PERFORMRx℠

Drug Information Update

April 2023

TABLE OF CONTENTS

NEWLY AVAILABLE GENERICS

Generic Name/ Dosage Form	Brand Name	Manufacturer	Indication
Posaconazole 200 mg/5 ml oral suspension	Noxafil	Merck Sharp & Dohme LLC	• Treatment of oropharyngeal candidiasis (OPC), including OPC refractory (rOPC) to itraconazole and/or fluconazole in adult and pediatric patients aged 13 years and older • For the prophylaxis of invasive Aspergillus and Candida infections in patients who are at high risk of developing these infections due to being severely immunocompromised, such as hematopoietic stem cell transplant (HSCT) recipients with graft versus-host disease (GVHD) or those with hematologic malignancies with prolonged neutropenia from chemotherapy in adults and pediatric patients 13 years and older
Topiramate 200 mg ER oral capsule	Trokendi XR	Catalent Pharma Solutions	• Initial monotherapy for the treatment of partial-onset or primary generalized tonic-clonic seizures in patients 6 years of age and older • Adjunctive therapy for the treatment of partial-onset, primary generalized tonic-clonic seizures, or seizures associated with Lennox-Gastaut syndrome (LGS) in patients 6 years of age and older • Preventive treatment of migraine in patients 12 years of age and older
Ciprofloxacin 500 mg/5 mL oral suspension	Cipro	Bayer HealthCare Pharmaceuticals Inc	Indicated for the following infections caused by designated, susceptible bacteria and in pediatric patients where indicated: skin and skin structure infections, bone and joint infections, complicated intra-abdominal infections, infectious diarrhea, typhoid fever (enteric fever), uncomplicated cervical and urethral gonorrhea, inhalational anthrax post-exposure in adult and pediatric patients, plague in adult and pediatric patients, chronic bacterial prostatitis, lower respiratory tract infections, urinary tract infections, acute sinusitis
Naftifine HCl 2% topical gel	Naftin	Sebela Pharmaceuticals Inc	Treatment of interdigital tinea pedis caused by the organisms Trichophyton rubrum, Trichophyton mentagrophytes, and Epidermophyton floccosum
Baclofen 25 mg/5 mL oral suspension	Fleqsuvy	Azurity Pharmaceuticals	Treatment of spasticity resulting from multiple sclerosis, particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity

Generic Name/ Dosage Form	Brand Name	Manufacturer	Indication
Budesonide 2 mg rectal foam	Uceris	Salix Pharmaceuticals	For the induction of remission in patients with active mild to moderate distal ulcerative colitis extending up to 40 cm from the anal verge

NEW DRUG ENTITIES/STRENGTHS/COMBINATIONS

Drug Name	Generic Name	Description	Comments
Zynyz 500 mg/20 mL IV solution	retifanlimab-dlwr	Anti-programmed death-1 (PD1) monoclonal antibody indicated for treatment of adults with metastatic or recurrent locally advanced Merkel cell carcinoma (MCC); cost is approximately $14,000 per month	New Entity
Joenja 70 mg oral tablet	leniolisib	Indicated for the treatment of activated phosphoinositide 3-kinase delta (PI3Kδ) syndrome (APDS) in adult and pediatric patients 12 years of age and older; first approved treatment for this condition; cost is approximately $45,000 per month	New Entity
Zolgensma 2 x 10^{13} vector genomes/mL IV suspension kit	onasemnogene abeparvovec-xioi	New dose kit of already existing gene therapy product	New Dose Kit
Tirosint 37.5 mcg, 44 mcg, 62.5 mcg oral capsules	levothyroxine sodium	New strength of branded levothyroxine	New Strength
Cuvrior 300 mg oral tablet	trientine tetrahydrochloride	Indicated for treatment of adult patients with stable Wilson disease who are de-coppered and penicillamine-tolerant	New Entity
Enoxiluv 40 mg/0.4 mL SQ syringe kit	enoxaparin sodium	New syringe kit of enoxaparin	New Kit
Iheezo (PF) 3 % eye gel in a dropperette	chloroprocaine hcl/pf	New strength and dosage form of ophthalmic chloroprocaine; ester anesthetic indicated for ocular surface anesthesia	New Strength and Dosage Form
Gohibic (EUA) 10 mg/mL intravenous solution	vilobelimab	New product under Emergency Use Authorization (EUA) by the FDA for the treatment of COVID-19 in hospitalized adults when initiated within 48 hours of receiving invasive mechanical ventilation (IMV), or extracorporeal membrane oxygenation (ECMO)	New Entity

Drug Name	Generic Name	Description	Comments
Mircera 120 mcg/0.3 mL injection syringe	methoxy peg-epoetin beta	New strength of already existing erythropoietin stimulating agent	New Strength
Primidone 125 mg oral tablet	primidone	New strength	New Strength
Austedo XR 6 mg, 12 mg, 24 mg ER oral tablets	deutetrabenazine	New dosage form and strength for once daily dosing	New Dosage Form and Strength
Omisirge IV suspension	omidubicel-onlv	A substantially modified allogeneic cord blood-based cell therapy to quicken the recovery of neutrophils in the body and reduce the risk of infection; indicated for use in adults and pediatric patients 12 years and older with blood cancers planned for umbilical cord blood transplantation following a myeloablative conditioning regimen; cost is approximately $338,000 per kit	New Kit

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†
Livmarli	maralixibat 9.5 mg/mL oral solution	Mirum Pharmaceuticals, Inc	Treatment of cholestatic pruritus in patients with Alagille syndrome (ALGS) ~~1 year~~ **3 months** of age and older
Tafinlar	dabrafenib 50 mg, 75 mg oral capsules; 10 mg tablets for oral suspension	Novartis	**In combination with trametinib for treatment of pediatric patients 1 year of age and older with low-grade glioma with a BRAF V600E mutation who require systemic therapy** *Note: Tafinlar has many other approved indications not mentioned here; see full prescribing information for details.*
Mekinist	trametinib 0.5 mg, 2 mg oral tablets	Novartis	**In combination with dabrafenib for treatment of pediatric patients 1 year of age and older with low-grade glioma with a BRAF V600E mutation who require systemic therapy** *Note: Mekinist has many other approved indications not mentioned here; see full prescribing information for details.*
Evkeeza	evinacumab-dgnb 345 mg/2.3 mL, 1200 mg/8 mL IV vials	Regeneron Pharmaceuticals, Inc	Indicated as an adjunct to other low-density lipoprotein-cholesterol (LDL-C) lowering therapies for the treatment of adult and pediatric patients, aged ~~12~~ **5 years** and older, with homozygous familial hypercholesterolemia (HoFH)
Keytruda	pembrolizumab 100 mg/4 ml IV vials	Merck	Treatment of adult and pediatric patients with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) solid tumors, as determined by an FDA-approved test, that have progressed following prior treatment and who have no satisfactory alternative treatment options ~~Limitations of Use: The safety and effectiveness of KEYTRUDA in pediatric patients with MSI-H central nervous system cancers have not been established.~~

Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication†
			Note: Keytruda has many other approved indications not mentioned here; see full prescribing information for details.
Padcev	enfortumab vedotin-ejfv 20 mg, 30 mg IV vials	Astellas Pharma	• As a single agent for the treatment of adult patients with locally advanced or metastatic urothelial cancer who: - have previously received a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor and platinum containing chemotherapy, or - are ineligible for cisplatin-containing chemotherapy and have previously received one or more prior lines of therapy • **In combination with pembrolizumab for the treatment of adult patients with locally advanced or metastatic urothelial cancer who are not eligible for cisplatin-containing chemotherapy**
Keytruda	pembrolizumab 100 mg/4 ml IV vials	Merck	Urothelial carcinoma: • **in combination with enfortumab vedotin, for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma who are not eligible for cisplatin-containing chemotherapy** • as a single agent for the treatment of patients with locally advanced or metastatic urothelial carcinoma who: are not eligible for any platinum-containing chemotherapy, or who have disease progression during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant treatment with platinumcontaining chemotherapy • as a single agent for the treatment of patients with Bacillus Calmette-Guerin (BCG)-unresponsive, high-risk, non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors who are ineligible for or have elected not to undergo cystectomy *Note: Keytruda has many other approved indications not mentioned here; see full prescribing information for details.*

Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication†
HyQvia	immune globulin 10% (human) with recombinant human hyaluronidase	Takeda	Treatment of Primary Immunodeficiency (PI) in adults **and pediatric patients two years of age and older**
Qulipta	atogepant 10 mg, 30 mg, 60 mg oral tablets	Allergan; AbbVie	For the preventive treatment of ~~episodic~~ migraine in adults
Polivy	polatuzumab vedotin-piiq 30 mg, 140 mg IV vials	Genentech, Inc.	~~Indicated in combination with bendamustine and a rituximab product for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma, not otherwise specified, after at least two prior therapies.~~ • **In combination with a rituximab product, cyclophosphamide, doxorubicin, and prednisone (R-CHP) for the treatment of adult patients who have previously untreated diffuse large B-cell lymphoma (DLBCL), not otherwise specified (NOS) or high-grade B-cell lymphoma (HGBL) and who have an International Prognostic Index score of 2 or greater** • **In combination with bendamustine and a rituximab product for the treatment of adult patients with relapsed or refractory DLBCL, NOS, after at least two prior therapies**

FDA DRUG SAFETY COMMUNICATIONS

[04/13/2023] FDA updates prescribing information for all opioid pain medicines to provide additional guidance for safe use

As part of its ongoing efforts to address the nation's opioid crisis, the U.S. Food and Drug Administration (FDA) is making several updates to the prescribing information of opioid pain medicines to provide additional guidance on the use of these powerful medicines. Opioid pain medicines are an important treatment option when used as prescribed; however, they also have serious risks, including misuse and abuse, addiction, overdose, and death.

Although there has been a substantial overall decrease in the number of dispensed prescriptions for opioid pain medicines, overdose deaths involving prescription opioids have remained steady. Data also suggest that:

- many acute pain conditions treated in the outpatient setting require no more than a few days of an opioid pain medicine, although the dose and duration of treatment needed to adequately manage pain will vary based on the underlying cause and individual patient factors.
- patients who use opioid pain medicines after surgery often have unused tablets, which may pose a risk of accidental use, misuse and abuse, addiction, and overdose, including by children and teenagers.
- extended-release/long-acting (ER/LA) opioid pain medicines have unique risks and should be used only for those with severe and persistent pain.

Based on review of available data, FDA has also determined that a new warning is needed about opioid-induced hyperalgesia (OIH), which is when an opioid that is prescribed and taken for pain relief causes an increase in pain (called hyperalgesia) or an increased sensitivity to pain (called allodynia). Although OIH can occur at any opioid dosage, it may occur more often with higher doses and longer-term use. This condition can be difficult to recognize and may result in increased opioid dosages that could worsen symptoms and increase the risk of respiratory depression.

Patients should always take your opioid medicines exactly as prescribed. Do not take more of the medicine or take it more often than prescribed without first talking to your health care professional. Talk with them if your pain increases, you feel more sensitive to pain, or if you have new pain, especially from touch or other things that are not usually painful such as combing your hair.

Store your opioid pain medicines securely, out of sight and reach of children, and in a location not accessible by others, including visitors to the home. Do not share these medicines with anyone else, and immediately dispose of unused or expired opioids or take them to a drug take-back site, location, or program. If provided, use the prepaid mail-back envelopes included with the prescription.

Seek emergency medical help or call 911 immediately if you or someone you are caring for experiences symptoms of respiratory problems, which can be life-threatening. Signs and symptoms include serious slowed, shallow, or difficult breathing, severe sleepiness, or not being able to respond or wake up.

Talk to your health care professionals about the benefits of naloxone, which can reverse and opioid overdose, and how to obtain it. Your health care professional can give you a prescription for naloxone. Additionally, in most states and the District of Columbia you can obtain naloxone from a pharmacy under a standing order that takes the place of an individual prescription. Some states also allow you to obtain naloxone without a prescription from a community-based program or pharmacy. Check with your state Health Department for more information. In March 2023, FDA approved an inhaled nasal spray version of naloxone to be sold over-the-counter without a prescription while multiple forms of naloxone remain available as prescription only.

Health care professionals should discuss with the patient the impact of the pain on their ability to function and their quality of life. Assessment of pain should consider both the cause of pain and individual patient factors.

If the patient's pain is severe enough to require an opioid pain medicine and alternative treatment options are insufficient, prescribe the lowest effective dose of an IR opioid for the shortest duration of time to reduce the risks associated with these products. Reserve increasing to higher doses only when lower doses are inadequate and the benefits of using a higher dose outweigh the substantial risks. Many acute pain conditions, such as pain occurring with a number of surgical procedures or musculoskeletal injuries, require no more than a few days of an IR opioid pain medicine.

Reserve ER/LA opioid pain medicines only for severe and persistent pain that requires an extended treatment period with a daily opioid pain medicine and for which alternative treatment options are inadequate. For patients currently on an ER/LA opioid who have pain severe enough to require an opioid but are not assessed as having severe and persistent pain, ensure that a multimodal approach to pain management is available, including mental health support. Discuss options for optimizing their treatment, which might include moving to an IR opioid or other alternative pain treatment, with the potential to appropriately and carefully taper the opioid but avoiding any abrupt discontinuation. Regularly reevaluate and discuss with your patients the optimum management of pain that appropriately balances the known benefits and risks, and frequently assess for development of addiction, misuse, or abuse. Inform patients of the added risks of using opioid pain medicines with benzodiazepines and other CNS depressants, and educate them on the signs and symptoms of respiratory depression.

For all patients prescribed opioid pain medicines, discuss the availability of naloxone, and consider prescribing it to those at increased risk of overdose. This may include patients who are also using benzodiazepines or other medicines that depress the central nervous system, with a

history of opioid use disorder (OUD), or have experienced a previous opioid overdose. Health care professionals should also consider prescribing naloxone if the patient has household members, including children, or other close contacts at risk for accidental ingestion or opioid overdose. In March 2023, FDA approved an inhaled nasal spray version of naloxone to be sold over-the-counter without a prescription.

Be aware that the symptoms of OIH, a condition where opioids cause an increase in pain (called hyperalgesia) or an increased sensitivity to pain (called allodynia), are distinct from opioid tolerance and withdrawal and can be difficult to recognize. If a patient is suspected to be experiencing OIH, carefully consider an appropriate decrease in dose of the current opioid pain medicine or safely switching them to a different opioid product, if tolerated. Advise patients about the risk of OIH and tell them to never increase the opioid dosage without first consulting a health care professional, because this could worsen the pain and increase the risk of respiratory depression.

