PERFORMRx℠

Drug Information Update

February 2022

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NEWLY AVAILABLE GENERICS

Generic Name/ Dosage Form	Brand Name	Manufacturer	Indication
Somatuline Depot	Lanreotide acetate 120 mg/0.5 mL syringe	Ipsen Biopharma	• The long-term treatment of acromegalic patients who have had an inadequate response to or cannot be treated with surgery and/or radiotherapy. • The treatment of adult patients with unresectable, well- or moderately-differentiated, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NETs) to improve progression-free survival. ** generic form currently does not list carcinoid syndrome indication on the label that brand Somatuline Depot carries.*
Restasis	Cyclosporine 0.05% droperette	Allergan	To increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca.
Cystadane	Betaine 1 gram/scoop powder	Orphan Europe	Treatment of homocystinuria
Selzentry	Maraviroc 150 mg, 300 mg tablet	ViiV	Indicated in combination with other antiretroviral agents for the treatment of only CCR5-tropic human immunodeficiency virus type 1 (HIV-1) infection in adult and pediatric patients weighing at least 2 kg.
Ambisome	Amphotericin B liposome 50 mg vial	Astellas	• Empirical therapy for presumed fungal infection in febrile, neutropenic patients. • Treatment of Cryptococcal Meningitis in HIV-infected patients • Treatment of patients with *Aspergillus* species, *Candida* species and/or *Cryptococcus* species infections (see above for the treatment of Cryptococcal Meningitis) refractory to amphotericin B deoxycholate, or in patients where renal impairment or unacceptable toxicity precludes the use of amphotericin B deoxycholate.

Generic Name/ Dosage Form	Brand Name	Manufacturer	Indication
			Treatment of visceral leishmaniasis. In immunocompromised patients with visceral leishmaniasis treated with AmBisome, relapse rates were high following initial clearance of parasites
Ferriprox (3 times a day)	Deferiprone 1,000 mg tablet	Chiesi USA	Treatment of transfusional iron overload in adult and pediatric patients 8 years of age and older with thalassemia syndromes, sickle cell disease or other anemias.

NEW DRUG ENTITIES/STRENGTHS/COMBINATIONS

Drug Name	Generic Name	Description	Comments
Pemfexy 25 mg/mL intravenous solution	pemetrexed	505(b)(2) drug approval for various uses in NSCLC and mesothelioma.	New Formulation
Kimmtrak 100 mcg/0.5 mL intravenous solution	tebentafusp-tebn	A bispecific gp100 peptide-HLA-directed CD3 T cell engager indicated for the treatment of HLA-A*02:01-positive adult patients with unresectable or metastatic uveal melanoma.	New Entity
Pfizer-BioNT COVID19 tris(6m-4y) Vacc(PF) 3 mcg/0.2 mL IM susp(maroon)	covid-19 vac, tris(pfizer)/pf	youngest age group pfizer mRNA COVID vaccine; not yet approved/authorized	New age range, 6 months through 4 years pending Emergency Use Authorization
Zimhi 5 mg/0.5 mL injection syringe	naloxone hcl	505(b)(2); high-dose naloxone injection product FDA-approved for use in the treatment of opioid overdose.	New Strength
Prehevbrio (PF) 10 mcg/mL intramuscular suspension	hepatitis b virus vac s,m,l/pf	Vaccine for prevention of infection caused by all known subtypes of hepatitis B virus (HBV) in adults age 18 years and older	New Formulation
Seglentis 44 mg-56 mg tablet	tramadol hcl/celecoxib	505 (b)(2) approved oral fixed-dose combination product for management of acute pain in adults.	New Combination
Vabysmo 6 mg/0.05 mL intravitreal solution	faricimab-svoa	Injectable VEGF andangiopoietin-2 inhibitor for the treatment of wet, or neovascular, age-related macular degeneration (AMD) and diabetic macular edema (DME).	New Entity
Spikevax	COVID-19 Vaccine, mRNA	Full FDA approval for Moderna's mRNA COVID-19 vaccine (specifically the two-dose primary series in adults 18 years and older)	EUA product granted FDA approval
Cibinqo 50, 100, 200 mg tablet	abrocitinib	Oral JAK inhibitor approved for treatment of atopic dermatitis not controlled with other systemic therapies.	New Entity

Drug Name	Generic Name	Description	Comments
Enjaymo 50 mg/mL intravenous solution	sutimlimab-jome	A classical complement inhibitor indicated to decrease the need for red blood cell (RBC) transfusion due to hemolysis in adults with cold agglutinin disease (CAD)	New Entity
Fleqsuvy 5 mg/mL oral suspension	baclofen	505(b)(2) approval; more concentrated oral solution for treatment of spasticity from multiple sclerosis (MS) or patients with spinal cord injuries and other spinal cord diseases	New Dosage Form
Quadracel (PF) 15 Lf-48 mcg-5 Lf unit/0.5 mL intramuscular suspension, syringe	diph,pertus(acel),tet,polio/pf	Diphtheria, tetanus, acellular pertussis and poliovirus vaccine, new strength	New Strength
bebtelovimab 175 mg/2 mL (87.5 mg/mL) intravenous solution (EUA)	bebtelovimab	EUA COVID-19 monoclonal antibody; active against Omicron	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†
Veklury	remdesivir for injection, 100 mg as a lyophilized powder in a single dose vial for reconstitution	Gilead	a SARS-CoV-2 nucleotide analog RNA polymerase inhibitor indicated for the treatment of coronavirus disease 2019 (COVID-19) in adults and pediatric patients (12 years of age and older and weighing at least 40 kg) with positive results of direct severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) viral testing, who are: • Hospitalized, or • **Not hospitalized and have mild-to-moderate COVID-19, and are at high risk for progression to severe COVID-19, including hospitalization or death**
Solosec	secnidazole oral granules, 2 g packet	Lupin	A nitroimidazole antimicrobial indicated for: • Treatment of bacterial vaginosis in ~~adult women~~ **female patients 12 years of age and older.** • Treatment of trichomoniasis in ~~adults~~ **patients 12 years of age and older**.
Delstrigo	doravirine, lamivudine, and tenofovir disoproxil fumarate, 100 mg-300 mg-300 mg tablets	Merck	A three-drug combination of doravirine (a nonnucleoside reverse transcriptase inhibitor [NNRTI]), lamivudine, and tenofovir disoproxil fumarate (both nucleoside analogue reverse transcriptase inhibitors) and is indicated as a complete regimen for the treatment of HIV-1 infection in adults **and pediatric patients weighing at least 35 kg**: • with no antiretroviral treatment history, OR • to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen with no history of treatment failure and no known substitutions associated with resistance to the individual components of DELSTRIGO.

Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication†
Pifeltro	doravirine, 100 mg tablets	Merck	A non-nucleoside reverse transcriptase inhibitor (NNRTI), is indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults **and pediatric patients weighing at least 35 kg:** • with no prior antiretroviral treatment history, OR • to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen with no history of treatment failure and no known substitutions associated with resistance to doravirine.
Vonvendi	Von Willebrand factor (recombinant) for injection, 650 or 1300 international units VWF:Rco as a lyophilized powder in single-dose vials	Baxalta US	A recombinant von Willebrand factor(rVWF)indicated for use in adults (age 18 and older) diagnosed with von Willebrand disease(VWD)for: • On-demand treatment and control of bleeding episodes. • Perioperative management of bleeding. • **Routine prophylaxis to reduce the frequency of bleeding episodes in patients with severe Type 3 von Willebrand disease receiving on-demand therapy**
Skyrizi	risankizumab-rzaa injection, 75 mg/0.83 mL syringe, 150 mg/mL syringe	AbbVie	An interleukin-23 antagonist indicated for the treatment of: • moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy. • **active psoriatic arthritis in adults.**
Xigduo XR	dapagliflozin and ER metformin hydrochloride 2.5 mg-1000 mg, 5 mg-500 mg, 5 mg-1000 mg, 10 mg-500 mg, 10 mg-1000 mg tablets	AstraZeneca	A combination of dapagliflozin, a sodium-glucose cotransporter 2 (SGLT2) inhibitor, and metformin, a biguanide, indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Dapagliflozin is indicated to reduce: • the risk of hospitalization for heart failure in adults with type 2 diabetes mellitus and established cardiovascular disease or multiple cardiovascular risk factors.

Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication†
			• **the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure (NYHA class II-IV) with reduced ejection fraction.** Limitations of use: • Not for treatment of type 1 diabetes mellitus. It may increase the risk of diabetic ketoacidosis in these patients. • Because of the metformin component, the use of Xigduo XR is limited to adults with type 2 diabetes mellitus for all indications.

RECALLS

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Senna Syrup (sennosides) Natural Vegetable Laxative 8.8 mg/5mL unit-dose cups, Mfg for: AvKARE TN 38478, NDC 50268-731-24	Class I	Drugs	Lot #: AM1115S, Exp. Date 01/2023	Microbial Contamination of Non-Sterile Product	Lohxa, LLC
Semglee (insulin glargine) injection, 100 units/mL (U-100), 3 mL Prefilled Pen (NDC 49502-0196-71), packaged in Five 3 mL Prefilled Pens per carton (NDC 49502-0196-75), Rx only, Manufactured in Malaysia for: Mylan Specialty L.P., Morgantown, WV, 26505.	Class I	Drugs	Batch # BF20003118, Exp. August 2022	Labeling: Missing Label: label missing from some Semglee prefilled pens.	Mylan Pharmaceuticals Inc
Polymyxin B for Injection USP, 500,000 Units per Vial, 10 mL vials, packaged in 10 vials per carton, Sterile, Rx Only, Distributed by: AuroMedics Pharma LLC, E. Windsor, NJ 08520, NDC 55150-234-10	Class I	Drugs	Lot CPB200013, exp 9/2022	Presence of Particulate Matter; product complaint of hair discovered in a vial within the lot	AuroMedics Pharma LLC
HARD DAWN, Rise and Shine capsules, 500 mg, packaged in 10-count blisters per carton, Made in Malaysia, UPC 680044 364926, ASIN: B077XCCL59	Class I	Drugs	Lot: 2107, Exp July 2024	Marketed Without an Approved NDA/ANDA: Firm was informed by Amazon that analytical testing showed the presence of tadalafil. Tadalafil is a FDA approved drug, making this product an unapproved drug.	Esupplements ales, LLC
MegMan Performance Booster, 800 mg capsules, packaged in 10-count blisters packaged in a carton, UPC 8 48998 00091 2, ASIN B08Z74KS88	Class I	Drugs	Lot # 2010291, Exp 01/07/2024	Marketed Without An Approved NDA/ANDA: product was found to contain undeclared tadalafil, an ingredient found in FDA approved products for the treatment of	Junp Hydration LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
				male sexual enhancement, making this an unapproved drug.	
365 SKINNY High Intensity Capsules, 600 mg, 30-count bottle, BODY BALANCE INTERNACIONAL	Class I	Drugs	Lot 102-26, Exp Dec 2022	Marketed Without an Approved NDA/ANDA: FDA analysis found the product to be tainted with undeclared sibutramine, a previously approved drug that was withdrawn from the US market due to safety concerns.	Je Dois Lavoir LLC
Hydromorphone HCL PF 10 mg/50 mL (0.2 mg/mL) in NaCL, 50 mL in 50 mL Syringe, Injection for IV Use Only, This is a compounded drug, Not for Resale, Office Use Only, Single Dose, Sterile Product, STAQ Pharma, Inc., Denver, CO 80239, NDC: 73177-0104-05.	Class I	Drugs	Lot Number: 21104221A, Expiration date: 05-22-2022	Labeling; label mix-up; A limited number of syringes containing Hydromorphone 0.2 mg/mL 50 mL, were mislabeled with Morphine 1 mg/mL 25 mL syringe labels, lot number: 21104221A.	STAQ Pharma, Inc.
Morphine Sulfate 25 mg/25 mL (1 mg/mL) in NaCl, 25 mL in 30 mL Syringe, For IV Use Only. This is a compounded drug, Not for Resale, Office Use Only, Single Dose, Sterile Product, STAQ Pharma, Inc., Denver, CO 80239, NDC: 73177-0105-04.	Class I	Drugs	Lot Number: 21104221A, Expiration date: 05-22-2022	Labeling; label mix-up; A limited number of syringes containing Hydromorphone 0.2 mg/mL 50 mL, were mislabeled with Morphine 1 mg/mL 25 mL syringe labels, lot number: 21104221A.	STAQ Pharma, Inc.
MAC DADDY RED Capsules, packaged in 10-count blisters per carton, ASIN B07TLDZLY2, UPC 742137 605191.	Class I	Drugs	Lot # 1230004, Exp. date 03/30/2024	Marketed Without An Approved NDA/ANDA: product was found to contain undeclared tadalafil and/or sildenafil, ingredients found in FDA approved products for the treatment of male sexual enhancement, making these unapproved drugs.	ABC Sales 1 Inc

