PERFORMRx℠

Drug Information Update

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NEWLY AVAILABLE GENERICS

Generic Name/ Dosage Form	Brand Name	Manufacturer	Indication
droxidopa 100 mg, 200 mg, 300 mg capsule	Northera	Lundbeck	• For the treatment of orthostatic dizziness, lightheadedness, or the "feeling that you are about to black out" in adult patients with symptomatic neurogenic orthostatic hypotension (nOH) caused by primary autonomic failure (Parkinson's disease [PD], multiple system atrophy, and pure autonomic failure), dopamine beta-hydroxylase deficiency, and non-diabetic autonomic neuropathy. Effectiveness beyond 2 weeks of treatment has not been established. The continued effectiveness of Northera should be assess periodically.
cyclophosphamide 200 mg/mL vial, IV	Cyclophosphamide	Ingenus	An alkylating drug indicated for treatment of: • Malignant Diseases: malignant lymphomas: Hodgkin's disease, lymphocytic lymphoma, mixed-cell type lymphoma, histiocytic lymphoma, Burkitt's lymphoma; multiple myeloma, leukemias, mycosis fungoides, neuroblastoma, adenocarcinoma of ovary, retinoblastoma, breast carcinoma.
hydrocodone bitartrate 20 mg, 30 mg, 40 mg, 60 mg, 80 mg, 100 mg, 120 mg tablet ER	Hysingla ER	Purdue	• An opioid agonist indicated 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
brinzolamide 1% ophthalmic drops, suspension	Azopt	Novartis	• A carbonic anhydrase inhibitor indicated for the treatment of elevated intraocular pressure in patients with ocular hypertension or open-angle glaucoma

Generic Name/ Dosage Form	Brand Name	Manufacturer	Indication
sodium fluoride 1.1% gel	Prevident 5000	Colgate	• A dental caries preventive; for once daily self-applied topical use. It is well established that 1.1% sodium fluoride is safe and extraordinarily effective as a caries preventive when applied frequently with mouthpiece applicators. PreviDent 5000 Dry Mouth brand of 1.1% sodium fluoride toothpaste in a squeeze bottle is easily applied onto a toothbrush. This prescription toothpaste should be used once daily in place of your regular toothpaste unless otherwise instructed by your dental professional. May be used in areas where drinking water is fluoridated since topical fluoride cannot produce fluorosis.

NEW DRUG ENTITIES/STRENGTHS/COMBINATIONS

Brand Name	Generic Name	Description	Comments
Ozempic 1 mg/dose (4 mg/3 mL) subcutaneous pen injector	semaglutide	New single pen containing 4 x 1 mg doses	New Package Size
Gamifant 5 mg/mL intravenous solution	emapalumab-lzsg	mAb for primary hemophagocytic lymphohistiocytosis (HLH). Larger size vial (100 mg/20 mL)	New Strength
Xtandi 40 mg, 80 mg tablet	enzalutamide	antiandrogen for prostate CA. new tablet formulation and 80 mg strength	New Dosage Form and Strength
Hetlioz LQ 4 mg/mL oral suspension	tasimelteon	Like Rozerem, melatonin RA. But limited, orphan indications. New liquid formulation only indicated for Nighttime sleep disturbances in Smith-Magenis syndrome in pts age 3-15 years.	New Dosage Form and Strength
Margenza 25 mg/mL intravenous solution	margetuximab-cmkb	A HER2/neu receptor antagonist indicated, in combination with chemotherapy, for the treatment of adult patients with metastatic HER2positive breast cancer who have received two or more prior anti-HER2 regimens, at least one of which was for metastatic disease	New Entity
acetaminophen 500 mg/50 mL (10 mg/mL) intravenous solution	acetaminophen	Generic APAP	New Strength
Trazimera 150 mg intravenous solution	trastuzumab-qyyp	New, smaller vial size	New Strength
Amondys-45 50 mg/mL intravenous solution	casimersen	An antisense oligonucleotide indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 45 skipping. Vyondys 53 and Viltepso are antisense	New Entity

Brand Name	Generic Name	Description	Comments
		oligonucleotides for DMD amenable to exon 53 skipping and Exondys 51 for DMD amenable to exon 51 skipping.	
Plegridy 125 mcg/0.5 mL intramuscular syringe	peginterferon beta-1a	New IM formulation, improved over SQ formulation b/c reduced injection site reactions	New Route of Admin
Pepaxto 20 mg intravenous solution	melphalan flufenamide hcl	An alkylating drug indicated in combination with dexamethasone, for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy and whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and one CD38-directed monoclonal antibody. Melphalan injection and oral are already marketed but do not share this indication. This was not a 505(b)2.	New Entity
Nulibry 9.5 mg intravenous solution	fosdenopterin hydrobromide	Cyclic pyranopterin monophosphate (cPMP) indicated to reduce the risk of mortality in patients with molybdenum cofactor deficiency (MoCD) Type A	New Entity
Breyanzi CD8 Component (1of 2) 1.5x to 70x10exp6 cell/mL IV suspension	lisocabtagene maraleucel	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 (including DLBCL arising from indolent lymphoma), high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B	CD8 Component of Breyanzi
Breyanzi CD4 Component (2of 2) 1.5x to 70x10exp6 cell/mL IV suspension	lisocabtagene maraleucel	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	CD4 component of Breyanzi

Brand Name	Generic Name	Description	Comments
		more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified (including DLBCL arising from indolent lymphoma), high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B	
REGEN-COV (EUA) 120 mg/mL-120 mg/mL intravenous solution	casirivimab/ imdevimab	New combination dose packs of 2 mAbs to tx mild to moderate SARS-CoV-2	New Combination and Strength
Prolate 10 mg-300 mg/5 mL oral solution	oxycodone hcl/ acetaminophen	Oxycodone/APAP oral soln	New Strength
Fluzone Quad Southern Hemis 2021(PF) 60 mcg (15 mcg x 4)/0.5 mL IM syr, vial	flu vac qs2021 south,6mo up	Flu vaccine meant for southern hemisphere	New Entity
Tyblume 0.1 mg-20 mcg chewable tablet	levonorgestrel/ethin. estradiol	Chewable oral contraceptive. Not new, only GCN change.	Dosage Form change from tablet to chewable tablet
allergen extract-Acremonium strictum 53,000 unit/mL injection solution	allerg ext-acremonium strictum	Therapeutic allergenic extract	New Strength
Foscavir 24 mg/mL intravenous solution	foscarnet sodium	New bottle packaging (previous formulations were bottles)	New Dosage Form
Glyrx-PF 0.6 mg/3 mL (0.2 mg/mL) injection syringe	glycopyrrolate/pf	New strength of injectable, preservative free glycopyrrolate	New Strength