RECALLS

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Fentanyl 500mcg (2mcg/mL) and Ropivacaine HCl 250mg (1mg/mL) added to 250mL 0.9% Sodium Chloride, For Epidural Use Only, Rx only, 3801 Mojave Ct. Suite 101, Columbia, MO 65202, NDC 71170-950-25	Class II	Drugs	Lot #: AC-016581	Lack of assurance of sterility: Suspected microbial growth present on external label packaging.	Apollo Care
Calcitonin Salmon Nasal Spray, USP, 2200 International Units per mL corresponding to 200 International Units/spray, 3.7 mL bottle, Rx only, Manufactured by: Par Pharmaceutical, Chestnut Ridge, NY 10977, NDC 49884-161-11.	Class II	Drugs	Lot #: 34770301, exp. date Mar-23; 34770401, exp. date May-23; 12981201, exp. date Nov-23; 13037201, exp. date Dec-23; 13037301, 13647801, exp. date Feb-24; 13722101, exp. date Mar-24; 13980101, 13980001, exp. date Apr-24; 14461701, 14461801, exp. date Jul-24; 14706201, exp. date Aug-24; 14935601, exp. date Oct-24; 5500131A, 5500132A, exp. date Mar-25	Failed Impurities/Degradation Specifications and Subpotent Drug: High Out of Specification results for a known and unknown impurity as well as low Out of Specification results for assay.	Endo Pharmaceuticals, Inc.
Dabigatran Etexilate Capsules, 75 mg, Rx Only, 60 Capsules per bottle, Manufactured by: Alkem Laboratories Ltd., INDIA, Distributed by: Ascend Laboratories, LLC, Parsippany, NJ 07054, NDC 67877-474-60.	Class II	Drugs	Lot #s: 22142462, 22142463, 22142464, Exp 5/2024; 22143000, 22143001, 22143002, Exp 6/2024.	CGMP Deviations: Detection of N-nitroso-dabigatran (NDAB) impurity levels above the Acceptable Daily Intake Limit.	Ascend Laboratories, LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Dabigatran Etexilate 150mg Capsules, 150 mg, Rx Only, 60 Capsules per bottle, Manufactured by: Alkem Laboratories Ltd., INDIA, Distributed by: Ascend Laboratories, LLC Parsippany, NJ 07054, NDC 67877-475-60.	Class II	Drugs	Lot #s: 22142448, 22142449, 22142450, Exp 5/2024; 22143845, Exp 7/2024.	CGMP Deviations: Detection of N-nitroso-dabigatran (NDAB) impurity levels above the Acceptable Daily Intake Limit.	Ascend Laboratories, LLC
Montelukast Sodium Tablets, USP, 10 mg Tablets, Rx Only, Packaged as: a) 30-count bottle, NDC 61919-0009-30; b) 90-count bottle, NDC 61919-0009-90; Packaged and Distributed By: Direct Rx, Dawsonville, GA 30534	Class II	Drugs	a) [30 count bottles] Lot, expiry: 20JU2211, exp 5/31/2024; b) [90 count bottles] Lot, expiry: 25JU2128 , exp 12/31/2023; 13SE2132 , exp 12/31/2023; 25JU2133 , exp 12/31/2023; 16JU2127 , exp 12/31/2023; 18MY2126 , exp 12/31/2023; 10JU2111 , exp 12/31/2023; 14SE2111 , exp 1/31/2024 ; 14JY2115 , exp 1/31/2024 ; 25OC2113 , exp 2/29/2024 ; 21SE2227 , exp 2/29/2024 ; 10DE2123 , exp 3/31/2024 ; 22NO2115 , exp 3/31/2024 ; 21JA2202 , exp 4/30/2024 ; 29DE2110 , exp 4/30/2024 ; 28FE2227 , exp	cGMP deviations	Direct Rx

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			4/30/2024 ; 06JU2208 , exp 5/31/2024 ; 30MA2229 , exp 5/31/2024 ; 30AU2216 , exp 6/30/2024 ; 23NO2203 , exp 6/30/2024 ; 14DE2216 , exp 7/31/2025 ; 12JA2305 , exp 7/31/2025 .		
Finasteride, USP, 5 mg Tablets, Rx Only, Packaged as a 90-count bottle, NDC 61919-0733-90; Packaged and Distributed By: Direct Rx	Class II	Drugs	Lot, expiry: 19AU2205, exp 12/31/24; 12OC2211, exp 12/31/24	cGMP deviations	Direct Rx
Ropinirole, USP, 0.25 mg Tablets, Rx Only, Packaged as a 30-count bottle, NDC 72189-0364-30; Packaged and Distributed By: Direct Rx, Dawsonville, GA 30534	Class II	Drugs	Lot, expiry: 21JU2210, exp 7/31/23	cGMP deviations	Direct Rx
Ropinirole, USP, 1 mg Tablets, Rx Only, Packaged as a 30-count bottle, NDC 72189-0364-30; Packaged and Distributed By: Direct Rx, Dawsonville, GA 30534	Class II	Drugs	Lot, expiry: 22JU2216 , exp 8/31/23	cGMP deviations	Direct Rx
Glimepiride, USP, 1 mg Tablets, Rx Only, Packaged as a a) 30-count bottle, NDC 61919-0723-30; b) 90-count bottle, NDC 61919-0723-90 Packaged and Distributed By: Direct Rx, Dawsonville, GA 30534	Class II	Drugs	a) [30 count bottles] Lot, expiry: 07MA2208, exp 5/31/2024 b) [90 count bottles] Lot, expiry: 09AU2128 , exp 1/31/2024; 28JY2102 , exp 1/31/2024; 06AU2103 , exp 1/31/2024 ; 03JA2210 ,	cGMP deviations	Direct Rx

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			exp 1/31/2024 ; 14JY2114 , exp 1/31/2024 ; 05NO2106 , exp 2/29/2024 ; 13OC2118 , exp 2/29/2024 ; 08DE2121 , exp 2/29/2024 ;		
Glimepiride, USP, 2 mg Tablets, Rx Only, Packaged as a a) 30-count bottle, NDC 61919-0488-30; b) 90-count bottle, NDC 61919-0448-90 Packaged and Distributed By: Direct Rx, Dawsonville, GA 30534	Class II	Drugs	a) [30 count bottles] Lot, expiry: 21JU2112 , exp 9/30/2023 b) [90 count bottles] Lot, expiry: 22DE2113 , exp 1/31/2024; 27JA2235 , exp 3/31/2024; 05AP2224 , exp 7/31/2024 ; 06AU2104 , exp 1/31/2024 ; 08JU2215 , exp 9/30/2024 ; 209AU2109 , exp 1/31/2024 ; 15JU2113 , exp 9/30/2023 ; 21FE2217 , exp 4/30/2024 ; 21OC2115 , exp 2/29/2024 ; 23JY2144 , exp 1/31/2024 ; 25JU2124 , exp 9/30/2023 ; 29AP2219 , exp 7/31/2024 ; 07DE2128 , exp 3/31/2024 .	cGMP deviations	Direct Rx

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Glimepiride, USP, 4 mg Tablets, Rx Only, Packaged as a a) 30-count bottle, NDC 61919-0250-30; b) 90-count bottle, NDC 61919-0250-90 Packaged and Distributed By: Direct Rx, Dawsonville, GA 30534	Class II	Drugs	a) [30 count bottles] Lot, expiry: 13DE2111 , exp 3/31/2024 b) [90 count bottles] Lot, expiry: 17NO2116 , exp 1/31/2024 ; 27JA2234 , exp 4/30/2024; 02MA2218, exp 6/30/2024 ; 12MY2211, exp 7/31/2024 ; 13JY2107, exp 10/31/2023; 15AP2221 , exp 7/31/2024 ; 17AU2110 , exp 10/31/2023; 20SE2108 , exp 10/31/2023; 23JU2115 , exp 10/31/2023; 28JY2101 ,exp 10/31/2023; 30JY2101 ,exp 10/31/2023; 05JA2212 , exp 3/31/2024 ; 13DE2130 , exp 3/31/2024 ; 21OC2111, exp 1/31/2024 ; 17NO2116 , exp 3/31/2024 .	cGMP deviations	Direct Rx
Simvastatin, USP, 5 mg Tablets, Rx Only, Packaged as a 90-count bottle, NDC 61919-	Class II	Drugs	Lot, expiry: 03JA2209, 28FE2225, 28AP2211, 07AP2203, exp 6/30/23	cGMP deviations	Direct Rx

