2023; 0161218, 5/31/2023; 0162594, 5/31/2023; 0162595,	for growth of Aspergillus penicillioides, a type of fungus, resulting in a breach of the package integrity.	

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
			5/31/2023; 0163255, 5/31/2023; 0164591, 6/30/2023; 0167383, 6/30/2023; 0168035, 6/30/2023; 0168225, 6/30/2023; 0169563, 6/30/2023; 0169624, 6/30/2023; 0170815, 6/30/2023; 0171463, 6/30/2023; 0171467, 6/30/2023; 0174318, 6/30/2023; 0174321, 6/30/2023; 0174763, 6/30/2023; 0176737, 6/30/2023; 0177382, 6/30/2023; 0178582, 6/30/2023; 0178584, 6/30/2023; 0188425, 6/30/2023; 0189107, 6/30/2023; 0190185, 6/30/2023; 0192851, 6/30/2023; 0197378, 6/30/2023; 0197837, 6/30/2023; 0198823, 7/31/2023; 0199710, 7/31/2023; 0199720, 6/30/2023; 0199721, 6/30/2023; 0202925, 7/31/2023; 0203832, 6/30/2023; 0204881, 6/30/2023; 0205329, 6/30/2023; 0205331, 6/30/2023; 0206178, 7/31/2023; 0206188, 7/31/2023; 0208782, 7/31/2023; 0209285, 7/31/2023; 0210048, 7/31/2023; 0210638, 7/31/2023; 0211069, 7/31/2023; 0212509, 7/31/2023; 0212627, 7/31/2023; 0213661, 7/31/2023; 0216135, 7/31/2023; 0216992, 7/31/2023; 0216995, 7/31/2023; 0225098, 7/31/2023; 0225257, 7/31/2023; 0226610, 7/31/2023; 0227802, 7/31/2023; 0227838, 7/31/2023; 0228011, 7/31/2023; 0229538, 7/31/2023; 0230050, 7/31/2023; 0230194, 7/31/2023; 0231645, 7/31/2023; 0231646, 7/31/2023; 0232170, 7/31/2023; 0232171, 7/31/2023; 0233607, 7/31/2023; 0233609, 7/31/2023; 0234326, 7/31/2023; 0236941, 8/31/2023;		

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
			0237345, 8/31/2023; 0238657, 8/31/2023; 0238658, 8/31/2023; 0239736, 8/31/2023; 0240258, 8/31/2023; 0240259, 8/31/2023; 0241313, 8/31/2023; 0241656, 8/31/2023; 0242880, 8/31/2023; 0244660, 8/31/2023; 0244662, 8/31/2023; 0245775, 7/31/2023; 0246170, 8/31/2023; 0246478, 8/31/2023; 0247206, 8/31/2023; 0248555, 8/31/2023; 0248737, 7/31/2023; 0252884, 8/31/2023; 0253778, 8/31/2023; 0253810, 8/31/2023; 0254567, 8/31/2023; 0254731, 8/31/2023; 0255645, 8/31/2023; 0258252, 8/31/2023; 0258659, 8/31/2023; 0259065, 9/30/2023; 0259898, 9/30/2023; 0260681, 9/30/2023; 0261975, 9/30/2023; 0262729, 9/30/2023; 0265184, 9/30/2023; 0279818, 9/30/2023; 0308327, 10/31/2023; 0309811, 10/31/2023; 0309816, 10/31/2023; 0311453, 10/31/2023; 0312698, 10/31/2023; 0314634, 10/31/2023; 0315662, 10/31/2023; 0316151, 11/30/2023; 0316372, 10/31/2023; 0317672, 11/30/2023; 0318148, 11/30/2023; 0321438, 11/30/2023; 0322315, 11/30/2023; 0323068, 11/30/2023; 0323448, 11/30/2023; 0323503, 11/30/2023; 0324263, 11/30/2023; 0324264, 11/30/2023; 0328929, 11/30/2023; 0329153, 11/30/2023; 0329996, 11/30/2023; 0330665, 11/30/2023; 0335120, 11/30/2023; 0335799, 11/30/2023; 0337020, 11/30/2023; 0338067, 11/30/2023; 0338974, 11/30/2023; 0340677, 11/30/2023; 0343589, 11/30/2023; 0343898, 11/30/2023; 0343903,		