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†
Zirabev	bevacizumab-bvzr injection, 100 mg/4 mL, 400 mg/16 mL in single-dose vials	Pfizer	A vascular endothelial growth factor inhibitor indicated for the treatment of: • metastatic colorectal cancer, in combination with intravenous fluorouracil-based chemotherapy for first- or second-line treatment. • metastatic colorectal cancer, in combination with fluoropyrimidineirinotecan- or fluoropyrimidine-oxaliplatin-based chemotherapy for second-line treatment in patients who have progressed on a first-line bevacizumab product-containing regimen. • Unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer, in combination with carboplatin and paclitaxel for first-line treatment. • Recurrent glioblastoma in adults. • Metastatic renal cell carcinoma in combination with interferon alfa. • Persistent, recurrent, or metastatic cervical cancer, in combination with paclitaxel and cisplatin or paclitaxel and topotecan. • **Epithelial ovarian, fallopian tube, or primary peritoneal cancer:** ○ **in combination with carboplatin and paclitaxel, followed by ZIRABEV as a single agent, for stage III or IV disease following initial surgical resection.**

Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication†
			○ **in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan for platinum-resistant recurrent disease who received no more than 2 prior chemotherapy regimens.** ○ **in combination with carboplatin and paclitaxel or carboplatin and gemcitabine, followed by ZIRABEV as a single agent, for platinum sensitive recurrent disease.**
Libtayo	cemiplimab-rwlc injection, 350 mg/7 mL solution in a single dose vial	Regeneron	A programmed death receptor-1 (PD-1) blocking antibody indicated: • Cutaneous Squamous Cell Carcinoma (CSCC) – for the treatment of patients with metastatic cutaneous squamous cell carcinoma (mCSCC) or locally advanced CSCC (laCSCC) who are not candidates for curative surgery or curative radiation. • Basal Cell Carcinoma (BCC) ○ for the treatment of patients with locally advanced BCC (laBCC) previously treated with a hedgehog pathway inhibitor or for whom a hedgehog pathway inhibitor is not appropriate. ○ for the treatment of patients with metastatic BCC (mBCC) previously treated with a hedgehog pathway inhibitor or for whom a hedgehog pathway inhibitor is not appropriate. • **Non-Small Cell Lung Cancer (NSCLC) – for the first-line treatment of patients with NSCLC whose tumors have high PD-L1 expression [Tumor Proportion Score (TPS) ≥ 50%] as determined by an FDA-approved test, with no EGFR, ALK or ROS1 aberrations, and is:** ○ **locally advanced where patients are not candidates for surgical resection or definitive chemoradiation or** ○ **metastatic.**

Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication†
Humira	adalimumab injection, 20 mg/0.2 mL prefilled syringe	Abbvie	A tumor necrosis factor (TNF) blocker indicated for: • Ulcerative Colitis (UC): treatment of moderately to severely active ulcerative colitis in adults **and pediatric patients 5 years of age and older**. *Note: Humira has many other indications however those unchanged have not been listed.*
Flucelvax Quadrivalent	influenza vaccine suspension for injection, 0.5 mL single dose pre-filled syringes and 5 mL multidose vials	Seqirus	An inactivated vaccine indicated for active immunization for the prevention of influenza disease caused by influenza virus subtypes A and type B contained in the vaccine. Approved for use in persons ~~4 years~~ **2 years** of age and older.
Lorbrena	lorlatinib 25 mg, 100 mg tablet	Pfizer	A kinase inhibitor indicated for the treatment of **adult** patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) **as detected by an FDA-approved test** ~~whose disease has progressed on~~ • ~~crizotinib and at least one other ALK inhibitor for metastatic disease; or~~ • ~~alectinib as the first ALK inhibitor therapy for metastatic disease; or~~ • ~~ceritinib as the first ALK inhibitor therapy for metastatic disease.~~ ~~This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.~~
Blincyto	blinatumomab for injection, 35 mcg lyophilized powder in a single-dose vial	Amgen	A bispecific CD19-directed CD3 T-cell engager indicated for the treatment of adults and children with: • **CD19-positive** B-cell precursor acute lymphoblastic leukemia (ALL) in first or second complete remission with minimal residual disease

Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication†
			(MRD) greater than or equal to 0.1%. This indication is approved under accelerated approval based on MRD response rate and hematological relapse-free survival. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials. • Relapsed or refractory **CD19-positive** B-cell precursor acute lymphoblastic leukemia (ALL).
Actemra	tocilizumab 80 mg/4 mL, 200 mg/10 mL, 400 mg/20 mL in single dose vials; 162 mg/0.9 mL in single-dose prefilled syringe	Genentech	• Rheumatoid Arthritis (RA): Adult patients with moderately to severely active RA who have had an inadequate response to one or more Disease-Modifying Anti-Rheumatic Drugs (DMARDs). • Giant Cell Arteritis (GCA): Adult patients with GCA. • **Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD): Slowing the rate of decline in pulmonary function in adult patients with systemic SSc-ILD** • Polyarticular Juvenile Idiopathic Arthritis (PJIA): Patients 2 years of age and older with active polyarticular juvenile idiopathic arthritis. • Systemic Juvenile Idiopathic Arthritis (SJIA): Patients 2 years of age and older with active systemic juvenile idiopathic arthritis. • Cytokine Release Syndrome (CRS): Adults and pediatric patients 2 years of age and older with chimeric antigen receptor (CAR) T cell-induced severe or life-threatening CRS.
Arcalyst	rilonacept for injection, 220 mg lyophilized powder in a single-dose vial	Regeneron	• Treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS), and Muckle-Wells Syndrome (MWS) in adults and children 12 years and older

Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication†
			• Maintenance of remission of Deficiency of Interleukin-1 Receptor Antagonist (DIRA) in adults and pediatric patients weighing 10 kg or more • **Treatment of recurrent pericarditis (RP) and reduction in risk of recurrence in adults and children 12 years and older**
Yescarta	axicabtagene ciloleucel suspension for intravenous infusion, 2 X 106 CAR-positive viable T cells per kg of body weight, with a maximum of 2 X 108 CAR-positive viable T cells	Kite Pharma	• 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 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, CareFusion 213, LLC, El Paso, TX 79912, subsidiary of Becton, Dickinson and Co, NDC 54365-400-32 REF 930400	Class I	Drugs	All lots including but not limited to the following lots distributed in Zone IV: Lot # 0161217 Exp. 05/31/2023; 0211068 Exp. 07/31/2023; 0176660 Exp. 06/30/2023; 0188805 Exp. 06/30/2023; 0175874 Exp. 06/30/2023; 0151977 Exp. 05/31/2023; 0149328 Exp. 04/30/2023; 0085419 Exp. 03/31/2023	Non-sterility: Product is being recalled to climatic Zone IV regions of the world where at the labeled storage conditions of 30*C/75% Relative Humidity for more than 6 months, there is the potential for growth of Aspergillus penicillioides, a type of fungus, resulting in a breach of the package integrity.	CareFusion 213, LLC
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	Class I	Drugs	All lots including but not limited to the following lots distributed in Zone IV: Lot # 0038209, Exp. 01/31/2023; 0098528, Exp. 02/28/2023.	Microbial Contamination of Non-Sterile Products:Product is being recalled to climatic Zone IV regions of the world where at the labeled storage conditions of	CareFusion 213, LLC

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
applicators in carton, CareFusion El Paso, TX 79912, NDC 054365-400-11 Cat. No. 260415				30*C/75% Relative Humidity for more than 6 months, there is the potential for growth of Aspergillus penicillioides, a type of fungus, resulting in a breach of the package integrity.	
ChlroraPrep 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. CareFusion El Paso, TX 79912, NDC 054365-400-01 Cat. No. 260400	Class I	Drugs	All lots including but not limited to the following lot distributed in Zone IV: Lot # 0192894, Exp. 06/30/2023; 9080812 Exp 03/31/2022	Non-sterility: Product is being recalled to climatic Zone IV regions of the world where at the labeled storage conditions of 30*C/75% Relative Humidity for more than 6 months, there is the potential for growth of Aspergillus penicillioides, a type of fungus, resulting in a breach of the package integrity.	CareFusion 213, LLC
BD ChloraPrep Hi-Lite Orange 2% w/v	Class I	Drugs	All lots including but not limited to the following lots distributed in Zone	Non-sterility: Product is being recalled to	CareFusion 213, LLC

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
chlorhexidine gluconate (CHG) and 70% v/v isopropyl alcohol (IPA), Sterile Solution, 0.01 fl. oz. (3 ml) each, 25 Applicators in carton, CareFusion El Paso, TX 79912, subsidiary of Becton, Dickinson and Co., NDC 54365-400-33 REF 930415			IV: Lot # 0107872, Exp. 04/30/2023; 0108556, Exp. 04/30/2023; 0148278, Exp. 04/30/2023; 0151978, Exp. 05/31/2023; 0155534, Exp. 05/31/2023; 0157085, Exp. 05/31/2023; 0160618, Exp. 05/31/2023; 0167907, Exp. 05/31/2023.	climatic Zone IV regions of the world where at the labeled storage conditions of 30*C/75% Relative Humidity for more than 6 months, there is the potential for growth of Aspergillus penicillioides, a type of fungus, resulting in a breach of the package integrity.	
ManukaGuard Medical Grade Manuka Honey Allercleanse Nasal Spray, 1.3 FL OZ (40mL) bottle, 270 measured sprays, Distributed by Ndal Laboratories, 449 Alvarado St., Monterey, CA 93940 (bottle); NDAL MFG	Class I	Drugs	LOT # 2010045; Best Before 10 2023	Microbial Contamination of Non-Sterile Products: Product confirmed to have yeast	NDAL Mfg Inc.

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
Inc., 80 Garden Court, Suite 100, Monterey, CA 93940 (carton); UPC 8 58631 00212 8. the Alvarado St. is for the bottle by putting "(bottle); NDAL MFG Inc., 80 Garden Court, Suite 100, Monterey, CA 93940 (carton); UPC 8 58631 00212 8." (according to the label)					
Cisatracurium Besylate Injection, USP, 10mg per 5mL (2 mg per mL), Single-Dose Vial (NDC 71288-712-05), packaged as 10 x 5 mL Single-Dose Vials per carton (NDC 71288-712-06), Rx only, Mfd.	Class I	Drugs	Lot C11507A	Labeling: Label mix-up: Carton of Cisatracurium Besylate Injection, USP was observed to contain ten vials mislabeled as Phenylephrine Hydrochloride Injection, USP, but	Meitheal Pharmaceuticals Inc

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
for Meitheal Pharmaceuticals, Chicago, IL 60631.				confirmed to contain Cisatracurium	
Spironolactone Tablets, USP, 25 mg, packaged in: a) 30-count bottles (NDC 63629-1064-01), b) 60-count bottles (NDC 63629-1064-02), c) 90-count bottles (NDC 63629-1064-03), Rx only, Manufactured by: Frontida BioPharm, Inc., Philadelphia, PA 19124 USA, Repackaged by: Bryant Ranch Prepack, Inc., Burbank, CA 91504 USA	Class I	Drugs	a) Lot #: 148969, Exp 7/31/2022, b) Lot #: 148791, Exp 7/31/2022, c) Lot #: 148991, Exp 7/31/2022	Labeling: Label Mix-Up - Prepackaged bottles labeled spironolactone 25 mg may contain spironolactone 50 mg tablets.	Bryant Ranch Prepack, Inc. dba BRP Pharmaceuticals
Dacarbazine for Injection USP, 200 mg, Single Use Vial (NDC 0703-5075-	Class II	Drugs	Lot # 31326582B, exp. date 02/2022; Lot # 31326964B, exp. date 04/2022	Lack of Assurance of Sterility: manufacturing areas for the recalled	Teva Pharmaceuticals USA

