



Drug Information Update

August 2021



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NEWLY AVAILABLE GENERICS

Generic Name/ Dosage Form	Brand Name	Manufacturer	Indication
potassium chloride 15 mEq tablet, ER	Klor-con M15	Upsher Smith	<ul style="list-style-type: none"> For the treatment of patients with hypokalemia with or without metabolic alkalosis, in digitalis intoxication and in patients with hypokalemic familial periodic paralysis. For the prevention of hypokalemia in patients who would be at particular risk if hypokalemia were to develop.
ibuprofen/famotidine 800 mg-26.6 mg tablet	Duexis	Horizon	For the relief of signs and symptoms of rheumatoid arthritis and osteoarthritis and to decrease the risk of developing upper gastrointestinal ulcers in patients who are taking ibuprofen for those indications.
dextroamphetamine sulfate 15 mg, 20 mg, 30 mg tablet	Zenzedi	Wilshire Pharma	<ul style="list-style-type: none"> For the treatment of narcolepsy. For the treatment of ADHD with hyperactivity.
sunitinib maleate 12.5 mg, 25 mg, 37.5 mg, 50 mg capsule	Sutent	Sun Pharmaceuticals	<ul style="list-style-type: none"> For the treatment of adult patients with gastrointestinal stromal tumor (GIST) after disease progression on or intolerance to imatinib mesylate. For the treatment of adult patients with advanced renal cell carcinoma (RCC). For the adjuvant treatment of adult patients at high risk of recurrent RCC following nephrectomy. For the treatment of progressive, well-differentiated pancreatic neuroendocrine tumors (pNET) in adult patients with unresectable locally advanced or metastatic disease.

Generic Name/ Dosage Form	Brand Name	Manufacturer	Indication
buprenorphine HCl 75 mcg, 150 mcg, 300 mcg, 450 mcg, 600 mcg, 750 mcg, 900 mcg film	Belbuca	Alvogen Inc.	For the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.
enalapril maleate 1 mg/mL solution	Epaned	Bionpharma Inc.	<ul style="list-style-type: none"> • For the treatment of hypertension in adults and children older than one month. • For the treatment of symptomatic heart failure. • For the treatment of asymptomatic left ventricular dysfunction.

NEW DRUG ENTITIES/STRENGTHS/COMBINATIONS

Drug Name	Generic Name	Description	Comments
Flumist Quad 2021-2022 6.5-7.5 FF unit/0.2 mL nasal spray syringe	Flu vacc qv live 2021(2-49yrs)	Influenza Virus Vaccine	New Entity
Bylvay 200, 600 mcg oral pellet Bylvay 400, 1,200 mcg oral capsule	Odevixibat	Ileal bile acid transporter (IBAT) inhibitor for the treatment of pruritus in patients 3 months of age and older with progressive familial intrahepatic cholestasis (PFIC).	New Entity
Rezurock 200 mg tablet	Belumosudil	A selective oral inhibitor of Rho-associated coiled-coil kinase 2 (ROCK2), a signaling pathway that modulates inflammatory response. Approved for the treatment of adult and pediatric patients 12 years and older with chronic graft-versus-host disease (cGVHD) after failure of at least two prior lines of systemic therapy.	New Entity
Myrbetriq 8 mg/mL oral suspension, extended release	Mirabegron	Oral suspension formulation of approved beta3 agonist for neurogenic detrusor overactivity.	New Dosage Form and Strength
Saphnelo 300 mg/2 mL (150 mg/mL) intravenous solution	Anifrolumab-fnia	A type I interferon (IFN) receptor antagonist indicated for the treatment of adult patients with moderate to severe systemic lupus erythematosus (SLE), who are receiving standard therapy	New Entity
Nexviazyme 100 mg intravenous solution	avalglucosidase alfa-ngpt	An enzyme replacement therapy targeting the mannose-6-phosphate (M6P) receptor, the key pathway for cellular uptake of enzyme replacement therapy in Pompe disease.	New Entity

Drug Name	Generic Name	Description	Comments
		Approved for patient 1 year or older with late-onset Pompe disease.	
Uptravi 1,800 mcg intravenous solution	selexipag	Treatment for pulmonary arterial hypertension (PAH); new intravenous route of administration for use temporarily in patients unable to take oral tablets	New Route, Dosage Form, and Strength

NEW INDICATIONS (EXISTING DRUGS)

†**Bolded** items reflect newly approved indication; ~~strike through~~ of removed indication/age limit/etc.

Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication†
Shingrix	zoster vaccine recombinant, adjuvanted suspension for intramuscular injection	Glaxo Smith Kline	A vaccine indicated for prevention of herpes zoster (HZ) (shingles): <ul style="list-style-type: none"> • in adults aged 50 years and older. • in adults aged 18 years and older who are or will be at increased risk of HZ due to immunodeficiency or immunosuppression caused by known disease or therapy.
Drizalma Sprinkle	duloxetine delayed-release capsules, 20 mg, 30 mg, 40 mg 60 mg	Sun Pharma Global	A serotonin and norepinephrine reuptake inhibitor (SNRI) indicated for the treatment of following conditions: <ul style="list-style-type: none"> • Major Depressive Disorder (MDD) in adults • Generalized Anxiety Disorder (GAD) in adults and pediatric patients ages 7 years of age and older • Diabetic Peripheral Neuropathic Pain (DPNP) in adults • Fibromyalgia (FM) in adults • Chronic Musculoskeletal Pain in adults
Bydureon Bcise	exenatide extended-release for injectable suspension, 2 mg in a single-dose auto-injector	Astra Zeneca	A glucagon-like peptide-1 (GLP-1) receptor agonist indicated as an adjunct to diet and exercise to improve glycemic control in <ul style="list-style-type: none"> • adults and pediatric patients aged 10 years and older with type 2 diabetes mellitus
Nucala	mepolizumab injection, 100 mg of lyophilized powder in a single-	GlaxoSmithKline	An interleukin-5 (IL-5) antagonist monoclonal antibody (IgG1 kappa) indicated for:

Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication†
	dose vial; for injection, 100 mg/mL auto-injector, syringe		<ul style="list-style-type: none"> • add-on maintenance treatment of adult and pediatric patients aged 6 years and older with severe asthma and with an eosinophilic phenotype • add-on maintenance treatment of chronic rhinosinusitis with nasal polyps (CRSwNP) in adult patients 18 years of age and older with inadequate response to nasal corticosteroids • treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA) • treatment of adult and pediatric patients aged 12 years and older with hypereosinophilic syndrome (HES) for ≥6 months without an identifiable non-hematologic secondary cause
Botox	onabotulinumtoxin A for injection, 100 units, 200 units vacuum-dried powder in a single-dose vial	Allergan	<p>An acetylcholine release inhibitor and a neuromuscular blocking agent indicated for treatment of spasticity in adults in the following muscles:</p> <ul style="list-style-type: none"> • Biceps brachii • Brachioradialis • Brachialis • Pronator teres • Pronator quadratus • Flexor carpi radialis • Flexor carpi ulnaris • Flexor digitorum profundus • Flexor digitorum sublimis • Lumbricals/Interossei • Adductor pollicis • Flexor pollicis longus • Flexor pollicis brevis/Opponens pollicis

Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication†
			<p><i>*Note: Botox has many other indications not presented here because there were no changes</i></p>
Keytruda	pembrolizumab injection, 100 mg/4 mL solution in a single-dose vial	Merck	<p><u>Triple-Negative Breast Cancer (TNBC)</u></p> <ul style="list-style-type: none"> • for the treatment of patients with high-risk early-stage TNBC in combination with chemotherapy as neoadjuvant treatment, and then continued as a single agent as adjuvant treatment after surgery. • in combination with chemotherapy, for the treatment of patients with locally recurrent unresectable or metastatic TNBC whose tumors express PD-L1 [Combined Positive Score (CPS) ≥10] as determined by an FDA approved test. <p><u>Renal Cell Carcinoma (RCC)</u></p> <ul style="list-style-type: none"> • in combination with axitinib, for the first-line treatment of adult patients with advanced RCC. • in combination with lenvatinib, for the first-line treatment of adult patients with advanced RCC. <p><i>*Note: Keytruda has many other indications not presented here because there were no changes</i></p>
Lenvima	lenvatinib capsules, 4 mg, 20 mg	Eisai	<p><u>Renal Cell Carcinoma</u></p> <ul style="list-style-type: none"> • in combination with pembrolizumab, is indicated for the first-line treatment of adult patients with advanced renal cell carcinoma (RCC). • in combination with everolimus, is indicated for the treatment of adult patients with advanced RCC following one prior anti-angiogenic therapy.
Mirena	levonorgestrel-releasing intrauterine system, 52 mg	Bayer	<ul style="list-style-type: none"> • Contraception: for prevention of pregnancy for up to 6 7 years; replace after the end of the sixth seventh year.

Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication†
			Heavy Menstrual Bleeding: for the treatment of heavy menstrual bleeding for up to 5 years in women who choose to use intrauterine contraception as their method of contraception; replace after the end of the fifth year if continued treatment of heavy menstrual bleeding is needed.
Xywav	calcium, magnesium, potassium, and sodium oxybates oral solution, 0.5 g/mL total salts (equivalent to 0.413 g/mL of oxybate)	Jazz Pharmaceutical	Indicated for the treatment of: <ul style="list-style-type: none"> • Cataplexy or excessive daytime sleepiness (EDS) in patients 7 years of age and older with narcolepsy • Idiopathic Hypersomnia (IH) in adults
Jardiance	empagliflozin tablets, 10mg, 25 mg	Boehringer Ingelheim	<ul style="list-style-type: none"> • As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus • To reduce the risk of cardiovascular death in adults with type 2 diabetes and established cardiovascular disease • To reduce the risk of cardiovascular death plus hospitalization for heart failure in adults with heart failure and reduced ejection fraction
Lexettte	halobetasol propionate topical foam, 0.05%	Mayne Pharma	For the topical treatment of plaque psoriasis in patients twelve (12) 18 years of age and older
Dalvance	Dalbavancin vial 500mg	Allergan	Dalvance is a lipoglycopeptide antibacterial indicated for the treatment of adult and pediatric patients with acute bacterial skin and skin structure infections (ABSSSI) caused by designated susceptible strains of Grampositive microorganisms.