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
			11/30/2023; 0344397, 12/31/2023; 0345866, 11/30/2023; 0345870, 11/30/2023; 0346321, 12/31/2023; 0349906, 12/31/2023; 0349907, 12/31/2023; 0350058, 12/31/2023; 0350772, 12/31/2023; 0351193, 12/31/2023; 0351226, 12/31/2023; 0351821, 12/31/2023; 0352445, 11/30/2023; 0352694, 11/30/2023; 0353338, 12/31/2023; 0354300, 12/31/2023; 1008731, 12/31/2023; 1009535, 12/31/2023; 1009538, 12/31/2023; 1012621, 12/31/2023; 1013421, 12/31/2023; 1013423, 12/31/2023; 1014132, 12/31/2023; 1014134, 12/31/2023; 1018037, 12/31/2023; 1018799, 12/31/2023; 1019769, 1/31/2024; 1020849, 1/31/2024; 1021641, 1/31/2024; 1021805, 1/31/2024; 1022415, 1/31/2024; 1022719, 1/31/2024; 1025105, 1/31/2024; 1025854, 1/31/2024; 1025950, 1/31/2024; 1026350, 1/31/2024; 1027907, 1/31/2024; 1028547, 1/31/2024; 1028799, 1/31/2024; 1029694, 1/31/2024; 1030487, 1/31/2024; 1032505, 1/31/2024; 1032717, 1/31/2024; 1033620, 1/31/2024; 1033708, 1/31/2024; 1034917, 1/31/2024; 1035640, 1/31/2024; 1036582, 1/31/2024; 1038982, 1/31/2024; 1039915, 1/31/2024; 1040816, 1/31/2024; 1041348, 1/31/2024; 1041631, 1/31/2024; 1043285, 2/29/2024; 1043350, 1/31/2024; 1048645, 2/29/2024; 1048656, 2/29/2024; 1049461, 2/29/2024; 1049465, 2/29/2024; 1050250, 2/29/2024; 1051583, 2/29/2024; 1051918, 2/29/2024; 1054135, 2/29/2024;		

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
			1054728, 2/29/2024; 1055950, 2/29/2024; 1055969, 2/29/2024; 1056752, 2/29/2024; 1057007, 2/29/2024; 1057987, 2/29/2024; 1057988, 2/29/2024; 1059824, 2/29/2024; 1060836, 2/29/2024; 1061724, 2/29/2024; 9305899, 10/31/2022; 9309166, 10/31/2022; 9339182, 11/30/2022;		
BD ChloraPrep Hi-Lite Orange 2% w/v chlorhexidine gluconate (CHG) and 70% v/v isopropyl alcohol (IPA), Sterile Solution, 0.10 fl. oz. (3 ml) each, 25 Applicators in carton, applicator is sterile if package is intact. CareFusion El Paso, TX 79912, subsidiary of Becton, Dickinson and Co., NDC 54365-400-33 REF 930415	Class II	Drugs	Lot and Exp Date: 0018578, 11/30/2022; 0058277, 2/28/2023; 0059141, 2/28/2023; 0066365, 2/28/2023; 0067289, 3/31/2023; 0070866, 3/31/2023; 0074038, 3/31/2023; 0076034, 3/31/2023; 0084619, 3/31/2023; 0086158, 3/31/2023; 0090894, 3/31/2023; 0093903, 3/31/2023; 0095838, 3/31/2023; 0097561, 3/31/2023; 0098470, 3/31/2023; 0100383, 2/28/2023; 0109632, 4/30/2023; 0111185, 4/30/2023; 0113339, 4/30/2023; 0115853, 4/30/2023; 0121982, 4/30/2023; 0122192, 4/30/2023; 0122193, 4/30/2023; 0122194, 4/30/2023; 0128821, 4/30/2023; 0129409, 4/30/2023; 0135287, 4/30/2023; 0157083, 5/31/2023; 0161219, 5/31/2023; 0164032, 6/30/2023; 0164595, 5/31/2023; 0168228, 6/30/2023; 0177338, 6/30/2023; 0177384, 6/30/2023; 0178587, 6/30/2023; 0198836, 7/31/2023; 0199909, 6/30/2023; 0204887, 7/31/2023; 0205674, 6/30/2023; 0206366, 7/31/2023; 0207651, 7/31/2023; 0210578, 7/31/2023; 0227493, 7/31/2023; 0241043, 8/31/2023; 0249695, 8/31/2023; 0252883, 8/31/2023; 0254864,	Lack of Assurance of Sterility: Product is being recalled because at labeled storage conditions of 30*C/75% Relative Humidity, there is the potential for growth of Aspergillus penicillioides, a type of fungus, resulting in a breach of the	CareFusion 213, LLC

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
			8/31/2023; 0255091, 8/31/2023; 0259156, 9/30/2023; 0263754, 9/30/2023; 0267575, 9/30/2023; 0272405, 9/30/2023; 0300187, 10/31/2023; 0304315, 10/31/2023; 0305488, 10/31/2023; 0306841, 10/31/2023; 0307140, 9/30/2023; 0312694, 10/31/2023; 0313824, 10/31/2023; 0319649, 11/30/2023; 0324409, 11/30/2023; 0325577, 11/30/2023; 0326746, 11/30/2023; 0330938, 11/30/2023; 0335971, 11/30/2023; 0340937, 11/30/2023; 0347570, 12/31/2023; 0347571, 12/31/2023; 0355671, 12/31/2023; 0356362, 12/31/2023; 1008758, 12/31/2023; 1009747, 12/31/2023; 1028187, 1/31/2024; 1033578, 1/31/2024; 1034948, 1/31/2024; 1035662, 1/31/2024; 1036544, 1/31/2024; 1055547, 2/29/2024; 1060432, 2/29/2024; 9324226, 10/31/2022; 9343836, 11/30/2022; 9344810, 10/31/2022;	package integrity.	
ChloraPrep One-Step 2% w/v chlorhexidine gluconate (CHG) and 70% v/v isopropyl alcohol (IPA) Non-Sterile Solution - Clear, 0.10 fl. oz. (3ml) each, 25 applicators per	Class II	Drugs	Lot and Exp Date: 0000192, 12/31/2022; 0007621, 12/31/2022; 0008775, 12/31/2022; 0009111, 12/31/2022; 0011738, 12/31/2022; 0011753, 12/31/2022; 0011754, 12/31/2022; 0011755, 12/31/2022; 0013604, 12/31/2022; 0015498, 12/31/2022; 0015500, 12/31/2022; 0016329, 1/31/2023; 0017929, 12/31/2022; 0021945, 1/31/2023; 0028887, 1/31/2023; 0031093, 1/31/2023; 0034660, 1/31/2023; 0035149, 1/31/2023; 0036460, 1/31/2023; 0037272, 1/31/2023; 0038213, 1/31/2023; 0038217, 1/31/2023; 0041893, 1/31/2023; 0042483, 1/31/2023;	CGMP Deviations: Product is being recalled because at labeled storage conditions of 30*C/75% Relative Humidity, there	CareFusion 213, LLC