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
01), packaged in 10X20 ML Single Use Vials per tray (NDC 0703-5075-03); Rx only, TEVA Pharmaceuticals USA, INC., North Wales, PA 19454.				products exceeded acceptance levels for microbial recovery leading to a lack of sterility assurance for these sterile injectable products.	
Desmopressin Acetate Injection USP, 4 mcg/mL, 1 mL Preserved Vial (NDC 0703-5051-01), packaged in 10X1 mL Vials per Tray (NDC 0703-5051-03), Rx only, Teva Pharmaceuticals USA, Inc., North Wales, PA 19454.	Class II	Drugs	Lot # 31326669B, exp. date 03/2021	Lack of Assurance of Sterility: manufacturing areas for the recalled products exceeded acceptance levels for microbial recovery leading to a lack of sterility assurance for these sterile injectable products.	Teva Pharmaceuticals USA
Sterile Diluent for Epoprostenol Sodium for Injection, 50 mL vial (NDC 0703-9258-	Class II	Drugs	Lot # 31326845B, exp. date 03/2021 Lot # 31327844B, exp. date 09/2021	Lack of Assurance of Sterility: manufacturing areas for the recalled products exceeded	Teva Pharmaceuticals USA

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
01), packaged in 2X50ML per tray (NDC 0703-9258-09), Rx only, TEVA PHARMACEUTICALS USA, INC., North Wales, PA 19454.				acceptance levels for microbial recovery leading to a lack of sterility assurance for these sterile injectable products.	
Epoprostenol Sodium for Injection, 0.5 mg/vial (500,000 ng), 1X10ML vial, Rx only, Teva Pharmaceuticals USA, Inc., North Wales, PA 19454, NDC 0703-1985-01.	Class II	Drugs	Lot # 31327537B, exp. date 09/2021	Lack of Assurance of Sterility: manufacturing areas for the recalled products exceeded acceptance levels for microbial recovery leading to a lack of sterility assurance for these sterile injectable products.	Teva Pharmaceuticals USA
MethylPREDNISolone Acetate Injectable Suspension USP, 40 mg/mL, 1 mL Single-Dose Vial (NDC 0703-0031-01), packaged in 25X1ML per tray (NDC 0703-	Class II	Drugs	Lot # 31327742B, exp. date 02/2021 Lot # 31328408B, exp. date 07/2021	Lack of Assurance of Sterility: manufacturing areas for the recalled products exceeded acceptance levels for microbial recovery leading to a lack of	Teva Pharmaceuticals USA

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
0031-04), Rx only, TEVA PHARMACEUTICALS USA, INC., North Wales, PA 19454.				sterility assurance for these sterile injectable products.	
Leucovorin Calcium for Injection, USP, 100 mg/vial, Single-Dose Vial, Rx only, Teva Parenteral Medicines, Inc., Irvine, CA 92618, NDC 0703-5140-01.	Class II	Drugs	Lot # 31326364B, exp. date 01/2022 31327120B, exp. date 05/2022 31327963B, exp. date 10/2022	Lack of Assurance of Sterility: manufacturing areas for the recalled products exceeded acceptance levels for microbial recovery leading to a lack of sterility assurance for these sterile injectable products.	Teva Pharmaceuticals USA
Metoclopramide Injection USP, 10 mg/2 mL (5 mg/mL), 2 mL Single-Use Vial NDC 0703-4502-01), packaged in 25 x 2 mL Single-Use Vials per tray (NDC 0703-4502-04), Rx only, Teva Parenteral	Class II	Drugs	Lot # 31325042B, exp. date 06/2021 31325336B, exp. date 07/2021 31326042B, exp. date 10/2021 31326137B, exp. date 11/2021 31326230B, exp. date 12/2021 31323816B, exp. date 02/2021	Lack of Assurance of Sterility: manufacturing areas for the recalled products exceeded acceptance levels for microbial recovery leading to a lack of sterility assurance for	Teva Pharmaceuticals USA

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
Medicines, Inc., Irvine, CA 92618.				these sterile injectable products.	
Toposar (etoposide injection USP), 1 gram/50 mL (20 mg/mL), 50 mL Multiple-dose Vial, Rx only, Teva Pharmaceuticals USA, Inc., North Wales, PA 19454, NDC 0703-5657-01.	Class II	Drugs	Lot # 31327600B, exp. date 08/2022	Lack of Assurance of Sterility: manufacturing areas for the recalled products exceeded acceptance levels for microbial recovery leading to a lack of sterility assurance for these sterile injectable products.	Teva Pharmaceuticals USA
Vecuronium Bromide for Injection, 10 mg, 1 mg/mL when reconstituted to 10 mL, 10 mL Vial (NDC 0703-2914-01), packaged in 10 x 10 mL Vials per tray (NDC 0703-2914-03), Rx only, Teva Pharmaceuticals	Class II	Drugs	Lot # 31325712B, exp. date 12/2021 31326320B, exp. date 02/2022 31326457B, exp. date 02/2022 31327880B, exp. date 10/2022	Lack of Assurance of Sterility: manufacturing areas for the recalled products exceeded acceptance levels for microbial recovery leading to a lack of sterility assurance for these sterile injectable products.	Teva Pharmaceuticals USA

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
USA, Inc., North Wales, PA 19454.					
Epoprostenol Sodium for Injection, 1.5 mg/vial (1,500,000 ng), 10 mL vial, Rx only, Teva Pharmaceuticals USA, Inc., North Wales, PA 19454, NDC 0703-1995-01.	Class II	Drugs	Lot # 31326456B, exp. date 02/28/2021	Lack of Assurance of Sterility: manufacturing areas for the recalled products exceeded acceptance levels for microbial recovery leading to a lack of sterility assurance for these sterile injectable products.	Teva Pharmaceuticals USA
MethylPREDNISolone Acetate Injectable Suspension USP, 80 mg/mL, 1 mL Single-Dose Vial (NDC 0703-0051-01), packaged in 25X1ML vials per tray (NDC 0703-0051-04), Rx only, Teva Pharmaceuticals USA, Inc., North Wales, PA 19454.	Class II	Drugs	Lot # 31327909B, exp. date 04/2021 Lot # 31328352B, exp. date 07/2021	Lack of Assurance of Sterility: manufacturing areas for the recalled products exceeded acceptance levels for microbial recovery leading to a lack of sterility assurance for these sterile injectable products.	Teva Pharmaceuticals USA