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
0710-90 Packaged and Distributed By: Direct Rx, Dawsonville, GA 30534					
Simvastatin, USP, 10 mg Tablets, Rx Only, Packaged as a a) 30-count bottle, NDC 61919-0688-30 b) 90-count bottle, NDC61919-0688-90, Packaged and Distributed By: Direct Rx, Dawsonville, GA 30534	Class II	Drugs	a) [30-count bottles] Lot, expiry: 05AU2206, exp 10/31/23; b) [90-count bottles] Lot, expiry: 30MA2213, exp 6/30/23; 10DE2124, exp 3/31/23; 15MA2224, exp 5/32/23; 27JA2229, exp 3/31/23.	cGMP deviations	Direct Rx
Simvastatin, USP, 20 mg Tablets, Rx Only, Packaged as a a) 30-count bottle, NDC 61919-0446-30 b) 90-count bottle, NDC 61919-0446-90, Packaged and Distributed By: Direct Rx, Dawsonville, GA 30534	Class II	Drugs	a) [30-count bottles] Lot, expiry: 09JA2312 , exp 2/28/2025; b) [90-count bottles] Lot, expiry: 22OC2111, exp 1/31/2023; 13OC2120, exp 3/31/2023; 16JY2104, exp 12/31/2023; 09AU2125 , exp 1/31/2024 ; 28JY2125 , exp 1/31/2024 ; 23SE2115 , exp 3/31/2024 ; 23SE2115 , exp 3/31/2024 ; 07JA2211 , exp 5/31/2024 ; 27JA2214 , exp 5/31/2024 ; 15AP2224 , exp 6/30/2024 ; 24MA2221 , exp 6/30/2024 ;	cGMP deviations	Direct Rx