RECALLS

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
Vy&Tea (Vietnamese Labeling with a green leaf and a bird underneath) 15/KLT 45.0G (15 tea sachets per box), Manufactured by Havyco No. 45, Group 1, National Highway 14, Son Hiep Hamlet, Tho Son Commune, Bu Dang District, Binh Phuoc Province, Vietnam, Website: trathaomocgiamcan.com.	Class I	Drugs	Best By Date: 9/2021	Marketed Without An Approved NDA/ANDA: FDA analysis detected the presence of sibutramine.	Qikmoov LLC
BUPIVACAINE HCL-BACLOFEN PF INJECTABLE 40MG-4000MCG/ML, 21 mL syringe, Rx only, Med Shop Total Care 470 East Loop 281 Longview, TX 75605	Class I	Drugs	Lot #: 09282020@94 BUD: 10/27/2020	Non-Sterility	Med Shop Total Care Inc.
BUPIVACAINE HCL-LIORESAL PF INJECTABLE 7.5MG-1625MCG/ML, 41 mL syringe, Rx only, Med Shop Total Care 470 East Loop 281 Longview, TX 75605	Class I	Drugs	Lot #: 09282020@38 BUD: 10/29/2020	Non-Sterility	Med Shop Total Care Inc.
FENTANYL-BUPIVACAINE HCL PF INJECTABLE 3000MCG-12MG/ML, 21 mL syringe, Rx only, Med Shop Total	Class I	Drugs	Lot #: 09302020@67 BUD: 10/29/2020	Non-Sterility	Med Shop Total Care Inc.

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
Care 470 East Loop 281 Longview, TX 75605					
FENTANYL-BUPIVACAINE HCL-BACLOFEN PF INJECTABLE 575MCG-18MG-6000MCG/ML, 21 mL syringe, Rx only, Med Shop Total Care 470 East Loop 281 Longview, TX 75605	Class I	Drugs	Lot #: 09282020@75 BUD: 10/27/2020	Non-Sterility	Med Shop Total Care Inc.
HYDROMORPHONE HCL-BUPIVACAINE HCL-BACLOFEN PF INJECTABLE 21 mL syringes in various strengths: a) 2.5MG-1.25MG-0.5MCG/ML, b) 10MG-5MG-10MCG/ML, c) 2MG-1MG-10MCG/ML, d) 10MG-5MG-10MCG/ML, e) 15MG-5MG-2000MCG/ML, f) 8MG-10MG-400MCG/ML, Rx only, Med Shop Total Care 470 East Loop 281 Longview, TX 75605	Class I	Drugs	Lot #: a)10012020@42, b) 10012020@43, c) 10012020@44, d) 10012020@46, e) 09302020@16, f) 09302020@44, BUD 10/29/2020	Non-Sterility	Med Shop Total Care Inc.
HYDROMORPHONE HCL-BUPIVACAINE HCL-CLONIDINE HCL PF INJECTABLE 21 mL syringes in two strengths: a) 20MG-20MG-60MCG/ML INJECTABLE, b) 5MG-5MG-100MCG/ML, Rx only, Med	Class I	Drugs	Lot #: a) 09302020@30, BUD 10/23/2020, b) 10022020@14, BUD 10/30/2020	Non-Sterility	Med Shop Total Care Inc.

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
Shop Total Care 470 East Loop 281 Longview, TX 75605					
MORPHINE-BUPIVACAINE PF INJECTABLE 21 mL, 22 mL, 23 mL, 41 mL and 43 mL syringes in various strengths: a) 20MG/ML-40MG/ML, b) 15MG-30MG/ML, c) 5MG/ML- 20MG/ML, d) 2MG-30MG/ML, e) 20MG-5MG/ML, f) 15MG-5MG/ML, g) 5MG-2MG/ML, h) 5MG-11MG/ML, i) 20MG-6MG/ML, j) 10MG- 10MG/ML, k) 6MG-4.8MG/ML, l) 30MG-10MG/ML, m) 5MG-4MG/ML, n) 10MG/ML-20MG/ML, o) 40MG- 5MG/ML, p) 20MG-20MG/ML, q) 30MG-20MG/ML, Rx only, Med Shop Total Care 470 East Loop 281 Longview, TX 75605	Class I	Drugs	Lot #: a) 09282020@62, BUD 10/27/2020, 09302020@25, BUD 10/29/2020, b) 09292020@56, c) 09292020@58, d)09292020@60, e) 09292020@66, 09292020@73, f) 09292020@70, g) 09292020@71, h) 09292020@77, i) 09302020@20 j) 09302020@33, k) 09302020@48, l) 09302020@61, m) 09302020@66, n) 09302020@70, o) 09302020@26, BUD 10/29/2020, p) 10012020@8, q)	Non-Sterility	Med Shop Total Care Inc.

