PERFORMRx℠

Drug Information Update

April 2024

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NEWLY AVAILABLE GENERICS

Generic Name/ Dosage Form	Brand Name	Manufacturer	Indication
sitagliptin 25 mg, 50 mg, 100 mg oral tablets	Zituvio	Zydus Pharmaceuticals	To be used as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

NEW DRUG ENTITIES/STRENGTHS/COMBINATIONS

Drug Name	Generic Name	Description
Alyglo intravenous solution 5 gm/50ml, 10gm/100ml, 20gm/200ml	Immune Globulin (Human)-stwk	New entity. New immunoglobulin product indicated for the treatment of adults with primary humoral immunodeficiency (PI).
Rezdiffra oral tablet 60 mg, 80mg, 100mg	Resmetirom	New entity. Thyroid hormone receptor-beta agonist indicated along with diet and exercise for the treatment of adults with noncirrhotic non-alcoholic steatohepatitis (NASH) with moderate to advanced liver fibrosis (consistent with F2 to F3 fibrosis). First FDA-approved medication for the treatment of NASH. Approved under the accelerated approval pathway based on the improvement of NASH and fibrosis.
Simlandi (2 pen) subcutaneous auto-injector kit 40 mg/0.4ml Simlandi (1 pen) subcutaneous auto-injector kit 40 mg/0.4ml	Adalimumab-ryvk	Humira biosimilar. Only available in high concentration strength. First high concentration biosimilar to Humira that is interchangeable.
Pemgarda intravenous solution 500 mg/4ml	Pemivibart	New entity. Emergency use authorization (EUA) for the pre-exposure prophylaxis (PrEP) of COVID-19 in adults and adolescents (>12 years of age weighing ≥40 kg) who have moderate to severe immune compromise due to certain medical conditions or have received certain immunosuppressive medications or treatments and are unlikely to mount an adequate immune response to COVID-19 vaccination. To be administered by intravenous infusion in outpatient settings, such as transplant centers as well as infusion centers where oncology patients receive care.
Lenmeldy intravenous suspension	Atidarsagene autotemcel	New entity. First gene therapy for the treatment of children with pre-symptomatic late infantile, pre-symptomatic early juvenile or early-symptomatic early juvenile metachromatic leukodystrophy (MLD).

Drug Name	Generic Name	Description
Winrevair subcutaneous kit 2 x 45 mg Winrevair subcutaneous kit 2 x 60 mg Winrevair subcutaneous kit 45 mg Winrevair subcutaneous kit 60 mg	Sotatercept-csrk	New entity. Indicated for the treatment of adults with pulmonary arterial hypertension (PAH, World Health Organization [WHO] Group 1) to increase exercise capacity, improve WHO functional class (FC), and reduce the risk of clinical worsening events. First FDA-approved activin signaling inhibitor, representing a new class of therapy that targets an underlying cause of PAH. Designed to work by enhancing the balance between pro- and anti-proliferative signaling pathways. Dosing is weight based.
Spevigo subcutaneous solution prefilled syringe 150 mg/ml	Spesolimab-sbzo	New strength & dosage form. Product is intended for new indication for maintenance treatment of generalized pustular psoriasis (GPP). Previously only available as 450 mg/7.5 ml intravenous vial, which is used for acute treatment of GPP flare.
Voydeya oral tablet 100 mg Voydeya oral tablet therapy pack 50 & 100 mg	Danicopan	New entity. First FDA-approved factor D inhibitor. Indicated as an add-on therapy to Ultomiris (ravulizumab) or Soliris (eculizumab) for the treatment of extravascular hemolysis (EVH) in adults with paroxysmal nocturnal hemoglobinuria (PNH). Designed to selectively inhibit the alternative complement pathway. Voydeya was developed to address the needs of patients with PNH who experience clinically significant EVH while receiving treatment with the complement C5 inhibitors, Ultomiris or Soliris, which reduce intravascular hemolysis (IVH) associated with PNH. Voydeya is not effective as monotherapy and is not for use as an add-on to other treatments approved for PNH, including Empaveli (pegcetacoplan) and Fabhalta (iptacopan), which target different molecules in the complement pathways that regulate both IVH and EVH. Only available through a Risk Evaluation and Mitigation Strategy (REMS) program due to a Boxed Warning regarding the risk of infections caused by encapsulated bacteria.
Baclofen oral tablet 15 mg	Baclofen	New stength. Previously only available as 5 mg, 10 mg, and 20 mg tablets.
Opsynvi oral tablet 10-20 mg, 10-40mg	Macitentan/Tadalafil	New entity. 505(b)(2) approval. Fixed-dose combination tablet of Opsumit (macitentan) and tadalafil for the chronic treatment of pulmonary arterial hypertension (World Health Organization [WHO] Group 1) in adult patients of WHO functional class (FC) II–III.