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			16AU2214 , exp 6/30/2024 .		
Simvastatin, USP, 40 mg, Rx Only, Packaged as a 90-count bottle, NDC 61919-0431-90, Packaged and Distributed By: Direct Rx, Dawsonville, GA 30534	Class II	Drugs	Lot, expiry: 28AP2212 , exp 7/31/2024 ; 24MA2230, exp 7/31/2024; 11JA2203 , exp 3/31/2023; 02FE2217 , exp 2/28/2023; 10DE2126 , exp 2/28/2023; 25MA2201, exp 5/31/2023; 28FE2230, exp 5/31/2023.	cGMP deviations	Direct Rx
Testosterone Cypionate Injection, USP, CIII, 200 mg/mL, packaged in: a) 10 mL multiple-dose vials (NDC 52536-625-10) and b) 1 mL single dose vials (NDC 52536-625-01), Rx only, Mfd for: Wilshire Pharmaceuticals, Inc., Atlanta, GA 30328.	Class II	Drugs	Lot #23804.034A, 23803.061A, Exp 9/2024	cGMP: complaints of crystals not redissolving into solution after warming and shaking the vials.	Azurity Pharmaceuticals, Inc.
Atorvastatin Calcium Tablets, USP, 10 mg, 90-count bottle, Rx only, Manufactured: Accord Healthcare, Inc., Durham, NC 27703, NDC 68788-7630-9	Class II	Drugs	Lot #: A0523D, Exp 5/31/2024, F14220, Exp 7/31/2023, J0622Q; Exp 1/31/2024.	cGMP Deviations for the manufacturing Firm (Accord Healthcare) after their inspection.	Preferred Pharmaceuticals, Inc.
Atorvastatin Calcium Tablets, USP, 20 mg, packaged in: a) 90-count bottle (NDC 68788-7631-9); b) 30-count bottle (NDC 68788-7631-3), Rx only, Manufactured: Accord Healthcare, Inc., Durham, NC 27703	Class II	Drugs	a) Lot: B1522B, Exp 4/30/2023; lot:C0222H, C0322B, Exp 5/31/2023; lot: E1022H, F13220, H2222P, Exp 6/30/2023; Lot: I1422V, K01220, Exp 12/31/2023; Lot: L2722H, Exp 3/31/2024; b)	cGMP Deviations for the manufacturing Firm (Accord Healthcare) after their inspection.	Preferred Pharmaceuticals, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			Lot:C0322B, Exp 5/31/2023; lot:H1122G, 12322Q, Exp 6/30/2023; lot: J1222U, Exp 12/31/2023.		
Clopidogrel Tablets USP, 75 mg, 90-count bottles, Rx only, Manufactured: Accord Healthcare, Inc., Durham, NC 27703, NDC 68788-8190-9	Class II	Drugs	Lot: E0922W, G1222E, I0922W and K3022W Exp 10/31/2023.	cGMP Deviations for the manufacturing Firm (Accord Healthcare) after their inspection.	Preferred Pharmaceuticals, Inc.
Doxazosin Tablets, USP, 2 mg, 100-count bottle, Rx only, Manufactured: Accord Healthcare, Inc., Durham, NC 27703, NDC 68788-7328-1	Class II	Drugs	Lot: H3122K, Exp 5/31/2024.	cGMP Deviations for the manufacturing Firm (Accord Healthcare) after their inspection.	Preferred Pharmaceuticals, Inc.
Doxazosin Tablets, USP, 4 mg, 100-count bottle, Rx only, Manufactured: Accord Healthcare, Inc., Durham, NC 27703, NDC 68788-7149-1	Class II	Drugs	Lot: L1522V, Exp 4/30/2025.	cGMP Deviations for the manufacturing Firm (Accord Healthcare) after their inspection.	Preferred Pharmaceuticals, Inc.
Finasteride Tablets, USP, 5 mg, packaged in: a) 30-count bottles (NDC 68788-6976-3); b) 90-count bottles (NDC 68788-6976-9), Rx only, Manufactured: Accord Healthcare, Inc., Durham, NC 27703.	Class II	Drugs	a) Lot: A1321V, D0221J, Exp. Date:8/31/2023; Lot: A1322J, Exp. Date: 5/31/2024; Lot: F0221Q, I0121E, I1021R, J1122D, Exp. Date: 10/31/2023; b) Lot: B0422J, Exp. Date: 5/31/2024; Lot: C1721K, Exp. Date: 8/31/2023; Lot: K1022Q, Exp. Date:11/30/2024.	cGMP Deviations for the manufacturing Firm (Accord Healthcare) after their inspection.	Preferred Pharmaceuticals, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Glimepiride Tablets, USP, 2 mg, 90-count bottle, Rx only, Manufactured: Accord Healthcare, Inc., Durham, NC 27703, NDC 68788-8095-9	Class II	Drugs	Lot: D0122K, Exp. Date: 6/30/2024; Lot: I1422N, Exp. Date: 9/30/2024; Lot: I2721B, Exp. Date: 1/31/2024.	cGMP Deviations for the manufacturing Firm (Accord Healthcare) after their inspection.	Preferred Pharmaceuticals, Inc.
Montelukast Sodium Tablets, USP, 10 mg, packaged in: a) 30-count bottle (NDC 68788-9438-3); b) 60-count bottle (NDC 68788-9438-6); c) 90-count bottle (NDC 68788-9438-9), Rx only, Manufactured: Accord Healthcare, Inc., Durham, NC 27703.	Class II	Drugs	a) Lot: F3021D, Exp 12/31/2023, Lot: L0722T, Exp 5/31/2025; b) Lot: F1021I, Exp 12/31/2023; c) Lot:H1721R, Exp 12/31/2023, Lot: L0722E, Exp 5/31/2025.	cGMP Deviations for the manufacturing Firm (Accord Healthcare) after their inspection.	Preferred Pharmaceuticals, Inc.
Rosuvastatin Tablets, USP, 10 mg, Packaged as: a) 30-count bottle (NDC 68788-7086-3); b) 90-count bottle (NDC 68788-7086-9), Rx only, Manufactured: Accord Healthcare, Inc., Durham, NC 27703.	Class II	Drugs	a) Lot: F2022N, Exp. Date: 2/29/2024; b) Lot: F0322I, Exp. Date: 8/31/2023; Lot: J1322H, Exp. Date: 2/29/2024; Lot: K0222N, Exp. Date: 6/30/2024; Lot: L2322D and Lot: L2822J, Exp. Date:7/31/2025.	cGMP Deviations for the manufacturing Firm (Accord Healthcare) after their inspection.	Preferred Pharmaceuticals, Inc.
Rosuvastatin Tablets, USP, 5mg, 30-count bottle, Rx only, Manufactured: Accord Healthcare, Inc., Durham, NC 27703, NDC 68788-7971-3	Class II	Drugs	Lot: A1723C, Exp 8/31/2025; Lot: A1922B, Exp 6/30/2024; Lot: D0622M and Lot: F2922I, Exp 7/31/2024; Lot: G3021L, Exp 1/31/2024; Lot:H2622P & Lot: J0722C, Exp 10/31/2024.	cGMP Deviations for the manufacturing Firm (Accord Healthcare) after their inspection.	Preferred Pharmaceuticals, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Pravastatin Sodium Tablets, USP, 20 mg, 90-count bottle, Rx only, Manufactured for: Accord Healthcare, Inc., Durham, NC 27703, NDC 68788-8215-9	Class II	Drugs	Lot: F1021I; H3122J, Exp 4/30/2024	cGMP Deviations for the manufacturing Firm (Accord Healthcare) after their inspection.	Preferred Pharmaceuticals, Inc.
Simvastatin Tablets, USP, 10 mg, 90-count bottle, Rx only, Manufactured for: Accord Healthcare, lnc., Durham, NC 27703, NDC 68788-9747-9	Class II	Drugs	Lot: C2222P, D1522L, E3122D, G2522J, Exp 9/30/2023; Lot: J1222R, Exp 10/31/2023.	cGMP Deviations for the manufacturing Firm (Accord Healthcare) after their inspection.	Preferred Pharmaceuticals, Inc.
Simvastatin Tablets, USP, 80 mg, 90-count bottle, Rx only, Manufactured for: Accord Healthcare, lnc., Durham, NC 27703, NDC 68788-9429-9	Class II	Drugs	Lot: B0222S, Exp 2/29/2024; Lot: F1121B, G2721L, Exp 11/30/2023.	cGMP Deviations for the manufacturing Firm (Accord Healthcare) after their inspection.	Preferred Pharmaceuticals, Inc.
Simvastatin Tablets, USP, 20 mg, Packaged as: a) 90-count bottle (NDC 68788-9869-9); b) 60-count bottle (NDC 68788-9869-6); c) 30-count bottle (NDC 68788-9869-3), Rx only, Manufactured for: Accord Healthcare, lnc., Durham, NC 27703.	Class II	Drugs	a) Lot: A0923R, Exp. Date: 2/28/2025, A1222K, B1822C, Exp. Date: 5/31/2024, C3022D, F2322V, Exp. Date: 6/30/2024, H1522H, Exp. Date: 8/31/2024, I1621O, Exp. Date: 1/31/2024, I2222G, J1822R, Exp. Date: 9/30/2024, L1621N, Exp. Date: 5/31/2024; b) Lot: F0822Q, Exp. Date: 6/30/2024, I0122J, Exp. Date: 8/31/2024, L0821C, Exp. Date: 5/31/2024; c) Lot: I1521P, Exp. Date: 1/31/2024, J1322R, Exp.	cGMP Deviations for the manufacturing Firm (Accord Healthcare) after their inspection.	Preferred Pharmaceuticals, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			Date: 9/30/2024, J1821H, Exp. Date: 2/29/2024.		
Simvastatin Tablets, USP, 40 mg, Packaged as: a) 90-count bottle (NDC 68788-9868-9); b) 60-count bottle (NDC 68788-9868-6); c) 30-count bottle (NDC 68788-9868-3), Rx only, Manufactured for: Accord Healthcare, lnc., Durham, NC 27703.	Class II	Drugs	a) Lot: B0922G, Exp. Date: 5/31/2023, F0322G, Exp. Date: 7/25/2024, H2622M, Exp. Date: 8/31/2024, J1422B, K0722G, Exp. Date: 10/31/2024, L1922A, Exp. Date: 2/28/2025; b) Lot: F2922S, Exp. Date: 8/31/2023, H0322G Exp. Date: 7/31/2023; c) Lot: A1322I, Exp. Date: 3/31/2023, H1122C, Exp. Date: 8/31/2024.	cGMP Deviations for the manufacturing Firm (Accord Healthcare) after their inspection.	Preferred Pharmaceuticals, Inc.
Tadalafil Tablets, USP, 20 mg, 7-count bottle, Rx only, Manufactured for: Accord Healthcare, lnc., Durham, NC 27703, NDC 68788-8153-7	Class II	Drugs	Lot: C0822E, Exp 1/31/2024, F1121B, Exp 1/31/2024, G2721L, Exp 1/31/2024.	cGMP Deviations for the manufacturing Firm (Accord Healthcare) after their inspection.	Preferred Pharmaceuticals, Inc.
Glimepiride Tablets USP, 4 mg, 90-count bottle, Rx only, Manufactured: Accord Healthcare, Inc., Durham, NC 27703, NDC 68788-8066-9	Class II	Drugs	Lot: H1221Z, I0121J, J0622X, Exp 10/31/2023.	cGMP Deviations for the manufacturing Firm (Accord Healthcare) after their inspection.	Preferred Pharmaceuticals, Inc.
Aripiprazole 5mg tablets, 30-count bottles, Rx only, Repackaged by: RemedyRepack Inc., Indiana, PA 15701, NDC 70518-2921-03	Class II	Drugs	Lot #: J0620431-052322, Exp. Date 05/31/23	cGMP Deviations	RemedyRepack Inc.
Atorvastatin 10 mg tablets, packaged in a) 30-count bottles (NDC 70518-1946-00) and b) 90-count bottles (NDC 70518-1946-01),	Class II	Drugs	Lot #: a) J0679046-020123, Exp. Date 02/28/2024; J0669807-	cGMP Deviations	RemedyRepack Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Rx only, Repackaged by: RemedyRepack Inc., Indiana, PA 15701.			122122, Exp. Date 01/31/2024; J0662695-112222, Exp. Date 12/31/2023; J0654076-101822, J0654076-101822, Exp. Date 11/30/2023; J0642765-082922, Exp. Date 09/30/2023 Lot #: b) B1672408-050322, B1765902-071322, B1769634-071622, Exp. Date 04/30/2023; B1776907-072122, Exp. Date 09/30/2023; B1836636-090322, Exp. Date 11/30/2023; B1870344-092422, Exp. Date 01/31/2024; B1908452-101522, B1966455-111722, B2043099-010423, Exp. Date 05/31/2024		
Doxazosin 2 mg tablets, packaged in a) 30-count (NDC 70518-1560-00) and b) 90-count bottles (NDC 70518-1560-01), Rx only, Repackaged by: RemedyRepack Inc., Indiana, PA 15701.	Class II	Drugs	Lot #: a) J0665197-120522, Exp. Date 12/31/2023; J0642497-082722, Exp. Date 09/30/2023 J0638552-080922, Exp. Date 08/31/2023. Lot #: b)	cGMP Deviations	RemedyRepack Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			B1808799-081622, Exp. Date 05/31/2024		
Glimepiride 2 mg tablets, packaged in a) 30-count bottles (NDC 70518-0405-03), b) 90-count bottles (NDC 70518-0405-00) and c)180-count bottles (NDC 70518-0405-02), Rx only, Repackaged by: RemedyRepack Inc., Indiana, PA 15701	Class II	Drugs	Lot #: a) J0674153-010923, Exp. Date 01/31/2024; J0649447-092822, Exp. Date 10/31/2023; J0644887-090722, Exp. Date 09/30/2023; J0627309-062222, Exp. Date 06/30/2023; J0622569-060222, Exp. Date 06/30/2023. b) B1646259-041222, Exp. Date 04/30/2023; B2032846-122722, Exp. Date 01/31/2025 B2018675-121722, Exp. Date 05/31/2025; B1708230-060122, B1709748-060122, Exp. Date 06/30/2023; B1692572-051822, Exp. Date 05/31/2023; B1803110-081122, Exp. Date 12/31/2024. c) B1820672-082422, B1814883-082022, Exp. Date 09/30/2024.	cGMP Deviations	RemedyRepack Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Ropinirole 0.5 mg tablets, packaged in 90-count bottles, Rx only, Repackaged by: RemedyRepack Inc., Indiana, PA 15701, NDC 70518-2439-00.	Class II	Drugs	Lot #: B1789178-080122, Exp. Date 07/31/2023; B1675475-050522, Exp. Date 05/31/2023	cGMP Deviations	RemedyRepack Inc.
Rosuvastatin 5mg tablets, 30-count bottles, Rx only, Repackaged by: RemedyRepack Inc., Indiana, PA 15701, NDC 70518-3519-00.	Class II	Drugs	Lot #: J0668398-121422, Exp. Date 12/31/2023; J0661225-111522, J0654053-101822 Exp. Date 11/30/2023; J0646383-091422, Exp. Date 09/30/2023	cGMP Deviations	RemedyRepack Inc.
Simvastatin 10 mg tablets, packaged in a) 30-count bottles (NDC 70518-0064-01) and b) 90-count bottles (NDC 70518-0064-00), Rx only, Repackaged by: RemedyRepack Inc., Indiana, PA 15701	Class II	Drugs	Lot #: a) J0675206-011223, J0669260-121922, Exp. Date 01/31/2024; J0656820-103122, J0647161-091722, Exp. Date 09/30/2023 Exp. Date 11/30/2023; J0621491-052722, Exp. Date 06/30/2023; J0638138-080822, Exp. Date 08/31/2023, J0610887-041122, Exp. Date 04/30/2023. Lot # b) B1887315-100422, Exp. Date 02/28/2024; B1829906-083122, B1769715-071622, Exp. Date 09/30/2023;	cGMP Deviations	RemedyRepack Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			B1906605-101422, Exp. Date 02/28/2024; B1965118-111622, Exp. Date 02/28/2025.		
Tadalafil 5 mg tablets, 30-count bottles, Rx only, Repackaged by: RemedyRepack Inc., Indiana, PA 15701, NDC 70518-2972-00	Class II	Drugs	Lot #: B1635780-040522, Exp. Date 04/30/2023	cGMP Deviations	RemedyRepack Inc.
Atorvastatin 20 mg tablets, packaged in a) 30-count bottles (NDC 70518-1977-00) and b)90-count bottles (NDC 70518-1977-01), Rx only, Repackaged by: RemedyRepack Inc., Indiana, PA 15701.	Class II	Drugs	Lot #: a) J0659819-110922, Exp. Date 11/30/2023; J0649932-093022, J0649917-093022 Exp. Date 10/31/2023, B2010060-121222, Exp. Date 03/31/24 Lot #: b) B1708575-060122, Exp. Date 05/31/2023; B1879236-092922, Exp. Date 12/31/2023	cGMP Deviations	RemedyRepack Inc.
Ropinirole 2mg tablets, packaged in 180-count bottles, Rx only, Repackaged by: RemedyRepack Inc., Indiana, PA 15701, NDC70518-2750-00	Class II	Drugs	Lot#: B1630017-040122, Exp. Date 04/30/2023	cGMP Deviations	RemedyRepack Inc.
Rosuvastatin 5mg tablets, 30-count bottles, Rx only, Repackaged by: RemedyRepack Inc., Indiana, PA 15701, NDC 70518-3519-00	Class II	Drugs	Lot#: J0668398-121422, Exp. Date 12/31/2023; J0661225-111522, J0654053-101822 Exp. Date 11/30/2023; J0646383-091422, Exp. Date 09/30/2023	cGMP Deviations	RemedyRepack Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Rosuvastatin 10mg tablets, packaged in a) 30-count bottles (NDC 70518-0375-03 and 70518-0375-01) and b) 90-count bottles (NDC 70518-0375-00), Rx only, Repackaged by: RemedyRepack Inc., Indiana, PA 15701.	Class II	Drugs	Lot#: a) NDC 70518-0375-03: J0674788-011123, Exp. Date 01/31/2024; J0664118-112922 J0664118-112922, Exp. Date 12/31/2023; J0653727-101722, Exp. Date 10/31/2023. NDC 70518-0375-01: B2057931-011223, Exp. Date 07/31/2025 b) Lot #: B2075815-012523, Exp. Date 09/30/2025; B2011634-121322, Exp. Date 07/31/2025 B1970205-112022, Exp. Date 06/30/2024; B1862598-092022, Exp. Date 03/31/2024; B2077226-012523, B2070444-012023, Exp. Date 07/31/2025.	cGMP Deviations	RemedyRepack Inc.
Rosuvastatin 40mg tablets, packaged in a) 45-count bottles (NDC 70518-1311-01), and b) 90-count bottles (NDC 70518-0484-00), Rx only, Repackaged by: RemedyRepack Inc., Indiana, PA 15701.	Class II	Drugs	Lot # a): B2038806-123022, B2014185-121422, B1925528-102522, Exp. Date 07/31/2025. Lot #: b): B2080829-012823, B1938007-110222,	cGMP Deviations	RemedyRepack Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			B2038746-123022, Exp. Date 07/31/2025.		
Simvastatin 40 mg tablets, packaged in a) 30-count bottles (NDC 70518-0060-01) and b) 90-count bottles (NDC 70518-0060-00), Rx only, Repackaged by: RemedyRepack Inc., Indiana, PA 15701	Class II	Drugs	Lot # a): J0656821-103122, Exp. Date 11/30/2023; J0638547-080922, Exp. Date 08/31/2023; J0633575-071822, Exp. Date 07/31/2023 Lot #: b): B1965081-111622, Exp. Date 03/31/2025; B1857922-091922, B1765298-071322, B1786319-072922, B1706842-053122, Exp. Date 04/30/2023; B2003311-120822, Exp. Date 04/30/2025; B1955679-111122, Exp. Date 02/28/2025; B1878942-092922, Exp. Date 11/30/2024; B1823203-082622. Exp. Date 10/31/2024; B1706843-053122, Exp. Date 05/31/2023	cGMP Deviations	RemedyRepack Inc.
Alprazolam Tab, USP 0.25mg, (CIV), 30-count bottle, Rx Only, Preferred Pharmaceuticals, Inc. Manufactured by: Breckenridge	Class II	Drugs	Lot: G1822K, Exp. Date:5/31/2023.	CGMP Deviations: Downstream recall from Breckenridge Pharmaceuticals, Inc due to	Preferred Pharmaceuticals, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Pharmaceuticals, Inc., Boca Raton, FL. Ins:NDC 68788-7594-3				potential risk of Cross Contamination.	
Alprazolam Tab, USP 0.5mg, (CIV), packaged in: a) 30-count bottle (NDC 68788-7595-3), b) 60-count bottle (NDC 68788-7595-6), c) 90-count bottle (NDC 68788-7595-9); Rx Only, Preferred Pharmaceuticals, Inc. Manufactured by: Breckenridge Pharmaceuticals, Inc., Boca Raton, FL.	Class II	Drugs	Lot # a) D2022P, Exp. Date:4/30/2023; F1022Y, E2022, I2822U, Exp. Date:6/30/2023; L2122W, Exp. Date: 8/31/2024; b) Lot #L0522A, Exp. Date:8/31/2024; B0823J, Exp. Date:11/31/2024; c) Lot# L1522P, Exp. Date: 10/31/2024.	CGMP Deviations: Downstream recall from Breckenridge Pharmaceuticals, Inc due to potential risk of Cross Contamination.	Preferred Pharmaceuticals, Inc.
Alprazolam Tab, USP 1mg, (CIV), packaged in: a) 30-count bottle (NDC 68788-7596-3), b) 60-count bottle (NDC68788-7596-6); Rx Only, Preferred Pharmaceuticals, Inc. Manufactured by: Breckenridge Pharmaceuticals, Inc., Boca Raton, FL.	Class II	Drugs	Lot # a) H3122D, Exp. Date:8/31/2024; b) Lot #A1123R, L0522E, J2622H, I1622F, H2422E, Exp. Date:8/31/2024.	CGMP Deviations: Downstream recall from Breckenridge Pharmaceuticals, Inc due to potential risk of Cross Contamination.	Preferred Pharmaceuticals, Inc.
Alprazolam C-IV, 0.5 mg, 30 Tabs per bottle, Rx only, Packaged and Distributed By: Direct Rx Dawsonville, GA 30534, NDC 72189-0240-30.	Class II	Drugs	Lot: 11AP2219 Exp. 4/30/23	CGMP Deviations: Repackaging firm recalling due to potential product cross contamination concerns at the manufacturer.	Direct Rx
Alprazolam C-IV, 1 mg, packaged in a) 30 Tabs per bottle, NDC 72189-213-30; b) 60 Tabs per bottle, NDC 72189-213-60; Rx only, Packaged and Distributed By: Direct Rx Dawsonville, GA 30534.	Class II	Drugs	Lots: a) 03FE2318, Exp. 8/31/24; b) 27FE2315, 28FE2313, 02MA2306, 21SE2201, 16NO2216, 17NO2216, 24FA2314, Exp. 8/31/24; 17FE2203, 12AP2204, 17MA2205, Exp. 3/31/23; 21JU2206,	CGMP Deviations: Repackaging firm recalling due to potential product cross contamination concerns at the manufacturer.	Direct Rx