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
			10022020@20, BUD 10/30/2020		
HYDROMORPHONE HCL-BUPIVACAINE HCL-FENTANYL PF INJECTABLE 21 mL syringe in various strengths, a)10MG-20MG-100MCG/ML, b) 20MG-10MG-450MCG/ML, c) 13.3MG-3MG-3000MCG/ML, Rx only, Med Shop Total Care 470 East Loop 281 Longview, TX 75605	Class I	Drugs	Lot #: a) 09282020@66, BUD 10/27/2020, 09302020@42, BUD 10/29/2020, b) 09282020@79, c) 09292020@32, BUD 10/27/2020 09282020@66 09302020@42 09282020@79 09292020@32 10/27/2020 10/29/2020 10/27/2020 10/27/2020	Non-Sterility	Med Shop Total Care Inc.
MORPHINE-HYDROMORPHONE-BUPIVACAINE PF 13MG-19MG-2MG/ML INJECTABLE 21 mL syringe, Rx only, Med Shop 470 E. Loop 281 Longview, TX 75605	Class I	Drugs	Lot #: 09292020@64, BUD 10/28/2020	Non-Sterility	Med Shop Total Care Inc.
MORPHINE-BUPIVACAINE-KETAMINE PF INJECTABLE 21 mL syringe in two	Class I	Drugs	Lot #: 09302020@31, BUD 10/28/2020, b)	Non-Sterility	Med Shop Total Care Inc.

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
strengths: a) 5MG-25MG-5MG/ML, b) 1MG-2MG-100MCG/ML, Rx only, Med Shop Total Care 470 East Loop 281 Longview, TX 75605			09302020@29, BUD 10/30/2020		
SUFENTANIL-BUPIVACAINE-BACLOFEN PF 25MCG-12.5MG-750MCG/ML INJECTABLE 41 mL syringe, Rx only, Med Shop Total Care 470 East Loop 281 Longview, TX 75605	Class I	Drugs	Lot #: 09302020@47 BUD 10/28/2020	Non-Sterility	Med Shop Total Care Inc.
MORPHINE-BUPIVACAINE-FENTANYL PF 30MG-15MG-2000MCG/ML INJECTABLE 21 mL syringe, Rx only, Med Shop Total Care 470 East Loop 281 Longview, TX 75605	Class I	Drugs	Lot #: 09302020@57 BUD 10/29/2020	Non-Sterility	Med Shop Total Care Inc.
HYDROMORPHONE HCL-BUPIVACAINE HCL-SUFENTANIL PF 25MG-9MG-110MCG/ML INJECTABLE 21 mL syringe, Rx only, Med Shop Total Care 470 East Loop 281 Longview, TX 75605	Class I	Drugs	Lot #: 09292020@59 BUD 10/28/2020	Non-Sterility	Med Shop Total Care Inc.
HYDROMORPHONE HCL-BUPIVACAINE HCL PF INJECTABLE 21 and 22 mL syringes in various strengths: a) 0.5MG-5MG/ML, b)	Class I	Drugs	Lot #: a) 09302020@40, BUD 10/28/2020, b) 09292020@55, BUD	Non-Sterility	Med Shop Total Care Inc.

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
2MG-35MG/ML, c) 25MG-15MG/ML, d) 6MG-1.5MG/ML, e) 3MG- 3MG/ML, f) 5MG-15MG/ML, g)12MG-8MG/ML, h)2MG-2MG/ML, i) 30MG-30MG/ML, j) 8MG- 20MG/ML, k) 20MG-10MG/ML, l)50MG-3.5MG/ML, m) 10MG- 30MG/ML, n)15MG-1.6MG/ML, o) 20MG-30MG/ML, p)15MG-6MG/ML, q)15MG-27MG/ML, Rx only, Med Shop Total Care 470 East Loop 281 Longview, TX 75605			10/27/2020, c) 09302020@58, BUD 10/29/2020, d) 10012020@6, e) 09302020@23, f)10012020@4, g) 10012020@11 BUD 10/29/2020, h) 10012020@64, i)10022020@22, j) 10012020@15 BUD 10/30/2020, k) 10012020@41 BUD 10/29/2020, l) 09282020@92, BUD 10/27/2020, m)10012020@20 BUD 10/30/2020, n) 09302020@9, BUD 10/28/2020, o) 09292020@36, BUD 10/27/2020, p) 09302020@11, q) 09302020@18, BUD 10/28/2020		

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
C-PROGESTERONE OIL 100 MG/ML, 10 mL vials, Compound, People's Custom Rx, Compounded, Rx only, People's Custom Rx, 785 E Brookhaven Cir, Memphis, TN 38117	Class I	Drugs	Lot: 11649 BUD: 07/07/2021	Non-Sterility	People's Custom Rx and Clinical Care, LLC
Estriol USP41 Micro 25 Grams, Distributed by: A.P.I. Solutions 25309 Friendship Rd Daphne, AL Distributed by: Syntec Pharma Corp., NY MFT by: Wuhan Fortune Chemical Co., Ltd., China, NDC: 46144-300-01	Class II	Drugs	Lot #: ETL181001, Exp 10/09/2021	cGMP Deviations	API Solutions Inc.
Azelaic Acid 99.0+% Micro 500 Grams, Distributed By: A.P.I. Solutions Daphne Alabama Manufactured by: Yicheng Chemicals Corp. China Distributed by: Syntec Pharma Corp New York	Class II	Drugs	Lot #: AZA181105, Exp 11/09/2021	cGMP Deviations	API Solutions Inc.
Chantix (varenicline) tablets, 0.5mg*, 56 Tablets, Rx Only, Distributed by Pfizer Labs, Division of Pfizer Inc., NY, NY 10017, Made in Ireland. NDC 0069-0468-56	Class II	Drugs	Lots 00019213, Exp 31 Jan 2022 & EC6994, Exp May 31, 2023	CGMP Deviations: Presence of the N-nitroso-varenicline impurity above FDA s acceptable interim acceptable intake limit	Pfizer Inc.
Chantix (varenicline)Tablets, Contains: 1 Starting Week (0.5 mg* x	Class II	Drugs	Lots 00020231, Exp 30 Sept 2021; 00020232,	CGMP Deviations: Presence of the N-	Pfizer Inc.