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
MethylPREDNISolone Acetate Injectable Suspension USP, 400 mg/10 mL (40 mg/mL), 10 mL Multiple-Dose Vial, Rx only, Teva Pharmaceuticals USA, Inc., North Wales, PA 19454, NDC 0703-0045-01.	Class II	Drugs	Lot # 31327725B, exp. date 02/2021 Lot # 31327906B, exp. date 03/2021	Lack of Assurance of Sterility: manufacturing areas for the recalled products exceeded acceptance levels for microbial recovery leading to a lack of sterility assurance for these sterile injectable products.	Teva Pharmaceuticals USA
MethylPREDNISolone Acetate Injectable Suspension USP, 200 mg/5 mL (0 mg/mL), 5 mL Multiple-Dose Vial, Rx only, Teva Pharmaceuticals USA, Inc., North Wales, PA 19454, NDC 0703-0043-01.	Class II	Drugs	Lot # 31328768B, exp. date 09/2021	Lack of Assurance of Sterility: manufacturing areas for the recalled products exceeded acceptance levels for microbial recovery leading to a lack of sterility assurance for these sterile injectable products.	Teva Pharmaceuticals USA
MethylPREDNISolone Acetate Injectable Suspension USP, 400 mg/5 mL (80	Class II	Drugs	Lot # 31327738B, exp. date 03/2021	Lack of Assurance of Sterility: manufacturing areas for the recalled	Teva Pharmaceuticals USA

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
mg/mL), 5 mL Multiple-Dose Vial, Rx only, Teva Pharmaceuticals USA, Inc., North Wales, PA 19454, NDC 0703-0063-01.				products exceeded acceptance levels for microbial recovery leading to a lack of sterility assurance for these sterile injectable products.	
Leucovorin Calcium for Injection, USP, 350 mg/vial, Rx only, labeled as a) Teva Parenteral Medicines, Inc., Irvine, CA 92618, and b) Manufactured By: Teva Pharmaceuticals USA, Inc., North Wales, PA 19454, novaplus+, NDC 0703-5145-01.	Class II	Drugs	Lot # a) 31324653B, exp. date 03/2021; 31326066B, exp. date 11/2021; 31326428B, exp. date 02/2022; 31327949B, exp. date 10/2022; 31327995B, exp. date 10/2022; 31328031B, exp. date 11/2022; 31328217B, exp. date 12/2022; 31328325B, exp. date 12/2022; 31328425B, exp. date 07/2021; Lot # b) 31324480B, exp. date 02/2021; Lot # 31327396B, exp. date 08/2022	Lack of Assurance of Sterility: manufacturing areas for the recalled products exceeded acceptance levels for microbial recovery leading to a lack of sterility assurance for these sterile injectable products.	Teva Pharmaceuticals USA
Imatinib Mesylate Tablets 100mg, packaged as a) 90-count bottles (NDC	Class II	Drugs	Lot #: a) H2000206, Exp 06/22; b) H2000138, Exp 06/22	Failed Dissolution Specifications	Dr. Reddy's Laboratories, Inc.

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
43598-344-90); and b) For Institutional Use Only 30-count (3 x 10 unit-dose) tablets per carton (NDC 43598-344-31); Rx only, Distributor: Dr. Reddy's Laboratories Inc., Princeton, NJ 08540; Made in India.					
Irinotecan Hydrochloride Injection, USP, 40 mg/2 mL (20 mg/mL), 2 mL Single-Dose Vial, Rx Only, Distributed by: Areva Pharmaceuticals, Inc., Gerogetown, IN 47122, Made in India, NDC 59923-714-02.	Class II	Drugs	Lot 7S10022A, Exp Jan-21	CGMP Deviations: based on a Warning Letter received by the manufacturer of the recalled product for inadequate out-of specification investigations, complaint and the investigation conclusions.	Areva Pharmaceuticals Inc

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
Fludeoxyglucose F 18 Injection, 20-300 mCi/mL at End of Synthesis (EOS) Solution, 50 mL glass vial, Rx only, Manufactured by Massachusetts General Hospital PET Center, Boston, MA NDC 76318-334-50	Class II	Drugs	Lot # P01-021721, exp 02/17/2021	Lack of Assurance of Sterility	The General Hospital Corporation
Famotidine Tablets USP 40mg, 1,000-count bottles, Rx only, Distributed by: Aurobindo Pharma USA, Inc. 279 Princeton-Hightstown Road East Windsor, NJ 08520 Made in India, NDC 65862-860-99	Class II	Drugs	Lot #: P2000467, Exp 7/2022	Presence of foreign tablets/capsules: Famotidine 20mg and ibuprofen 400mg tablets were found in a lot of famotidine 40mg.	Aurobindo Pharma USA Inc.
Metoclopramide Injection USP, 10	Class II	Drugs	Lot # 31325335B, exp. date 07/2021	Chemical contamination;	Teva Pharmaceuticals USA

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
mg/2 mL (5 mg/mL), 25x2mL Single Dose Vials, Rx only, Distributed by Teva Pharmaceuticals, USA, Inc., Parsippany, NJ Vial NDC 0703-4502-01 (vial) NDC# 0703-4502-04 (tray)				Unknown brown residue adhering to the inside of one vial.	
Daytrana (methylphenidate transdermal system), Delivers 10 mg over 9 hours (1.1 mg/hr), Contains: 30 Patches in a foil-sealed polypropylene tray, packed in a paper carton, Rx only, Manufactured for Noven Therapeutics, LLC, Miami, FL, 33186, By Noven Pharmaceuticals,	Class II	Drugs	Lots #: 87579, Exp 3/2021 & 88243, Exp 7/2021.	Defective Delivery System: Out of specification for mechanical peel.	Noven Pharmaceuticals Inc

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
Inc., Miami, FL, 33186, NDC 68968-5552-3.					
Daytrana (methylphenidate transdermal system), Delivers 15 mg over 9 hours (1.6 mg/hr), Contains: 30 Patches in in a foil-sealed polypropylene tray, packed in a paper carton, Rx only, Manufactured for Noven Therapeutics, LLC, Miami, FL, 33186, By Noven Pharmaceuticals, Inc., Miami, FL, 33186, NDC 68968-5553-3.	Class II	Drugs	Lots #: 87818, Exp 4/2021, 88274, Exp 5/2021 & 88531, Exp 7/2021.	Defective Delivery System: Out of specification for mechanical peel.	Noven Pharmaceuticals Inc
Daytrana (methylphenidate transdermal system) Delivers 20 mg over	Class II	Drugs	Lots #: 87580, Exp 4/2021, 87819, Exp 4/2021, 88244, Exp 6/2021, 88245, Exp 6/2021, 88532, Exp 06/2021 & 88533, Exp 7/2021.	Defective Delivery System: Out of specification for mechanical peel.	Noven Pharmaceuticals Inc