Drug Name	Generic Name	Description
Dyclopro external solution 0.5 %	Dyclonine	Topical anesthetic for dental procedures.
Cyclophosphamide intravenous solution 500 mg/5ml, 1000 mg/10ml, 2000 mg/20ml	Cyclophosphamide	New strength.
Tyenne intravenous solution 80 mg/4ml, 200 mg/10ml, 400 mg/20ml	Tocilizumab-aazg	Actemra biosimilar. First Actemra biosimilar to hit the market. Is approved for only a subset of Actemra's indications, specifically, rheumatoid arthritis (RA) in adults, giant cell arteritis (GCA) in adults, polyarticular juvenile idiopathic arthritis (PJIA) in patients 2 years of age and older, and systemic juvenile idiopathic arthritis (SJIA) in patients 2 years of age and older. Actemra also has indications for systemic sclerosis-associated interstitial lung disease (SSc-ILD), cytokine release syndrome (CRS), and coronavirus disease 2019 (COVID-19).
Ogsiveo oral tablet 100 mg, 150 mg	Nirogacestat	New strength. Indicated for treatment of adult patients with progressing desmoid tumors (DTs) who require systemic treatment. Previously only available as 50 mg tablets.
Adalimumab-aaty (1 pen) subcutaneous auto-injector kit 80 mg/0.8ml Adalimumab-aaty (2 pen) subcutaneous auto-injector kit 40 mg/0.4ml Adalimumab-aaty (2 syringe) subcutaneous prefilled syringe kit 20 mg/0.2ml Adalimumab-aaty (2 syringe) subcutaneous prefilled syringe kit 40 mg/0.4ml	Adalimumab-aaty	Humira biosimilar. Unbranded version of Yuflyma. Only available in high concentration strengths.

Drug Name	Generic Name	Description
Adalimumab-aaty (1 pen) subcutaneous auto-injector kit 40 mg/0.4ml		

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†
Edurant	rilpivirine 25 mg oral tablets	Janssen	• To be used in combination with other antiretroviral agents for the treatment of HIV-1 infection in treatment-naïve patients ~~12~~ **2** years of age and older and weighing at least ~~35~~ **14** kg with HIV-1 RNA less than or equal to 100,000 copies/mL • To be used in combination with cabotegravir, for short-term treatment of HIV-1 infection in adults and adolescents 12 years and older and weighing at least 35 kg who are virologically suppressed (HIV-1 RNA less than 50 copies/mL) on a stable regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine
Iclusig	ponatinib 10 mg, 15 mg, 30 mg, 45 mg oral tablets	Takeda Pharmaceuticals	• **Newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL), in combination with chemotherapy**[1] • Treatment of adult patients with chronic phase (CP) chronic myeloid leukemia (CML) with resistance or intolerance to at least two prior kinase inhibitors • Treatment of adult patients with accelerated phase (AP) or blast phase (BP) CML or Ph+ ALL for whom no other kinase inhibitors are indicated • Treatment of adult patients with T315I-positive CML (chronic phase, accelerated phase, or blast phase) or T315I-positive Ph+ ALL

Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication†
			Limitations of Use: Iclusig is not indicated and is not recommended for the treatment of patients with newly diagnosed CP-CML. **This indication is approved under accelerated approval based on minimal residual disease (MRD)-negative complete remission (CR) at the end of induction. Continued approval for this indication may be contingent upon verification of clinical benefit in a confirmatory trial(s).**
Elahere	mirvetuximab soravtansine-gynx 100 mg/20 ml intravenous vial	ImmunoGen, Inc.	• Treatment of adult patients with FRα positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received one to three prior systemic treatment regimens. ~~This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.~~
Ultomiris	ravulizumab-cwvz 300 mg/3 ml, 1100 mg/11 ml intravenous vials	Alexion Pharmaceuticals	• Treatment of adult and pediatric patients one month of age and older with paroxysmal nocturnal hemoglobinuria (PNH) • Treatment of adult and pediatric patients one month of age and older with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy (TMA) o Limitations of Use: Ultomiris is not indicated for the treatment of patients with Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS) • Treatment of adult patients with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody-positive

Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication†
			• **Treatment of adult patients with neuromyelitis optica spectrum disorder (NMOSD) who are anti-aquaporin-4 (AQP4) antibody positive**
Ixinity	coagulation factor IX (recombinant) 250 unit, 500 unit, 1000 unit, 1500 unit, 2000 unit, 3000 unit intravenous vials	Medexus Pharma, Inc.	Human blood coagulation factor indicated in adults and children ~~12 years of age and older~~ with hemophilia B for: • On-demand treatment and control of bleeding episodes • Perioperative management • Routine prophylaxis to reduce the frequency of bleeding episodes Ixinity is not indicated for induction of immune tolerance in patients with hemophilia B.
Nexletol	bempedoic acid 180 mg oral tablets	Esperion Therapeutics, Inc.	• As an adjunct to diet ~~and statin therapy~~**, in combination with other low-density lipoprotein cholesterol (LDL-C) lowering therapies, or alone when concomitant LDL-C lowering therapy is not possible, to reduce LDL-C** ~~for the treatment of~~ **in adults with** primary hyperlipidemia ~~in adults with~~**, including** heterozygous familial hypercholesterolemia (HeFH) ~~or atherosclerotic cardiovascular disease, who require additional lowering of LDL-C~~ • **To reduce the risk of myocardial infarction and coronary revascularization in adults who are unable to take recommended statin therapy (including those not taking a statin) with:** o **Established cardiovascular disease (CVD), or** o **A high risk for a CVD event but without established CV**
Nexlizet	bempedoic acid/ezetimibe 180 mg-10 mg oral tablets	Esperion Therapeutics, Inc.	• As an adjunct to diet ~~and statin therapy~~**, alone or in combination with other low-density lipoprotein cholesterol (LDL-C) lowering**

Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication†
			therapies, to reduce LDL-C ~~for the treatment of~~ **in adults with** primary hyperlipidemia ~~in adults with~~**, including** heterozygous familial hypercholesterolemia (HeFH) ~~or atherosclerotic cardiovascular disease, who require additional lowering of LDL-C~~ **The bempedoic acid component of Nexlizet is indicated:** • **To reduce the risk of myocardial infarction and coronary revascularization in adults who are unable to take recommended statin therapy (including those not taking a statin) with:** o **Established cardiovascular disease (CVD), or** o **A high risk for a CVD event but without established CVD**
Vemlidy	tenofovir alafenamide 25 mg oral tablets	Gilead Sciences	Treatment of chronic hepatitis B virus infection in adults and pediatric patients ~~12~~ **6** years of age and older **and weighing at least 25 kg** with compensated liver disease
Abecma	idecabtagene vicleucel intravenous suspension	Bristol-Myers Squibb	Treatment of adult patients with relapsed or refractory multiple myeloma after **two** ~~four~~ or more prior lines of therapy including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody
Fasenra	benralizumab 30 mg/ml subcutaneous syringe; 30 mg/ml subcutaneous pen-injector	AstraZeneca	Add-on maintenance treatment of patients aged **6** ~~12~~ years and older with severe asthma, and with an eosinophilic phenotype
Dovato	dolutegravir/lamivudine 50 mg-300 mg oral tablets	ViiV Healthcare	Treatment of HIV1 infection in adults **and adolescents 12 years of age and older and weighing at least 25 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/mL) on a stable antiretroviral regimen with no history of treatment failure and no known

Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication†
			substitutions associated with resistance to the individual components of Dovato
Carvykti	ciltacabtagene autoleucel intravenous suspension	Janssen Biotech, Inc.	Treatment of adult patients with relapsed or refractory multiple myeloma who have received at least **1** ~~four or more~~ prior line~~s~~ of therapy, including a proteasome inhibitor **and** an immunomodulatory agent, and ~~an anti-CD38 monoclonal antibody~~ **are refractory to lenalidomide**
Enhertu	fam-trastuzumab deruxtecan-nxki 100 mg intravenous vial	Daiichi Sankyo, Inc.	• Treatment of adult patients with unresectable or metastatic HER2-positive **(IHC 3+ or ISH positive)** breast cancer who have received a prior anti-HER2-based regimen either: o In the metastatic setting, or o In the neoadjuvant or adjuvant setting and have developed disease recurrence during or within six months of completing therapy • Treatment of adult patients with unresectable or metastatic HER2-low (IHC 1+ or IHC 2+/ISH-) breast cancer, as determined by an FDA-approved test, who have received a prior chemotherapy in the metastatic setting or developed disease recurrence during or within 6 months of completing adjuvant chemotherapy • Treatment of adult patients with unresectable or metastatic non-small cell lung cancer (NSCLC) whose tumors have activating HER2 (ERBB2) mutations, as detected by an FDA-approved test, and who have received a prior systemic therapy[1] • Treatment of adult patients with locally advanced or metastatic HER2-positive **(IHC 3+ or IHC 2+/ISH positive)** gastric or

Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication†
			gastroesophageal junction adenocarcinoma who have received a prior trastuzumab-based regimen • **Treatment of adult patients with unresectable or metastatic HER2-positive (IHC 3+) solid tumors who have received prior systemic treatment and have no satisfactory alternative treatment options**[1] These indications are approved under accelerated approval based on objective response rate and duration of response. Continued approval for these indications may be contingent upon verification and description of clinical benefit in a confirmatory trial.
Fanapt	iloperidone 1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, 12 mg oral tablets	Vanda Pharmaceuticals	• Treatment of schizophrenia in adults • **Acute treatment of manic or mixed episodes associated with bipolar I disorder in adults**
Alecensa	alectinib 150 mg oral capsules	Genentech	• **Adjuvant treatment in adult patients following tumor resection of anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC) (tumors ≥ 4 cm or node positive) as detected by an FDA-approved test** • Treatment of adult patients with ALK-positive metastatic NSCLC as detected by an FDA-approved test
Lutathera	lutetium Lu 177 dotatate 370 MBq/ml intravenous vial	Novartis	Treatment of adult **and pediatric patients 12 years and older** with somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs), including foregut, midgut, and hindgut neuroendocrine tumors

RECALLS

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Neptune's Fix, Tianeptine Elixir, Fast Acting, 0.338 fl.oz. (10 mL) bottle, Distributed By Superchill Products, 827 6th Avenue, New York, New York 10001.	Class I	Drugs	All lots within expiry	Marketed without an approved NDA/ANDA: Product contains tianeptine, a substance not FDA-approved for any medical use in the United States.	Super Chill Products
Treprostinil Injection, 20 mg/20 mL (1 mg/mL), For Subcutaneous or Intravenous Infusion Only, 20 mL Multiple-Dose Vial, Rx Only, Distributed by: Par Pharmaceutical, Chestnut Ridge, NY 10977. NDC: 42023-206-01	Class I	Drugs	Lot#: 57014; Exp, 04/30/2024	Presence of Particulate Matter.	Par Sterile Products LLC
Methocarbamol Injection, USP 1000mg/10mL, (100mg/mL), 10 mL Single-Dose Vial packed 25 vials per carton, Rx Only, Mfd. in India for: Eugia US LLC. E. Windsor, NJ 08520, NDC 55150-223-10	Class I	Drugs	Lot #: 3MC23011, Exp 11/30/2026	Presence of Particulate Matter	Eugia US LLC
Vancomycin Hydrochloride for Oral Solution, USP, 250 mg per 5 mL, packaged as (a) 80 mL bottle, NDC 69238-2261-3; (b) 150 mL bottle, NDC 69238-2261-7; (c)300 mL bottle, NDC 69238-2261-5; Rx only, Distributed by: Amneal Pharmaceuticals LLC, Bridgewater, NJ 08807	Class I	Drugs	Lot # (a) 22613003A, Exp. date 09/30/2025; (b) 22613004A, 22613005A, Exp. date 09/30/2025; (c) 22613005B, Exp. date 09/30/2025	Superpotent Drug: Due to overfilling of drug powder	Amneal Pharmaceuticals of New York, LLC
Atovaquone Oral Suspension USP, 750 mg per 5 mL sachets, 20 Units x 5 mL cartons, Rx Only,	Class I	Drugs	Lot: AW0221A Exp. 08/30/2025	Microbial contamination of a non-sterile product:	AvKARE