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
11 tablets), 3 Continuing Weeks (1 mg x 42 tablets), Rx Only, Distributed by Pfizer Labs, Division of Pfizer Inc, NY, NY 10017, Made in Ireland, NDC 0069-0471-03.			Exp 30 Nov 2021; 00020357, Exp 31 Dec 2021; 00020358, Exp 31, Jan 2022; 00020716, Exp 31, Jan 2022 ; ET1600, Exp 31, Jan 2023; ET1607, Exp 31, Jan 2023 & ET1609, Exp 31, Jan 2023.	nitroso-varenicline impurity above FDAs acceptable interim acceptable intake limit	
Chantix (varenicline) tablets, 1 mg, 56 Tablets, Rx Only, Distributed by Pfizer Labs, Division of Pfizer Inc., NY, NY 10017, Made in Ireland. NDC 0069-0469-56	Class II	Drugs	Lots EC9843, Exp 31, Mar 2023; EA6080, Exp. 31, Mar 2023.	CGMP Deviations: Presence of the N-nitroso-varenicline impurity above FDAs acceptable interim acceptable intake limit	Pfizer Inc.
Global Hand Sanitizer with moisturizer, Alcohol-based Antiseptic 80%, Non-sterile Topical Solution, 4 fl. oz./119 mL, Alcohol 80% v/v, Manufactured by: Cascade Kelly Holdings LLC, NDC 80253-001-01	Class II	Drugs	All distributed lots within expiry	CGMP Deviations: Does not meet monograph for denaturant.	Cascade Kelly Holdings LLC
Global Hand Sanitizer with moisturizer, Alcohol-based Antiseptic 80%, Non-sterile Topical Solution, 8	Class II	Drugs	All distributed lots within expiry	CGMP Deviations: Does not meet	Cascade Kelly Holdings LLC

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
fl. oz./236 mL, Alcohol 80% v/v, Manufactured by: Cascade Kelly Holdings LLC, NDC 80253-001-02				monograph for denaturant.	
Succinylcholine Chloride 100 mg/5 mL (20 mg/mL), 5 mL Syringes, Rx only, For IV Use only, BayCare Central Pharmacy, 7802 E. Telecom Parkway, Temple Terrace, FL 33837	Class II	Drugs	Lot: SUCC10020210624 Exp. 09/22/2021	Lack of sterility assurance	BayCare Integrated Service Center, LLC /dba BayCare Central Pharmacy
Zyprexa Intramuscular, Olanzapine for Injection, 10 MG per Single Use Vial, Rx only, Marketed by: Lilly USA, LLC, Indianapolis, IN 46285, NDC# 0002-7597-01	Class II	Drugs	Lot # 197	cGMP deviations: Atypical appearance, decrease in size and change in color of the lyophilized cake of drug product.	Eli Lilly & Company
Sulfamethoxazole and Trimethoprim Tablets, USP, 800mg/160mg Double Strength, 500 Tablets, Rx Only, Distributed by: Aurobindo Pharma USA, Inc. 279 Princeton-Hightstown Road, EAs Windsor, NJ 08520, Made in India, NDC 65862-420-05	Class II	Drugs	Batch SP1D19082AA3 & Batch SP1D19085AA3; Exp 08/2022	Presence of Foreign Substance- Potential of metal contamination.	Aurobindo Pharma USA Inc.
Venlafaxine Tablets, USP 50 mg*, 100 Tablets Manufactured for Northstar Rx LLC Memphis, TN 38141 Manufactured by: ALKALOIDA	Class II	Drugs	AVK1175A, exp 9/2023	Presence of Foreign Tablets/Capsules; Venlafaxine Tablets, USP 37.5 mg found in	SUN PHARMACEUTICAL INDUSTRIES INC

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
Chemical Company Zrt. 4440 Tiszavasvari, Kabay Janos u.29.Hungary. Product of India NDC 16714-657-01				bottles labeled as Venlafaxine Tablets, USP, 50 mg	
Nystatin Oral Suspension, USP 100,000 units per mL, Cherry/Peppermint Flavor, Rx ONLY, packaged in a) 16 fl oz (473 mL) NDC 0121-0868-16; b) 2 fl oz (60 mL) NDC 0121-0868-02; Manufactured by: Pharmaceutical Associates, Inc. Greenville, SC 29605	Class II	Drugs	Lots: a) C98F, C990 Exp. 30SEP2022, C9C2 Exp. 31OCT2022; b) C9E1 Exp. 31OCT2022	Lack of CGMP: This recall is being carried out due to potential for carryover of Senna Syrup.	PAI Holdings, LLC. dba Pharmaceutical Associates Inc
Cimetidine Hydrochloride Oral Solution 300 mg/5 mL, 8 fl oz (237 mL) Rx ONLY, Pharmaceutical Associates, Inc. Greenville, SC 29605, NDC 0121-0649-08	Class II	Drugs	Lot: C62F Exp. 31OCT2022	Lack of CGMP: This recall is being carried out due to potential for carryover of Senna Syrup.	PAI Holdings, LLC. dba Pharmaceutical Associates Inc
Ethosuximide Oral Solution USP 250 mg/5 mL, 16 fl oz (473 mL), Rx ONLY, Pharmaceutical Associates, Inc. Greenville, SC 29605, NDC 0121-0670-16	Class II	Drugs	Lot: C9BC Exp. 31OCT2022	Lack of CGMP: This recall is being carried out due to potential for carryover of Senna Syrup.	PAI Holdings, LLC. dba Pharmaceutical Associates Inc
Econazole Nitrate Cream 1%, 85 grams bulk shippers, Rx Only, Teligent Pharma, Inc. Buena, New	Class II	Drugs	Lot # 16630; Exp 03/2023	Correct Labeled Product Mispack	Teligent Pharma, Inc.