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
carton, applicator is sterile if package is intact. CareFusion El Paso, TX 79912, NDC 054365-400-01 Cat. No. 260400			0042501, 1/31/2023; 0043105, 1/31/2023; 0044739, 1/31/2023; 0094838, 2/28/2023; 0098051, 2/28/2023; 0104859, 3/31/2023; 0129330, 4/30/2023; 0133069, 4/30/2023; 0220728, 7/31/2023; 0223036, 7/31/2023; 8078998, 3/31/2021; 8079620, 3/31/2021; 8079621, 3/31/2021; 8082921, 3/31/2021; 8082923, 3/31/2021; 8085804, 3/31/2021; 8088708, 3/31/2021; 8089621, 3/31/2021; 8093619, 3/31/2021; 8093813, 3/31/2021; 8094833, 3/31/2021; 8096706, 3/31/2021; 8097822, 3/31/2021; 8099727, 3/31/2021; 8099783, 3/31/2021; 8100947, 3/31/2021; 8101636, 3/31/2021; 8101719, 3/31/2021; 8102691, 3/31/2021; 8103673, 4/30/2021; 8108795, 4/30/2021; 8109707, 4/30/2021; 8110645, 4/30/2021; 8110674, 4/30/2021; 8114540, 4/30/2021; 8114547, 4/30/2021; 8115574, 4/30/2021; 8116705, 4/30/2021; 8120701, 4/30/2021; 8120985, 4/30/2021; 8122873, 4/30/2021; 8122874, 4/30/2021; 8124914, 4/30/2021; 8127649, 4/30/2021; 8127650, 4/30/2021; 8129680, 4/30/2021; 8129686, 4/30/2021; 8134847, 4/30/2021; 8134850, 4/30/2021; 8136811, 5/31/2021; 8137525, 5/31/2021; 8138867, 5/31/2021; 8141821, 5/31/2021; 8143659, 5/31/2021; 8144768, 5/31/2021; 8144882, 5/31/2021; 8145889, 5/31/2021; 8150625, 5/31/2021; 8151713, 5/31/2021; 8151736, 5/31/2021; 8152581, 5/31/2021; 8156507, 5/31/2021; 8156735,	is the potential for growth of Aspergillus penicillioides, a type of fungus, resulting in a breach of the package integrity.	

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
			5/31/2021; 8157866, 5/31/2021; 8157993, 5/31/2021; 8158595, 5/31/2021; 8158633, 5/31/2021; 8159995, 5/31/2021; 8164525, 6/30/2021; 8165696, 6/30/2021; 8167970, 6/30/2021; 8170535, 6/30/2021; 8170538, 6/30/2021; 8171503, 6/30/2021; 8172910, 6/30/2021; 8173655, 6/30/2021; 8176731, 6/30/2021; 8177746, 6/30/2021; 8178576, 6/30/2021; 8178654, 6/30/2021; 8179928, 6/30/2021; 8179974, 6/30/2021; 8180627, 6/30/2021; 8186700, 6/30/2021; 8190916, 6/30/2021; 8190987, 6/30/2021; 8192557, 6/30/2021; 8192881, 6/30/2021; 8197514, 6/30/2021; 8197515, 6/30/2021; 8198763, 7/31/2021; 8199675, 7/31/2021; 8204574, 7/31/2021; 8206898, 7/31/2021; 8211903, 7/31/2021; 8212879, 7/31/2021; 8214989, 7/31/2021; 8214995, 7/31/2021; 8215994, 7/31/2021; 8218645, 7/31/2021; 8219946, 7/31/2021; 8219988, 7/31/2021; 8222798, 7/31/2021; 8225863, 7/31/2021; 8225868, 7/31/2021; 8228632, 8/31/2021; 8229682, 8/31/2021; 8232739, 8/31/2021; 8233569, 8/31/2021; 8235983, 8/31/2021; 8239901, 8/31/2021; 8239902, 8/31/2021; 8240966, 8/31/2021; 8241848, 8/31/2021; 8243756, 8/31/2021; 8247510, 8/31/2021; 8248570, 8/31/2021; 8249934, 8/31/2021; 8257619, 8/31/2021; 8260778, 9/30/2021; 8261945, 9/30/2021; 8261946, 9/30/2021; 8262674, 9/30/2021; 8263865, 9/30/2021; 8265679, 9/30/2021;		