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			22JU2220, 12JY2206, Exp. 5/31/23; 10AU2209, Exp. 6/30/23; 14DE2215, Exp. 9/30/24; 05JA2304, 27JA2301, Exp. 11/30/24.		
Alprazolam C-IV, 2 mg, 60 Tabs per bottle, Rx only, Packaged and Distributed By: Direct Rx Dawsonville, GA 30534, NDC 72189-121-60.	Class II	Drugs	Lots: 03FE2319 Exp. 2/28/25, 13MY2217 Exp. 5/31/23	CGMP Deviations: Repackaging firm recalling due to potential product cross contamination concerns at the manufacturer.	Direct Rx
Pantoprazole Sodium Delayed Release Tablets USP 40mg, 1000-count bottles, Rx only, Manufactured for: Camber Pharmaceuticals Inc., Piscataway, NJ, 08854, By: Hetero Labs Limited, Unit V, Polepally, Jadcherla, Mahabubnagar- 509 301, India NDC 31722-713-10	Class II	Drugs	Lot #: PAN22542, Exp. Date: 9/2024	CGMP Deviations: Discoloration	Hetero USA Inc
Aripiprazole Tablets, USP, 20 mg, Rx Only, Packaged in 500-count bottle Manufactured by: Alkem Laboratories Ltd., INDIA Distributed by: Ascend Laboratories, LLC Parsippany, NJ 07054, NDC#: 67877-434-05	Class II	Drugs	Lot #22143120, Exp. Date: June 2024	Out of specification (OOS) for Spectroscopic Identification test by IR.	Ascend Laboratories, LLC
Verapamil Hydrochloride Extended-Release Tablets, USP, 180 mg, 100 Tablets (10 x 10) per carton, Rx only, Distributed by: American Health Packaging, Columbus, Ohio 43217. NDC Carton: 60687-504-01; NDC Unit Dose: 60687-504-11, barcode (01) 003 60687 504 11 7.	Class II	Drugs	Lots: 1008622, 1010026, Exp 2/29/24	Failed Dissolution Specifications: Out of specification dissolution results above specified values.	Amerisource Health Services LLC
Fast Acting Earwax Removal System (carbamide peroxide), 6.5%, 0.5 FL OZ (15	Class II	Drugs	Lots: A70293, A70294, A70295, Exp. 12/2023;	CGMP Deviations: active ingredient may be subpotent	Pharma Nobis LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
mL) Drops per bottle, OTC, Distributed by: CVS Pharmacy, Inc., One CVS Drive, Woonsocket, RI 02895, CVS Product # 999532, UPC 0 50428 36475 8.			A70746, A70747, A70748, A70749, Exp. 01/2024; A73051, A73052, Exp. 05/2024	before the labeled expiry due to degradation.	
C-Semaglutide 5mg/mL injection, 0.5mL vials, Rx only, Vital Care Compounder 115 South 40th Ave, Suite A Hattiesburg, MS 39402	Class II	Drugs	Lot #: 73810, Exp. Date 5/1/2023	Lack of assurance of sterility.	Pharmacy Plus, Inc. dba Vital Care Compounder
Montelukast Sodium Oral Granules USP, 4 mg, packaged in a carton containing 30 packets, Rx only, Distributed By: Teva Pharmaceuticals USA, Inc., Parsippany, NJ 07054, Carton NDC 0093-7487-56, Packet NDC 0093-7487-19	Class III	Drugs	Lot # 3007556A, Exp 5/2023	Failed Impurities/Degradation Specifications: failed impurities for Sulphoxide and Impurity A.	Teva Pharmaceuticals USA Inc
Dodex Injectable Cyanocobalamin Injection, USP 1,000 mcg/mL, 25 x1 ML Multiple dose vials, For Intramuscular or Subcutaneous Use Only, Rx Only, Sterile, Manufactured by: Intas Pharmaceuticals Limited Pharmaz Ahnedabad 382 213, INDIA, Manufactured for: Accord Healthcare, Inc., Durham, NC 27703, NDC 16729-533-08.	Class III	Drugs	Lot #: R2200394 Exp. 03/2024	Sub-potent drug: assay test result below specifications at 9-month timepoint.	Accord Healthcare, Inc.
MEKTOVI (binimetinib) tablets, 15 mg, 180-count bottle, Rx only, Distributed by: Array BioPharma Inc., a wholly owned subsidiary of Pfizer Inc., Boulder, CO 80301. NDC: 70255-010-02	Class III	Drugs	Lot W054586A, EXP 03/2026	Labeling: Incorrect or Missing Lot and/or Exp Date: The carton and bottle labels state an expiry date of March 2026; the correct expiration date is February 2025.	Pfizer Inc.
Epinephrine Professional EMS, Epinephrine Convenience Kit, Epinephrine 1 mg/mL, Rx Only, Focus Health Group, Manufactured	Class III	Drugs	Lot numbers: 57943EMS, exp 5/31/2023; 56276EMS, exp 4/30/2024	Labeling; Incorrect NDC number on outer carton of product.	Focus Health Group Inc