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
Jersey 08310, NDC 52565-022-85 ; packaged in tubes.					
Triamcinolone Acetonide Ointment USP, 0.1% 80 g cartons, Rx Only, Teligent Pharma, Inc. Buena, New Jersey 08310, NDC 52565-014-80 ; packaged in tubes.	Class II	Drugs	Lot # 16630; Exp 03/2023	Correct Labeled Product Mispack	Teligent Pharma, Inc.
Tizanidine HCl Tablets, USP 4 mg, 150-count bottles, Rx only, Mfd By: Dr. Reddy's Laboratories limited, Srikakulam District, 532 409 INDIA, NDC 55111-180-15.	Class II	Drugs	Lot #: T2000471, exp date 09/2023	Failed Tablet/Capsule Specification: Some tablets are shaved	Dr. Reddy's Laboratories, Inc.
Cholestene capsules, 1200 mg of red yeast rice per 2 capsules, 120-count bottle, Manufactured by: High Performance Formulas, L.L.C. (HPF, L.L.C.) P.O. Box 1311, Morrisville, PA 19067, UPC 640485-10093-4	Class II	Drugs	Lot #30317, exp. date 02/2026	Marketed Without an Approved NDA/ANDA	High Performance Formulas, L.L.C. (HPF, L.L.C.)
Acetaminophen 325 mg tablets, Regular Strength Pain Reliever, 100-count bottle, Distributed by: Walmart Inc., Bentoville, AR 72716, NDC 79903-052-10	Class II	Drugs	Lot #: S210240, Exp. 03/2023	cGMP deviations: Discolored acetaminophen	Spirit Pharmaceuticals

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
Combipatch (estradiol/norethindrone acetate transdermal system) 0.05/0.14 mg per day, 50/140 Twice Weekly, Rx Only a) 2 Systems NDC 68968-0514-2 b) 8 Systems NDC 68968-0514-8, Mfd. by: Noven Pharmaceuticals, Inc., Miami, Florida 33186, Dist. by: Noven Therapeutics LLC, Miami, Florida 33186	Class II	Drugs	Lots: 88542 Exp. 03/2022; 88227 Exp. 12/2021; 88696 Exp. 05/2022; 89357 Exp. 08/2022	Failed Stability Specifications; out of specification for shear.	Noven Pharmaceuticals Inc
Combipatch (estradiol/norethindrone acetate transdermal system) 0.05/0.25 mg per day 50/250 Twice Weekly Rx Only a) 2 Systems NDC 68968-0525-2; b) 8 Systems NDC 68968-0525-8, Mfd. by: Noven Pharmaceuticals, Inc., Miami, Florida 33186, Dist. by: Noven Therapeutics LLC, Miami, Florida 33186	Class II	Drugs	Lots: 88540 Exp. 03/2022; 89118 Exp. 05/2022; 89244 Exp. 07/2022; 89244 (sample lot) Exp. 07/2022	Failed Stability Specifications; out of specification for shear.	Noven Pharmaceuticals Inc
GaviLyte™ - C PEG-3350 (240g) and Electrolytes for Oral Solution, USP with Flavor Pack Manufactured by Novel Laboratories, Inc. Somerset, NJ 08873, USA Manufactured for Lupin Pharmaceuticals, Inc. Baltimore, MD 21202 NDC 43386-060-19	Class II	Drugs	Lot S001133, exp 7/2022	Failed Stability Specification; Out of specification for Osmolarity	Novel Laboratories, Inc. d.b.a LUPIN