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
MAC DADDY PURPLE Capsules, packaged in 10-count blisters per carton, ASIN B08Z63Z4QK, UPC 742137 605764.	Class I	Drugs	Lot # 1230005, Exp. date 03/30/2024	Marketed Without An Approved NDA/ANDA: product was found to contain undeclared tadalafil and/or sildenafil, ingredients found in FDA approved products for the treatment of male sexual enhancement, making these unapproved drugs.	ABC Sales 1 Inc
THE RED PILL, EXTRA STRENGTH capsules, 800 mg, packaged in 10-count blisters packaged in a carton, ASIN B0847BSQQ5, Barcode X002G5GMJ1.	Class I	Drugs	Lot # 26436989, Exp. date 10/30/2023	Marketed Without An Approved NDA/ANDA: Product was found to contain undeclared tadalafil, an ingredient found in FDA approved products for the treatment of male sexual enhancement, making this an unapproved drug.	Your Favorite Shop
ALUM Concentrate (Aluminum Potassium Sulfate Dodecahydrate in Sterile Water (PF) 30 g/300 ml, IV bag, Rx Only, Edge Pharma, LLC, 856 Hercules Dr, Colchester, VT 05446, NDC 05446-0637-03	Class II	Drugs	08-2021-25@2 12/08/2021 09-2021-08@1 12/23/2021 10-2021-20@3 02/01/2022	Lack of Assurance of Sterility	Edge Pharma, LLC
Lidocaine HCl Sterile Buffered Solution for Injection (PF) 1%, 10mL per syringe, Single Use Syringe for Infiltration and Nerve Block, Edge Pharma, LLC, 856 Hercules Dr., Colchester, VT 05446, NDC 05446-0850-10	Class II	Drugs	08-2021-27@3 12/09/2021 09-2021-24@1 01/06/2022 10-2021-14@2 01/31/2022	Lack of Assurance of Sterility	Edge Pharma, LLC
Lidocaine HCl/Epinephrine, Sterile Buffered Solution for Injection (PF) 1% / 1:100,000, 3 mL per syringe, Edge Pharma, LLC, 856 Hercules Dr., Colchester, VT 05446, (802) 992-1178, NDC 05446-1268-01	Class II	Drugs	10-2021-25@4 12/08/2021 11-2021-08@6 12/22/2021	Lack of Assurance of Sterility	Edge Pharma, LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Ceftazidime, Sterile Ophthalmic Solution for Injection, Preservative Free (11.25 mg/0.5 mL (22.5 mg/mL), 0.5mL single use syringe for Intraocular Injection, Edge Pharma, LLC, 656 Hercules Dr., Colchester, VT 05446, NDC 05446-0733-01	Class II	Drugs	09-2021-01@6 12/14/2021 & 10-2021-27@4 01/01/2022	Lack of Assurance of Sterility	Edge Pharma, LLC
Cefuroxime, Sterile Ophthalmic Solution for Injection, Preservative Free, 3mg/0.3mL (10 mg/mL), 0.3 mL single use syringe for Intraocular Injection, Edge Pharma, LLC, 656 Hercules Dr., Colchester, VT 05446 NDC 05446-1003-01	Class II	Drugs	08-2021-30@1 12/20/2021, 09-2021-21@5 01/03/2022 & 10-2021-18@5 02/07/2022	Lack of Assurance of Sterility	Edge Pharma, LLC
Dexamethasone sodium phosphate, sterile otic solution for injection Preservative free, 19.2 mg/0.8mL (24mg/mL), 0.8 mL per syringe Single Use Syringe For Otic Injection, Edge Pharma LLC, 856 Hercules Dr., Colchester, VT 05446, NDC 05446-0848-01	Class II	Drugs	09-2021-28@1 01/10/2022	Lack of Assurance of Sterility	Edge Pharma, LLC
Edetate Disodium (EDTA), Sterile Ophthalmic Solution (PF) 1.5%, 10 mL per dropper, Single Dose Droptainer for Topical Ophthalmic Use, Edge Pharma, LLC, 856 Hercules Dr., Colchester, VT, 05446, NDC 05446-1427-10	Class II	Drugs	10-2021-20@1 02/10/2022	Lack of Assurance of Sterility.	Edge Pharma, LLC
Edetate Disodium (EDTA), Sterile Ophthalmic Solution, (PF) 3%, 10mL per dropper, Single Dose Droptainer for Topical Ophthalmic Use, Edge Pharma, LLC, 856 Hercules Dr., Colchester, VT, 05446, NDC 05446-1428-10	Class II	Drugs	09-2021-22@1 01/04/2022	Lack of Assurance of Sterility	Edge Pharma, LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Epinephrine/Lidocaine HCl Sterile Ophthalmic Solution for Injection, Preservative Free, 0.025%/0.75%, 0.8 mL per syringe, Single Use Syringe, For Intraocular Injection, Edge Pharma, LLC, 856 Hercules Dr. Colchester, VT 05446, NDC 05446-0863-01	Class II	Drugs	10-2021-18@4 12/08/2021& 11-2021-01@3 12/22/2021	Lack of Assurance of Sterility	Edge Pharma, LLC
Gemcitabine, Sterile Intravesical Solution, Preservative Free, 1g/50mL (20 mg/mL), 50 mL per syringe, Single Dose Syringe for Intravesical Use, Edge Pharma, LLC, 856 Hercules Dr., Colchester, VT 05446, NDC 05446-1566-50	Class II	Drugs	08-2021-18@1 12/14/2021, 08-2021-27@1 12/09/2021, 09-2021-01@4 12/14/2021, 09-2021-08@2 12/21/2021, 09-2021-14@6 01/05/2021, 09-2021-16@4 12/29/2021, 09-2021-17@4 12/30/2021, 09-2021-22@3 01/04/2022 & 10-2021-27@3 02/08/2022	Lack of Assurance of Sterility	Edge Pharma, LLC
Lidocaine HCL / Bupivacaine HCL (contains Hyaluronidase 15 units/mL), Sterile Ophthalmic Solution for Injection (PF), 2%/0.375%, 8 mL per syringe, Edge Pharma, LLC, 856 Hercules Dr., Colchester, VT 05446, NDC 05446-1548-18	Class II	Drugs	10-2021-26@3 12/04/2021 11-2021-09@1 12/23/2021	Lack of Assurance of Sterility	Edge Pharma, LLC
Methacholine Challenge 5-Syringe Test Kit, Sterile Inhalation Solution, Preservative Free, 3 mL per syringe,(NDC 05446-1600-05), Kit includes; individual syringe: Methacholine Chloride,16 mg/mL (contains	Class II	Drugs	09-2021-03@6 12/16/2021 & 10-2021-06@7 01/18/2022	Lack of Assurance of Sterility	Edge Pharma, LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
48 mg) NDC 05446-1241-01; Methacholine Chloride 4 mg/mL (contains 12mg), NDC 05446-1246-01; Methacholine chloride 1mg/mL (contains 3 mg), NDC 05446-1247-01; Methacholine chloride 0.25mg/mL (contains 0.75mg), NDC 05446-1248-01; and Methacholine chloride 0.0625mg/mL NDC 05446-1249-01 Edge Pharma, LLC, 856 Hercules Dr., Colchester, VT 05446					
Methotrexate, USP, Sterile Solution for Injection (PF), 125 mg/5mL (2mg/mL), 5 mL per syringe, Edge Pharma, LLC, 856 Hercules Dr, Colchester, VT 05446, NDC 05446-1505-05	Class II	Drugs	09-2021-10@2 12/23/2021, 10-2021-21@2 02/01/2022 & 11-2021-09@5 02/21/2022	Lack of Assurance of Sterility	Edge Pharma, LLC
Mitomycin-C, 40mg/40mL (1mg/mL), 40 mL per syringe, Single Dose Syringe for Intravesical Use, Edge Pharma, LLC, 856 Hercules Dr., Colchester, VT 05446, NDC 05446-1416-01	Class II	Drugs	08-2021-24@5 12/09/2021, 08-2021-27@2 12/21/2021, 08-2021-31@5 12/14/2021, 09-2021-02@2 12/15/2021, 09-2021-09@2 12/22/2021, 09-2021-15@3 12/29/2021, 09-2021-22@2 01/04/2022 & 10-2021-26@5 02/07/2022	Lack of Assurance of Sterility	Edge Pharma, LLC
Mitomycin-C Sterile Ophthalmic Solution, Preservative Free, 0.32mg/0.8 mL (0.4mg/mL) 0.8 mL per syringe, Single Use Syringe, For Topical Ophthalmic Use, Edge	Class II	Drugs	11-2021-08@8 12/18/2021	Lack of Assurance of Sterility	Edge Pharma, LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Pharma LLC, 856 Hercules Dr. Colchester, VT 05446, NDC 05446-1009-01					
Mitomycin-C, Sterile Ophthalmic Solution, Preservative Free, 0.16mg/0.8mL (0.2 mg/mL), 0.8 mL per syringe, Single Use Syringe, For Topical Ophthalmic Use, Edge Pharma, LLC, 856 Hercules Dr., Colchester, VT 05446, NDC 05446-1011-01	Class II	Drugs	11-2021-08@9 12/18/2021	Lack of Assurance of Sterility	Edge Pharma, LLC
Moxifloxacin, Sterile Ophthalmic Solution for Injection, Preservative Free, 0.8mg/0.8 mL (1mg/mL), 0.8 mL per syringe, Single Use Syringe, For Intraocular Injection, Edge Pharma, LL, 856 Hercules Dr., Colchester, VT 05446, NDC 05446-1050-01	Class II	Drugs	08-2021-26@2 12/09/2021 & 09-2021-23@1 01/05/2022	Lack of Assurance of Sterility	Edge Pharma, LLC
Neostigmine methylsulfate, 5 mg/5mL (1 mg/mL), 5 mL per syringe, Single Use Syringe for IV or IM Injection, Edge Pharma, LLC, 856 Hercules Dr. Colchester, VT 05446, NDC 05446-1549-05	Class II	Drugs	10-2021-07@1 01/19/2022	Lack of Assurance of Sterility	Edge Pharma, LLC
MVASI, (bevacizumab-awwb), Sterile Ophthalmic Solution for Injection, 3.25mg/0.13mL (25 mg/mL) 0.13 mL per syringe, Dose: 1.25mg/0.05mL, Single Use Syringe For Intraocular Injection, Edge Pharma, LLC, 856 Hercules Dr. Colchester, VT 05446, NDC 05446-1661-13	Class II	Drugs	11-2021-01@2 12/15/2021	Lack of Assurance of Sterility	Edge Pharma, LLC
Phenol, Sterile Solution for Injection (PF), 6%, 5 mL per vial, Single Use Vial for Perineural Injection, Edge Pharma, LLC, 856	Class II	Drugs	09-2021-14@5 12/29/2021, 10/21/21 & 11-2021-04@2, 02/15/2022	Lack of Assurance of Sterility	Edge Pharma, LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Hercules Dr., Colchester, VT 05446, NDC 05446-1476-05, packaged in vials.					
Phenylephrine HCl / Tropicamide / Ciprofloxcin / Ketorolac Sterile Ophthalmic Solution, 10%/1%/0.3%/0.125%, 0.8 mL per syringe, Single Use Syringe, For Topical Ophthalmic Use, Edge Pharma, LLC, 856 Hercules Dr., Colchester, VT 05446, NDC 05446-1270-01	Class II	Drugs	08-2021-31@8 12/21/2021 & 10-2021-13@1 01/19/2022	Lack of Assurance of Sterility	Edge Pharma, LLC
Phenylephrine HCl 0.5 mg/5mL, (0.1 mg/mL), 5 mL per syringe, Single Use Syringe for IV Injection, Edge Pharma, LLC, 856 Hercules Dr, Colchester, VT 05446, NDC 05446-1545-05	Class II	Drugs	09-2021-09@4 12/22/2021 & 10-2021-14@1 01/26/2022	Lack of Assurance of Sterility	Edge Pharma, LLC
Phenylephrine HCl, 1mg/10mL (0.1mg/mL), 10 mL per syringe, Single Use Syringe for IV Injection, Edge Pharma, LLC, 856 Hercules Dr, Colchester, VT 05446 NDC 05446-1544-10	Class II	Drugs	08-2021-26@3 12/16/2021, 09-2021-16@5 12/29/2021, 10-2021-07@2 01/19/2022 & 10-2021-22@1 02/03/2022.	Lack of Assurance of Sterility	Edge Pharma, LLC
Phenylephrine HCl, Sterile Solution for Injection, (PF), 800 mcg/10mL (80 mcg/mL), Single Use Syringe for IV Injection, Edge Pharma, LLC 856 Hercules Dr., Colchester, VT 05446, NDC 05446-1652-01	Class II	Drugs	08-2021-27@4 12/09/2021, 09-2021-17@1 12/30/2021, 10-2021-15@1 01/27/2022 & 10-2021-28@1 02/09/2022	Lack of Assurance of Sterility	Edge Pharma, LLC
PHENYLephrine, 0.9% Sodium Chloride Injection, USP, 20 mg/250mL, (0.08 mg/mL), Single use bag for IV injection (Preservative Free), Rx Only, Edge Pharma, LLC, 856	Class II	Drugs	08-2021-24@6 12/06/2021, 08-2021-31@7 12/12/2021, 09-2021-07@3 12/21/2021,	Lack of Assurance of Sterility	Edge Pharma, LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Hercules Dr, Colchester, VT NDC 05446-1667-01			10-2021-20@2 02/02/2022 & 10-2021-28@2 02/10/2022.		
Phenylephrine HCl/Lidocaine, Sterile Ophthalmic Solution for Injection, Preservative Free, 1.5%/1%, 0.8mL per syringe, Single Use Syringe For Intraocular Injection, Edge Pharma LLC, 856 Hercules Dr, Colchester, VT 05446, NDC 05446-1118-01	Class II	Drugs	09-2021-16@1 12/29/2021	Lack of Assurance of Sterility	Edge Pharma, LLC
Phenylephrine HCl/Tropicamide, Sterile Ophthalmic Solution, 2.5%/1%, 15 mL per dropper, Multiple Dose Droptainer for Topical Ophthalmic Use, Edge Pharma, LLC, 856 Colchester, VT 05446, NDC 05446-0815-01	Class II	Drugs	09-2021-15@1 12/28/2021	Lack of Assurance of Sterility	Edge Pharma, LLC
Phenylephrine HCl/Tropicamide/Cyclopentolate HCl/Ketorolac Sterile Ophthalmic Solution, 2.5%/0.25%/0.25%/0.125%, 0.5 mL syringe, Single Use Syringe, For Topical Ophthalmic Use, NDC 05446-0993-01	Class II	Drugs	09-2021-15@2 12/28/2021 & 11-2021-02@3 02/14/2022	Lack of Assurance of Sterility	Edge Pharma, LLC
Phenylephrine HCl/Tropicamide/Cyclopentolate HCl/ Ketorolac Sterile Ophthalmic Solution, 10%/ 0.25%/ 0.25%/0.125%, 10 mL per dropper, Multiple Dose Droptainer for Topical Ophthalmic Use, Edge Pharma, LLC, 856 Hercules Dr., Colchester, VT, NDC 05446-0859-03	Class II	Drugs	11-2021-02@2 12/16/2021	Lack of Assurance of Sterility	Edge Pharma, LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Betadine (povidone-iodine), Sterile Ophthalmic Solution, Preservative Free, 5% 0.5mL per syringe, Single Use Syringe, For Topical Ophthalmic Use, Edge Pharma, LLC, 656 Hercules Dr., Colchester, VT 05446, NDC 05446-1680-01	Class II	Drugs	10-2021-25@5 12/09/2021	Lack of Assurance of Sterility	Edge Pharma, LLC
Vancomycin HCl, Sterile Ophthalmic Solution for Injection, Preservative Free, 8 mg/0.8mL (10 mg/mL) (vancomycin equivalent), 0.8 mL per syringe, Single Use Syringe, For Intraocular Injection, Edge Pharma LLC, 856 Hercules Dr., Colchester, VT, 05446, NDC 05446-0736-01	Class II	Drugs	08-2021-31@2 12/12/2021 & 09-2021-20@4 01/02/2022	Lack of Assurance of Sterility	Edge Pharma, LLC
"Vancomycin HCl in 0.9 % Sodium Chloride Injection, USP, 1,250 mg/250 mL, Single Use Bag for IV Injection (Preservative Free), 250 mL pre-filled bag, Edge Pharma, LLC, 856 Hercules Dr., Colchester, VT 05446,	NDC 05446-1456-01"	Class II	Drugs	09-2021-13@3 12/27/2021 & 09-2021-30@5 01/13/2022	Lack of Assurance of Sterility
Vancomycin HCl in 0.9% Sodium Chloride Injection, 1,500 mg/500 mL, USP, Single Use Bag for IV Injection (Preservative Free), 500 mL pre-filled bag, Edge Pharma, LLC, 856 Hercules Dr., Colchester, VT 05446, NDC 05446-1458-01	Class II	Drugs	08-2021-26@4 12/08/2021 & 09-2021-21@3 01/04/2022	Lack of Assurance of Sterility	Edge Pharma, LLC
Vancomycin HCl in 0.9% Sodium Chloride Injection, USP, 1,750mg/500mL, Single Use Bag for IV Injection (Preservative Free), 500 mL pre-filled bag, Rx Only, Edge Pharma, LLC, 856 Hercules Dr., Colchester, VT 05446 NDC 05446-1459-01	Class II	Drugs	09-2021-09@6 12/23/2021 & 10-2021-13@5 01/27/2022	Lack of Assurance of Sterility	Edge Pharma, LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
BLT Topical Cream, Benzocaine/Lidocaine/Tetracaine, 20%/8%/4%, 60gm per jar, Multiple Dose Container For Topical Use, Edge Pharma, LLC, 856 Hercules Dr., Colchester, VT, 05446, NDC 05446-1235-01	Class II	Drugs	06-2021-10@11 12-07-2021, 06-2021-10@9 12-07-2021, 06-2021-17@6 12-14-2021, 06-2021-17@7 12-14-2021, 06-2021-24@5 12-21-2021, 06-2021-24@8 12-21-2021, 07-2021-01@6 12-28-2021, 07-2021-01@7 12-28-2021, 07-2021-09@5 01-01-2022, 07-2021-09@6 01-05-2022, 07-2021-15@5 01-01-2022, 07-2021-15@6 01-01-2022, 07-2021-22@16 01-19-2022, 07-2021-22@8 01-01-2022, 07-2021-29@12 01-25-2022, 07-2021-29@24 01-25-2022, 08-2021-05@7 02-01-2022, 08-2021-05@8 02-01-2022, 08-2021-19@7 02-15-2022, 08-2021-19@8 02-15-2022, 08-2021-26@5 02-22-2022, 09-2021-01@10 02-28-2022, 09-2021-03@7 03-02-2022, 09-2021-09@7 03-08-2022, 09-2021-16@7 03-15-2022,	CGMP Deviations	Edge Pharma, LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			09-2021-17@7 03-16-2022, 09-2021-22@8 03-21-2021, 09-2021-23@2 03-22-2022, 09-2021-23@3 03-22-2022, 09-2021-30@10 03-29-2022, 09-2021-30@8 03-29-2022, 10-2021-07@10 04-05-2022, 10-2021-07@7 04-05-2022, 10-2021-08@1 04-06-2022, 10-2021-14@4 04-12-2022, 10-2021-14@5 04-12-2022, 10-2021-21@7 04-19-2022 & 10-2021-28@3 04-26-2022		
Cantharidin Gel-Forming Suspension, 0.7%, 10 mL per vial, Multiple Dose Vial for Topical Use, Edge Pharma, LLC, 856 Hercules Dr., Colchester, VT 05546 NDC 05446-0572-03	Class II	Drugs	06-2021-11@6 12-08-2021, 07-2021-08@13 01-04-2022, 08-2021-06@6 02-02-2022, 08-2021-20@10 02-16-2022, 08-2021-26@6 02-22-2022, 08-2021-27@7 02-23-2022, 09-2021-02@5 03-01-2022, 09-2021-17@8 03-16-2022 & 09-2021-29@12 03-28-2022	CGMP Deviations	Edge Pharma, LLC
Cantharidin PLUS, Cantharidin/Salicylic Acid Gel-Forming Suspension, 10 mL per vial, Multiple Dose Vials for Topical Use, Edge	Class II	Drugs	06-2021-09@9 12-06-2021, 06-2021-16@11 12-13-2021, 06-2021-23@7	CGMP Deviations	Edge Pharma, LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Pharma, LLC, 856 Hercules Dr., Colchester, VT, 05446, NDC 05446-0970-03			12-20-2021, 06-2021-30@11 12-27-2021, 07-2021-07@9 01-03-2022, 07-2021-13@6 01-09-2021, 07-2021-14@5 01-10-2022, 07-2021-21@8 01-17-2022, 07-2021-26@10 01-22-2022, 08-2021-04@5 01-31-2022, 08-2021-09@11 02-05-2022, 08-2021-10@6 02-06-2022, 08-2021-17@5 02-13-2022, 08-2021-25@4 02-21-2022, 09-2021-01@8 02-28-2022, 09-2021-08@8 03-07-2022, 09-2021-15@6 03-14-2022, 09-2021-21@8 03-20-2022, 09-2021-27@10 03-26-2022, 10-2021-06@8 04-04-2022, 10-2021-13@7 04-11-2022, 10-2021-20@7 04-18-2022, 10-2021-20@9 04-18-2021 & 10-2021-26@9, 04-24-2022		
CSF Otic Insufflation Capsule, Sulfacetamide Sodium/ Ciprofloxacin/ Amphotericin B Otic Powder, 50mg / 30mg / 5mg, 5 count bottle, For Otic Use with Insufflator, Edge Pharma,	Class II	Drugs	10-2021-27@8 01-25-2022	CGMP Deviations	Edge Pharma, LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
LLC 856 Hercules Dr., Colchester, VT 05446, NDC 05446-1633-05					
"CSF-HC Otic Insufflation Capsule, Sulfacetamide Sodium/Ciprofloxacin/Hydrocortisone/Amphotericin B Otic Powder, 50mg/ 30mg/ 25mg/ 5mg, 5 count bottle, Edge Pharma, LLC, 856 Hercules Dr., Colchester, VT 05446, NDC	05446-1634-01 "	Class II	Drugs	10-2021-05@9 01-01-2022 & 10-2021-28@4 01-26-2022	CGMP Deviations
Dexamethasone sodium phosphate 0.4%, 120 mL per bottle, Multiple Dose Container For Topical Use, Edge Pharma, LLC, 856 Hercules Dr., Colchester, VT 05446, NDC 05446-0622-01	Class II	Drugs	06-2021-23@6 12-20-2021, 09-2021-15@4 03-14-2022 & 10-2021-04@10 04-02-2022	CGMP Deviations	Edge Pharma, LLC
Dibutyl Squaric Acid, Topical Solution (PF), Multiple Dose Vial, 2%, 10 mL per vial, Edge Pharma, LLC, 856 Hercules Dr, Colchester VT, 05446, NDC 05446-1047-03	Class II	Drugs	09-2021-15@5 12-14-2021 & 10-2021-01@4 12-30-2021	CGMP Deviations	Edge Pharma, LLC
Dibutyl Squaric Acid, Topical Solution (PF) Multiple Dose Vial, 1%, 10 mL per vial, Edge Parma, LLC, 856 Hercules Dr., Colchester, VT 05446, NDC 05446-1156-03	Class II	Drugs	08-2021-03@8 12-31-2021 & 09-2021-07@10 02-04-2022	CGMP Deviations	Edge Pharma, LLC
LT Topical Cream, Lidocaine/Tetracaine, 23%/7%, 60gm per jar, Multiple Dose Container for Topical Use, Edge Pharma, LLC, 856 Hercules, VT, Colchester, VT 05446, NDC 05446-1647-01	Class II	Drugs	08-2021-23@9 02-19-2022, 09-2021-07@13 03-06-2022 & 10-2021-22@5 04-20-2022.	CGMP Deviations	Edge Pharma, LLC
LET Topical Gel, Lidocaine HCL / Epinepherine / Tetracaine HCl, 4%/0.05%/0.5%, 3 mL per syringe, Single	Class II	Drugs	07-2021-12@6 12-09-2021, 07-2021-19@7 12-16-2021, 07-2021-26@5	CGMP Deviations	Edge Pharma, LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Dose Syringe for Topical Use, Edge Pharma, LLC, 856 Hercules Dr. Colchester, VT, NDC 05446-0607-01			12-23-2021, 08-2021-02@8 12-30-2021, 08-2021-09@10 01-06-2022, 08-2021-13@6 01-10-2022, 08-2021-18@4 01-15-2022, 08-2021-24@8 01-21-2022, 08-2021-30@5 01-27-2022, 09-2021-07@11 02-04-2022, 09-2021-13@5 02-10-2022 & 10-2021-04@9 03-03-2022.		
Lidocaine HCl / Oxymetazoline HCl Nasal Solution, 4% / 0.05%, 240mL per bottle, Multiple Dose Container for Intranasal Use, Edge Pharma, LLC, 856 Hercules Dr., Colchester, VT 05446, NDC 05446-1256-01, packaged in bottles. no label	Class II	Drugs	06-2021-18@3 12-15-2021 07/07/21 - 07/22/21 06-2021-30@10 12-27-2021 07/20/21 - 08/17/21 07-2021-14@4 01-10-2022 08/05/21 - 08/20/21 07-2021-21@4 01-17-2022 08/23/21 - 09/16/21, 07-2021-28@9 01-24-2022 09/13/21 - 10/05/21 08-2021-12@8 02-08-2022 10/01/21 - 10/19/21 08-2021-24@9 02-20-2022 10/19/21 - 11/11/21 09-2021-09@10 03-08-2022 11/10/21 - 11/30/21 10-2021-05@6 04-03-2022 11/30/21	CGMP Deviations	Edge Pharma, LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Profound Dental Gel, Lidocaine HCl/Prilocaine HCl/Tetracaine HCl, 10%/10%/4% Raspberry Marshmallow, 30 grams per jar, Multiple Dose Container For Topical Oral Use,Edge Pharma LLC, 856 Hercules Dr. Colchester, VT 05446, NDC 05446-0790-10	Class II	Drugs	07-2021-20@7 01-16-2022, 08-2021-11@6 02-07-2022, 08-2021-31@11 02-01-2022, 09-2021-14@11 02-01-2022, 09-2021-21@6 02-01-2022 & 10-2021-12@4 04-10-2022.	CGMP Deviations	Edge Pharma, LLC
Profound Dental Gel, Lidocaine HCl/Prilocaine HCl/Tetracaine HCl, 10% / 10% / 4%, Spearmint-Peppermint, Multiple Dose Container for Topical Oral Use, Edge Pharma, LLC, 856 Hercules Dr. Colchester, VT NDC 05446-0407-10	Class II	Drugs	08-2021-16@12 02-01-2022 09/21/21 - 10/19/21 09-2021-13@8 02-01-2022 11/04/21 - 11/17/21 09-2021-29@8 03-01-2022 10/18/21 - 11/11/21 10-2021-26@7 04-24-2022 11/17/21 - 12/01/21	CGMP Deviations	Edge Pharma, LLC
Profound-PE Dental Gel, Lidocaine HCl/ Prilocaine HCl/ Tetracaine HCl/ Phenylephrin HCl, 10% / 10% / 4% / 2% Raspberry-Marshmallow, Multiple Dose Container for Topical Oral Use, Edge Pharma, LLC, 856 Hercules Dr. Colchester, VT NDC 05446-1018-10	Class II	Drugs	06-2021-29@15 12-26-2021, 07-2021-12@7 01-08-2022, 08-2021-03@7 01-30-2022, 08-2021-25@5 02-01-2022, 09-2021-10@4 02-01-2022, 09-2021-22@6 03-01-2022 & 10-2021-06@11 04-04-2022	CGMP Deviations	Edge Pharma, LLC
Profound-PE Dental Gel, Lidocaine HCl/Prilocaine HCl/Tetracaine HCl/Phenylephrine, 10% / 10% / 4% / 2%, Spear-Peppermint, Multiple Dose Container for Topical Oral Use, 30 grams per jar, Edge	Class II	Drugs	07-2021-13@7 01-09-2022 08/24/21 - 10/06/21 07-2021-27@8 01-23-2022 10/06/21 - 11/02/21	CGMP Deviations	Edge Pharma, LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Pharma, LLC, 856 Hercules Dr., Colchester, VT, 05446, NDC 05446-0408-10			08-2021-10@5 02-01-2022 10/28/21 - 12/01/21		
Phenol, Topical Solution (PF) Multiple Dose Vial, 89%, 3 mL per vial, Edge Pharma, LLC, 856 Hercules Dr., Colchester, VT, NDC 05446-1211-03	Class II	Drugs	07-2021-12@9 01-08-2022 07/22/21 - 08/11/21 08-2021-11@10 02-07-2022 08/25/21 - 09/10/21 08-2021-12@12 02-08-2022 09/07/21 - 10/06/21 09-2021-22@5 03-21-2022 10/12/21 - 10/28/21 10-2021-07@8 04-05-2022 10/25/21 - 10/28/21 10-2021-08@4 04-06-2022 10/28/21 - 11/12/21 11-2021-01@7 04-30-2022 11/15/21 - 12/01/21	CGMP Deviations	Edge Pharma, LLC
Lidocaine HCl/Phenylephrine HCl Nasal Solution, 4%/1%, 240 mL per bottle, Multiple Dose Container, Edge Pharma, LLC 856 Hercules Dr., Colchester, VT 05446, NDC 05446-1045-03	Class II	Drugs	07-2021-02@7 12-29-2021, 07-2021-23@4 01-19-2022, 08-2021-11@7 02-07-2022, 08-2021-23@8 02-19-2022 & 09-2021-24@10 03-23-2022	CGMP Deviations	Edge Pharma, LLC
Vitamin K (Vitamin K) Oral Solution (PF), 5 mg/mL, 1mL per syringe, single Dose Syringe for Oral Use, Edge Pharma, LLC, 856 Hercules Dr., Colchester, VT 05446, NDC 05446-1132-03	Class II	Drugs	10-2021-11@6 01-09-2022 10/27/21 - 11/16/21 11-2021-01@8 01-30-2022 11/16/21 - 12/01/21	CGMP Deviations	Edge Pharma, LLC
Promethazine HCl Topical Ointment, 2.5% (25 mg/mL), 1.2 mL per syringe, Single Dose Syreinge for Topical Use Only, Edge Pharma,	Class II	Drugs	08-2021-02@9 12-15-2021, 08-2021-16@10 12-29-2021, 09-2021-08@6	CGMP Deviations	Edge Pharma, LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
LLC, 856 Hercules Dr., Colchester, VT 05446, NDC 05446-1341-01			01-21-2022, 09-2021-20@6 02-02-2022 & 10-2021-18@6 03-02-2022		
Tetracaine HCl Nasal Solution, 4%, 240 mL per bottle, Multiple Dose Container for Intranasal Use, Edge Pharma, LLC, 856 Hercules Dr., Colchester, VT, 05446, NDC 05446-1195-03, packaged in bottles.	Class II	Drugs	06-2021-08@5 12-05-2021, 07-2021-07@7 01-03-2022, 07-2021-27@10 01-23-2022 & 10-2021-06@12 04-04-2022	CGMP Deviations	Edge Pharma, LLC
Vancomycin HCl Oral Solution (PF) 125mg / 2.5mL (50 mg/mL), 2.5 mL per syringe, Single Dose Syringe for Oral Use Only, Edge Pharma, LLC, 856 Hercules Dr., Colchester, VT 05446, NDC 05446-1348-01	Class II	Drugs	09-2021-10@3 12-09-2021, 09-2021-17@6 12-16-2021, 09-2021-24@8 12-23-2021, 09-2021-30@7 12-29-2021 & 10-2021-13@6 01-11-2022 .	CGMP Deviations	Edge Pharma, LLC
Trypan Blue 0.03%, 0.5mL per syringe, Sterile Ophthalmic Solution for Injection Preservative Free, Single Use Syringe, For Intraocular Injection, Edge Pharma, LLC, 856 Hercules Dr., Colchester, VT 05446, NDC 05446-1348-01	Class II	Drugs	09-2021-10@3 12-09-2021, 09-2021-17@6 12-16-2021, 09-2021-24@8 12-23-2021, 09-2021-30@7 12-29-2021 & 10-2021-13@6 01-11-2022 .	CGMP Deviations	Edge Pharma, LLC
Metformin Hydrochloride Extended-Release Tablets, USP 750 mg, 100 count HDPE bottles NDC# 72578-036-01	Class II	Drugs	M008130 06/2022, M008131 06/2022, M008132 06/2022, M008133 06/2022, M010080 07/2022, M010081 07/2022, M011029 08/2022, M011030 08/2022, M011031 08/2022, M011032 08/2022,	CGMP Deviations- Detection of N-Nitrosodimethylamine (NDMA) levels in excess of the Acceptable Daily Intake Limit.	VIONA PHARMACEUTICALS INC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			M011304 08/2022, M013394 09/2022, M013395 09/2022, M013396 09/2022, M013966 09/2022, M013967 09/2022, M100831 12/2022, M100832 12/2022, M100833 01/2023, M100834 01/2023, M101267 01/2023, M102718 01/2023, M102719 01/2023		
Pioglitazone Tablets USP, 45 mg, 500 count bottles, Distributed by: Aurobindo Pharma USA, Inc., East Windsor, NJ -- NDC 57237-221-05	Class II	Drugs	Batch # PF4520028B & PF4520028A, Exp. Date 11/2022	Superpotent and Failed Tablet/Capsule Specifications	Aurobindo Pharma USA Inc.
Metoprolol Succinate Extended-Release Tablets, USP 50 mg, 500-count bottle, Rx Only, Manufactured by: Alkem Laboratories Ltd., Mumbai - 400 013 INDIA. NDC 68001-501-03	Class II	Drugs	Lots# 21141983, 21141984 and 21141985, Exp 03/31/2023; Lots# 21142017, 21142018, 21142019, Exp 02/28/2023	Failed Dissolution Specifications	American Health Packaging
Metoprolol Succinate Extended-Release Tablets, USP, 25 mg, Rx Only, 100 Tablets per bottle, Manufactured by: Alkem Laboratories Ltd., Mumbai - 400 013, India, Distributed by: Ascend Laboratories, LLC, Parsippany, NJ, 07054, NDC 67877-590-01.	Class II	Drugs	Lot #: 21143093, Exp. March 2023	Failed Dissolution Specifications.	Ascend Laboratories, LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Proctofoam HC (hydrocortisone acetate 1% and pramoxine hydrochloride 1%) topical aerosol, 10 g aerosol containers, Rx Only, Distributed by Meda Pharmaceuticals Inc, Somerset, New Jersey 08873-1120, NDC 0037-6822-10.	Class II	Drugs	Lot #: 32925, Exp. date May 2023, 33010, Exp. date June 2023; 33119, 33123, Exp. date August 2023	cGMP deficiencies	Mylan Pharmaceuticals Inc
Brinzolamide Ophthalmic Suspension, USP 1%, packaged as a)10 ml dropper bottles (NDC 0591-2127-79), and b) 15 ml dropper bottles (NDC 0591-2127-12), Rx Only, Manufactured in India By: Indoco Remedies Limited Verna, Goa - 403722, India, Manufactured For: Teva Pharmaceuticals USA, Inc. Parsippany, NJ	Class II	Drugs	Lots: a)BCB1LB2, BCB2LB2, BCB7LB2, Exp. 11/2022; Lots: BCB11AC2, BCB12AC2, BCB3AC2, BCB4AC2, BCB5AC2, BCB6AC2, BCB10AC2, Exp. 12/2022; b) Lots: BCB4LB2, BCB5LB2, Exp. 11/2022; Lots: BCB1AC2, BCB2AC2, Exp. 12/2022; Lots: BCB1DC2, BCB2DC2, Exp. 03/2023	Defective Container: The notch in the cap that fits into the nozzle of the dropper could break off and block the dropper possibly resulting in the product not dispensing.	Teva Pharmaceuticals USA
Red Blood Cells, Leukocytes Reduced, Irradiated	Class II	Biologics	W051721615950	Blood products, collected from a donor whose arm preparation was not performed in a manner that ensures sterility, were distributed.	Rhode Island Blood Center, A Division of New York Blood Center, Inc.
Pooled Cryoprecipitate AHF	Class II	Biologics	W0517218058281	Blood products, collected from a donor whose arm preparation was not performed in a manner that ensures sterility, were distributed.	Rhode Island Blood Center, A Division of New York Blood Center, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Red Blood Cells, Leukocytes Reduced	Class II	Biologics	W202021551300	Blood product, collected in a manner that may have compromised the sterility of the collection system, was distributed.	American National Red Cross (The), Lewis and Clark Region
Apheresis Platelets, Platelet Additive Solution Added, Leukocytes Reduced	Class II	Biologics	W201121879707006	Leukoreduced Apheresis Platelets, Platelet Additive Solution Added, which were labeled as leukocytes reduced but were not tested to verify white blood cell count, were distributed.	American Red Cross Blood Services
Apheresis Platelets, Leukocytes Reduced, Irradiated	Class II	Biologics	W200921815241001 (Double Collection); W200921815253000; W200921815254000; W200921815255000 (Double Collection); W200921815306000*	Blood Products, not tested for pH, were distributed.	American Red Cross Biomedical Services
Apheresis Platelets, Platelet Additive Solution Added, Leukocytes Reduced	Class II	Biologics	W200921815214007 (Double Collection); W200921815218000*(Double Collection); W200921815219000; W200921815221009; W200921815223005 (Double Collection); W200921815229000 (Double Collection); W200921815233001 (Double Collection);	Blood Products, not tested for pH, were distributed.	American Red Cross Biomedical Services