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
for: Focus Health Group, 5802 Kingston Pike, Knoxville, TN 37919. Incorrect NDC (kit): 24357-011-13					
Bevacizumab 2.5 mg/0.1 mL, Solution for Injection in 1mL, silicone free slip tip syringe, each Syringe supplied in individually labeled poly envelopes (primary packaging). Repackaged by Pine Pharmaceuticals, Pine Pharmaceuticals 355 Riverwalk Parkway, Tonawanda, NY 14150, Office Use Only, Not for Resale. Secondary packaging consists of a coated cardboard box, with order-specific label indicating lot number housed within order/container. NDC # 69194-0458-1	Class III	Drugs	Lot # 66377, Exp. Date: 06/28/2023. Syringe may be labeled incorrectly as lot# 66316	Labeling: Incorrect or Missing Lot and/or Exp Date: Lot code on primary packaging is incorrect.	Pine Pharmaceuticals, LLC
Norepinephrine Bitartrate Injection, USP, 4 mg/4 mL* (1 mg/mL), 4 mL Single-dose Fliptop Vial (NDC 47335-615-40); packaged in 10 x 4 mL Single-dose Fliptop Vials per carton (NDC 47335-615-44); Rx only, Manufactured by: Gland Pharma Limited, Hyderabad-502307 India; Distributed by: Sun Phamaceutical Industries, Inc., Cranbury, NJ 08512.	Class III	Drugs	Lot Number: G1510001, Exp 11/2023; G151002, Exp. 12/2023; and G151003, Exp 02/2024	Failed Impurities/Degradation Specifications: Above the specification limits yielded for related substance norepinephrine sulfonic acid impurity during routine product monitoring.	SUN PHARMACEUTICAL INDUSTRIES INC