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
			8267928, 9/30/2021; 8267929, 9/30/2021; 8268617, 9/30/2021; 8268618, 9/30/2021; 8269913, 9/30/2021; 8271911, 9/30/2021; 8274999, 9/30/2021; 8275615, 9/30/2021; 8275625, 9/30/2021; 8276694, 9/30/2021; 8277635, 9/30/2021; 8277637, 9/30/2021; 8282884, 9/30/2021; 8283738, 9/30/2021; 8284622, 9/30/2021; 8285592, 9/30/2021; 8288852, 9/30/2021; 8290569, 9/30/2021; 8291769, 10/31/2021; 8292703, 10/31/2021; 8292708, 10/31/2021; 8296693, 10/31/2021; 8296695, 10/31/2021; 8299673, 10/31/2021; 8303606, 10/31/2021; 8304839, 10/31/2021; 8306692, 10/31/2021; 8309553, 10/31/2021; 8310641, 10/31/2021; 8311789, 10/31/2021; 8313646, 10/31/2021; 8313687, 10/31/2021; 8319821, 10/31/2021; 8320984, 11/30/2021; 8323514, 11/30/2021; 8323745, 11/30/2021; 8325725, 11/30/2021; 8325749, 11/30/2021; 8331695, 11/30/2021; 8341526, 11/30/2021; 8344689, 11/30/2021; 8345987, 11/30/2021; 8345988, 11/30/2021; 8346840, 11/30/2021; 8347713, 11/30/2021; 8348560, 11/30/2021; 8351524, 12/31/2021; 8351527, 12/31/2021; 8354841, 12/31/2021; 8355555, 12/31/2021; 8355665, 12/31/2021; 9007932, 12/31/2021; 9008954, 12/31/2021; 9008963, 12/31/2021; 9009962, 12/31/2021; 9010973, 12/31/2021; 9014968, 12/31/2021; 9017714, 12/31/2021; 9017716, 12/31/2021; 9021962, 1/31/2022; 9022804, 12/31/2021; 9022808, 12/31/2021; 9023539,		

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
			1/31/2022; 9023541, 1/31/2022; 9028693, 1/31/2022; 9030936, 1/31/2022; 9035603, 1/31/2022; 9036759, 1/31/2022; 9036761, 1/31/2022; 9037816, 1/31/2022; 9038527, 1/31/2022; 9039888, 1/31/2022; 9039889, 1/31/2022; 9042932, 1/31/2022; 9043626, 1/31/2022; 9044570, 1/31/2022; 9049788, 2/28/2022; 9049790, 2/28/2022; 9051558, 2/28/2022; 9053553, 2/28/2022; 9053605, 2/28/2022; 9056781, 2/28/2022; 9057597, 2/28/2022; 9057600, 2/28/2022; 9058797, 2/28/2022; 9064561, 2/28/2022; 9067661, 2/28/2022; 9070712, 2/28/2022; 9072853, 2/28/2022; 9073968, 2/28/2022; 9074967, 2/28/2022; 9077861, 2/28/2022; 9079525, 3/31/2022; 9079746, 3/31/2022; 9085737, 3/31/2022; 9093920, 3/31/2022; 9094797, 3/31/2022; 9098940, 3/31/2022; 9099817, 3/31/2022; 9100771, 3/31/2022; 9100776, 3/31/2022; 9106945, 3/31/2022; 9106950, 3/31/2022; 9107765, 4/30/2022; 9107767, 4/30/2022; 9112666, 4/30/2022; 9112668, 4/30/2022; 9113527, 4/30/2022; 9114610, 4/30/2022; 9114611, 4/30/2022; 9116696, 4/30/2022; 9116698, 4/30/2022; 9119832, 4/30/2022; 9120522, 4/30/2022; 9120523, 4/30/2022; 9121774, 4/30/2022; 9122536, 4/30/2022; 9123755, 4/30/2022; 9127963, 4/30/2022; 9127968, 4/30/2022; 9128862, 4/30/2022; 9129660, 4/30/2022; 9130717, 4/30/2022; 9136917, 5/31/2022; 9138989, 5/31/2022;		

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
			9140678, 5/31/2022; 9140679, 5/31/2022; 9141792, 5/31/2022; 9143507, 5/31/2022; 9143509, 5/31/2022; 9144771, 5/31/2022; 9144772, 5/31/2022; 9154934, 5/31/2022; 9155527, 5/31/2022; 9155529, 5/31/2022; 9157896, 5/31/2022; 9161567, 5/31/2022; 9162902, 5/31/2022; 9164894, 5/31/2022; 9168973, 6/30/2022; 9171622, 6/30/2022; 9172951, 6/30/2022; 9175686, 6/30/2022; 9179857, 6/30/2022; 9190047, 6/30/2022; 9191255, 6/30/2022; 9192026, 6/30/2022; 9192028, 6/30/2022; 9194258, 6/30/2022; 9196197, 6/30/2022; 9200423, 6/30/2022; 9201209, 7/31/2022; 9204095, 7/31/2022; 9204283, 7/31/2022; 9206983, 7/31/2022; 9207534, 7/31/2022; 9207913, 7/31/2022; 9208099, 7/31/2022; 9211089, 7/31/2022; 9211677, 7/31/2022; 9212097, 7/31/2022; 9213911, 7/31/2022; 9214450, 7/31/2022; 9217995, 7/31/2022; 9218456, 7/31/2022; 9218466, 7/31/2022; 9220319, 7/31/2022; 9220320, 7/31/2022; 9222097, 7/31/2022; 9222098, 7/31/2022; 9222208, 7/31/2022; 9224704, 7/31/2022; 9225074, 7/31/2022; 9225081, 7/31/2022; 9226653, 7/31/2022; 9227526, 7/31/2022; 9227930, 7/31/2022; 9228303, 8/31/2022; 9232762, 8/31/2022; 9234176, 8/31/2022; 9234899, 8/31/2022; 9235837, 8/31/2022; 9236528, 8/31/2022; 9236529, 8/31/2022; 9238869, 8/31/2022; 9239631, 8/31/2022; 9239660, 8/31/2022; 9240736,		