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
DAUNOrubicin Hydrochloride Injection 20 mg/4mL, 4mL Single Dose vials, 10 in 1 carton, Rx only, Teva Parenteral Medicines, Inc. Irvine, CA 92618 Vial NDC# 0703-5233-11, Carton NDC # 0703-5233-13	Class II	Drugs	Lot #: 31329250B, exp. date 08/2022	Lack of Assurance of Sterility	Teva Pharmaceuticals USA
Methylprednisolone Acetate Injectable Suspension USP, 40 mg/mL, packaged in a) 1 mL Single-Dose vials (0703-0031-01), and b) 5mL Multi Dose Vials (NDC 0703-0043-01), and c) 10 mL Multi-Dose Vials (NDC 0703-0045-01), Rx only, TEVA PHARMACEUTICALS USA, INC. North Wales, PA 19454.	Class II	Drugs	Lot #: a) 31328455B, exp. date 09/2021; 31329340B, exp. date 12/2021; 31329439B, exp. date 01/2022; 31328347B, exp. date 07/2021 b) 31328321B, exp. date 07/2021; c) 31328368B, 31328394B, exp. date 07/2021; 31328699B, exp. date 09/2021; 31328834B, exp. date 10/2021; 31329286B, exp. date 12/2021	Lack of Assurance of Sterility	Teva Pharmaceuticals USA
Haloperidol Decanoate Injection 100 mg/mL, packaged in a) 1 mL single-dose vials (NDC 0703-7131-01), b) 5	Class II	Drugs	Lot #: a) 31327056B, exp. date 03/2022; 31328547B, exp. date	Lack of Assurance of Sterility	Teva Pharmaceuticals USA

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
mL multi-dose vials (NDC 0703-7133-01), Rx only, Teva Pharmaceuticals USA, Inc. North Wales, PA 19454.			01/2023; b) 31327066B, exp. date 03/2022		
Amikacin Sulfate Injection USP 1 gram/4mL (250mg/ML), 4 mL single-dose vials, Rx only, Teva Pharmaceuticals USA Inc. North Wales, PA 19454, NDC 0703-9040-01	Class II	Drugs	Lot #: 31329243B, exp. date 05/2022	Lack of Assurance of Sterility	Teva Pharmaceuticals USA
Idarubicin Hydrochloride Injection 20 mg/20 mL, 20 mL single-dose vial, Rx only, Teva Pharmaceuticals USA, Inc. North Wales, PA 19454, NDC 0703-4156-11	Class II	Drugs	Lot #: 31328668B, exp. date 04/2023	Lack of Assurance of Sterility	Teva Pharmaceuticals USA
Vecuronium Bromide for Injection 10 mg, 10mL vial, Rx only, Teva Pharmaceuticals USA, North Wales, PA 19454, NDC 0703-2914-01	Class II	Drugs	Lot #: 31325960B, exp. date 12/2021; 31326111B, exp. date 01/2022; 31326875B, exp. date 03/2022; 31326915B, exp. date 03/2022; 31326916B, 31326917B, exp. date 04/2022; 31329079B, exp. date 04/2023; 31329085B, exp. date 05/2023	Lack of Assurance of Sterility	Teva Pharmaceuticals USA

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
Octreotide Acetate Injection 1000 mcg/5mL, 5 mL multi-dose vial, Rx only, Teva Pharmaceuticals USA, Inc. North Wales, PA 19454, NDC 0703-3333-01	Class II	Drugs	Lot #: 31329150B, exp. date 06/2022	Lack of Assurance of Sterility	Teva Pharmaceuticals USA
Leucovorin Calcium for Injection, USP 350 mg/vial, 17.5 mL single-use vials, Rx only, Teva Parenteral Medicines, Inc. Irvine, CA 92618, NDC 0703-5145-01	Class II	Drugs	Lot #: 31325852B, 31325985B, exp. date 10/2021; 31326349B, exp. date 01/2022; 31326873B, exp. date 03/2022; 31326995B, exp. date 05/2022 31327158B, exp. date 06/2022; 31328946B, 31329180B, exp. date 05/2023.	Lack of Assurance of Sterility	Teva Pharmaceuticals USA
Epoprostenol Sodium for Injection, 1.5 mg/vial, 10 mL vials, Rx only, Teva Pharmaceuticals USA, Inc. North Wales, PA 19454, NDC 0703-1995-01	Class II	Drugs	Lot #: 31329113B, exp. date 05/2022	Lack of Assurance of Sterility	Teva Pharmaceuticals USA
Norepinephrine Bitartrate Injection, USP 4 mg/4 mL, 4 mL single dose vials, packaged in 10 vial cartons (NDC 0703-1153-03) Rx only, Teva Pharmaceuticals USA Inc. North	Class II	Drugs	Lot #: 31329045B, exp. date 07/2021; 31329077B, exp. date 08/2021; 31329312B, exp. date 09/2021	Lack of Assurance of Sterility	Teva Pharmaceuticals USA

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
Wales, PA 19454, vial NDC 0703-1153-01					
Adenosine Injection, USP, 60mg/20mL (3 mg/mL), 20 mL single-dose vial, Rx only, Manufactured by: Teva Pharmaceuticals USA Inc. Parsippany, NJ 07054, NDC 0703-8776-01	Class II	Drugs	Lot #: 100022400, exp. date 04/2023	Lack of Assurance of Sterility	Teva Pharmaceuticals USA
Metoclopramide Injection USP, 10 mg/2mL (5 mg/mL) 2 mL single-use vial, Rx only, Teva Parenteral Medicines, Inc. Irvine, CA 92618, NDC 0703-4502-01	Class II	Drugs	Lot #: 31326043B, exp. date 10/2021; 31326138B, exp. date 11/2021 31329399B, 31329539B, exp. date 08/2023; 31329599B, exp. date 09/2023	Lack of Assurance of Sterility	Teva Pharmaceuticals USA
Alprostadil Injection USP, 500 mg/mL, 1 mL single dose, vials, 5 mL single use vial per carton (NDC 0703-1501-02), Rx only, Teva Pharmaceuticals USA, Inc. Parsippany, NJ 07054, Vial NDC 0703-1501-01	Class II	Drugs	Lot #: 31329295B, exp date. 01/2022	Lack of Assurance of Sterility	Teva Pharmaceuticals USA
Methylprednisolone Acetate Injectable Suspension USP, 80 mg/mL, packaged in a) 1 mL Single-Dose vials (0703-0051-01), and b)	Class II	Drugs	Lot #: a) 31329363B, exp. date 01/2022; 31329484B, exp. date 03/2022 b)	Lack of Assurance of Sterility	Teva Pharmaceuticals USA