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
9 hours (2.2 mg/hr) Contains: 30 Patches in a foil-sealed polypropylene tray, packed in a paper carton, Rx only, Manufactured for Noven Therapeutics, LLC, Miami, FL, 33186, By Noven Pharmaceuticals, Inc., Miami, FL, 33186, NDC 68968-5554-3.					
Daytrana (methylphenidate transdermal system) Delivers 30 mg over 9 hours (3.3 mg/hr) Contains: 30 Patches in a foil-sealed polypropylene tray, packed in a paper carton, Rx only,	Class II	Drugs	Lots #: 87377, Exp 3/2021, 87572, Exp 3/2021, 87581, Exp 4/2021, 87820, Exp 5/2021, 88246, Exp 6/2021, 88535, Exp 7/2021, 88536, Exp 8/2021, 88537, Exp 8/2021 & 88939, Exp 8/2021.	Defective Delivery System: Out of specification for mechanical peel.	Noven Pharmaceuticals Inc

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
Manufactured for Noven Therapeutics, LLC, Miami, FL, 33186, By Noven Pharmaceuticals, Inc., Miami, FL, 33186, NDC 68968-5555-3.					
Progesterone Capsules, 200 mg, 100-count bottles, Rx Only, MADE IN FRANCE; Distributed by: Dr. Reddy's Laboratories, Inc., Princeton, NJ 08540; NDC 43598-350-01.	Class II	Drugs	Batch # 1399851P1, Exp 02/2021	Failed Dissolution Specifications: Out-of-specification results observed for dissolution during stability testing.	Dr. Reddy's Laboratories, Inc.
Spironolactone Tablets, USP, 50 mg, packaged in 30-count bottles, Rx only, Manufactured by: Frontida BioPharm, Inc., Philadelphia, PA 19124 USA,	Class II	Drugs	Lot #: 148992, Exp 5/31/2022	Labeling: Label Mix-Up - Prepackaged bottles labeled spironolactone 50 mg may contain spironolactone 25 mg tablets.	Bryant Ranch Prepack, Inc. dba BRP Pharmaceuticals

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
Repackaged by: Bryant Ranch Prepack, Inc., Burbank, CA 91504 USA, NDC 63629-1067-01					
Nortriptyline HCL capsules, 10 mg, packaged in 30-count bottles, Rx only, Packaged and Distributed By: Direct Rx Dawsonville, GA, NDC 6191985330	Class II	Drugs	Lot#: 28DE2002 Exp 10/31/22	cGMP deviations: The quantity of active ingredient used for the product lot was inadvertently taken from an ingredient lot from an alternate supplier before that specific lot was formally qualified for use by the manufacturing site.	Direct Rx
Gabapentin Oral Solution, 250 mg/5 mL, 5 mL per unit dose cup, four unit dose cups per tray, For Institutional Use Only, Rx only, Hi-	Class II	Drugs	Lot 369409, Exp. Date 05/2021; Lot 372393, Exp. Date 01/2022; Lot 373112, Exp. Date 04/2022	Failed Impurities/Degradation Specifications; out of specification for unknown impurity observed during 6	Akorn, Inc.

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
Tech Pharmacal Co., Inc, Amityville, NY 11701, NDC Tray: 50383-311-07; NDC Unit Dose Cup 50383-311-07				month stability testing	
Phenylephrine HCl Injection, USP, 10 mg per mL, 1 mL per Single-Dose Vial packaged in 25 x 1 mL Single-Dose Vials per carton, For Intravenous Use, Rx only, Mfd. for: SAGENT Pharmaceuticals, Schaumburg, IL 60195; Made in India, NDC: 25021-315-01.	Class II	Drugs	Lots: PHT8IB2, PHT9IB2, exp 08/2022; PHT1JB2, exp 09/2022	Lack of Assurance of Sterility: customer complaints of loose crimped vial overseals which may result in a non-sterile product.	Sagent Pharmaceuticals Inc
Omeprazole Delayed-Release Capsules, USP, 20 mg, 1000 count bottles, Rx Only,	Class II	Drugs	Lot # 191659, exp. date 05/2021	Failed Impurities/Degradation Specifications: Out-of-Specification results obtained for	Breckenridge Pharmaceutical, Inc

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
distributed by Breckenridge Pharmaceutical, Inc., Berlin, CT, Manufactured by Tow Pharmaceutical Europe, S.L., Martorelles (Barcelona), Spain NDC 51991-643-10				unknown impurities during stability testing.	
Methylprednisolone Tablets USP, 4 MG, packaged in a 21-count blister pack, Rx only, Jubilant Cadista Pharmaceuticals, Inc., Salisbury, MD 21801, NDC 59746-001-03	Class III	Drugs	Lot #: 20K0043P, 20K0044P, 20K0042P, Exp 08/2022; 20L0026P, 20L0027P, 20L0028P, 20L0029P, 20L0030P, Exp 09/2022	Labeling: Illegible label: Customer complaint received of mis-alignment print of the printed dosing instructions on the blister card.	Jubilant Cadista Pharmaceuticals, Inc.
Cequa (cyclosporine ophthalmic solution) 0.09%, 60 Single-Use Vials (6 pouches x 10 single-use vials (0.25 mL	Class III	Drugs	Lot 10007, exp. date 01/2022	Subpotent	SUN PHARMACEUTICAL INDUSTRIES INC

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
each)), Rx only, Manufactured for Sun Pharma Global FZE by: Laboratoire Unither, Coutances, France NDC 47335-506-96					
Atorvastatin Calcium Tablets, 40mg, packaged in a) 90-count bottles, NDC 55111-123-90; b) 500-count bottles, NDC 55111-123-05; Rx only, Mfd By: Dr. Reddy's Laboratories Limited Srikakulam - 532 409 INDIA	Class III	Drugs	a) T900406, exp 3/2021 b) T000078 exp 12/2021 T000079 exp 12/2021 T000080 exp 12/2021 T000081 exp 12/2021 T000082 exp 12/2021 T000083 exp 12/2021 T000084 exp 12/2021 T000085 exp 12/2021 T000086 exp 12/2021 T000087 exp 12/2021 T000088 exp 1/2022 T000311 exp 1/2022 T000312 exp 1/2022 T000313 exp 1/2022 T000314 exp 1/2022 T000315 exp 1/2022 T000316 exp 1/2022 T000317 exp 1/2022 T000318 exp 1/2022 T000319 exp 1/2022 T000320 exp 1/2022 T000500 exp 2/2022 T000501 exp 2/2022 T000502 exp 2/2022 T000503 exp 2/2022 T000504 exp 2/2022 T000505 exp 2/2022 T000506 exp	Failed Impurities/ Degradation Specifications: presence of ATV cyclo IP and FP, Dihydroxy epoxy and Dieto epoxy impurities	Dr. Reddy's Laboratories, Inc.