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
			8/31/2022; 9241927, 8/31/2022; 9242195, 8/31/2022; 9243015, 8/31/2022; 9247747, 8/31/2022; 9248036, 8/31/2022; 9250289, 8/31/2022; 9250290, 8/31/2022; 9250395, 8/31/2022; 9255902, 8/31/2022; 9256126, 8/31/2022; 9259343, 8/31/2022; 9260247, 8/31/2022; 9260249, 9/30/2022; 9261887, 9/30/2022; 9262353, 9/30/2022; 9263126, 9/30/2022; 9264104, 9/30/2022; 9264107, 9/30/2022; 9266082, 9/30/2022; 9266337, 9/30/2022; 9267130, 9/30/2022; 9267132, 9/30/2022; 9268809, 9/30/2022; 9269989, 9/30/2022; 9269991, 9/30/2022; 9270898, 9/30/2022; 9271954, 9/30/2022; 9275594, 9/30/2022; 9276137, 9/30/2022; 9276159, 9/30/2022; 9278674, 9/30/2022; 9281274, 9/30/2022; 9282883, 9/30/2022; 9283393, 9/30/2022; 9287360, 9/30/2022; 9288429, 9/30/2022; 9289665, 9/30/2022; 9290448, 9/30/2022; 9293444, 10/31/2022; 9295579, 9/30/2022; 9296389, 10/31/2022; 9296399, 10/31/2022; 9297775, 10/31/2022; 9298637, 10/31/2022; 9298640, 10/31/2022; 9301749, 10/31/2022; 9301762, 10/31/2022; 9302581, 10/31/2022; 9302586, 10/31/2022; 9303414, 10/31/2022; 9303758, 10/31/2022; 9305773, 10/31/2022; 9309480, 10/31/2022; 9309567, 10/31/2022; 9311065, 10/31/2022; 9313838, 10/31/2022; 9313839, 10/31/2022; 9316341, 10/31/2022; 9317266, 11/30/2022; 9318804, 11/30/2022; 9318806, 11/30/2022; 9319143, 11/30/2022;		

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
			9320067, 11/30/2022; 9323280, 11/30/2022; 9323406, 11/30/2022; 9324538, 11/30/2022; 9324707, 11/30/2022; 9325125, 11/30/2022; 9327963, 11/30/2022; 9329366, 11/30/2022; 9329368, 11/30/2022; 9330598, 11/30/2022; 9331805, 11/30/2022; 9338115, 11/30/2022; 9338129, 11/30/2022; 9340890, 11/30/2022; 9343956, 11/30/2022; 9343958, 11/30/2022; 9344779, 11/30/2022; 9347277, 10/31/2022; 9351555, 12/31/2022; 9353728, 12/31/2022; 9354163, 12/31/2022; 9354165, 12/31/2022;		
ChloraPrep With Tint 2% w/v chlorhexidine gluconate (CHG) and 70% v/v isopropyl alcohol (IPA) Non-Sterile Solution - Hi-Lite Orange, 0.10 fl. oz. (3 ml) each, 25 applicators in carton, applicator is sterile if package is intact. CareFusion El Paso, TX 79912, NDC 054365-400-11 Cat. No. 260415	Class II	Drugs	Lots and Exp dates: 0009104, 12/31/2022; 0013602, 12/31/2022; 0016431, 1/31/2023; 0022273, 1/31/2023; 0023788, 1/31/2023; 0029135, 1/31/2023; 0032694, 1/31/2023; 0038211, 1/31/2023; 0044741, 1/31/2023; 0064598, 2/28/2023; 0104862, 3/31/2023; 0127010, 4/30/2023; 0196060, 6/30/2023; 0224915, 7/31/2023; 8024958, 1/9/2021; 8025595, 1/31/2021; 8025597, 1/31/2021; 8031857, 1/31/2021; 8033645, 1/31/2021; 8038971, 1/28/2021; 8043969, 1/22/2021; 8043978, 1/31/2021; 8046513, 2/1/2021; 8046721, 1/29/2021; 8053669, 2/28/2021; 8053699, 2/28/2021; 8053947, 2/28/2021; 8055949, 2/28/2021; 8059513, 2/28/2021; 8059562, 2/28/2021; 8061970, 2/19/2021; 8064854, 2/28/2021; 8066666, 2/28/2021; 8068686, 2/28/2021; 8069986, 2/28/2021; 8073868, 2/28/2021; 8087798, 3/31/2021; 8099735, 3/31/2021; 8101641, 3/31/2021;	CGMP Deviations: Product is being recalled because at labeled storage conditions of 30*C/75% Relative Humidity, there is the potential for growth of Aspergillus penicillioides, a type of fungus, resulting in a	CareFusion 213, LLC