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Manufactured for: AvKARE, Pulaski, TN 38478, NDC 50268-086-12.				potential Bacillus cereus contamination.	
Nicardipine Hydrochloride Injection (2.5mg/mL), US, 25mg per 10mL, 10mL Vial, Rx only, Distributed by: AuroMedics Pharma LLC 279 Princeton-Hightstown Rd. E. Windsor, NJ 08520 NDC 55150-183-10	Class II	Drugs	Lot #: 3NC23002, Exp. Date 7/24; 3NC22013, 3NC22014, 3NC22015, 3NC22016, 3NC22017, 3NC22018, Exp. Date 2/24; 3NC22020, Exp. Date 3/24	Failed Impurities/Degradation Specifications: Out of specification for organic impurities	Eugia US LLC
Nicardipine Hydrochloride Injection, USP 25mg/mL (2.5 mg/mL) 10 mL vials, Distributed by: AuroMedics Pharma LLC 279 Princeton-Hightstown Rd. E. Windsor, NJ 08520, NDC 55150-183-11	Class II	Drugs	Lot #: 3NC22019, Exp. Date 2/24	Failed Impurities/Degradation Specifications: Out of specification for organic impurities	Eugia US LLC
Infumorph (Preservative-free Morphine Sulfate Sterile Solution), 20 mL ampul, Rx only, Manufactured by Hikma Berkeley Heights, NJ 07922, NDC 0641-6039-01	Class II	Drugs	Lot #: 052001, 052003, Exp. Date 11/2024; 023012, 023014, Exp. Date 08/2024	The filter included in the carton has an expiration date that has expired prior to the expiration date of the actual product lot.	Hikma Pharmaceuticals USA Inc.
Diltiazem HCl 125 mg in 0.9% Sodium Chloride Injection (Concentration = 1mg/mL), 125 mL Bag, Rx only, SCA Pharmaceuticals, 755 Rainbow Rd., Windsor, CT 06095; NDC 70004-0541-35, Bar Code 70004054135	Class II	Drugs	Lot #: 1223049625, Exp 1/24/24	Lack of Assurance of Sterility	SCA Pharmaceuticals, LLC
fentaNYL 2,500 mcg/250 mL in 0.9% Sodium Chloride Injection (Concentration = 10 mcg/mL), 250 mL Bag, Rx only, SCA Pharmaceuticals, 755	Class II	Drugs	Lot #: 1223045757, Exp 12/27/23;	Lack of Assurance of Sterility	SCA Pharmaceuticals, LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Rainbow Rd., Windsor, CT 06095, 877.550.5059, NDC 70004-0229-40 BAR code 70004022940			1223049716, Exp 5/25/24		
fentaNYL 2,500 mcg/50 mL Injection (Concentration = 50 mcg/mL), INTRAVENOUS USE ONLY, 50 mL Bag, Rx only, SCA Pharma, 755 Rainbow Rd., Windsor, CT 06095, NDC 70004-0222-30 BAR code 70004022230	Class II	Drugs	Lot #: 1223048351, Exp 11/30/23; 1223048532, Exp 12/07/23	Lack of Assurance of Sterility	SCA Pharmaceuticals, LLC
fentaNYL 200 mcg/100 mL, Bupivacaine HCl 0.125% in 0.9% Sodium Chloride 100 mL Injection (fentaNYL Concentration = 2 mcg/mL), EPIDURAL USE ONLY, 100 mL Bag, Rx only, SCA Pharmaceuticals, 755 Rainbow Rd., Windsor, CT 06095, NDC 70004-0231-32, Bar Code 70004023132	Class II	Drugs	Lot #: 1223048855, Exp 12/6/23	Lack of Assurance of Sterility	SCA Pharmaceuticals, LLC
fentaNYL 200 mcg/100 mL, Bupivacaine HCl 0.125% in 0.9% Sodium Chloride 100 mL Injection, (fentaNYL Concentration = 2 mcg/mL), EPIDURAL USE ONLY, 100 mL Yellow CADD Cassette, Rx only, SCA Pharmaceuticals, 755 Rainbow Rd., Windsor, CT 06095, NDC 70004-0231-64, Bar Code 70004023164	Class II	Drugs	Lot #: 1223049754, Exp 01/12/24; 1223049992, Exp 01/23/24; 1223050066, Exp 01/25/24	Lack of Assurance of Sterility	SCA Pharmaceuticals, LLC
fentaNYL 100 mcg/50 mL, Bupivacaine HCl 0.125% in 0.9% Sodium Chloride 50 mL Injection (fentaNYL Concentration = 2 mcg/mL), EPIDURAL USE ONLY, 50 mL fill Syringe, Rx only, SCA Pharmaceuticals, 755 Rainbow Rd, Windsor, CT 06095, NDC 70004-0231-22, Bar Code 70004023122	Class II	Drugs	Lot #: 1223049125, Exp 12/04/23	Lack of Assurance of Sterility	SCA Pharmaceuticals, LLC