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
			2/2022 T000507 exp 2/2022 T000508 exp 2/2022 T000509 exp 3/2022 T000510 exp 3/2022 T000647 exp 3/2022 T000648 exp 3/2022 T000651exp 3/2022 T000652 exp 3/2022 T000653 exp 3/2022 T000654 exp 3/2022 T000875 exp 4/2022 T000876 exp 4/2022 T000877 exp 4/2022 T000878 exp 4/2022 T000879 exp 4/2022 T000880 exp 4/2022 T000881 exp 4/2022 T000882 exp 4/2022 T000883 exp 4/2022 T000884 exp 4/2022 T001120 exp 5/2022 T001121 exp 5/2022 T001122 exp 5/2022 T001124 exp 5/2022 T001125 exp 5/2022 T001126 exp 5/2022 T001127 exp 5/2022 T001128 exp 5/2022 T001129 exp 5/2022 T001130 exp 5/2022 T001260 exp 5/2022 T001261 exp 5/2022 T900506 exp 4/2021 T900507 exp 4/2021 T900508 exp 4/2021 T900655 exp 5/2021 T900656 exp 5/2021 T900657 exp 5/2021 T900658 exp		

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
			5/2021 T900659 exp 5/2021 T900673 exp 5/2021 T900674 exp 5/2021 T901024 exp 7/2021 T901025 exp 7/2021 T901026 exp 7/2021 T901027 exp 7/2021 T901029 exp 7/2021 T901030 exp 7/2021 T901031 exp 7/2021 T901032 exp 7/2021 T901033 exp 7/2021 T901424 exp 10/2021 T901425 exp 10/2021 T901426 exp 10/2021 T901427 exp 10/2021 T901428 exp 10/2021 T901429 exp 10/2021 T901430 exp 10/2021 T901431 exp 10/2021 T901432 exp 10/2021 T901433 exp 10/2021 T901568 exp 10/2021 T901569 exp 10/2021 T901570 exp 11/2021 T901571 exp 11/2021 T901572 exp 11/2021 T901573 exp 11/2021 T901574 exp 11/2021 T901575 exp 11/2021 T901576 exp 11/2021 T901577 exp 11/2021		
Menopur 75 IU, (menotropins for injection), packaged as a) 5 single dose	Class III	Drugs	Lots# a) P12585AC, Exp. Date 31-Mar-2020 P12677AA, Exp. Date 31-Mar-2020 P12678AA, Exp. Date 31-Jul-2020 P12679AA, Exp. Date 31-	Failed pH specifications: Out of Specification pH	Ferring Pharmaceuticals Inc

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
vials of Menotropins for injection, 5 single dose vials of 0.9% Sodium Chloride Injection, USP 2 mL, NDC 55566-7501-2; b) Professional Sample Kit: 3 single dose vials of Menotropins for injection, 3 single dose vials of 0.9% Sodium Chloride Injection, USP 2 mL, NDC 55566-7501-3; Rx Only, Manufactured for Ferring Pharmaceuticals Inc. Parsippany. NJ 07054. Diluent manufactured for Ferring Pharmaceuticals Inc.			Jul-2020 P12680EA, Exp. Date 31- Jul-2020 P15461AA, Exp. Date 31- Jul-2020 P15462AA, Exp. Date 31- Aug-2020 P15463AA, Exp. Date 31- Aug-2020 P15870AA, Exp. Date 31- Aug-2020 P15872AA, Exp. Date 31- Aug-2020 P16099AA, Exp. Date 31- Aug-2020 P16100AA, Exp. Date 30- Sep-2020 P16101AC, Exp. Date 30- Sep-2020 P16248AA, Exp. Date 30- Sep-2020 P16770AA, Exp. Date 30- Nov-2020 P16771AA, Exp. Date 30- Nov-2020 R10623AA, Exp. Date 31- Jan-2021 R10624AA, Exp. Date 31- Jan-2021 R10980AA, Exp. Date 31- Jan-2021 R11085AA, Exp. Date 31- Jan-2021 R11086AA, Exp. Date 31- Jan-2021 R11088AA, Exp. Date 28- Feb-2021 R11343AA, Exp. Date 28- Feb-2021 R11416AA, Exp. Date 28- Feb-2021 R11417AA, Exp. Date 28- Feb-2021 R11418AA, Exp. Date 28- Feb-2021 R11419AA, Exp. Date 28- Feb-2021 R12100AA, Exp. Date 28- Feb-2021 R12101AA, Exp. Date 28- Feb-2021 R12102AA, Exp. Date 31-	results for 0.9% Sodium Chloride, USP	

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
			Mar-2021 R12263CA, Exp. Date 31- Mar-2021 R12264AA, Exp. Date 31- Mar-2021 R12598AA, Exp. Date 31- Mar-2021 R12599AA, Exp. Date 31- Mar-2021 R12858AA, Exp. Date 30- Apr-2021 R12859AA, Exp. Date 30- Apr-2021 R12860AA, Exp. Date 31- Jul-2021 R12861AA, Exp. Date 31- Jul-2021 R14321AA, Exp. Date 30- Nov-2021 R14753AA, Exp. Date 31- Jul-2021 R14865AA, Exp. Date 31- Jul-2021 R14866AA, Exp. Date 31- Jul-2021 R15132AA, Exp. Date 31- Aug-2021 R15133AA, Exp. Date 31- Aug-2021 R15330AA, Exp. Date 31- Aug-2021 R15331AA, Exp. Date 31- Aug-2021 R15332AA, Exp. Date 31- Aug-2021 R15333AA, Exp. Date 31- Aug-2021 R15969AA, Exp. Date 30- Sep-2021 R15970AA, Exp. Date 30- Sep-2021 R16231AA, Exp. Date 30- Sep-2021 R16379AA, Exp. Date 31- Oct-2021 R16403AA, Exp. Date 31- Oct-2021 R16405AA, Exp. Date 31- Oct-2021 R16660AA, Exp. Date 31- Oct-2021 R16696AA, Exp. Date 30-		