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
			8106743, 4/30/2021; 8107945, 4/30/2021; 8120678, 4/30/2021; 8122947, 4/30/2021; 8131539, 4/30/2021; 8145833, 5/31/2021; 8155989, 5/31/2021; 8172690, 6/30/2021; 8173860, 6/30/2021; 8191600, 6/30/2021; 8221942, 7/31/2021; 8234936, 8/31/2021; 8243851, 8/31/2021; 8247688, 8/31/2021; 8250928, 8/31/2021; 8253987, 8/31/2021; 8256638, 8/31/2021; 8260782, 8/31/2021; 8265685, 9/30/2021; 8274504, 9/30/2021; 8276704, 9/30/2021; 8282698, 9/30/2021; 8284625, 9/30/2021; 8288853, 9/30/2021; 8338776, 11/30/2021; 8339985, 11/30/2021; 8351538, 12/31/2021; 8355672, 12/31/2021; 9007942, 12/31/2021; 9014571, 12/31/2021; 9017726, 1/31/2022; 9021969, 12/31/2021; 9024576, 1/31/2022; 9030949, 1/31/2022; 9078586, 3/31/2022; 9087987, 3/31/2022; 9092771, 3/31/2022; 9128867, 4/30/2022; 9129671, 4/30/2022; 9135822, 5/31/2022; 9143840, 5/31/2022; 9154907, 5/31/2022; 9154939, 5/31/2022; 9158658, 5/31/2022; 9164579, 5/31/2022; 9175663, 6/30/2022; 9176284, 6/30/2022; 9197931, 6/30/2022; 9199822, 6/30/2022; 9200426, 7/31/2022; 9205380, 7/31/2022; 9207927, 7/31/2022; 9213913, 7/31/2022; 9221459, 7/31/2022; 9224855, 7/31/2022; 9231815, 8/31/2022; 9232764, 8/31/2022; 9233646, 8/31/2022; 9235839, 8/31/2022; 9248040, 8/31/2022; 9261980, 9/30/2022; 9270896, 9/30/2022; 9301763,	breach of the package integrity.	

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
			10/31/2022; 9310176, 10/31/2022; 9317270, 11/30/2022; 9327966, 11/30/2022; 9327969, 11/30/2022; 9339209, 11/30/2022; 9344806, 11/30/2022; 9345964, 10/31/2022; 9351402, 12/31/2022;		
PremierZen Black 5000 capsules, 1 capsule per card/24 capsules per box, Distributed by New Premier Group Los Angeles CA 90006 UPC 7 2817542189 4	Class II	Drugs	All lots within expiry	Marketed without Approved NDA/ANDA: FDA analysis results obtained the presence of tadalafil and sildenafil.	Namoo Enterprise LLC
Imperial Extreme 2000 Capsules, 2000 mg, 1 count blister cards, distributed S&B Shopper LLC. Little Ferry, NJ UPC 7 18122 04073 5	Class II	Drugs	all lots and expirys	Marketed without Approved NDA/ANDA: FDA analysis results obtained the presence of tadalafil and sildenafil.	S & B Story LLC
PremierZen Platinum 5000, Packaged in paper	Class II	Drugs	Lot #: GATCO 01671, Exp Date 12/30/2024 Serial # 728175421856	Marketed without Approved	Na Na Collection

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
packaging with a pill blister, 1 capsule per box, Distributed by New Premier Group Los Angeles CA 90006				NDA/ANDA: FDA analysis results obtained the presence of tadalafil and/or sildenafil.	
Triple SupremeZen Gold 3500, Packaged in paper packaging with a pill blister,1 capsule per box, Distributed by VIEW LIFE Distributors Los Angeles CA 90005 UPC 7 15122 05089 4	Class II	Drugs	Lot #: GATCO 1805, Exp. Date 12/30/2024 Serial # 715122050894	Marketed without Approved NDA/ANDA: FDA analysis results obtained the presence of tadalafil and/or sildenafil.	Na Na Collection
Cephalexin for Oral Suspension, Generic for Keflex, USP, Powder for Oral Suspension, 250 mg/5mL, Pkg Size 100, Rx only, Repackaged by	Class II	Drugs	Lot #: B1121W, Exp.Date: 04/2022	Failed Impurities/degradation specifications: Repackager recall due to Out of Specification	Preferred Pharmaceuticals, Inc.