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			W20092181523400*; W20092181523500Y (Double Collection); W20092181523600W (Double Collection); W20092181523900Q (Triple Collection); W20092181524400W; W20092181524600S (Double Collection); W20092181524700Q (Triple Collection); W20092181525400S; W20092181525700M; W20092181526500M (Double Collection); W20092181527100Q; W20092181527200O; W20092181528700A (Double Collection); W20092181529400C (Triple Collection); W20092181529500A; W200921815296008 (Double Collection); W200921815299002 (Double Collection); W20092181530000B; W200921815301009 (Triple Collection);		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			W200921815303005; W200921815304003 (Triple Collection); W20092181530600*; W200921815311005; W200921815313001(Triple Collection); W20092181531700U; W200921815231005; W20092181526200S; W20092181527500I; W20092181528400G; W200921815288008; W200921815298004 (Double Collection); W200921815302007 (Double Collection); W200921815312003		
Apheresis Platelets, Platelet Additive Solution Added, Leukocytes Reduced	Class II	Biologics	W202921802079 00J	Leukoreduced Apheresis Platelets, Platelet Additive Solution Added, which were labeled as leukocytes reduced but were not tested to verify white blood cell count, were distributed.	American Red Cross Blood Services Mid Atlantic Region
Pooled Cryoprecipitated AHF	Class II	Biologics	W205321988819007	Blood products, for which donor eligibility screening was incomplete, were distributed.	American Natl. Red Cross-Greater Chesapeake & Potomac Region

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Apheresis Platelets, Platelet Additive Solution Added, Leukocytes Reduced	Class II	Biologics	W239921004886	Leukoreduced Apheresis Platelets, Platelet Additive Solution Added, which were labeled as leukocytes reduced but were not tested to verify white blood cell count, were distributed.	One Blood Inc
Apheresis Red Blood Cells, Leukocytes Reduced	Class II	Biologics	W200318378607006 (Double Collection)	Misbranded Blood Products were distributed.	The American National Red Cross - Southern Region
Red Blood Cells, Leukocytes Reduced	Class II	Biologics	W200318370918OOU	Misbranded Blood Products were distributed.	The American National Red Cross - Southern Region
Apheresis Red Blood Cells, Leukocytes Reduced	Class II	Biologics	W202021464182 (double collection)	Apheresis Red Blood Cell products, for which quality control for residual WBC count was not performed, were distributed.	American National Red Cross (The), Lewis and Clark Region
Apheresis Platelets, Leukocytes Reduced, Irradiated	Class II	Biologics	W201121872683OOS; W201121863275002; W201121863275002; W201121863275002; W201121863277OOZ; W201121863277OOZ; W201121872683OOS; W201121872683OOS;	Blood products, which did not meet quality control specifications, were distributed.	American Red Cross Blood Services

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Apheresis Platelets, Platelet Additive Solution Added, Leukocytes Reduced	Class II	Biologics	W201121863269002 (Triple Collection)	Leukoreduced Apheresis Platelets, Platelet Additive Solution Added, not tested for pH, were distributed.	American Red Cross Blood Services
Apheresis Red Blood Cells, Leukocytes Reduced	Class II	Biologics	W204221307102000 (double collection)	Misbranded Red Blood Cell products were distributed.	American National Red Cross
Red Blood Cells, Leukocytes Reduced	Class II	Biologics	W204221352102000	Misbranded Red Blood Cell products were distributed.	American National Red Cross
Apheresis Platelets, Platelet Additive Solution Added, Leukocytes Reduced	Class II	Biologics	W205321836702 (Double Collection)	Leukoreduced Apheresis Platelets, Platelet Additive Solution Added, which were labeled as leukocytes reduced but were not tested to verify white blood cell count, were distributed.	American Natl. Red Cross-Greater Chesapeake & Potomac Region
Apheresis PF24 Plasma	Class II	Biologics	W201221838292	Blood product, which was not quarantined subsequent to receiving information regarding a post donation illness, was distributed.	American National Red Cross (The) Carolinas Region
Apheresis Platelets, Platelet Additive Solution Added, Leukocytes Reduced	Class II	Biologics	W203621855282	Plateletpheresis, not meeting product specifications, was distributed.	The American National Red Cross - Southern Region
Red Blood Cells, Leukocytes Reduced	Class II	Biologics	W121621272767; W121621272775; W121621272781; W121621272769;	Leukoreduced Red Blood Cells, which were made from a unit not stored at the correct temperature, were distributed.	The Blood Connection, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			W121621272777; W121621272779; W121621272780		
Red Blood Cells, Leukocytes Reduced	Class II	Biologics	W333419023234	Red Blood Cell product, collected from a donor who was taking antibiotics, was distributed.	Mississippi Valley Regional Blood Center
Red Blood Cells, Leukocytes Reduced	Class II	Biologics	W036220132787001	Misbranded Leukoreduced Red Blood Cells were distributed.	Vitalant
Apheresis Platelets, Leukocytes Reduced	Class II	Biologics	W115121212291V	Leukoreduced Apheresis Platelets, in which the platelet yield did not meet specifications, were distributed.	Lifesouth Community Blood Centers - Montgomery Region
Apheresis Platelets, Leukocytes Reduced	Class II	Biologics	W115121235857N	Plateletpheresis, for which platelet yield did not meet product specifications, was distributed.	Lifesouth Community Blood Centers - Montgomery Region
Apheresis Platelets, Leukocytes Reduced	Class II	Biologics	W115121263630Y	Leukoreduced Apheresis Platelets, in which the platelet yield did not meet specifications, were distributed.	LifeSouth Community Blood Centers Inc
Pooled Cryoprecipitated AHF	Class II	Biologics	W20042099443500Y, W20042099443600W, W20042099445100Y, W20042099445200W, W20042099446100U, W20042099448700A, W20042099480300I,	Blood products, collected in a manner that may have compromised the sterility of the collection system, were distributed.	American Red Cross Blood Services - Massachusetts Region