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
5mL Multi Dose Vials (NDC 0703-0063-01), Rx only, TEVA PHARMACEUTICALS USA, INC. North Wales, PA 19454.			31328367B, 31328431B, exp. date 07/2021; 31329014B, exp. date 11/2021		
Octreotide Acetate Injection 100 mcg/mL, 1 mL single-dose vial, Rx only, Teva Pharmaceuticals USA. Inc. North Wales, PA 19454, NDC 0703-3311-01	Class II	Drugs	Lot #: 31327466B, exp. date 08/2021	Lack of Assurance of Sterility	Teva Pharmaceuticals USA
Octreotide Acetate Injection 50 mcg/mL, 1 mL single-dose vial, Rx only, Teva Pharmaceuticals USA. Inc. North Wales, PA 19454, NDC 0703-3301-01	Class II	Drugs	Lot #: 31329169B, 31329231B, exp. Date 06/2022	Lack of Assurance of Sterility	Teva Pharmaceuticals USA
Leucovorin Calcium for Injection, USP 100 mg/vial, 10 mL single-use vials, Rx only, Teva Parenteral Medicines, Inc. Irvine, CA 92618, NDC 0703-5140-01	Class II	Drugs	Lot #: 31325596B, exp. date 08/2021; 31328129B, exp. date 11/2022; 31328356B, exp. date 01/2023; 31329297B, exp. date 06/2023; 31329569B, 31329821B, exp. date 08/2023	Lack of Assurance of Sterility	Teva Pharmaceuticals USA

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
Leucovorin Calcium for Injection, USP 350 mg/vial, 17.5 mL single-use vials, Rx only, Manufactured by: Teva Pharmaceuticals USA, Inc. North Wales, PA 19454, NDC 0703-5145-91	Class II	Drugs	Lot #: 313282585B, exp. date 11/2022	Lack of Assurance of Sterility	Teva Pharmaceuticals USA
Adenosine Injection, USP, 60mg/20 mL (3 mg/mL), 20 mL single-dose vial, Rx only, Mfd in the USA for: NorthStar Rx LLC Memphis, TN 38141, NDC 16714-180-01	Class II	Drugs	Lot #: 100022401, exp. date 04/2023	Lack of Assurance of Sterility	Teva Pharmaceuticals USA
Carvedilol Tablets, USP 25 mg, 500 Tablets bottles, Rx Only, Manufactured by: Cadila Healthcare Ltd., India, Distributed by: Zydus Pharmaceuticals (USA) Inc., Pennington, NJ 0853, NDC 68382-095-05	Class II	Drugs	Z006279, exp 12/31/2022	Presence of Foreign Tablets/Capsules; report of two Paroxetine tablets were found in the bottle	Zydus Pharmaceuticals (USA) 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

Amifostine Injection
Amino Acids
Amoxapine Tablets
Amphetamine Aspartate; Amphetamine Sulfate;
Dextroamphetamine Saccharate; Dextroamphetamine
Sulfate Tablets
Anagrelide Hydrochloride Capsules
Atropine Sulfate Injection
Atropine Sulfate Ophthalmic Ointment
Azacitidine for Injection
Azithromycin (Azasite) Ophthalmic Solution 1%
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
Continuous Renal Replacement Therapy (CRRT) Solutions
Cortisone Acetate Tablets
Crisantaspase (Erwinase)
Cyclopentolate Ophthalmic Solution
Cysteamine Hydrochloride Ophthalmic Solution
Desmopressin Acetate Nasal Spray
Dexamethasone Sodium Phosphate Injection
Dexmedetomidine Injection
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
Famotidine Injection
Famotidine Tablets
Fentanyl Citrate (Sublimaze) Injection
Floxuridine for Injection
Fluvoxamine ER Capsules
Furosemide Injection
Gemifloxacin Mesylate (Factive) Tablets
Gentamicin Sulfate Injection
Guanfacine Hydrochloride Tablets
Heparin Sodium and Sodium Chloride 0.9% Injection
Histreline Acetate Implant
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
Mepivacaine Hydrochloride Injection
Methohexital Sodium (Brevital) Injection
Methyldopa Tablets
Midazolam Injection
Misoprostol Tablets
Morphine Sulfate Injection
Multi-Vitamin Infusion (Adult and Pediatric)
Nefazodone Hydrochloride Tablets
Nizatidine Capsules



Ondansetron Hydrochloride Injection
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
Tocilizumab Injection
Triamcinolone Hexacetonide Injectable suspension
Trimethobenzamide Hydrochloride Capsules
Valproate Sodium Injection
Varenicline Tartrate (Chantix) Tablets
Vecuronium Bromide for Injection