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
Preferred Pharmaceuticals, Inc., Mfg: Ascend Laboratories, LLC, NDC #: 68788-7529-1,				detected by manufacturer for Individual Unidentified Impurity found during related substance test analysis of Cephalexin	
Oxygen, Compressed, USP UN 1072, packaged in cylinders labeled as: a) M6 Medical Gas Cylinder, b) C Medical Gas Cylinder; c) D Medical Gas Cylinder; d) E Medical Gas Cylinder; e) M Medical Gas Cylinder; f) H Medical Gas Cylinder, Rx only,	Class II	Drugs	All lots manufactured and distributed 04/01/2019-04/09/2021	cGMP deviations	Grace Healthcare Medical, Inc

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
Grace Healthcare 1418 31st Avenue Gulfport, MS 39501 228-863-3331					
Losartan Potassium USP, 50 mg, RX Only, Pkg By PD-Rx Pharmaceuticals Incorporated Oklahoma City, OK 73127 a) 60 Tablets NDC: 43063-854-60; b) 90 Tablets NDC: 43063-0854-90	Class II	Drugs	Lots: A19B99 Exp. 11/30/2019; B19A26 Exp. 11/30/2019; B19A69 Exp. 11/30/2019; E18F12 Exp.: 09/30/19; F18A12 Exp.: 09/30/19; F18F06 Exp.: 09/30/19; G18B43 Exp.: 09/30/19; G18C43 Exp.: 09/30/19; G18F75 Exp.: 09/30/19; H18D55 Exp.: 09/30/19; I18A11 Exp.: 09/30/19; I18E32 Exp.: 09/30/19; J18A90 Exp.: 09/30/19; J18D50 Exp. 11/30/2019; L18D01 Exp. 11/30/2019	CGMP deviation: Product found to contain trace amounts of NMBA	PD-Rx Pharmaceuticals, Inc.
Thumbs Up 7 Red 70K, 10 count blister pack cartons, Distributed by Ummzy LLC., Made in USA, UPC 6 17135 89467 3.	Class II	Drugs	All lots within expiry.	Marketed without Approved NDA/ANDA: FDA analysis results obtained the presence of sildenafil and tadalafil.	Antoto-K
IMPERIAL GOLD 2000, Male Sexual	Class II	Drugs	All	Marketed without	QMart

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
Performance Enhancement, 1 Capsule, UPC 718122040702				Approved NDA/ANDA: FDA analysis results obtained the presence of tadalafil and/or sildenafil.	
PremierZen Extreme 3000, Male Sexual Performance Enhancement, 1 Capsule, UPC 728175421887	Class II	Drugs	All	Marketed without Approved NDA/ANDA: FDA analysis results obtained the presence of tadalafil and/or sildenafil.	QMart
Burro en Primavera, 2 capsules, UPC 638632431055	Class II	Drugs	All	Marketed without Approved NDA/ANDA: FDA analysis results obtained the presence of tadalafil and/or sildenafil.	QMart

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
Imperial Platinum 2000, 1 capsule, UPC 718122040702	Class II	Drugs	All	Marketed without Approved NDA/ANDA: FDA analysis results obtained the presence of tadalafil and/or sildenafil.	QMart
Metformin HCl Extended-Release Tablets, USP, 500 mg, packaged in 500-count bottles, Rx only, Distributed by: Sun Pharmaceutical Industries, Inc. Cranbury, NJ 08512, Manufactured by: Sun Pharmaceutical Industries Ltd., Halol-Baroda Highway, Halol-389	Class II	Drugs	Lots #: JKX2749A, JKX2803A, JKX2805A, JKX806A, JKX2945A,JKX2946A, JXK2947A, JKX2948A, JKX2952A, JKX2953A, JKX2954A & JKX3224A, Exp 6/2032; JKX3211A, JKX3212A, Exp 7/2023.	Presence of foreign substance: identified as activated carbon.	SUN PHARMACEUTICAL INDUSTRIES INC

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
350, Gujarat, India, NDC 62756-142-02.					
Betamethasone Dipropionate Ointment USP, 0.05% (Augmented), packaged in 15 grams tubes, Manufactured by: Teligent Pharma, Inc. Buena, New Jersey 08310, NDC 52565-019-15	Class III	Drugs	Lot #: 14297, Exp 9/2021; 15372, Exp 3/2022; 15841, Exp 8/2022	Failed Impurities/ Degradation Specifications - OOS for know impurity Betamethasone 17- propionate.	Teligent Pharma, Inc.
Betamethasone Dipropionate Ointment USP, 0.05% (Augmented), packaged in 50 grams tubes, Manufactured by: Teligent Pharma, Inc. Buena, New Jersey 08310, NDC 52565-019-51	Class III	Drugs	Lot #: 14297, Exp 9/2021; 15757, Exp 6/2022; 15840, Exp 7/2022; 15970, Exp 9/2022; 15993, Exp 9/2022	Failed Impurities/ Degradation Specifications - OOS for know impurity Betamethasone 17- propionate.	Teligent Pharma, Inc.

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
Betamethasone Dipropionate Ointment USP, 0.05% (Augmented), packaged in 15 grams tubes, Manufactured by: Teligent Pharma, Inc. Buena, New Jersey 08310, Distributed by: McKesson Corporation dba Sky Packaging 4971 Southbridge Blvd., Suite 101 Memphis, TN 38141, NDC 63739-996-15	Class III	Drugs	Lot #: 15644, Exp 5/2022	Failed Impurities/ Degradation Specifications - OOS for know impurity Betamethasone 17- propionate.	Teligent Pharma, Inc.
Evrysdi (risdiplam) for oral solution, 60 mg/80mL (0.75mg/mL), 80 mL total volume after constitution, Rx only, Distributed by:	Class III	Drugs	Lot #: B1001B05; B1001B08, Exp. Feb-2022	Defective Container: complaints received regarding some incorrect press-in-bottle-	Genentech Inc