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			W200420994826004, W200420994835002, W20042099488200P, W20042099491900V, W20042099493400X, W20042099494400T, W200420994996005, W200420995071005, W20042099509700M, W20042099510600F, W20042099511300H, W200420995117009, W200420995118007, W200420995134007, W20042099507900Q, W20042099508700Q, W20042099509800K W20042099510500H, W20042099510700D, W20042099510800B, W20042099511600B, W200420995119005, W200420995125009, W20042099534300Q, W20042099535700E, W20042099536700A, W20042099540600S, W20042099542200S, W20332011749500K, W200420995866009,		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			W200420995882009, W200420995883007, W20042099588900W, W20042099590200X, W20042099592400L, W200420996782001, W200420996818009, W20042099687300W, W20042099678700S, W20042099685800U, W20042099686900O, W20042099687100*, W20042099687600Q, W20042099688300S, W20042099688800I, W20042099689700G, W20042099690300F, W200420996909003, W20332012596800N, W200420997058004, W200420997137006, W200420997139002, W200420997148000, W20042099718300V, W20042099715700Z, W20042099720300I, W200420997233006, W20042199774100N, W200421997765007, W20042199781100R,		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			W200421997930000D, W200421997940009, W200421997941007, W200421997942005, W200421997962000Y, W200421997965000S, W200421997996000E, W200421997969000K, W200421997990000Q, W200421998020000*, W200421998044000K, W200421998049000A, W200421998084004, W200421998147006, W200421998059006, W200421998066008, W200421998252004, W200421998268000P, W200421900029000R, W200421900033000Z, W200421900054000P, W200421900076000D, W200421900077000B, W200421900078009, W200421900028000T, W200421900114000X, W200421900155000F, W203320142109000J, W203320142117000J W200421900308000D,		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			W20042190031000P, W20042190031600D, W20042190033000H, W20042190033200D, W20042190035900S, W20042190036005, W20042190036400Y, W20332115812200S, W20042199869400Q, W20042199869700K, W20042199871200H W20042199871500B, W20042199871600S, W20042199871800S, W20042199872100F, W20042199902000K, W20042199902900T, W20042199906600T, W20042199899800V, W20042199903200C, W20042199903800S, W20042199904700Z, W20042199905000S W20042199905500Z, W20042199930004, W20042199930700R, W20042199930900N, W20042199932400P, W20042199953800Y, W20042199958500K,		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			W20042199940900F, W20042199942000P, W20042199943500B, W200421999437007, W200421999460009, W20042190050800Y, W20042190053900K, W200421900051800U, W20042190055600I, W200421900682006, W20042190063600I, W20042190064300K, W200421900640000Q, W200421900766002, W200421900770006, W200421900801000, W200421900813000G, W20042190085500X, W200421900899009, W200421900931004, W200421900934002, W200421900937001, W200421900948001N, W200421900982001J, W200421901038009, W200421901048005, W200421901226001, W200421901264000Q, W200421902118001U W200421902125001W,		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			W200421902151005, W200421902150000, W200421902327000, W200421902340000, W200421902380002, W200421902195004, W200421902280000, W200421902268002, W200421902349000, W200421902420000, W200421902260000 W200421902328000, W200421902334000, W200421902383000, W200421902419004		
Plasma Frozen, Cryoprecipitate Reduced	Class II	Biologics	W200421902445000, W200421902455000	Blood products, collected in a manner that may have compromised the sterility of the collection system, were distributed.	American Red Cross Blood Services - Massachusetts Region
PF24 Plasma	Class II	Biologics	W200420993567000, W200420993870000	Blood products, collected in a manner that may have compromised the sterility of the collection system, were distributed.	American Red Cross Blood Services - Massachusetts Region
Fresh Frozen Plasma	Class II	Biologics	W200420994330001	Blood products, collected in a manner that may have compromised the sterility of the collection system, were distributed.	American Red Cross Blood Services - Massachusetts Region

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
PF24 Plasma	Class II	Biologics	W200121671455; W200121671476	Blood products, collected in a manner that may have compromised the sterility of the collection system, were distributed.	American National Red Cross (the)
Liquid Plasma	Class II	Biologics	W200121685956	Blood products, collected in a manner that may have compromised the sterility of the collection system, were distributed.	American National Red Cross (the)
Plasma Frozen, Cryoprecipitate Reduced	Class II	Biologics	W200121685289; W200121685305	Blood products, collected in a manner that may have compromised the sterility of the collection system, were distributed.	American National Red Cross (the)
Red Blood Cells, Leukocytes Reduced	Class II	Biologics	W200121685945; W200121685956; W200121685959; W200121685962; W200121687236; W200121687267; W200121684465; W200121684482; W200121685242; W200121685250; W200121685256; W200121685279; W200121685283; W200121685298; W200121685303;	Blood products, collected in a manner that may have compromised the sterility of the collection system, were distributed.	American National Red Cross (the)

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			W200121685305; W200121684805; W200121684817; W200121708165; W200121708175; W200121685295; W200121685300; W200121684803; W200121684813; W200121708163; W200121708170; W200121708637; W200121671465; W200121671476; W200121685938; W200121685949; W200121685961; W200121687261; W200121684459; W200121684478; W200121685229; W200121685246; W200121685260; W200121685275; W200121685289; W200121671455; W200121671461; W200121671467; W200121685942		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Red Blood Cells, Leukocytes Reduced	Class II	Biologics	W20332119263400M; W20332119574400*; W20332120650600D; W20332120651000L; W20332119574600W;	Blood products, collected in a manner that may have compromised the sterility of the collection system, were distributed.	American Red Cross Blood Services
Cryoprecipitate AHF	Class II	Biologics	W20332009643400I; W20332011518000G; W20332012920100G; W20332007683100J;	Blood products, collected in a manner that may have compromised the sterility of the collection system, were distributed.	American Red Cross Blood Services
Fresh Frozen Plasma	Class II	Biologics	W203320104449001; W20332010677600D; W20332012122500H; W20332012123500D; W20332010014600L; W203320098820003; W203320107336008; W20332011502600*; W203320114803002; W20332011713700R; W20332011714400T; W20332011715600L; W20332012122000R; W20332012123400F; W20332007664200T; W20332007225100C; W20332007463800G; W20332007810000K; W20332007827300F; W20332007496200T;	Blood products, collected in a manner that may have compromised the sterility of the collection system, were distributed.	American Red Cross Blood Services

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			W203320075995000W; W203320094963000; W20332007991700X; W203320074632005; W203320084053000Y; W203320078107006; W20332007826200L; W20332007494800P; W20332007498100N; W203320090684004; W20332007599600U; W20332009441100R; W203320094955000;		
PF24 Plasma	Class II	Biologics	W20332010015000T; W20332010281500L; W20332010556700A; W203320104454007; W203320105488008; W20332010549200G; W203320110848003; W20332011364100M; W203320114787007; W203320106798001; W20332011716300N; W20332012057300U; W203320120859002; W203320121159005; W203320109339007; W203320130651002; W20332010014100V;	Blood products, collected in a manner that may have compromised the sterility of the collection system, were distributed.	American Red Cross Blood Services

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			W20332009878700A; W20332010147000I; W20332010556300I; W20332010561500Q; W20332010562500M; W20332010732400G; W20332010799806; W20332011085700I; W20332011480400O; W20332011480700V; W20332011674000S; W20332011942600E; W20332011943900A; W20332012086700Z; W20332012116800C; W20332012123800Z; W20332010934700Z; W20332010935600S; W20332007227000I; W20332007227600V; W20332010708400G; W20332007461500U; W20332007824500N; W20332008183000W; W20332008192000S; W20332008578300O; W20332008331500I; W20332008333600S; W20332007599900O; W20332009440500N;		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			W20332007076600R; W20332007462000*; W20332007826400H; W20332008431000W; W203320081887002; W20332008760100*; W203320088396002; W20332009403200C; W20332009405700V; W20332009800200Y; W20332010011600X;		
Pooled Cryoprecipitated AHF	Class II	Biologics	W202721911938	Blood products, for which donor eligibility screening was incomplete, were distributed.	American Red Cross Greater Alleghenies Region
Red Blood Cells, Leukocytes Reduced	Class II	Biologics	W20222130502300M	Misbranded Red Blood Cell product was distributed.	American National Red Cross, Penn Jersey Region
Red Blood Cells, Leukocytes Reduced	Class II	Biologics	W071221049296	Leukoreduced Red Blood Cells, for which donor eligibility screening was incomplete, were distributed.	Medic Inc
Pooled Cryoprecipitate AHF	Class II	Biologics	W125621082919	Blood products, for which donor eligibility was incomplete, were distributed.	Blood Bank Of San Bernardino And Riverside Counties
Red Blood Cells, Leukocytes Reduced	Class II	Biologics	W125621085094	Blood products, for which donor eligibility was incomplete, were distributed.	Blood Bank Of San Bernardino

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
					And Riverside Counties
Platelets, Pathogen Reduced	Class II	Biologics	W065621033149	Platelets, Pathogen Reduced, inappropriately prepared by recording the incorrect volume on label, were distributed.	Bergen Comm Reg Blood Center
Apheresis Red Blood Cells, Leukocytes Reduced	Class II	Biologics	W115121140177Z (double)	Blood products, for which transfusion-transmitted infection test/testing was performed, interpreted, or documented incorrectly, were distributed.	LifeSouth Community Blood Centers, Inc.
PF24 Plasma	Class II	Biologics	W115121257253K	Blood product, which was collected from a donor in which donor suitability was not adequately determined, was distributed.	LifeSouth Community Blood Centers, Inc.
Platelets, Pathogen Reduced	Class II	Biologics	W051721114891	Platelet product, for which quality control for residual WBC count was not performed, was distributed.	Rhode Island Blood Center, A Division of New York Blood Center, Inc.
Physicians CARE Extra Strength PAIN RELIEVER [Acetaminophen, Aspirin (NSAID), and Caffeine], 250 mg, 250 mg, 65 mg, packaged as 100-count Tablets (50 Packets, 2 tablets each) per carton, Manufactured for: Acme United Corporation 55 Walls Dr, Fairfield, CT 06824, UPC 0 73577 90316 6	Class II	Drugs	Lots: (Packet, Carton) 6151, 4360 Exp. 10/2021; 6240, 4446 Exp. 12/2021; 6331, 4484 Exp. 02/2022; 6413, 4551 Exp. 04/2022; 6699, 4679 Exp. 10/2022; 6751, 4714 Exp. 12/2022; 6855, 4750 Exp. 01/2023;	CGMP Deviations: manufacturer recalled after an FDA inspection noted that these products were not manufactured under Current Good Manufacturing Practices.	Medique Products

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			6868, 4761 Exp. 02/2023; 6899, 4776 Exp. 02/2023; 6899, 4776 Exp. 02/2023; 7061, 4821 Exp. 05/2023.		
Medique Pain-Off (Acetaminophen 250 mg, Aspirin (NSAID*) 250 mg, Caffeine 65 mg) Tablets, packaged in 2-count Tablets per Unit Dose Packet, packaged as a) 200-count Tablets (100 x 2) Unit Dose packets per carton, UPC 3 47682 22847 7, Reorder #22847; b) 500-count Tablets (250 x 2) Unit Dose packets per carton, UPC 3 47682 22813 2, Reorder #22813; c) 100-count Tablets (50 x 2) Unit Dose packets per carton, UPC 3 47682 22833 0, Reorder #22833; d) 24-count Tablets (12 x 2) Unit Dose packets per carton, UPC 3 47682 22864 4, Reorder #22864; Manufactured for Medique Products, Fort Myers, FL 33967.	Class II	Drugs	Lots: (packet lot, carton lot) a) 7062, 10611 Exp. 05/2023; 7062, 10110 Exp. 05/2023; 7062, 10067 Exp. 05/2023; 6414, 07378 Exp. 04/2022; 6700, 08047 Exp. 10/2022; 6152, 05553 Exp. 10/2022; 6239, 07120 Exp. 12/2021; 6239, 06504 Exp. 12/2021; 6152, 05737 Exp. 10/2021; 6700, 08653 Exp. 10/2022; 6330, 07217 Exp. 02/2022; 6414, 07360 Exp. 04/2022; 6749, 08717 Exp. 12/2022; 6794, 09012 Exp. 12/2022; b) 6856, 09108 Exp. 01/2023; 6867, 09460 Exp. 02/2023; 6900, 10105 Exp. 02/2023; 6749, 09139 Exp. 12/2022; 6152, 05944 Exp.	CGMP Deviations: manufacturer recalled after an FDA inspection noted that these products were not manufactured under Current Good Manufacturing Practices.	Medique Products

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			10/2021; 6152, 05483 Exp. 10/2021; 6414, 07488 Exp. 04/2022; 6493, 07662 Exp. 06/2022; 6414, 07286 Exp. 04/2022; 6493, 07709 Exp. 06/2022; 6414, 07524 Exp. 04/2022; 6330, 06728 Exp. 02/2022; 6330, 06366 Exp. 02/2022; 6239, 06503 Exp. 12/2021; 6330, 06460 Exp. 02/2022; c) 7070, 10605 Exp. 06/2023; 7063, 11089 Exp. 06/2023; 7070, 11020 Exp. 06/2023; 6867, 09545 Exp. 02/2023; 7062, 10066 Exp. 05/2023; 6749, 08650 Exp. 12/2022; 6493, 07784 Exp. 06/2022; 6493, 07920 Exp. 06/2022; 6330, 06949 Exp. 02/2022; 6239, 06945 Exp. 12/2021; 6239, 05973 Exp. 12/2021; 6152, 05687 Exp. 10/2021; 6493,		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			07950 Exp. 06/2022; 6493, 07825 Exp. 06/2022; d) 7062, 10265 Exp. 05/2023; 7070, 10980 Exp. 06/2023; 6867, 09607 Exp. 02/2023; 6152, 06039 Exp. 10/2021; 6330, 07121 Exp. 02/2022; 6700, 08040 Exp. 10/2022; 6493, 07985 Exp. 06/2022; 6152, 05783 Exp. 10/2021; 6749, 08866 Exp. 12/2022.		
Extra Strength Headache (acetaminophen 250 mg, aspirin 250 mg, caffeine 65 mg) tablets, packaged in 2-count tablets per packet, Manufactured for: Lil' Drug Store Products, Inc., Cedar Rapids, IA 52404	Class II	Drugs	Lots: 6492 Exp. 06/2022; 6701 Exp. 10/2022; 6750 Exp. 12/2022; 6853 Exp. 01/2023; 6854 Exp. 01/2023; 6869 Exp. 02/2023; 6898 Exp. 02/2023; 6901 Exp. 02/2023; 7059 Exp. 05/2023; 7060 Exp. 05/2023; 7064 Exp. 06/2023; 7065 Exp. 06/2023	CGMP Deviations: manufacturer recalled after an FDA inspection noted that these products were not manufactured under Current Good Manufacturing Practices.	Medique Products
Clobetasol Propionate Foam, 0.05%, packaged in a) 50 g can (NDC 50742-304-50), and b) 100 g can (NDC 50742-304-01), Rx only, Manufactured for: Ingenus	Class II	Drugs	a) Lots: 32921 Exp. 06/2022; 33152 Exp. 08/2022; 33340 Exp. 11/2022; b) Lots: 33152	CGMP Deviations	Ingenus Pharmaceuticals Llc

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Pharmaceuticals, LLC, Orlando, FL 32839-6408.			Exp. 08/2022; 33340 Exp. 11/2022.		
Clobazam Oral Suspension 2.5 mg/mL, 120 mL bottles, Rx only, Manufactured by: VistaPharm, Inc. Largo, FL 33771, NDC 66689-058-04	Class II	Drugs	Lots #: 678900, 682000, 682400, Exp. 5/31/2022; 680600, 680800, 681000 Exp. 5/30/2022; 683200, 685200 Exp. 6/30/2022; 728900, 733100 Exp. Date 12/31/2022; 738600 Exp. 1/31/2023; 740600, 741600 Exp. 2/28/2023; 749800, 750900, 752400 Exp. 3/31/2023; 775700 Exp. 6/30/2023	Failed Stability Specifications	VistaPharm, Inc.
Lexette (halobetasol propionate) Topical Foam, 0.05% 50 g canisters, Rx ONLY, Distributed by: Mayne Pharma Greenville, NC 27834, NDC 51862-604-50	Class II	Drugs	Lot #: 32451 Exp. 03/2022; 32532 Exp. 04/2022; 32552 Exp. 05/2022; 32701 32733 Exp. 10/2022; 32855 Exp. 02/2023; 32872 Exp. 03/2023.	CGMP Deviation: Difficulty dispensing/does not dispense or dispensing liquid instead of foam.	Mayne Pharma Inc
Cornea	Class II	Biologics	210951OSCN; 210951ODCN	Cornea, recovered from an ineligible donor, was distributed.	Lions Eye Bank of West Central Ohio
Medroxyprogesterone Acetate Injection, IM, 150 mg/mL, packaged in 1 ml Single Dose Vial, RX Only, Ideal Pharmacy, 2333 Morris Ave, Union, NJ 07083	Class II	Drugs	All lots within expiry	Lack of Assurance of Sterility	Ideal Specialty Apothecary, Inc. dba Ideal Pharmacy
Platelets, Pathogen Reduced	Class II	Biologics	W067120704075 (double)	Blood product, collected from a donor who previously tested	The Blood Center

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
				positive for Hepatitis B core antigen (anti-HBc) on two separate occasions, was distributed.	
Apheresis Platelets, Platelet Additive Solution Added, Leukocytes Reduced	Class II	Biologics	W239821034722	Plateletpheresis product, for which quality control for residual white blood cell count testing was not performed, was distributed.	OneBlood, Inc.
Tretinoin Capsules, 10 mg, 100 count bottle, Rx Only, Teva Pharmaceuticals USA, Inc., North Wales, PA 19454, NDC 0555-0808-02	Class II	Drugs	Lot #: 100022970, Exp. 08/2022	Failed Dissolution Specifications; Low Out of specification (OOS) results for dissolution.	Teva Pharmaceuticals USA
Red Blood Cells, Leukocytes Reduced	Class II	Biologics	W125621112012	Misbranded Leukoreduced Red Blood Cells were distributed.	Blood Bank Of San Bernardino And Riverside Counties
Apheresis Red Blood Cells, Leukocytes Reduced	Class II	Biologics	W239921053984	Leukoreduced Apheresis Red Blood Cells, which were labeled as leukocytes reduced but were not tested to verify white blood cell count, were distributed.	OneBlood, Inc.
Apheresis Red Blood Cells, Leukocytes Reduced	Class II	Biologics	W036820783456 (double collection)	Apheresis Red Blood Cell products, for which quality control for residual WBC count was not performed, were distributed.	One Blood Inc
Platelets, Pathogen Reduced	Class II	Biologics	W040721097150 (Double Collection); W040721080767 (Double Collection); W040721107219;	Platelets, Pathogen Reduced, inappropriately prepared by recording the incorrect volume on label, were distributed.	Versiti Indiana Inc

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			W040721090998; W040721090999		
Apheresis Platelets, Platelet Additive Solution Added, Leukocytes Reduced	Class II	Biologics	W036821622725 (Double Collection)	Leukoreduced Apheresis Platelets, Platelet Additive Solution Added, which were labeled as leukocytes reduced but were not tested to verify white blood cell count, were distributed.	OneBlood, Inc.
Red Blood Cells, Leukocytes Reduced	Class II	Biologics	W270121538419	Red Blood Cell product, collected from a donor whose eligibility to donate was inadequately determined for malarial travel, was distributed.	Central Pennsylvania Blood Bank
Red Blood Cells, Leukocytes Reduced	Class II	Biologics	W038620811666	Leukoreduced Red Blood Cells, collected from a donor who recently traveled to a malarial endemic area, were distributed.	Suncoast Communities Blood Bank, Inc.
Doxylamine Succinate and Pyridoxine Hydrochloride Delayed-Release Tablets 10 mg/10 mg, 100-count bottle, Rx Only, Manufactured by: Actavis Laboratories FL, Inc., Fort Lauderdale, FL 33314, USA, Distributed by: Actavis Pharma, Inc., Parsippany, NJ 007045 USA, NDC 0591-2132-01	Class II	Drugs	Lot# 100025842, 100028023, Exp Date 08/2023	Failed Dissolution Specification: Dissolution results are below specification limits for the active ingredient	Teva Pharmaceuticals USA
Apheresis Red Blood Cells, Leukocytes Reduced	Class II	Biologics	W239921090522 (double collection)	Apheresis Red Blood Cell products, for which quality control for residual WBC count was not performed, were distributed.	One Blood Inc