fentaNYL 500 mcg/100 mL, Bupivacaine HCl 0.04% in 0.9% Sodium Chloride 100 mL Injection	Class II	Drugs	Lot #: 1223049261, Exp 12/25/23;	Lack of Assurance of Sterility	SCA Pharmaceuticals, LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
(fentaNYL Concentration = 5 mcg/mL), EPIDURAL USE ONLY, 100 mL Yellow CADD Cassette, Rx only, SCA Pharmaceuticals, 755 Rainbow Rd., Windsor, CT 06095, NDC 70004-0289-64, Bar Code 70004028964			1223049724, Exp 01/11/24		
fentaNYL 500 mcg/100 mL, Bupivacaine HCl 0.075% in 0.9% Sodium Chloride 100 mL Injection (fentaNYL Concentration = 5 mcg/mL), EPIDURAL USE ONLY, 100 mL Yellow CADD Cassette, Rx only, SCA Pharmaceuticals, 755 Rainbow Rd., Windsor, CT 06095, NDC 70004-0251-64, Bar Code 70004025164	Class II	Drugs	Lot #: 1223048722, Exp 11/29/23; 1223049096, Exp 12/15/23	Lack of Assurance of Sterility	SCA Pharmaceuticals, LLC
fentaNYL 1,250 mcg/25 mL Injection (Concentration = 50 mcg/mL), 25 mL fill in a 30 mL Single Dose Syringe, RX Only, repackaged by SCA Pharma. SCA Pharmaceuticals, 755 Rainbow Rd. Windsor, CT 06095, NDC 70004-0200-17, Bar code 70004020017	Class II	Drugs	Lot #: 1223048522, Exp 12/07/23; 1223049168, Exp 01/04/24; 1223049552, Exp 01/19/24	Lack of Assurance of Sterility	SCA Pharmaceuticals, LLC
fentaNYL 2,500 mcg/50 mL in 0.9 % Sodium Chloride Injection (Concentration = 50 mcg/mL) 50 mL Single Dose Syringe, Rx Only, SCA Pharmaceuticals, 755 Rainbow Rd. Windsor, CT 06095, NDC 70004-0202-22, Bar code 70004020022,	Class II	Drugs	Lot #: 1223048959, Exp 12/11/23; 1223049009, Exp 12/12/23; 1223049170, Exp 12/20/23; 1223049245, Exp 12/22/23	Lack of Assurance of Sterility	SCA Pharmaceuticals, LLC
HYDROmorphone HCl 20 mg/100mL in 0.9% Sodium Chloride Injection, 100 mL Grey CADD Cassette (20 mg/100 mL), CII, Rx only, SCA Pharmaceuticals, 755 Rainbow Rd., Windsor, CT	Class II	Drugs	Lot #: 1223049529, Exp 01/03/24	Lack of Assurance of Sterility	SCA Pharmaceuticals, LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
06095, NDC 70004-0300-63, Bar Code 70004030063					
HYDROmorphone HCl 6 mg/30 mL in 0.9% Sodium Chloride Injection, (Concentration = 0.2 mg/ml) 30 mL fill 35 mL Plungerless Syringe, Rx only, SCA Pharmaceuticals, 755 Rainbow Rd., Windsor, CT 06095, NDC 70004-0300-16, Bar Code 70004030016	Class II	Drugs	Lot #: 1223048530, Exp 11/22/23; 1223048692 Exp 11/29/23; 1223048739 EXP 11/30/23; 1223048826 Exp 12/05/23; 1223048963 Exp 12/08/23; 1223048964 EXP 12/11/23; 1223049111 Exp 12/15/23; 1223049128 Exp12/19/23; 1223049210 EXP 12/21/23; 1223049234 Exp 12/22/23; 1223049257 Exp 12/22/23; 1223049322 Exp 12/27/23; 1223049416 Exp 12/28/23; 1223049528 Exp 01/03/24;	Lack of Assurance of Sterility	SCA Pharmaceuticals, LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			1223049559 Exp 01/04/24; 1223049614 Exp 01/05/24; 1223049632 Exp 01/08/24; 1223049725 Exp 01/11/24; 1223049792 Exp 01/15/24; 1223049793 Exp 01/15/24; 1223049905 Exp 01/19/24; 1223050029 Exp 1/24/24; 1223050061 Exp 01/25/24; 1223050179 Exp 01/29/24		
HYDROmorphone HCl 6 mg/30 mL in 0.9% Sodium Chloride, (Concentration = 0.2mg/ml) 30 mL Syringe, Rx only, SCA Pharmaceuticals, 755 Rainbow Rd., Windsor, CT 06095, NDC 70004-0300-18, Bar Code 70004030018	Class II	Drugs	Lot #: 1223048451 Exp 11/20/23; 1223048923 Exp 12/07/23; 1223049097 Exp 12/15/23; 1223049129 Exp 12/19/23;	Lack of Assurance of Sterility	SCA Pharmaceuticals, LLC
HYDROmorphone HCl 10 mg/50 mL in 0.9% Sodium Chloride Injection (Concentration = 0.2 mg/ml) 50 mL fill Syringe, Rx only, SCA	Class II	Drugs	Lot#: 1223048801 Exp 12/04/23; 1223049225 Exp	Lack of Assurance of Sterility	SCA Pharmaceuticals, LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Pharmaceuticals, 755 Rainbow Rd., Windsor, CT 06095, NDC 70004-0300-22, Bar Code 70004030022			12/21/23; 1223049264 Exp 12/25/23; 1223049291 Exp 12/26/23; 1223049726 exp 01/11/24		