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
Genentech, Inc. NDC:50242-175-05				adapters (PIBA), the incorrect PIBAs have a female instead of male fit so they cannot be used in combination with co-packed syringes.	
Acyclovir Tablets, USP, 400 mg, 100 Tablets, Rx Only, Distributed by: Avet Pharmaceuticals Inc., East Brunswick, NJ 08816, NDC 23155-227-01. Packaged in 150 cc white HDPE bottle	Class III	Drugs	Lot A120036, Exp DEC 2023	Labeling: Incorrect or Missing Lot and/or Exp Date	Heritage Pharmaceuticals Inc

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

CURRENT DRUG SHORTAGES

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

Generic Name or Active Ingredient

Acetazolamide Injection
Amifostine Injection
Amino Acids
Amoxapine Tablets
Amphetamine Aspartate; Amphetamine Sulfate; Dextroamphetamine Saccharate; Dextroamphetamine Sulfate Tablets
Anagrelide Hydrochloride Capsules
Asparaginase Erwinia Chrysanthemi (Erwinaze)
Atropine Sulfate Injection
Atropine Sulfate Ophthalmic Ointment
Azacitidine for Injection
Belatacept (Nulojix) Lyophilized Powder for Injection
Bumetanide Injection
Bupivacaine Hydrochloride and Epinephrine Injection
Bupivacaine Hydrochloride Injection
Calcitriol Injection 1MCG/ML
Calcium Disodium Versenate Injection
Calcium Gluconate Injection
Cefazolin Injection
Cefotaxime Sodium Injection
Cefotetan Disodium Injection
Cefoxitin for Injection
Ceftazidime and Avibactam (AVYCAZ®) for Injection, 2 grams/0.5 grams
Ceftolozane and Tazobactam (Zerbaxa) Injection
Chlordiazepoxide Hydrochloride Capsules
Chloroprocaine Hydrochloride Injection
Cisatracurium Besylate Injection
Continuous Renal Replacement Therapy (CRRT) Solutions
Cortisone Acetate Tablets
Cyclopentolate Ophthalmic Solution
Cysteamine Hydrochloride Ophthalmic Solution
Desmopressin Acetate Nasal Spray
Dexamethasone Sodium Phosphate Injection
Dexmedetomidine Injection
Diltiazem Hydrochloride Injection
Dimercaprol (Bal in Oil) 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
Famotidine Injection
Famotidine Tablets
Fentanyl Citrate (Sublimaze) Injection
Floxuridine for Injection
Fluorescein Strips
Fluvoxamine ER Capsules
Furosemide Injection
Gemifloxacin Mesylate (Factive) Tablets
Guanfacine Hydrochloride Tablets
Heparin Sodium and Sodium Chloride 0.9% Injection
Histreline Acetate Implant
Hydralazine Hydrochloride Injection
Hydrocortisone Tablets
Hydromorphone Hydrochloride Injection
Hydroxocobalamin Injection
Hydroxypropyl (Lacrisert) Cellulose Ophthalmic Insert
Imipenem and Cilastatin for Injection
Isoniazid Injection
Ketamine Injection
Ketoprofen Capsules
Ketorolac Tromethamine Injection
Letermovir (Prevymis) Injection
Leucovorin Calcium Lyophilized Powder for Injection
Leuprolide Acetate Injection
Lidocaine Hydrochloride (Xylocaine) and Dextrose Injection Solution-Premix Bags
Lidocaine Hydrochloride (Xylocaine) Injection
Lidocaine Hydrochloride (Xylocaine) Injection with Epinephrine
Lithium Oral Solution
Lorazepam Injection
Loxapine Capsules
Methadone Hydrochloride Injection
Methohexital Sodium (Brevital) Injection
Methyldopa Tablets
Midazolam Injection

Misoprostol Tablets
Morphine Sulfate Injection
Multi-Vitamin Infusion (Adult and Pediatric)
Nalbuphine Hydrochloride Injection
Nefazodone Hydrochloride Tablets
Nizatidine Capsules
Ondansetron Hydrochloride Injection
Oxytocin Injection (Synthetic)
Pantoprazole Sodium for Injection
Parathyroid Hormone (Natpara) Injection
Physostigmine Salicylate Injection
Pindolol Tablets
Potassium Acetate Injection
Promethazine (Phenergan) Injection
Propofol Injectable Emulsion
Protamine Sulfate Injection
Rifampin Injection
Rifapentine Tablets
Ropivacaine Hydrochloride Injection
Sclerosol Intrapleural Aerosol
Sincalide (Kinevac) Lyophilized Powder for Injection
Sodium Acetate Injection
Sodium Bicarbonate Injection
Sodium Chloride 23.4% Injection
Sodium Chloride Injection USP, 0.9% Vials and Syringes
Succimer (Chemet) Capsules
Sulfasalazine Tablets
Tacrolimus Capsules
Technetium Tc99m Succimer Injection (DMSA)
Teprotumumab-trbw
Thiothixene Capsules
Timolol Maleate Ophthalmic Gel Forming Solution
Triamcinolone Hexacetonide Injectable suspension
Trimethobenzamide Hydrochloride Capsules
Valproate Sodium Injection
Vecuronium Bromide for Injection