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Apheresis Platelets, Leukocytes Reduced, Irradiated	Class II	Biologics	W20112188081700W (Double Collection)	Leukoreduced Irradiated Apheresis Platelets, which were labeled as leukocytes reduced but were not tested to verify white blood cell count, were distributed.	American Red Cross Blood Services
Apheresis Red Blood Cells, Leukocytes Reduced	Class II	Biologics	W091021436066	Leukoreduced Apheresis Red Blood Cells, which were not stored at the correct temperature, were distributed.	Oklahoma Blood Institute - Sylvan N Goldman Center
Apheresis Platelets, Platelet Additive Solution Added, Leukocytes Reduced	Class II	Biologics	W203421800330006; W203421800330800R	Plateletpheresis products, for which quality control procedures were not performed, were distributed.	American Red Cross Biomedical Services Northern New England Region
Red Blood Cells, Leukocytes Reduced	Class II	Biologics	W201221746398	Blood products, collected from a donor whose arm preparation was not performed in a manner that ensures sterility, were distributed.	American Red Cross Blood Svcs
Pooled Cryoprecipitated AHF	Class II	Biologics	W201221969553	Blood products, collected from a donor whose arm preparation was not performed in a manner that ensures sterility, were distributed.	American Red Cross Blood Svcs
Bone	Class II	Biologics	03521014151045; 03521014151046; 03521014151049; 03521014151050;	Bone and tendon, recovered from a donor in which donor suitability was not adequately determined, were distributed.	Musculoskeletal Transplant Foundation, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			03521014151040; 03521014151041; 03521014151044; 035210141510200001; 03521014151047; 03521014151048; 03521014151038; 03521014151039; 03521014151042; 03521014151043; 035210141510200002; 035210141510200003; 035210141510200006; 035210141510200007; 035210141510200011; 035210141510200012; 035210141510200013; 035210141510200014; 035210141510200015; 035210141510200016; 035210141510200017; 035210141510200018; 035210141510200019; 035210141510200020; 035210141510210001; 035210141510210002; 035210141510210003; 035210141510210004; 035210141510210005; 035210141510210006;		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			035210141510210007; 035210141510210008; 035210141510210009; 035210141510210010; 035210141510210011; 035210141510210012; 035210141510210013; 035210141510210014; 035210141510210015; 035210141510210016; 035210141510210017; 035210141510210018; 035210141510210019; 035210141510210020; 035210141510210021; 035210141510220001; 035210141510220002; 035210141510220003; 035210141510220004; 035210141510220005; 035210141510220006; 035210141510220007; 035210141510220008; 035210141510220009; 035210141510220010; 035210141510220011; 035210141510220013; 035210141510220015; 035210141510220017; 035210141510220019;		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			035210141510220021; 035210141510220022; 035210141510220024; 035210141510220025; 035210141510230001; 035210141510230002; 035210141510230005; 035210141510230006; 035210141510220014; 035210141510220016; 035210141510220018; 035210141510220023; 035210141510220026; 035210141510220027; 035210141510230003; 035210141510230004; 035210141510230007; 035210141510220020; 035210141510200004; 035210141510200005; 035210141510200008; 035210141510200009; 035210141510220012		
Tendon	Class II	Biologics	03521014151032; 03521014151033; 03521014151035; 03521014151036; 03521014151037; 03521014151030; 03521014151031;	Bone and tendon, recovered from a donor in which donor suitability was not adequately determined, were distributed.	Musculoskeletal Transplant Foundation, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			03521014151028 ; 03521014151036		
Nasal & Sinus Decongestant (phenylephrine HCl 5mg) 2 tablets per packet, Mfd. for Cintas First Aid & Safety, Mason OH 45040	Class II	Drugs	Lot #: AK9491, AK9496, Exp. Date 02/2022; K9817, Exp. Date 09/2022	cGMP deviations	Ultra Seal Corporation
Cold Tablet Pain Reliever/Fever Reducer/Expectorant/Nasal Decongestant (acetaminophen 325 mg, Guaifenesin 200mg, Phenylephrine HCl 5 mg) 2 tablets per packet, Mfg, for Respond Industries and American First Aid, Mason, OH 45040	Class II	Drugs	Lot #: K9824, Exp. Date 09/2022	cGMP deviations	Ultra Seal Corporation
AERO TAB Cold Relief (acetaminophen 325 mg, Guaifenesin 200mg, Phenylephrine HCl 5mg) 2 tablet packets, Mfg. for: Aero Healthcare, Valley Cottage, NY 10989	Class II	Drugs	Lot #: AK9565, Exp. Date 04/2022	cGMP deviations	Ultra Seal Corporation
Maximum Strength Non Aspirin Pain Reliever/Fever Reducer (acetaminophen 500 mg) 2 tablet packets, Mfg. for: Advanced First Aid, Baltimore MD 21237, American Safety & First Aid, Osceola, IN 46561, NDC 67060-210-68	Class II	Drugs	Lot #: AK9495, Exp. Date 02/2022; AK9613, Exp. Date 05/2022	cGMP deviations	Ultra Seal Corporation
CHLORESIN (acetaminophen 325mg, dextromethorphan HBr 15mg, Guaifenesin 200mg, Phenylephrine HCl 5mg) 2 tablet packets, Manufactured For Afassco Inc. Minden NV 89423, NDC 51532-0107-2	Class II	Drugs	Lot #: AK9492, Exp. Date 02/2022	cGMP deviations	Ultra Seal Corporation
Extra Strength (ES) PAIN RELIEVER (acetaminophen 500 mg) 2 tablet packets, Manufactured by Ultratab Laboratories, Inc.	Class II	Drugs	Lot #: AK9602, Exp. Date 05/2022	cGMP deviations	Ultra Seal Corporation

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Legatrin PM Pain Reliever/Sleep Aid (acetaminophen 500 mg, diphenhydramine HCl 50mg caplets) 50-count bottles, Manufactured for: Church & Dwight Co., Inc. Ewing, NJ 08628 NDC 10237-907-50	Class II	Drugs	Lot #: HY9042, Exp. Date 02/2022; HY9094, HY9112, Exp. Date 04/2022; HY9134, Exp. Date 05/2022; HY9267, Exp. Date 09/2022	cGMP deviations	Ultra Seal Corporation
Cystex Urinary Pan Relief (NSAID) (methenamine 162mg, sodium salicylate 162.5mg tablets) packaged in a) 40-count blisters and b) 20-count blisters, Distributed by: Clarion Brands, LLC 27070 Miles Road, Suite A Solon, OH 44139, NDC 69693-512-40	Class II	Drugs	Lot #: a) 19A043, 19A093, Exp. Date 01/2022; 19B062,19C079,19C080, Exp. Date 03/2022; 19D041, Exp. Date 04/2022; 19E035, 19E087, Exp. Date 05/2022; 19G084, Exp. Date 08/2022; 19H098, Exp. Date 09/2022 b) 19H098A, Exp. Date 09/2022	cGMP deviations	Ultra Seal Corporation
DBI 357 Super Magnum Quick Energy Stimulant (caffeine 200mg) tablets, packaged in a) 36-count bottles, b) 100-count bottles, c) 500-count bottles, and d) 3-count packets, Marketed by: DBI Distribution A Division of King Richard Promotions, Inc. P.O. Box 78546, Indianapolis, IN 46270	Class II	Drugs	Lot #: a) C19065, Exp. Date 03/2022; F19081, Exp. Date 06/2022; 19H083, Exp. Date 08/2022; b) H19083, 1H9083, Exp. Date 08/2022; c) 19F081, Exp. Date 06/2022; 19083H, Exp. Date 08/2022; d) 19C065, Exp. Date 03/2022; 19081F, Exp. Date 06/2022	cGMP deviations	Ultra Seal Corporation

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Ephedrine Plus (Ephedrine HCl 25mg, Guaifenesin 200mg) tablets, 24-count bottles, Marketed by: DMD Pharmaceuticals A Division of Dickery Consumer Products, Inc. Noblesville, IN 46060, NDC 65193-320-24	Class II	Drugs	Lot#: 18M063, Exp. Date 01/2022; 19G076, Exp. Date 09/2022	cGMP deviations	Ultra Seal Corporation
Dologen (acetaminophen 325 mg and dexbrompheniramine maleate 1mg) caplets, packaged in a) 90-count bottles, b) 2-count packets, Manufactured in the USA for Kramer-Novis, San Juan, Puerto Rico 00917, NDC 52083-482-02	Class II	Drugs	Lot #: a) 19G074, 19G075, Exp. Date 07/2022; b) 19G075, Exp. Date 07/2022	cGMP deviations	Ultra Seal Corporation
MidNite Sleep Health (melatonin 1.5 mg) tablets, 30-count bottles, Distributed by: Mylan Consumer Healthcare, Inc. Morgantown, WV 26505 USA	Class II	Drugs	Lot #: 18L124, 18L125, 18L126, Exp. Date 02/2022; 19C037, 19C038, 19C039, 19C040, Exp. Date 03/2022; 19D029, 19D030, Exp. Date 04/2022; 19D031, Exp. Date 06/2022; 19G047, Exp. Date 07/2022	cGMP deviations	Ultra Seal Corporation
Back Pain-Off (caffeine 50mg, magnesium salicylate 290mg) Tablets 2-count packets, Mfd for MEDIQUE PRODUCTS, Fort Myers, FL 33967, NDC 47682-073-00	Class II	Drugs	Lot #: 9708, Exp. Date 07/2022; AK9810, Exp. Date 09/2022; AK9946, K9946, Exp. Date 12/2022	cGMP deviations	Ultra Seal Corporation
Cetafen Non-aspirin pain reliever (acetaminophen 325mg) tablets, 2-count packets, Manufactured for: HARTHealth Seattle, WA 98124	Class II	Drugs	Lot #: A-K-9668, Exp. Date 06/2022; A-K-9475, Exp. Date 02/2022	cGMP deviations	Ultra Seal Corporation

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Multi Symptom Cold Relief (acetaminophen 325 mg, Dextromethorphan HBr 15mg, Guaifenesin 200mg, Phenylephrine HCl 5mg) tablets, 2-count packets, Dist. by Honeywell Safety Products USA, Smithfield, RI 02917	Class II	Drugs	Lot #: AK9715, K9715, Exp. Date 07/2022	cGMP deviations	Ultra Seal Corporation
Lite Remfresh Advanced Ion-Powered Melatonin (Melatonin 0.5mg) Tablets, 36-count blisters, Physician's Seal LLC, Boca Raton, FL 33487	Class II	Drugs	Lot #: 19E058A, 19E058B, Exp. Date 05/2022	cGMP deviations	Ultra Seal Corporation
Cold Relief Severe Pain/Cough (acetaminophen 325mg, Dextromethorphan HBr 15mg, Guaifenesin 200mg, phenylephrine HCl 5mg), 2-tablet packets, Manufactured for Select Corporation, Carrollton, TX 75007	Class II	Drugs	Lot #: AK9436, Exp. Date 01/2022	cGMP deviations	Ultra Seal Corporation
Multi-Symptom Cramp Relief (acetaminophen 325mg and Pamabrom 25mg), 2- tablet packets, Mfd. for First Aid Direct, Mason, OH 45040	Class II	Drugs	Lot #: AK9453, Exp. Date 01/2022; AK9716, 07/2022	cGMP deviations	Ultra Seal Corporation
Backache & Muscle Relief (acetaminophen 250 mg, magnesium salicylate-tetrahydrate 290mg, caffeine 50 mg) 2 tablets per packet, Mfd. for First Aid Direct, Mason, OH 45040, NDC 42961-111-832	Class II	Drugs	Lot #: K9770, AK9770 Exp. Date 08/2022; AK9958, K9958 Exp. Date 12/2022; AK9717, Exp. Date 07/2022; AK9522, AK9641 , Exp. Date 03/2022; AK9817, Exp. Date 09/2022	cGMP deviations	Ultra Seal Corporation
Cold Relief (acetaminophen 250 mg, guaifenesin 200mg, phenylephrine HCl 5 mg) 2 tablets per packet, Mfd. for First Aid	Class II	Drugs	Lot #: K9456, AK9454, 9456, AK9456, Exp. Date 01/2022; AK9524, AK9528	cGMP deviations	Ultra Seal Corporation

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Direct, Mason, OH 45040, NDC 42961-112-03			Exp. Date 03/2022; K9767, AK9767, Exp. Date 08/2022; AK9824, AK9823, Exp. Date 09/2022; AK9564, Exp. Date 04/2022		
Headache & Congestion Sinus Relief (acetaminophen 250 mg, phenylephrine HCl 5 mg) 2 tablets per packet, Mfd. for First Aid Direct, Mason, OH 45040, NDC 42961-0206-02	Class II	Drugs	Lot #: 9445, AK9445, K9445, Exp. Date 01/2022; K9486, Exp. Date 02/2022; AK9708, Exp. Date 07/2022; AK9515, Exp. Date 03/2022; K9810, Exp. Date 09/2022; AK9658, Exp. Date 06/2022	cGMP deviations	Ultra Seal Corporation
Pain Away Pain Reliever/Fever Reducer (NSAID) (acetaminophen 110 mg, aspirin 162 mg, salicylamide 152mg, caffeine 32.4 mg), 2 tablets per packet, Mfg, for Respond Industries and American First Aid, Mason, OH 45040	Class II	Drugs	Lot #: AK9493, Exp. Date 02/2022	cGMP deviations	Ultra Seal Corporation
Cold/Sinus Pain Reliever/Fever Reducer Nasal Decongestant (acetaminophen 325 mg, Phenylephrine HCl 5mg), 2 tablets per packet, Mfg, for Respond Industries and American First Aid, Mason, OH 45040	Class II	Drugs	Lot #: K9708, Exp. Date 07/2022	cGMP deviations	Ultra Seal Corporation
COLD TERMINATOR decongestant/cold relief (acetaminophen 325 mg, Guaifenesin 200mg, 5.0 Phenylephrine HCl) 2 tablet packets, Manufactured for: Tellus Medical	Class II	Drugs	Lot #: AK9587, Exp. Date 02/2022	cGMP deviations	Ultra Seal Corporation

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Products, Carlsbad, CA 92011, NDC 69103-2556					
PAIN TERMINATOR extra strength pain relief (aspirin 162 mg, acetaminophen 110 mg, Caffeine 32.4mg, Salicylamide 152 mg) 2 tablet packets, Manufactured for: Tellus Medical Products, Palm Desert, CA 92211, NDC 69103-2507	Class II	Drugs	Lot #: AK9451, Exp. Date 01/2022	cGMP deviations	Ultra Seal Corporation
SINU-PHEN PLUS sinus pain and congestion tabs (acetaminophen 500 mg, Phenylephrine HCl 5.0 mg) 2 tablet packets, Manufactured for: Tellus Medical Products, Palm Desert, CA 92211, NDC 69103-2536-00	Class II	Drugs	Lot #: AK9766, Exp. Date 08/2022	cGMP deviations	Ultra Seal Corporation
DILOTAB II, SINUS AND COLD RELIEF NON DROWSY (acetaminophen 325 mg, Phenylephrine HCl 5 mg) 2 tablet packets, Dist. by ZEE Medical Distributors, LLC Mason, OH 45040, NDC 42961-052-03	Class II	Drugs	Lot #: AK9548, (L) 106, Exp. Date 04/2022; AK9647, (L)103, Exp. Date 06/2022; AK9598, Exp. Date 05/2022	cGMP deviations	Ultra Seal Corporation
EXTRA STRENGTH UN-ASPIRIN (acetaminophen 500 mg) 2 Caplet packets, Dist. by ZEE Medical Distributors, LLC Mason, OH 45040, NDC 42961-041-03	Class II	Drugs	Lot #: AK9599, Exp. Date 05/2022; AK9648, (L) 104, Exp. Date 06/2022	cGMP deviations	Ultra Seal Corporation
PAINAID (acetaminophen 110 mg, aspirin 162mg, caffeine 32.4 mg, salicylamide 152mg) 2 tablet packets, Dist. by ZEE Medical Distributors, LLC Mason, OH 45040	Class II	Drugs	Lot #: AK9433, Exp. Date 01/2022; AK9749, Exp. Date 08/2022	cGMP deviations	Ultra Seal Corporation
PAINAID BRF Back Relief Formula (acetaminophen 250 mg, caffeine 50 mg, Magnesium salicylate 290 mg) 2 tablet	Class II	Drugs	Lot #: AK9698, Exp. Date 07/2022	cGMP deviations	Ultra Seal Corporation

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
packets, Dist. by ZEE Medical Distributors, LLC Mason, OH 45040, NDC 42961-0003-00					
PAINAID PMF Premenstrual Formula (acetaminophen 500 mg, pamabrom 25mg) 2 caplet packets, Dist. by ZEE Medical Distributors, LLC Mason, OH 45040, NDC 42961-0046-03	Class II	Drugs	Lot #: AK9434, (L)101, Exp. date 01/2022	cGMP deviations	Ultra Seal Corporation
CONGESTAID II Nasal Decongestant (Phenylephrine HCl 5mg) 2 tablet packets, Dist. by ZEE Medical Distributors, LLC Mason, OH 45040	Class II	Drugs	Lot #: AK9478, Exp. Date 02/2022; AK9799, Exp. Date 09/2022	cGMP deviations	Ultra Seal Corporation
Mint Flavored Antacid (Calcium Carbonate 420mg) 2 tablet packets, Mfg for Just American Safety, Osceola, IN 46561, NDC 67060-303-68	Class II	Drugs	Lot #: AK9523, K9523 Exp. Date 03/2022; AK9670, Exp. Date 06/2022	cGMP deviations	Ultra Seal Corporation
Pain & Sinus Reliever Pain Reliever/Nasal Decongestant (acetaminophen 500mg, Phenylephrine HCl 5mg) 2 tablet packets, Mfg for Advanced First Aid, Baltimore, MD 21237, NDC 67060-194-68	Class II	Drugs	Lot #: AK9527, Exp. Date 03/2022	cGMP deviations	Ultra Seal Corporation
Regular Strength Pain Reliever (acetaminophen 110 mg, aspirin 162 mg, Caffeine 32.4 mg, Salicylamide 152 mg) 2 tablet packets, Mfg for Advanced First Aid, Baltimore, MD 21237, NDC 67060-0113-00	Class II	Drugs	Lot #: AK9450, Exp. Date 01/2022	cGMP deviations	Ultra Seal Corporation
PAPENOL (acetaminophen 500 mg), 2 tablet packets, Manufactured for: Afassco Inc. Minden, NV 89423	Class II	Drugs	Lot #: K9495, Exp. Date 02/2022; AK9614, Exp. Date 05/2022	cGMP deviations	Ultra Seal Corporation