HYDROmorphone HCl 25 mg/25 mL in 0.9% Sodium Chloride Injection, (Concentration = 1mg/mL), 25 mL fill 30 mL Syringe, Rx only, SCA Pharmaceuticals, 755 Rainbow Rd., Windsor, CT 06095, NDC 70004-0303-17, Bar Code 7004030317	Class II	Drugs	Lot #: 1223048491 Exp 11/21/23	Lack of Assurance of Sterility	SCA Pharmaceuticals, LLC
HYDROmorphone HCl 30 mg/30mL in 0.9% Sodium Chloride Injection, (Concentration = 1 mg/ml) 30 mL fill 35 mL Plungerless Syringe, Rx only, SCA Pharmaceuticals, 755 Rainbow Rd., Windsor, CT 06095, NDC 70004-0303-16, Bar Code 70004030316	Class II	Drugs	Lot #: 1223048357 Exp 11/15/23; 1223048461 EXP 11/20/23; 1223048486 EXP 11/21/23; 1223048694 EXP 12/01/23; 1223048865 EXP 12/06/23; 1223048967 EXP 12/11/23; 1223049098 EXP 12/15/23; 1223049133 EXP 12/19/23; 1223049175 EXP	Lack of Assurance of Sterility	SCA Pharmaceuticals, LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			12/20/23; 1223049268 EXP 12/25/23; 1223049457 EXP 01/01/24; 1223049561 EXP 01/04/24; 1223049604 EXP 01/05/24; 1223049648 EXP 01/09/24; 1223049870 EXP 01/17/24; 1223049942 EXP 01/19/24; 1223049973 EXP 01/23/24; 1223050060 EXP 01/25/24;		
HYDROmorphone HCl 30 mg/30 mL in 0.9% Sodium Chloride Injection, (Concentration = 1mg/mL) 30 mL fill Syringe, Rx only, SCA Pharmaceuticals, 755 Rainbow Rd., Windsor, CT 06095, NDC 70004-0303-21, Bar Code 70004030321	Class II	Drugs	Lot#: 1223048258 Exp 11/10/23; 1223048890 Exp 12/07/23; 1223049134 Exp 12/19/23	Lack of Assurance of Sterility	SCA Pharmaceuticals, LLC
labetalol HCl 20 mg/4mL Injection, (Concentration=5 mg/mL), 4 mL fill Syringe, Rx Only, SCA Pharma, 755 Rainbow Rd., Windsor, CT 06095, NDC 70004-0700-28, Bar Code 70004070028	Class II	Drugs	Lot #: 1223047334 Exp 12/23/23; 1223048170 Exp 02/01/24	Lack of Assurance of Sterility	SCA Pharmaceuticals, LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Midazolam HCl 100 mg/100 mL in 0.9% Sodium Chloride Injection, (Concentration = 1mg/mL) 100 mL Bag, Rx Only, SCA Pharmaceuticals, 755 Rainbow Rd., Windsor, CT 06095, NDC 70004-0411-59, Bar Code 70004041159	Class II	Drugs	Lot#: 1223044958 Exp 11/10/23; 1223045436 Exp 11/30/23; 1223046132 Exp 12/28/23; 1223046385 Exp 01/06/24; 1223048807 Exp 04/17/24; 1223049030 Exp 04/26/24 Expanded Recall lots: 1223049328, Exp 05/10/2024;1223048948, Exp 04/21/2024; 1223048631, Exp 04/10/2024; 1223050389, Exp 06/21/2024.	Lack of Assurance of Sterility	SCA Pharmaceuticals, LLC
neostigmine methylsulfate 5 mg/5 mL Injection, (Concentration = 1mg/mL), 5 mL fill 6 mL Syringe, Rx Only, SCA Pharma, 755 Rainbow Rd., Windsor, CT 06095, NDC 70004-0750-09, Bar Code 70004075009	Class II	Drugs	Lot #: 1223048138 exp 1/31/24	Lack of Assurance of Sterility	SCA Pharmaceuticals, LLC
PHENYLephrine HCl 1000 mcg/10 mL in 0.9% Sodium Chloride Injection, (Concentration = 100 mcg/mL), 10 mL fill 12 mL Syringe, Rx Only, SCA Pharmaceuticals, 755 Rainbow Rd. Windsor, CT	Class II	Drugs	Lot #: 1223045536 Exp 12/06/23; 1223045710 Exp 12/10/23; 1223046574 Exp	Lack of Assurance of Sterility	SCA Pharmaceuticals, LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
06095, NDC 70004-0810-12, Bar Code 70004081012			01/12/24; 1223047579 Exp 02/21/24; 1223047764 Exp 03/06/24; 1223048363 Exp 03/30/24; 1223048364 Exp 03/30/24; 1223048566 Exp 04/06/24; 1223048573 Exp 04/07/24; 1223048574 Exp 04/07/24; 1223048643 Exp 04/11/24; 1223048697 Exp 04/12/24; 1223048742 Exp 04/13/24 Expanded lots#: 1223048065, Exp 04/06/2024; 1223048395, 1223048397, Exp 03/27/2024; 1223049980, Exp 06/05/2024		