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

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

Albuterol Sulfate Inhalational Solution
Alprostadil (Muse) Suppository
Amifostine Injection
Amino Acids
Amoxapine Tablets
Amoxicillin Oral Powder for Suspension
Amphetamine; Dextroamphetamine Tablets
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
Belladonna and Opium Suppositories
Bumetanide Injection
Bupivacaine Hydrochloride and Epinephrine Injection
Bupivacaine Hydrochloride Injection
Calcium Gluconate Injection
Capecitabine Tablets
Cefixime Oral Capsules
Cefotaxime Sodium Injection
Cefotetan Disodium Injection
Chloramphenicol Sodium Succinate Injection
Chloroprocaine Hydrochloride Injection
Chlorothiazide Oral Suspension
Cisplatin Injection
Clindamycin Phosphate Injection
Clonazepam Tablets
Collagenase Ointment
Conivaptan Hydrochloride (Vaprisol) in 5% Dextrose Plastic Container
Conjugated Estrogens/Bazedoxifene (DUAVEE) Tablet, Film Coated
Cyclopentolate Ophthalmic Solution
Cytarabine Injection
Dacarbazine Injection
Desmopressin Acetate Nasal Spray
Dexamethasone Sodium Phosphate Injection
Dexmedetomidine Injection
Dextrose 10% Injection

Dextrose 25% Injection
Dextrose 5% Injection
Dextrose 50% Injection
Diazepam Rectal Gel
Diflunisal Tablets
Difluprednate Ophthalmic Emulsion
Digoxin Injection
Diltiazem Hydrochloride Injection
Dimercaprol (Bal in Oil) Injection
Disopyramide Phosphate (Norpace) Capsules
Dobutamine Hydrochloride Injection
Dopamine Hydrochloride Injection
Dulaglutide (Trulicity) Injection
Echothiophate Iodide (Phospholine Iodide) Ophthalmic Solution
Edetate Calcium Disodium Injection
Enalaprilat Injection
Epinephrine Injection, 0.1 mg/mL
Erythromycin Ophthalmic Ointment
Etomidate Injection
Fentanyl Citrate (Sublimaze) Injection
Fludarabine Phosphate Injection
Fluorescein Injection
Flurazepam Hydrochloride Capsules
Furosemide Injection
Gentamicin Sulfate Injection
Guanfacine Hydrochloride Tablets
Heparin Sodium and Sodium Chloride 0.9% Injection
Hydrocortisone Sodium Succinate Injection
Hydromorphone Hydrochloride Injection
Hydroxypropyl (Lacrisert) Cellulose Ophthalmic Insert
Ibutilide Fumarate Injection
Indigotindisulfonate Sodium Injection
Isoniazid Injection
IV Fat Emulsion
Ketamine Injection
Ketorolac Tromethamine Injection
Leucovorin Calcium Lyophilized Powder for Injection
Lidocaine Hydrochloride (Xylocaine) and Dextrose Injection Solution-Premix Bags
Lidocaine Hydrochloride (Xylocaine) Injection
Lidocaine Hydrochloride (Xylocaine) Injection with Epinephrine
Lorazepam Injection
Lutetium Lu 177 Vipivotide Tetraxetan (Pluvicto) Injection
Mannitol Injection
Mepivacaine Hydrochloride Injection
Methamphetamine Hydrochloride Tablets
Methotrexate Injection

Methyldopa Tablets
Methylprednisolone Acetate Injection
Metronidazole Injection
Midazolam Injection
Morphine Sulfate Injection
Multi-Vitamin Infusion (Adult and Pediatric)
Neomycin Sulfate Tablets
Nizatidine Capsules
Oxybutynin Chloride Syrup
Oxytocin Injection
Palifermin (Kepivance) Lyophilized Powder for Injection
Pantoprazole Sodium for Injection
Parathyroid Hormone (Natpara) Injection
Penicillin G Benzathine Injectable Suspension
Pentostatin Injection
Physostigmine Salicylate Injection
Potassium Acetate Injection
Potassium Chloride Concentrate Injection
Quinapril and Hydrochlorothiazide Tablets
Quinapril Hydrochloride Tablets
Remifentanil Injection
Rifampin Capsules
Rifampin Injection
Rifapentine Tablets
Rocuronium Bromide Injection
Ropivacaine Hydrochloride Injection
Semaglutide (Ozempic) Injection
Semaglutide (Wegovy) Injection
Sincalide (Kinevac) Lyophilized Powder for Injection
Sodium Acetate Injection
Sodium Bicarbonate Injection
Sodium Chloride 0.9% Injection Bags
Sodium Chloride 14.6% Injection
Sodium Chloride 23.4% Injection
Sodium Chloride Injection USP, 0.9% Vials and Syringes
Sodium Phosphates Injection
Somatropin Injection
Sterile Water for Injection
Streptozocin (Zanosar) Sterile Powder
Sucralfate Tablets
Sufentanil Citrate Injection
Sulfasalazine Tablets
Technetium TC-99M Mebrofenin Injection
Teprotumumab-trbw
Tirzepatide Injection
Triamcinolone Acetonide Injectable Suspension

Triamcinolone Hexacetonide Injectable suspension
Trimethobenzamide Hydrochloride Capsules
Valproate Sodium Injection
Vecuronium Bromide for Injection