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
MAGNACAL (calcium carbonate 420 mg), 2 tablet packets, Manufactured for: Afassco Inc. Minden, NV 89423	Class II	Drugs	Lot #: AK9768, Exp. Date 08/2022	cGMP deviations	Ultra Seal Corporation
PEPTIME Energy (caffeine 250mg) tablets, 100-count bottles, Marketed by: DMD Pharmaceuticals, A Division of Dickery Consumer Products, Inc., Noblesville, IN 46060.	Class II	Drugs	Lot #: 19E021, 19E022	cGMP deviations	Ultra Seal Corporation
PEPTIME Energy (caffeine 300mg) tablets, packaged in a) 6 count packets and b) 100-count bottles, Marketed by: DMD Pharmaceuticals, A Division of Dickery Consumer Products, Inc., Noblesville, IN 46060.	Class II	Drugs	Lot #: a)19E030, b)19E031	cGMP deviations	Ultra Seal Corporation
PEPTIME Energy (caffeine 350mg) tablets, packaged in a) 6 count packets and b) 100-count bottles, Marketed by: DMD Pharmaceuticals, A Division of Dickery Consumer Products, Inc., Noblesville, IN 46060.	Class II	Drugs	Lot #: a)19E032, b)19E033	cGMP deviations	Ultra Seal Corporation
PEPTIME Energy (caffeine 250mg) tablets, packaged in a) 6 count packets and b) 100-count bottles, Marketed by: DMD Pharmaceuticals, A Division of Dickery Consumer Products, Inc., Noblesville, IN 46060.	Class II	Drugs	Lot #: a)19E021, b)19E022	cGMP deviations	Ultra Seal Corporation
CVS Health Natural Sleep Aid Chewable Tablets Cherry Flavor (melatonin 1.5mg), 30-count bottles, Distributed by: CVS Pharmacy Inc. One CVS Drive, Woonsocket, RI 02895	Class II	Drugs	Lot #: 18L124, Exp. Date 02/2022; 19D029, Exp. Date 04/2022	cGMP deviations	Ultra Seal Corporation

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
MidNite Natural sleep aid Chewable Tablets Cherry Flavor (melatonin 1.5mg), 30-count bottles, BGP Pharma ULC, Etobicoke, ON M8Z 2S6	Class II	Drugs	Lot #: 19C038C, Exp. Date 03/2022; 19G047C, Exp. Date 07/2022; 18L124C, Exp. Date 02/2022	cGMP deviations	Ultra Seal Corporation
Exaprin pain reliever (acetaminophen 110 mg, aspirin 162 mg, caffeine 32.4mg, salicylamide 152mg) tablets, 2- tablet packets, Manufactured for: HARTHealth Seattle, WA 98124	Class II	Drugs	Lot #: AK9796, Exp. Date 09/2022	cGMP deviations	Ultra Seal Corporation
Nutralox Mint Antacid (calcium carbonate 420mg) Chewable tablets, 2-count packets, Manufactured for: HARTHealth Seattle, WA 98124	Class II	Drugs	Lot #: AK9566, Exp. Date 04/2022; AK9612, Exp. Date 05/2022	cGMP deviations	Ultra Seal Corporation
FEM-PRIN MENSTRUAL RELIEF (acetaminophen 325 mg, pamabrom 25mg) tablets, 2-count packets, Manufactured for: HARTHealth Seattle, WA 98124	Class II	Drugs	Lot #: AK9695, Exp. Date 07/2022	cGMP deviations	Ultra Seal Corporation
CETAFEN COUGH & COLD COUGH & COLD RELIEF (Acetaminophen 325 mg, Dextromethorphan HBr 15mg, Guaifenesin 200mg, phenylephrine HCl 5mg) Coated tablets, 2-count packets, Manufactured for: HARTHealth Seattle, WA 98124	Class II	Drugs	Lot #: AK9841, Ex. Date 10/2022	cGMP deviations	Ultra Seal Corporation
CETAFEN Extra Non-Aspirin Pain Relieve (Acetaminophen 500 mg) caplets, 2-count packets, Manufactured for: HARTHealth Seattle, WA 98124	Class II	Drugs	Lot #: AK9475, Exp. Date 02/2022	cGMP deviations	Ultra Seal Corporation
AYPANAL Non-aspirin Pain Reliever (acetaminophen 325 mg) tablets, 2-count	Class II	Drugs	Lot #: AK9640, Exp. Date 03/2022	cGMP deviations	Ultra Seal Corporation

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
packets, Dist. by Honeywell Safety Products USA, Smithfield, RI 02917					
SINUS DECONGESTANT Nasal Decongestant (phenylephrine HCl 5mg) tablets, 2-count packets, Dist. by Honeywell Safety Products USA, Smithfield, RI 02917	Class II	Drugs	Lot #: AK9859, Exp. Date 10/2022	cGMP deviations	Ultra Seal Corporation
MIRALAC (calcium carbonate 420mg) tablets, Mint Flavor, 2-count packets, Dist. by Honeywell Safety Products USA, Smithfield, RI 02917	Class II	Drugs	Lot #: AK9486, Exp. Date 02/2022	cGMP deviations	Ultra Seal Corporation
ELECTROLYTE Supplement Tablets (calcium 5.2 mg, Potassium 20.8 mg, Magnesium 6 mg) 2-count packets, Dist. by Honeywell Safety Products USA, Smithfield, RI 02917	Class II	Drugs	Lot #: AK9797, AK9254	cGMP deviations	Ultra Seal Corporation
REMfresh Advanced Ion-Powered Melatonin (Melatonin 2 mg) Caplets, packaged in a) 12-count blisters b) 36-count blisters Physician's Seal LLC, Boca Raton, FL 33487	Class II	Drugs	Lot #: a) 19B050A, 19B050B, 19B050C, 19B050D, 19B050E, Exp. Date 06/2022; 19F063, 19F063A, 19F063B, Exp. Date 08/2022; b) 19B050-A, Exp. Date 06/2022	cGMP deviations	Ultra Seal Corporation
REMfresh Advanced Ion-Powered Melatonin (Melatonin 5 mg) Caplets, packaged in 36-count blisters Physician's Seal LLC, Boca Raton, FL 33487	Class II	Drugs	Lot #: 19B011, 19B012, 19B012A, 19E023, Exp. Date 05/2022	cGMP deviations	Ultra Seal Corporation
Sinus Relief (acetaminophen 325mg, Guaifenesin 200mg, phenylephrine HCl 5mg), 2-tablet packets, Manufactured for Select Corporation, Carrollton, TX 75007	Class II	Drugs	Lot #: AK9651, Exp. Date 06/2022; AK9437, Exp. Date 01/2022	cGMP deviations	Ultra Seal Corporation

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Sinus Relief Headache/Nasal (acetaminophen 325mg, phenylephrine HCl 5mg), 2 tablet packets, Manufactured for Select Corporation, Carrollton, TX 75007	Class II	Drugs	Lot #: AK9436, Exp. Date 01/2022	cGMP deviations	Ultra Seal Corporation
3-Component Cold Tabs (Acetaminophen 325 mg, Guaifenesin 200 mg, Phenylephrine HCl 5mg) Bulk Container, ULTRAtab Laboratories, Inc., Highland, NY NDC 62959-106-00	Class II	Drugs	Product Code C106L; Bulk lots: 18J080, 18L029, 19A103, 19B063, 19D019, 19F065, Product Code C106LA; Bulk lots: 18K045, 18K046, 18L008, 18L105, 19A068, 19A094, 19A106, 19B009, 19C031, 19C032, 19C033, 19G085, 19H070, 19D018, 19H071, 19H082, 19J027	CGMP Deviations	ULTRAtab Laboratories, Inc.
4-Component Cold Tabs (Acetaminophen 325 mg, Guaifenesin 200 mg, Dextromethorphan HBr 15mg, Phenylephrine HCL 5mg) Bulk Container, ULTRAtab Laboratories, Inc., Highland, NY NDC 62959-107-00	Class II	Drugs	Product Code: C107L Bulk Lots: 18G085, 19B061, 19F066, 19J068 Product Code: C107LB Bulk Lots: 18J051, 18M079, 18M080, 19B017, 19B018, 19C001, 19C081, 19D056, 19D057 Product C107LA: Bulk lots: 19F067	CGMP Deviations	ULTRAtab Laboratories, Inc.
Zee Cold Tabs (Acetaminophen 325 mg, Guaifenesin 100 mg, Phenylephrine HCl 5 mg Bulk Container, ULTRAtab Laboratories, Inc., Highland, NY NDC 62959-111-xx	Class II	Drugs	Product Codes: C111L Bulk Lot: 18L028	CGMP Deviations	ULTRAtab Laboratories, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Kramer Novis Tusicof Caplet (Guaifenesin 400 mg, Dextromethorphan HBr 20 mg, Phenylephrine HCl 10 mg) Bulk Container, ULTRAtab Laboratories, Inc., Highland, NY NDC 62959-124-00	Class II	Drugs	Product Codes: C119L Bulk Lots: 18K028	CGMP Deviations	ULTRAtab Laboratories, Inc.
Dologen 325 Caplet (Acetaminophen 325 mg, Dexbrompheniramine Maleate 1.0 mg) Bulk Container, ULTRAtab Laboratories, Inc., Highland, NY NDC 62959-121-00	Class II	Drugs	Product Codes: C121L Bulk Lots: 19G074, 19G075	CGMP Deviations	ULTRAtab Laboratories, Inc.
Coated APAP 325 mg Phenyl HCl 5 mg tablet (Acetaminophen 325 mg, Phenylephrine HCl 5mg) Bulk Container, ULTRAtab Laboratories, Inc., Highland, NY NDC 62959-134-00	Class II	Drugs	Product Codes: C134LC Bulk Lots: 18K055 18M081 19A097 19B024 19C054 19E092 19G094 19J042	CGMP Deviations	ULTRAtab Laboratories, Inc.
APAP 325 mg/Phenylephrine HCl, 5mg Tablets Bulk Container, ULTRAtab Laboratories, Inc., Highland, NY NDC 62959-135-00	Class II	Drugs	Product Codes: C135LA Bulk Lots: 19F077	CGMP Deviations	ULTRAtab Laboratories, Inc.
APAP 500 mg Phenyl HCl 5mg tablet (Acetaminophen 500mg, Phenylephrine HCl 5mg), Bulk Container, ULTRAtab Laboratories, Inc., Highland, NY NDC 62959-140-00	Class II	Drugs	Product Codes: C140L Bulk Lots: 18K017, 18L002, 19C064, 19E067, 19F064, 19H053, 19J023, 19J051	CGMP Deviations	ULTRAtab Laboratories, Inc.
APAP 325 mg (Acetaminophen 325 mg) Bulk Container, ULTRAtab Laboratories, Inc., Highland, NY NDC 62959-200-00	Class II	Drugs	Product Codes: L200L Bulk Lots: 18K072, 19C049	CGMP Deviations	ULTRAtab Laboratories, Inc.
Coated APAP 325mg (Acetaminophen 325 mg) Bulk Container, ULTRAtab Laboratories, Inc., Highland, NY NDC 62959-202-00	Class II	Drugs	Product Codes: L202L Bulk Lots: 18K013, 18K014, 18K015, 19A040,	CGMP Deviations	ULTRAtab Laboratories, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			18M076, 19A041, 19H072, 19H073, 19H074		
Normed APAP 325 mg (Acetaminophen 325 mg) Bulk Container, ULTRAtab Laboratories, Inc., Highland, NY NDC 62959-203-00	Class II	Drugs	Product Codes: L203L Bulk Lots: 18K012, 19E091	CGMP Deviations	ULTRAtab Laboratories, Inc.
Coated APAP 500 mg caplet (Acetaminophen 500 mg) Bulk Container, ULTRAtab Laboratories, Inc., Highland, NY NDC 62959-206-00	Class II	Drugs	Product Codes: L206L Bulk Lots: 19B002	CGMP Deviations	ULTRAtab Laboratories, Inc.
Extra-Strength Unaspirin caplet (Acetaminophen 500 mg) Bulk Container, ULTRAtab Laboratories, Inc., Highland, NY NDC 62959-207-00	Class II	Drugs	Product Codes: L207L Bulk Lots: 18K111, 19E104, 19F050	CGMP Deviations	ULTRAtab Laboratories, Inc.
APAP 500 mg tablet (Acetaminophen 500 mg) Bulk Container, ULTRAtab Laboratories, Inc., Highland, NY NDC 62959-210-00	Class II	Drugs	Product Codes: L210L Bulk Lots: 18L120, 19B044, 19E082	CGMP Deviations	ULTRAtab Laboratories, Inc.
APAP 500 mg SRC Coated (Acetaminophen 500 mg) Bulk Container, ULTRAtab Laboratories, Inc., Highland, NY NDC 62959-211-00	Class II	Drugs	Product Codes: L211L Bulk Lots: 18M043, 18M044, 18M045, 19B032, 19B033, 19B034, 19F008, 19F009, 19F010	CGMP Deviations	ULTRAtab Laboratories, Inc.
HPC Tablet (Acetaminophen 110 mg, Aspirin 162 mg, Caffeine 32.4 mg, Salicylamide 152 mg) Bulk Container, ULTRAtab Laboratories, Inc., Highland, NY NDC 62969-242-00	Class II	Drugs	Product Codes: L242SRC Bulk Lot: 18K086, 18L009, 18L050, 18L083, 18M025, 18M073, 18M098, 19A010, 19A084, 19A105, 19A107; Product Code: L242L Bulk Lot: 19H014; Product Code: L242PA Bulk Lot: 18F072, 18L119,	CGMP Deviations	ULTRAtab Laboratories, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			19A067, 19G043; Product Code: L242N Bulk Lot: 19H040		
Peppermint Antacid tablet (Calcium Carbonate 420 mg) Bulk Container, ULTRAtab Laboratories, Inc., Highland, NY NDC 62959-303-00	Class II	Drugs	Product Code: M303 Bulk lots: 19C042, 19C043, 19F083; Product Code: M303A Bulk Lot: 19E105	CGMP Deviations	ULTRAtab Laboratories, Inc.
Cherry Antacid Tablet (Calcium Carbonate 420 mg) Bulk Container, ULTRAtab Laboratories, Inc., Highland, NY NDC 62959-304-00	Class II	Drugs	Product Codes: M304 Bulk Lots: 18K059, 18L106, 18L117, 18M067, 18M068	CGMP Deviations	ULTRAtab Laboratories, Inc.
Trial Antacid Tablet (Calcium Carbonate 420 mg) Bulk Container, ULTRAtab Laboratories, Inc., Highland, NY NDC 62959-310-00	Class II	Drugs	Product Codes: M310 Bulk Lots: 19C044, 19H015	CGMP Deviations	ULTRAtab Laboratories, Inc.
Spearmint Antacid Tablet (Calcium Carbonate 420 mg) Bulk Container, ULTRAtab Laboratories, Inc., Highland, NY NDC 62959-311-00	Class II	Drugs	Product Codes: M311 Bulk Lots: 19A069	CGMP Deviations	ULTRAtab Laboratories, Inc.
Nutralox Peppermint Antacid (Calcium Carbonate 420 mg) Bulk Container, ULTRAtab Laboratories, Inc., Highland, NY NDC 62959-312-00	Class II	Drugs	Product Codes: M312 Bulk Lots: 18J004, 18J005, 18C045, 19C046	CGMP Deviations	ULTRAtab Laboratories, Inc.
Ephedrine 25 Guaifenesin 200 Tablet (Ephedrine HCl 25 mg, Guaifenesin 200 mg) Bulk Container, ULTRAtab Laboratories, Inc., Highland, NY NDC 62959-320-00	Class II	Drugs	Product Codes: M320L Bulk Lots: 18M063, 19G076	CGMP Deviations	ULTRAtab Laboratories, Inc.
Phenylephrine HCl 5 mg Tablet (Phenylephrine HCl 5mg) Bulk Container, ULTRAtab Laboratories, Inc., Highland, NY NDC 62959-333-00	Class II	Drugs	Product Codes: M333 Bulk Lots: 18M065, 19J078	CGMP Deviations	ULTRAtab Laboratories, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Coated Phenylephrine HCl 5mg Tablet (Phenylephrine HCl 5mg) Bulk Container, ULTRAtab Laboratories, Inc., Highland, NY NDC 62959-338-00	Class II	Drugs	Product Codes: M338 Bulk Lots: 19A070, 19B080, 19J043	CGMP Deviations	ULTRAtab Laboratories, Inc.
Migrenol Caplet (Acetaminophen 500 mg, Caffeine 65 mg) Bulk Container, ULTRAtab Laboratories, Inc., Highland, NY NDC 62959-565-00	Class II	Drugs	Product Codes: M565L Bulk Lots: 19F014	CGMP Deviations	ULTRAtab Laboratories, Inc.
APAP 325 mg (Acetaminophen 325 mg, Pamabrom 25 mg tablet) Bulk Container, ULTRAtab Laboratories, Inc., Highland, NY NDC 62959-700-00	Class II	Drugs	Product Codes: M700LA Bulk Lots: 18K037, 18L093, 18M006, 19A121, 19G044, 19G045, 19G046	CGMP Deviations	ULTRAtab Laboratories, Inc.
Normed Fem Tablet (Acetaminophen 325 mg, Pamabrom 25 mg) Bulk Container, ULTRAtab Laboratories, Inc., Highland, NY NDC 62959-701-00	Class II	Drugs	Product Codes: M701L Bulk Lots: 19G077	CGMP Deviations	ULTRAtab Laboratories, Inc.
Pain Aid PMF Caplet (Acetaminophen 500 mg, Pamabrom 25 mg) Bulk Container, ULTRAtab Laboratories, Inc., Highland, NY NDC 62959-710-00	Class II	Drugs	Product Codes: M710L Bulk Lots: 19A071	CGMP Deviations	ULTRAtab Laboratories, Inc.
Back Relief II (Acetaminophen 200 mg, Magnesium Salicylate 200 mg) Bulk Container, ULTRAtab Laboratories, Inc., Highland, NY NDC 62959-740-00	Class II	Drugs	Product Codes: M740LA Bulk Lots: 19C022, 19C023	CGMP Deviations	ULTRAtab Laboratories, Inc.
Legatrin (Acetaminophen 500 mg, Diphenhydramine HCl 50 mg) Bulk Container, ULTRAtab Laboratories, Inc., Highland, NY NDC 62959-785-00	Class II	Drugs	Product Codes: M785L Bulk Lots: 18K029, 18L059, 18M100, 19B013, 19D024, 19D059, 19E029, 19J050	CGMP Deviations	ULTRAtab Laboratories, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Coated Back Relief Tablet (Acetaminophen 250 mg, Magnesium Salicylate 290 mg, Caffeine 50 mg) Bulk Container, ULTRAtab Laboratories, Inc., Highland, NY NDC 62959-800-00	Class II	Drugs	Product Codes: M800L Bulk Lots: 18K005, 18K075, 18K098, 18M064, 19C021, 19C050, 19G081, 19G082, 19H012, 19H013, 19J036, 19J037	CGMP Deviations	ULTRAtab Laboratories, Inc.
DBI Magnums Tablet (Caffeine 200 mg) 100 and 500 count & 3 and 36 count packets & Bulk Container, ULTRAtab Laboratories, Inc., Highland, NY NDC 62959-941-00	Class II	Drugs	Product Codes: M941L M940LA Bulk Lots: 19C065, 19F081, 19H083, 17D088	CGMP Deviations	ULTRAtab Laboratories, Inc.
Cystex Tablet (Sodium Salicylate 162.5 mg, Methenamine 162 mg) Bulk Container, ULTRAtab Laboratories, Inc., Highland, NY 62959-945-00	Class II	Drugs	Product Codes: M945 Bulk Lots: 18J072, 18K030, 18L123, 19A043, 19A093, 19B062, 19C079, 19C080, 19D041, 19E035, 19E087, 19G084, 19H098	CGMP Deviations	ULTRAtab Laboratories, Inc.
Apheresis Red Blood Cells, Leukocytes Reduced	Class II	Biologics	W1151213240295 (double collection)	Apheresis Red Blood Cell products, for which unit sterility was compromised during collection, were distributed.	LifeSouth Community Blood Centers, Inc.
Pooled Cryoprecipitated AHF	Class II	Biologics	W125621026456	Blood products, for which donor eligibility was incomplete, were distributed.	Blood Bank Of San Bernardino And Riverside Counties
Red Blood Cells, Leukocytes Reduced	Class II	Biologics	W125621024013; W125621067755	Blood products, for which donor eligibility was incomplete, were distributed.	Blood Bank Of San Bernardino And Riverside Counties