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
			Nov-2021 R16770AA, Exp. Date 31-Oct-2021 R17019AA, Exp. Date 31-Oct-2021 R17020AA, Exp. Date 30-Nov-2021 R17148AA, Exp. Date 30-Nov-2021 S11615AA, Exp. Date28-Feb-2022 S11616AA, Exp. Date 28-Feb-2022 S11617AA, Exp. Date 28-Feb-2022 S11618AA, Exp. Date 28-Feb-2022 S11619AA, Exp. Date 28-Feb-2022 S11620AA, Exp. Date 28-Feb-2022 S11621AA, Exp. Date 28-Feb-2022 S11623AA, Exp. Date 28-Feb-2022 S12026AA, Exp. Date 31-Mar-2022 S12413AA, Exp. Date 31-Mar-2022 S12436AA, Exp. Date 31-Mar-2022 S12437AA, Exp. Date 30-Apr-2022 S12438AA, Exp. Date 31-May-2022 S12439AA, Exp. Date 31-May-2022 b) Physician Samples P16101AA, Exp. Date 30-Sep-2020 R15332AC, Exp. Date 31-Aug-2021 S11625AA, Exp. Date 28-Feb-2022		
Methacholine Challenge 5-Syringe Test Kits, Sterile Inhalation Solution,	Class III	Drugs	Lot # 12-2020-16@10, BUD 3-30-21 Lot # 11-2020-18@11, BUD 3-02-21	Temperature Abuse; labeled with the incorrect room temperature (15-25	Edge Pharma, LLC

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
Preservative Free, 3 mL per syringe, Edge Pharma, LLC, 856 Hercules Dr., Dolchester, VT 06448 NDC # 05446-1600-05				¿C) storage conditions rather than the correct refrigerated (2 - 8 ¿C) storage conditions	
Romidepsin Injecton, 27.5 mg/5.5 mL (5 mg/mL) Rx Only, 5.5 ml vial, Teva Pharmaceuticals USA, Inc. NDC 0703-4004-01	Class III	Drugs	Lot # 31328184C, exp. date 11/2021 Lot # 31327686C, exp. date 08/2021 Lot # 31327685C, exp. date 08/2021	Failed Impurity/Degradation Specifications: Out-of-specifications results observed for impurities during stability testing.	Teva Pharmaceuticals USA
Epinephrine/Lidocaine HCl, Sterile Ophthalmic Solution for Injection, 0.8 mL per syringe, Single Use Syringe, 0.025%/0.75%, Rx only, Edge Pharma LLC 856 Hercules Dr. Colchester, VT	Class III	Drugs	Lot #: 10-2020-13@8, exp. date 12/03/2020	Labeling: Incorrect or Missing Lot and/or Exp Date	Edge Pharma, LLC

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
05446, NDC 05446-0863-01					

*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, USP
Bupivacaine Hydrochloride and Epinephrine Injection, USP
Bupivacaine Hydrochloride Injection, USP
Calcitriol Injection USP 1MCG /ML
Calcium Disodium Versenate Injection
Calcium Gluconate Injection
Capreomycin Injection, USP
Cefazolin Injection
Cefotaxime Sodium Injection
Cefotetan Disodium Injection
Cefoxitin for Injection, USP
Ceftazidime and Avibactam (AVYCAZ®) for Injection, 2 grams/0.5 grams
Ceftolozane and Tazobactam (Zerbaxa) Injection
Cisatracurium Besylate Injection
Continuous Renal Replacement Therapy (CRRT) Solutions
Cyclopentolate Ophthalmic Solution
Cysteamine Hydrochloride Ophthalmic Solution
Desmopressin Acetate (Stimate) Nasal Spray
Dexamethasone Sodium Phosphate Injection
Dexmedetomidine Injection
Diltiazem Hydrochloride Injection
Dimercaprol (Bal in Oil) Injection USP
Disopyramide Phosphate (Norpace) Capsules
Dobutamine Hydrochloride Injection

Dopamine Hydrochloride Injection
Dorzolamide Hydrochloride and Timolol Maleate (Cosopt) Ophthalmic Solution
Dorzolamide Hydrochloride Ophthalmic Solution
Echothiophate Iodide (Phospholine Iodide) Ophthalmic Solution
Enalaprilat Injection, USP
Epinephrine Injection, 0.1 mg/mL
Epinephrine Injection, Auto-Injector
Erythromycin Ophthalmic Ointment
Etomidate Injection
Famotidine Injection
Famotidine Tablets
Fentanyl Citrate (Sublimaze) Injection
Floxuridine for Injection, USP
Fluorescein Strips
Fluvoxamine ER Capsules
Furosemide Injection, USP
Gemifloxacin Mesylate (Factive) Tablets
Guanfacine Hydrochloride Tablets
Heparin Sodium and Sodium Chloride 0.9% Injection
Histreline Acetate Implant
Hydralazine Hydrochloride Injection, USP
Hydrocortisone Tablets, USP
Hydromorphone Hydrochloride Injection, USP
Hydroxypropyl (Lacrisert) Cellulose Ophthalmic Insert
Imipenem and Cilastatin for Injection, USP
Isoniazid Injection USP
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, USP
Loxapine Capsules
Methadone Hydrochloride Injection
Methyldopa Tablets
Midazolam Injection, USP

Misoprostol Tablets
Morphine Sulfate Injection
Multi-Vitamin Infusion (Adult and Pediatric)
Nalbuphine Hydrochloride Injection
Nefazodone Hydrochloride Tablets
Nizatidine Capsules
Ondansetron Hydrochloride Injection
Ondansetron Hydrochloride Tablets
Oxytocin Injection, USP Synthetic
Pantoprazole Sodium for Injection
Parathyroid Hormone (Natpara) Injection
Physostigmine Salicylate Injection, USP
Pindolol Tablets
Potassium Acetate Injection, USP
Promethazine (Phenergan) Injection
Propofol Injectable Emulsion
Rifampin Injection
Rifapentine Tablets
Ropivacaine Hydrochloride Injection
Sclerosol Intrapleural Aerosol
Sertraline Hydrochloride Oral Solution, USP
Sincalide (Kinevac) Lyophilized Powder for Injection
Sodium Acetate Injection, USP
Sodium Bicarbonate Injection, USP
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
Timolol Maleate Ophthalmic Solution
Tobramycin Lyophilized Powder for Injection
Trimethobenzamide Hydrochloride Capsules
Valproate Sodium Injection, USP
Vecuronium Bromide for Injection
Zinc Acetate Capsules