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Apheresis Platelets, Leukocytes Reduced	Class II	Biologics	W041021065500009	Leukoreduced Apheresis Platelets, in which platelet yield did not meet specifications, were distributed.	Blood Systems Inc
Red Blood Cells, Leukocytes Reduced	Class II	Biologics	W066521270072	Misbranded Leukoreduced Red Blood Cells were distributed.	Blood Bank of Alaska, Inc.
Red Blood Cells, Leukocytes Reduced	Class II	Biologics	W037721059509	Blood products, collected from a donor who had recently traveled to a malarial endemic area, were distributed.	Hoxworth Blood Center University of Cincinnati Medical Center
Cryoprecipitated AHF	Class II	Biologics	W037721059509	Blood products, collected from a donor who had recently traveled to a malarial endemic area, were distributed.	Hoxworth Blood Center University of Cincinnati Medical Center
Platelets, Leukocytes Reduced	Class II	Biologics	W036821970692	Platelet product, for which quality control for residual WBC count was not performed, was distributed.	OneBlood, Inc.
Apheresis Red Blood Cells, Leukocytes Reduced	Class II	Biologics	W036821843535 (Double Collection)	Leukoreduced Apheresis Red Blood Cells, which were labeled as leukocytes reduced but were not tested to verify white blood cell count, were distributed.	OneBlood, Inc.
Apheresis Red Blood Cells, Leukocytes Reduced	Class II	Biologics	W036821946783 (double collection)	Apheresis Red Blood Cell products, for which quality control for	OneBlood, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
				residual WBC count was not performed, were distributed.	
Red Blood Cells, Leukocytes Reduced	Class II	Biologics	W115921089540	Leukoreduced Red Blood Cell, for which donor eligibility screening was incomplete, was distributed.	Central California Blood Center
Apheresis Platelets, Platelet Additive Solution Added, Leukocytes Reduced	Class II	Biologics	W036920200373	Plateletpheresis product, for which for pH testing was not performed, was distributed.	Blood Bank Of Delmarva, a Division of New York Blood Center, Inc.
Apheresis Platelets, Leukocytes Reduced, Irradiated	Class II	Biologics	W042521084207000D	Blood products, which were labeled as leukocytes reduced but failed the monthly QC residual white blood cell count, were distributed.	Vitalant
Apheresis Platelets, Leukocytes Reduced	Class II	Biologics	W042521084207000D	Blood products, which were labeled as leukocytes reduced but failed the monthly QC residual white blood cell count, were distributed.	Vitalant
Red Blood Cells, Leukocytes Reduced	Class II	Biologics	W040721109382	Leukoreduced Red Blood Cells, collected from a donor who was at a higher risk for variant Creutzfeldt-Jakob disease (vCJD), was distributed.	Versiti Indiana Inc
Apheresis Platelets, Leukocytes Reduced	Class II	Biologics	W044221811579; W044221813014; W044221808981;	Leukoreduced Apheresis Platelets, which were labeled as irradiated but were not irradiated, were distributed.	San Diego Blood Bank

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			W044221811582 (Double Collection)		
PF24 Plasma	Class II	Biologics	W202920485636	PF24 Plasma, for which donor eligibility screening was incomplete, were distributed.	American Red Cross Greater Alleghenies Region
Red Blood Cells Frozen, Leukocytes Reduced	Class II	Biologics	W140919046659; W140919115971; W140919081339	Blood products, collected from a donor who had recently traveled to a malarial endemic area, were distributed.	South Texas Blood & Tissue Center
Platelets, Irradiated	Class II	Biologics	W140919046659	Blood products, collected from a donor who had recently traveled to a malarial endemic area, were distributed.	South Texas Blood & Tissue Center
Cornea	Class II	Biologics	2138819ODC; 2138819OSC	Corneas, recovered from a donor who was at risk for variant Creutzfeldt-Jakob disease (vCJD), were distributed.	Donor Network of Arizona
NaturesPlus Advanced Therapeutics Glucosamine Chondroitin MSM Ultra Rx-Joint Cream, 4 oz tubes, Manufactured for NaturesPlus 548 Broadhollow Road, Melville, NY 11747, USA	Class II	Drugs	Product code 4929, Lot # 23622	MICROBIAL CONTAMINATION OF NON-STERILE PRODUCT: microbial contaminant identified as Pluralibacter gergoviae.	Organics Corporation of America DBA Ambix Laboratories
Moxifloxacin Ophthalmic Solution, USP 0.5% w/v, 3 mL bottle, Sterile, Rx Only, Distributed by: Aurobindo Pharma USA, Inc., East Windsor, NJ 08520, Made in India, NDC 65862-840-03	Class II	Drugs	Lot#: CMF210001, CMF210003, CMF210004, Exp 6/2023	Failed impurities/degradation specifications -Out of Specification (OOS) results of 0.78% to 1.02%; Spec NMT 0.1% for Other Single impurities	Aurobindo Pharma USA Inc.
Chlorthalidone Tablets USP 25 mg, Rx Only, 100 Tablets, Sun Pharma, Mfg. by: Fontida	Class II	Drugs	Lot #: P0602, Exp. Date 03/2023	Foreign Matter identified as stainless steel microscopic wear	SUN PHARMACEUT

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Bio Pharm Inc., 1100 Orthodox St. Philadephia, PA 19124, Dist. by: Sun Pharmaceutical Industries, Inc., Cranbury, NJ 08512, NDC 57664-648-88.				particles mixed with punch lubricant oil and silicone particles from the dust cup	ICAL INDUSTRIES INC
Diazepam Oral Solution (Concentrate), 25 mg per 5 mL (5 mg/mL), 30 mL BOTTLE and DROPPER, Rx Only, Distributed by: Lannett Company, Inc., Philadelphia, PA 19136, NDC 0527-1768-36.	Class II	Drugs	Lot #: 2664A, 2664B, Exp. date 07/2022; 2874A, 2874B, Exp. date 01/2023	Failed Impurities/Degradation Specifications: Out of specification results for related substances.	Lannett Company, Inc.
Alprazolam Tablets, USP 0.25 mg, packaged in a) 100-count bottles (NDC 67253-900-10), b) 500-count bottles (NDC 67253-900-50), and c) 1000-count bottles (NDC 67253-900-11), Rx only, Distributed by: Par Pharmaceutical Chestnut Ridge, NY 10977	Class II	Drugs	Lot #: a) 19C003A, Exp. Date 03/2022; 19G002A, exp. date 07/2022; b) 19C004B, Exp. Date 03/2022; c) 19C048C, Exp. Date 03/2022	cGMP Deviations	ANI Pharmaceuticals, Inc.
Alprazolam Tablets, USP 0.5 mg, packaged in a) 100-count bottles (NDC 67253-901-10), b) 500-count bottles (NDC 67253-901-50), and c) 1000-count bottles (NDC 67253-901-11), Rx only, Distributed by: Par Pharmaceutical Chestnut Ridge, NY 10977	Class II	Drugs	Lot #: a) 19B029A, Exp. Date 02/2022; 19D021A, Exp. Date 04/2022. b) 19A087B, 19A088B, 19A089B, 19A090B, Exp. Date 02/2022; 19A086B, 19A091B, 19B019B, Exp. Date 02/2022. c) 19B020C, 19B021C, 19B027C, 19B028C, Exp. Date 02/2022, 19E056C, 19E057C, Exp. Date 05/2022; 19E059C, Exp. Date 06/2022 19G072C, Exp. Date 07/2022	cGMP Deviations	ANI Pharmaceuticals, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Alprazolam Tablets, USP 1.0 mg, packaged in a) 100-count bottles (NDC 67253-902-10), b) 500-count bottles (NDC 67253-902-50), and c) 1000-count bottles (NDC 67253-902-11), Rx only, Distributed by: Par Pharmaceutical Chestnut Ridge, NY 10977	Class II	Drugs	Lot #: a) 19B081A, Exp. Date 02/2022; 19E088A, 19E089A, Exp. Date 05/2022 b) 19A102B, Exp. Date 02/2022; 19D067B, 19D068B, Exp. Date 04/2022; 19D070C, Exp. Date 05/2022. c) 19F045C, 19F046C, Exp. Date 06/2022; 19B082C, 19B083C, Exp. Date 03/2022; 19D069C, Exp. Date 05/2022.	cGMP Deviations	ANI Pharmaceuticals, Inc.
Alprazolam Tablets, USP 2.0 mg, packaged in a) 100-count bottles (NDC 67253-903-10), b) 500-count bottles (NDC 67253-903-50), Rx only, Distributed by: Par Pharmaceutical Chestnut Ridge, NY 10977	Class II	Drugs	Lot #: a) 19C002A, Exp. Date 03/2022; 19E012A, 19E013A, Exp. Date 05/2022. b) 19C100B, Exp. Date 04/2022; 19E001B, 19E002B, Exp. Date 05/2022.	cGMP Deviations	ANI Pharmaceuticals, Inc.
Pyrazinamide Tablets, USP 500 mg, 100-count bottles, Rx only, Manufactured by: ULTRAtab Laboratories, Inc. Highland, NY 12528, Distributed by Par Pharmaceuticals, Chestnut Ridge, NY 10977, NDC 67253-660-10.	Class II	Drugs	Lot #: 19B064A, Exp. Date 03/2022	cGMP Deviations	ANI Pharmaceuticals, Inc.
CariFree CTx4 GEl 5000 1.1% Neutral Sodium Fluoride Mint, 2 oz (57 g) Rx only NDC: 61578-205-01 Manufactured by Oral	Class III	Drugs	Lot #: 142017 Exp. Date 06/22	Subpotent Drug: Product contains less Sodium Fluoride than listed on product label.	Dental Alliance Holdings LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
BioTech Albany, Oregon 97321 Distributed in 12-pk/cases					
CTx7 Kit, contains one tube CariFree CTx4 Gel 5000, 1.1% Neutral Sodium Fluoride Mint, 2 oz (57 g) Rx only NDC: 61578-205-01 Manufactured by Oral BioTech Albany, Oregon 97321 and one bottle of CariFree CTx3 Rinse, Mint Anticavity Rinse, 16 fl oz. bottle.	Class III	Drugs	Lot #: 192107 and lot 192108 Exp. Date 06/22 (contains recalled CariFree CTx4 5000 gel tube lot 142017)	Subpotent Drug: Product contains less Sodium Fluoride than listed on product label.	Dental Alliance Holdings LLC
CTx21 Kit, contains three tubes of CariFree CTx4 Gel 5000, 1.1% Neutral Sodium Fluoride Mint, 2 oz (57 g) Rx only NDC: 61578-205-01 Manufactured by Oral BioTech Albany, Oregon 97321 and three bottles of CariFree CTx3 Rinse, Mint Anticavity Rinse, 16 fl oz. bottle.	Class III	Drugs	Lot #: 272109, 272110 Exp. Date 06/22; (contains recalled CariFree CTx4 5000 gel tube lot 142017)	Subpotent Drug: Product contains less Sodium Fluoride than listed on product label.	Dental Alliance Holdings LLC
CTx26 Kit, contains three tubes of CariFree CTx4 Gel 5000, 1.1% Neutral Sodium Fluoride Mint, 2 oz (57 g) Rx only NDC: 61578-205-01 Manufactured by Oral BioTech Albany, Oregon 97321 and two bottles of CariFree CTx3 Rinse, Mint Anticavity Rinse, 16 fl oz. bottle an two boxes of 4fl.oz. Carifree CTx4 Treatment Rinse.	Class III	Drugs	Lot#: 312107, 312108 Exp. Date 06/22; (contains recalled CariFree CTx4 5000 gel tube lot 142017)	Subpotent Drug: Product contains less Sodium Fluoride than listed on product label.	Dental Alliance Holdings LLC
CTx36 Kit, contains three tubes of CariFree CTx4 Gel 5000, 1.1% Neutral Sodium Fluoride Mint, 2 oz (57 g) Rx only NDC: 61578-205-01 Manufactured by Oral	Class III	Drugs	Lot #: 352110, 352111 Exp. Date 06/22; (contains recalled CariFree CTx4 5000 gel tube lot 142017)	Subpotent Drug: Product contains less Sodium Fluoride than listed on product label.	Dental Alliance Holdings LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
BioTech Albany, Oregon 97321 and six boxes of 4fl.oz. Carifree CTx4 Treatment Rinse.					
CariFree sample boxes, contains one tube of CariFree CTx4 Gel 5000, 1.1% Neutral Sodium Fluoride Mint, 2 oz (57 g) Rx only NDC: 61578-205-01 Manufactured by Oral BioTech Albany, Oregon 97321.	Class III	Drugs	Lot #: 492106, 492107 Exp. Date 06/22 (contains recalled CariFree CTx4 5000 gel tube lot 142017).	Subpotent Drug: Product contains less Sodium Fluoride than listed on product label.	Dental Alliance Holdings LLC
CTx12 5000 Kit which contains 3 boxes of CariFree CTx4 GEl 5000 gel tubes. 1.1% Neutral Sodium Fluoride Mint, 2 oz (57 g) Rx only NDC: 61578-205-01 Manufactured by Oral BioTech Albany, Oregon 97321.	Class III	Drugs	Lot #: 142017, exp. Date 06/22	Subpotent Drug: Product contains less Sodium Fluoride than listed on product label.	Dental Alliance Holdings LLC
Blood and Blood Products for Reprocessing	Class III	Biologics	W201919598190000B	Blood product, for which donor eligibility was incomplete, was distributed.	American Red Cross Blood Services Tennessee Valley Region
Blood and Blood Products for Reprocessing	Class III	Biologics	W20212128091300L	Blood and Blood Products for Reprocessing, for which donor eligibility screening was incomplete, were distributed.	American National Red Cross
Blood and Blood Products for Reprocessing	Class III	Biologics	W204021285078000Y	Blood product, for which donor eligibility was incomplete, was distributed	American Red Cross Blood Services Heart of America Region
Blood and Blood Products for Reprocessing	Class III	Biologics	W205321625986002	Blood products, for which donor eligibility screening was incomplete, were distributed.	American Natl. Red Cross-Greater Chesapeake &

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
					Potomac Region
Red Blood Cells, Leukocytes Reduced	Class III	Biologics	W115921088984	Red Blood Cell, collected from a donor whose body temperature was not documented, was distributed.	Central California Blood Center
Reagent Red Blood Cells 0.8% Resolve Panel A	Class III	Biologics	Lot: VRA394 Product Code: 6902317	Ortho Clinical Diagnostics 0.8% Resolve Panel cell, demonstrating weak or negative reactions, was distributed.	Ortho Clinical Diagnostics Inc
Red Blood Cells, Leukocytes Reduced	Class III	Biologics	W040821206916; W040821206917; W040821206920; W040821206921; W040821206922; W040821206923; W040821206925; W040821206926; W040821206927; W040821206929; W040821206930; W040821206933; W040821206934; W040821206935; W040821206936; W040821206937; W040821206938; W040821206939; W040821206940; W040821206941;	Blood products, bearing an incorrect donor classification, were distributed.	West TN Regional Blood Center, dba Lifeline Blood Services

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			W040821206942; W040821206943; W040821206944; W040821206945; W040821206946; W040821206947; W040821206949; W040821206966; W040821206950; W040821206953; W040821206958; W040821206961; W040821206969; W040821206970; W040821206971;		
Fresh Frozen Plasma	Class III	Biologics	W040820118105; W040820118109; W040820118114; W040820118116; W040820119228; W040821107868; W040821107872; W040821114651; W040821114653; W040821114662; W040821114666; W040821101429; W040821101182; W040821101185; W040821101191;	Blood products, bearing an incorrect donor classification, were distributed.	West TN Regional Blood Center, dba Lifeline Blood Services

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			W040821101192; W040821103280; W040821103286; W040821103294; W040821103297; W040820111601; W040820112380; W040820112382; W040820112386; W040820112387; W040820112388; W040820112389; W040820112390; W040820112393; W040820112394; W040820112395; W040820112398; W040820118097; W040820118100; W040820118103; W040820118104;		
Blood and Blood Products for Reprocessing	Class III	Biologics	W202721277712	Blood products, for which donor eligibility screening was incomplete, were distributed.	American Red Cross Greater Alleghenies Region
Red Blood Cells, Leukocytes Reduced	Class III	Biologics	W20532160646000*; W20532162697300X; W205321641149002; W20532164845100Q;	Blood products, for which transfusion-transmitted infection test/testing was performed, interpreted, or documented incorrectly, were distributed.	American Natl. Red Cross-Greater Chesapeake &

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
					Potomac Region
Red Blood Cells, Leukocytes Reduced, Irradiated	Class III	Biologics	W20532165320900K	Blood products, for which transfusion-transmitted infection test/testing was performed, interpreted, or documented incorrectly, were distributed.	American Natl. Red Cross-Greater Chesapeake & Potomac Region
Apheresis Platelets, Platelet Additive Solution Added, Leukocytes Reduced	Class III	Biologics	W20532181822200K; W20532181822200K; W20532181822300I; W20532181822300I; W20532181822400G; W20532181822400G; W20532181822500E; W20532181822600C; W20532182084800B; W205321820849009; W20532182085000N; W20532182085000N; W20532182085200J; W20532182085300H; W20532182085400F; W20532182203700C; W20532182203700C; W205321822039008; W205321823491000Q; W205321823491000Q; W20532182573900F; W20532182574100R;	Blood products, for which transfusion-transmitted infection test/testing was performed, interpreted, or documented incorrectly, were distributed.	American Natl. Red Cross-Greater Chesapeake & Potomac Region

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			W20532182574600H; W20532182574600H; W20532182695200Q; W20532182695400M; W20532182695600I; W20532182695700G; W20532182695700G; W20532182695800E; W20532183148000W; W20532183148000W; W205321831942004; W205321831943002; W205321831944000; W205321831944000; W205321831945002; W205321831947000; W205321831949000; W205321831952000; W205321837265000; W205321837265000; W205321837266000M; W205321837266000M; W205321837271000S; W205321837271000S; W205321820852000J; W205321820853000H; W205321820854000F; W205321822038000A; W205321822039008; W205321825738000H;		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			W205321825739O0F; W205321825742O0P; W205321826952O0Q; W205321826954O0M; W205321826956O0I; W205321826957O0G; W205321826958O0E; W205321831480O0W; W205321831942004; W205321831943002; W205321831943002; W205321831945O0Z; W205321831947O0V; W205321831949O0R; W205321831952000; W205321837265O0O; W205321818226O0C; W205321818226O0C; W205321820849009; W205321820850O0N;		
Blood and Blood Products for Reprocessing	Class III	Biologics	W125621085094	Blood products, for which donor eligibility was incomplete, were distributed.	Blood Bank Of San Bernardino And Riverside Counties
Apheresis Red Blood Cells, Leukocytes Reduced	Class III	Biologics	W1151212437604	Blood product, for which transfusion-transmitted infection test/testing was performed, interpreted, or documented incorrectly, was distributed.	LifeSouth Community Blood Centers, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Red Blood Cells, Leukocytes Reduced	Class III	Biologics	W115921213996	Blood product, collected from a donor whose body temperature was not documented during the donor screening process, was distributed.	Central California Blood Center
Wal-Fex D, Fexofenadine HCl 60mg/Antihistamine & Pseudoephedrine HCl 120mg/Nasal Decongestant, Extended Release Tablets USP, a) 20 Extended Release Tablets per box, NDC 0363-1606-20, b) 30 Extended Release Tablets per box, NDC 0363-1606-30, Distributed by: Walgreen Co, 200 Wilmot Rd., Deerfield, IL 60015, Made in India.	Class III	Drugs	Lot #s: a) (20-count box): AC2000968D, Exp. 8/31/2022; AC2103330J, Exp. 1/31/2023; AC2106452A; AC2106452H, Exp. 3/31/2023. b) (30-count box): 79C002624C, Exp. 4/30/2022; AC2103328B; AC2103328C; AC2103330A; AC2103330B, Exp. 1/31/2023.	Failed Dissolution Specifications	Dr. Reddy's Laboratories, Inc.
Rugby, Antihistamine and Nasal Decongestant, Fexofenadine HCl 60mg and Pseudoephedrine HCl 120mg, Extended-Release Tablets USP, 30 Tablets per box, NDC 0536-1242-07, Distributed by: Rugby Laboratories, 17177 N Laurel Park Drive, Suite 233, Livonia, MI, 49152, Made in India.	Class III	Drugs	Lot #: AC2106452F, Exp. 3/31/2023	Failed Dissolution Specifications	Dr. Reddy's Laboratories, Inc.
Rite Aid Pharmacy, Allergy & Congestion, Fexofenadine HCl 60mg & Pseudoephedrine HCl 120mg, Extended Release Tablets USP, 20 Extended-Release Tablets per box, UPC 011822738873, Distributed by Rite Aid, 30	Class III	Drugs	Lot #: AC2103330D, Exp.1/31/2023; AC2106452E, Exp. 3/31/2023.	Failed Dissolution Specifications	Dr. Reddy's Laboratories, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
United Lane, Camp Hill, PA 17011, Made in India.					
Kroger, Allergy Relief-D, Fexofenadine HCl 60mg/Antihistamine Pseudoephedrine HCl 120mg/Nasal Decongestant, Extended-Release Tablets USP, 20 tablets per box, NDC 30142-611-14, Distributed by the Kroger Co., Cincinnati, Ohio, 45202, Made in India.	Class III	Drugs	Lot #s: AC2000968E, Exp. 8/31/2022; AC2103328A; AC2103330I, Exp. 1/31/2023; AC2106452B, Exp. 3/31/2023.	Failed Dissolution Specifications	Dr. Reddy's Laboratories, Inc.
Dr. Reddys, Fexofenadine HCl 60 mg & Pseudoephedrine HCl 120 mg Extended-Release Tablets USP, a) 10 tablets per box, UPC 343598823355, b) 20 tablets per box, UPC 343598823140, c) 30 tablets per box, UPC 343598823317, Distributed by: Dr. Reddy's Laboratories, Inc. Princeton, NJ 08540, Made in India.	Class III	Drugs	Lot #s: a) (10-count): AC2103328D, Exp. 1/31/2023. b) (20-count) :AC2000968C, Exp. 8/31/2022. c) (30-count): AC2103330C, Exp. 1/31/2023; AC2106452D, Exp. 3/31/2023.	Failed Dissolution Specifications	Dr. Reddy's Laboratories, Inc.
equate, Allergy Relief D, Fexofenadine HCl 60mg/Antihistamine, Pseudoephedrine HCl 120mg/Nasal Decongestant Extended-Release Tablets USP, a) 20 Extended Release Tablets per box, NDC 49035-273-20, b) 30 Extended Release Tablets per box, NDC 49035-273-30, Distributed by: Walmart Inc., Bentonville, AR 72716, Product of India.	Class III	Drugs	Lot #s: a) (20-count): 79C002624A, Exp. 4/30/2022; AC2000968B, Exp. 8/31/2022; AC2103328F; AC2103330E, Exp.1/31/2023; AC2106452I, Exp. 3/31/2023. b) (30-count): 79C002625A, Exp. 4/30/2022; AC2103328E; AC2103330F, Exp. 1/31/2023; AC2106452G, Exp. 3/31/2023.	Failed Dissolution Specifications	Dr. Reddy's Laboratories, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
QC QUALITY CHOICE, Fexofenadine HCl 60mg and Pseudoephedrine HCl 120mg, Extended-Release Tablets, USP, Allergy & Congestion, 10 Tablets per box, NDC 63868-729-10, Distributed by C.D.M.A., Inc., 43157 W 9 Mile Rd, Novi, MI 48375, Made in India.	Class III	Drugs	Lot #s: 79C002624D; 79C002625C, Exp. 4/30/2022.	Failed Dissolution Specifications	Dr. Reddy's Laboratories, Inc.
CVS Health, Allergy Relief D, Fexofenadine HCl 60mg/Antihistamine Pseudoephedrine HCl 120mg/Nasal Decongestant, a) 20 Extended Release Tablets per box, UPC 050428436189, b) 30 Extended Release Tablets per box, UPC 050428290538, Distributed by CVS Pharmacy Inc., One CVS Drive, Woonsocket, RI, 02895, Made in India.	Class III	Drugs	Lot #s: a) (20-count): AC2000968A; AC2000968F, Exp. 8/31/2022. b) (30-count): 79C002624B, Exp. 4/30/2022; AC2103330G; AC2103330H, Exp. 1/31/2023.	Failed Dissolution Specifications	Dr. Reddy's Laboratories, Inc.
Leader, 12HR Allergy & Congestion Relief, Fexofenadine HCl, 60mg Pseudoephedrine HCl 120mg Antihistamine Nasal Decongestant, 20 Extended Release Tablets per box, NDC 70000-0518-1, Distributed by Cardinal Health, Dublin, Ohio 43077, Made in India.	Class III	Drugs	Lot #s: 79C002625B, Exp. 4/30/2022; AC2103328G, Exp. 1/31/2023; AC2106452C, Exp. 3/31/2023.	Failed Dissolution Specifications	Dr. Reddy's Laboratories, Inc.
Mucus Relief D, Guaifenesin Pseudoephedrine HCl ER Tablets, 600 mg/60mg, packaged in 36-count blister pack packed into cartons, Distributed by: Walgreen Co., 200 Wilmot Rd., Deerfield, IL 60015, Made in India, NDC 0363-164-3	Class III	Drugs	Lot #: AT2102065A, AT2102065B, Exp 04/2023.	Subpotent drug	Dr. Reddy's Laboratories, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Mimvey (estradiol and norethindrone acetate tablets USP), 1 mg/0.5 mg, packaged in cartons of 28 Tablets, Rx only, Manufactured By: Barr Laboratories, Inc., Pomona, NY 10970, Manufactured For: Teva Pharmaceuticals USA Inc. North Wales, PA 19454, NDC 0093-5455-28	Class III	Drugs	Lot#: 100018611, Exp 03/2022; 100019834, Exp 06/2022; 100022226, Exp 09/2022; 100024574, Exp 01/2023	Mislabeling	Teva Pharmaceuticals USA
Mimvey (estradiol and norethindrone acetate tablets USP) 1 mg/0.5 mg, packaged in cartons of 28 Tablets, Rx Only, Manufactured By: Barr Laboratories, Inc., Pomona, NY 10970, Manufactured For: Teva Pharmaceuticals USA Inc. North Wales, PA 19454, NDC 0093-5455-42	Class III	Drugs	Lot#: 100018610, Exp 03/2022; 100021521, Exp 09/2022; 100024575, Exp 01/2023	Mislabeling	Teva Pharmaceuticals USA
Red Blood Cells, Leukocytes Reduced	Class III	Biologics	W04112103742300	Leukoreduced Red Blood Cells, in which the donor's hemoglobin was documented non-concurrently, was distributed.	Vitalant
Red Blood Cells, Leukocytes Reduced	Class III	Biologics	W115921203854	Red Blood Cell product, for which the donor's body temperature was not documented, was distributed.	Central California Blood Center
Red Blood Cells, Leukocytes Reduced, Irradiated	Class III	Biologics	W120621292449; W120621268038	Blood products, for which storage temperature was not documented, were distributed.	Versiti Michigan Inc
Apheresis Red Blood Cells, Leukocytes Reduced, Irradiated	Class III	Biologics	W120621268127 (double collection)	Blood products, for which storage temperature was not documented, were distributed.	Versiti Michigan Inc
Red Blood Cells, Leukocytes Reduced	Class III	Biologics	W120621600324; W120621600325	Red Blood Cell products, for which storage temperature was not documented, were distributed.	Versiti Michigan Inc

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Apheresis Red Blood Cells, Leukocytes Reduced	Class III	Biologics	W20532168245600L	Leukoreduced Apheresis Red Blood Cells were distributed without a final visual check.	American Natl. Red Cross-Greater Chesapeake & Potomac Region
Red Blood Cells, Leukocytes Reduced	Class III	Biologics	W20012170214500N	Red Blood Cell, identified as unsuitable due to a collection deviation, was distributed.	American National Red Cross (the)
Red Blood Cells, Leukocytes Reduced	Class III	Biologics	W044621301172; W037721073893	Leukoreduced Red Blood Cells were distributed without a final visual check.	Hoxworth Blood Center University of Cincinnati Medical Center
Fresh Frozen Plasma	Class III	Biologics	W035221396825W	Blood products, collected from a donor in which donor suitability was not adequately determined, were distributed.	Carter BloodCare
Red Blood Cells, Leukocytes Reduced	Class III	Biologics	W035221396825W	Blood products, collected from a donor in which donor suitability was not adequately determined, were distributed.	Carter BloodCare
Blood and Blood Products for Reprocessing	Class III	Biologics	W202221367152	Blood products, for which donor eligibility screening was incomplete, were distributed.	American National Red Cross, Penn Jersey Region
Paragard T 380A (Intrauterine Copper Contraceptive), package in cartons containing one sterile unit together with an	Not Yet Classified	Drugs	Lot # 517001,Exp 1/2024	Non-sterility	CooperSurgical, Inc

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
insertion tube and solid white rod in a Tyvek polyethylene pouch, Rx only, Manufactured by Teva Women's Health Inc. a subsidiary of Teva Pharmaceuticals USA, Inc., North Wales, PA 19454, NDC 51285-204-01					
Erythromycin Topical Gel USP, 2%, Net Wt 30 g tube, Rx only, Manufactured by: Teligent Pharma, Inc., Buena, NJ 08310, Distributed by: McKesson Corporation, dba Sky Packaging, 4971 Southridge Blvd., Suite 101, Memphis, TN 38141, NDC 63739-053-66.	Not Yet Classified	Drugs	Lot: 15724, Exp. 06/2022	Failed Impurities/Degradation Specifications: Lot not meeting specification for Unknown Max Related Compounds.	Teligent Pharma, Inc.
RED MAMMOTH capsules, 400 mg, packaged in 10-count blisters per carton, ASIN B00KA8FBNI, barcode X001ANE0I5.	Not Yet Classified	Drugs	Lot # DK1027, Exp. 08/01/2023	Marketed Without An Approved NDA/ANDA: Product was found to contain undeclared sildenafil and tadalafil, ingredients found in FDA approved products for the treatment of male sexual enhancement, making this an unapproved drug.	Celebrate Today
HCG 6,000iu (lyo) Human Chorionic Gonadotropin Inj., For Sub-Q or IM Use Only, Not For IV Use, Rx Only, 88888-1739-01, Compounded by: Compounded By: Revive Rx 3831 Golf Dr., Houston, TX 77018.	Not Yet Classified	Drugs	Lot: 631359 BUD: 05/01/2022	Non-sterility.	Revive Rx LLC dba Revive Rx Pharmacy

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

FDA DRUG SAFETY COMMUNICATIONS

[2/3/2022] FDA investigating possible increased risk of death with lymphoma medicine Ukoniq (umbralisib)

Consider risks and benefits of continued use versus other treatments

The U.S. Food and Drug Administration (FDA) is investigating a possible increased risk of death with the cancer medicine Ukoniq (umbralisib) approved to treat two specific types of lymphomas, which are cancers that affect the body's immune system. We determined that initial findings from a clinical trial evaluating Ukoniq to treat a related type of cancer found a possible increased risk of death in patients taking the medicine. Because of the seriousness of this safety concern and the similarities between the two types of cancer for which this drug is approved and the type of cancer that was studied in the clinical trial, we are alerting patients and health care professionals that we are re-evaluating this risk against the benefits of Ukoniq for its approved uses.

We are continuing to evaluate the results from the clinical trial called UNITY. FDA may also hold a future public meeting to discuss these findings and explore the continued marketing of Ukoniq. We have also suspended enrollment of new patients in other ongoing clinical trials of Ukoniq while we continue to review the UNITY findings. We will communicate our final conclusions and recommendations when we have completed our review or have more information to share.

Health care professionals should review patients' progress on Ukoniq and discuss with them the risks and benefits of continuing Ukoniq in the context of other available treatments.

Patients should talk to your health care professionals about the risks and benefits of Ukoniq or any concerns you may have, including about possible alternative treatments.

Ukoniq is a prescription medicine approved in February 2021 to treat adults with marginal zone lymphoma (MZL) when the disease has returned or it did not respond to prior treatment with at least one specific type of medicine. Ukoniq is also approved to treat adults with follicular lymphoma (FL) when the disease has returned or it did not respond to at least three prior treatments. Both MZL and FL are slow-growing cancers that start in white blood cells called lymphocytes, which are part of the body's immune system. Ukoniq, which is in a class of medicines called PI3 kinase inhibitors, works by blocking the action of an abnormal protein that signals cancer cells to multiply, which helps stop their spread. The medicine is available as a tablet to take by mouth.

We conducted an initial review of data from UNITY, a phase 3, randomized, controlled clinical trial in patients with chronic lymphocytic leukemia (CLL). The trial is evaluating Ukoniq in combination with a monoclonal antibody drug that targets a specific protein called CD20 compared to the control arm in which patients received standard treatment. The results showed a possible increased risk of death in patients receiving the combination of Ukoniq and the monoclonal antibody compared to the control arm. Those receiving the combination of Ukoniq and the monoclonal antibody also experienced more serious adverse events than those in the control arm. The UNITY trial was conducted in CLL patients, which is not an approved use but rather a use of this drug that is being studied; however, we believe

these findings have implications for its approved uses for MZL and FL. In addition, clinical trials of other medicines in the same PI3 kinase inhibitor class as Ukoniq have shown similar safety concerns.

We urge health care professionals and patients to report side effects involving Ukoniq or other medicines to the FDA MedWatch program.

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

CURRENT DRUG SHORTAGES

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

Generic Name or Active Ingredient

Acetazolamide Injection
Amifostine Injection
Amino Acids
Amoxapine Tablets
Amphetamine Oral Suspension, Extended Release
Atropine Sulfate Injection
Azacitidine for Injection
Azithromycin (Azasite) Ophthalmic Solution 1%
Bacteriostatic 0.9% Sodium Chloride Injection
Bacteriostatic Water for Injection
Belatacept (Nulojix) Lyophilized Powder for Injection
Bumetanide Injection
Bupivacaine Hydrochloride and Epinephrine Injection
Bupivacaine Hydrochloride Injection
Calcium Disodium Versenate Injection
Calcium Gluconate Injection
Cefazolin Injection
Cefixime Oral Capsules
Cefotaxime Sodium Injection
Cefotetan Disodium Injection
Ceftolozane and Tazobactam (Zerbaxa) Injection
Chlordiazepoxide Hydrochloride Capsules
Chloroprocaine Hydrochloride Injection
Continuous Renal Replacement Therapy (CRRT) Solutions
Cortisone Acetate Tablets
Cyclopentolate Ophthalmic Solution
Cysteamine Hydrochloride Ophthalmic Solution
Cytarabine Injection
Dacarbazine Injection
Desmopressin Acetate Nasal Spray
Dexamethasone Sodium Phosphate Injection
Dexmedetomidine Injection
Dextrose 25% Injection
Dextrose 5% Injection
Dextrose 50% Injection
Digoxin Injection
Disopyramide Phosphate (Norpace) Capsules
Dobutamine Hydrochloride Injection

Dopamine Hydrochloride Injection
Echothiophate Iodide (Phospholine Iodide) Ophthalmic Solution
Enalaprilat Injection
Epinephrine Injection, 0.1 mg/mL
Epinephrine Injection, Auto-Injector
Fentanyl Citrate (Sublimaze) Injection
Floxuridine for Injection
Fluvoxamine ER Capsules
Furosemide Injection
Gemifloxacin Mesylate (Factive) Tablets
Gentamicin Sulfate Injection
Guanfacine Hydrochloride Tablets
Heparin Sodium and Sodium Chloride 0.9% Injection
Hydrocortisone Tablets
Hydromorphone Hydrochloride Injection
Hydroxypropyl (Lacrisert) Cellulose Ophthalmic Insert
Imipenem and Cilastatin for Injection
Isoniazid Injection
Ketamine Injection
Ketoprofen Capsules
Ketorolac Tromethamine Injection
Leucovorin Calcium Lyophilized Powder for Injection
Leuprolide Acetate Injection
Lidocaine Hydrochloride (Xylocaine) and Dextrose Injection Solution-Premix Bags
Lidocaine Hydrochloride (Xylocaine) Injection
Lidocaine Hydrochloride (Xylocaine) Injection with Epinephrine
Lipid Injection
Lithium Oral Solution
Lorazepam Injection
Mannitol Injection
Mepivacaine Hydrochloride Injection
Methyldopa Tablets
Methylprednisolone Acetate Injection
Metronidazole Injection
Midazolam Injection
Misoprostol Tablets
Morphine Sulfate Injection
Multi-Vitamin Infusion (Adult and Pediatric)
Nefazodone Hydrochloride Tablets
Nizatidine Capsules
Ondansetron Hydrochloride Injection
Paclitaxel Injection (protein-bound particles)
Pantoprazole Sodium for Injection
Parathyroid Hormone (Natpara) Injection
Physostigmine Salicylate Injection
Potassium Acetate Injection

Potassium Chloride Concentrate 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 0.9% Injection Bags
Sodium Chloride 23.4% Injection
Sodium Chloride Injection USP, 0.9% Vials and Syringes
Sodium Phosphates Injection
Sterile Water for Injection
Sulfasalazine Tablets
Tacrolimus Capsules
Technetium Tc 99m Sulfur Colloid Injection
Technetium Tc99m Succimer Injection (DMSA)
Teprotumumab-trbw
Thiothixene Capsules
Tocilizumab Injection
Triamcinolone Acetonide Injectable Suspension
Triamcinolone Hexacetonide Injectable suspension
Valproate Sodium Injection
Varenicline Tartrate (Chantix) Tablets
Vecuronium Bromide for Injection
Vitamin A Palmitate (Aquasol A) Injection