PHENYLephrine HCl 500 mcg/5 mL in 0.9% Sodium Chloride Injection, (Concentration = 100	Class II	Drugs	Lot #: 1223045053 Exp 11/15/23;	Lack of Assurance of Sterility	SCA Pharmaceuticals, LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
mcg/mL), 5 mL fill 12 mL Syringe, Rx Only, SCA Pharmaceuticals, 755 Rainbow Rd. Windsor, CT 06095, NDC 70004-0810-11, Bar Code 70004081011			1223046179 Exp 12/28/23; 1223047477 Exp 02/16/24; 1223047602 Exp 02/22/24; 1223047971 Exp 03/14/24; 1223048269 Exp 03/27/24 Expanded lot#: 1223048181, exp. date 03/22/2024		
PHENYLephrine HCl 500 mcg/5 mL in 0.9% Sodium Chloride Injection, (Concentration = 100 mcg/mL), 5 mL fill 12 mL Syringe, Rx Only, SCA Pharmaceuticals, 755 Rainbow Rd. Windsor, CT 06095, NDC 70004-0810-11-K, Bar Code 70004081011. (same finished product as F078140, but with RFID for KitCheck	Class II	Drugs	Lot #: 1223048431 exp 04/05/24; 1223049023 exp 04/25/24	Lack of Assurance of Sterility	SCA Pharmaceuticals, LLC
PHENYLephrine HCl 5000 mcg/50 mL in 0.9% Sodium Chloride Injection, (Concentration = 100 mcg/mL), 50 mL Syringe, Rx Only, SCA Pharmaceuticals, 755 Rainbow Rd. Windsor, CT 06095, NDC 70004-0810-22, Bar Code 70004081022.	Class II	Drugs	Lot #: 1223045282 Exp 11/24/23; 1223045370 Exp 11/26/23; 1223045624 Exp 12/07/23; 1223045723 Exp 12/10/23; 1223045732 Exp 12/10/23; 1223046128 Exp	Lack of Assurance of Sterility	SCA Pharmaceuticals, LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			12/24/23; 1223046133 Exp 12/24/23; 1223047112 Exp 02/02/24; 1223047232 Exp 2/07/24; 1223047398 Exp 02/15/24; 1223047456 Exp 02/16/24; 1223047569 Exp 02/18/24; 1223047694 Exp 02/24/24; 1223047780 Exp 03/07/24; 1223047859 Exp 03/08/24; 1223048119 Exp 03/20/24; 1223048183 Exp 03/22/24; 1223048837 Exp 04/18/24; 1223048838 Exp 04/18/24; 1223048982 Exp 04/24/24; 1223049144 Exp 05/02/24;		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			1223049145 Exp 05/02/24; 1223049147 Exp 05/02/24; 1223049821 Exp 05/30/24 Expanded Lot #: 1223048037, Exp 03/16/2024; 1223048047, Exp 03/17/2024; 1223049146, 1223049149, Exp 05/02/2024; 1223049373, Exp 05/10/2024; 1223048909, Exp 04/20/2024; 1223048696, Exp 04/12/2024; 1223050181, Exp 06/12/2024		
PHENYLephrine HCl 400 mcg/10 mL in 0.9% Sodium Chloride Injection, (Concentration = 40 mcg/mL), 10 mL fill 12 mL Syringe, Rx Only, SCA Pharmaceuticals, 755 Rainbow Rd. Windsor, CT 06095, NDC 70004-0811-12, Bar Code 70004081112.	Class II	Drugs	Lot #: 1223045040 Exp 11/13/23, 1223046397 Exp 01/06/24, 1223046505 Exp 01/10/24, 1223047254 Exp 02/08/24, 1223047436 Exp	Lack of Assurance of Sterility	SCA Pharmaceuticals, LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			02/15/24, 1223047938 Exp 03/13/24, 1223049150 Exp 05/02/24, 1223049300 Exp 05/09/24, Expanded Lot #: 1223048569, Exp 04/06/2024; 1223049600, Exp 05/19/2024		
PHENYLephrine HCl 40 mg in 0.9% Sodium Chloride Injection, (Concentration = 160 mcg/mL), 250 mL Bag, Rx Only, SCA Pharmaceuticals, 755 Rainbow Rd. Windsor, CT 06095, NDC 70004-0825-40, Bar Code 70004082540.	Class II	Drugs	Lot #: 1223050005 Exp 01/13/24	Lack of Assurance of Sterility	SCA Pharmaceuticals, LLC
PHENYLephrine HCl 800 mcg/10 mL in 0.9% Sodium Chloride Injection, (Concentration = 80mcg/mL) 10 mL fill 12 mL Syringe, Rx Only, SCA Pharmaceuticals, 755 Rainbow Rd., Windsor, CT 06095, NDC 70004-0816-12, Bar Code 700040081612.	Class II	Drugs	Lot #: 1223045974 Exp 12/18/23; 1223046535 Exp 01/11/24; 1223049152 Exp 05/02/24 Expanded Lot #: 1223048067, Exp 04/06/2024; 1223048792, Exp 04/17/2024.	Lack of Assurance of Sterility	SCA Pharmaceuticals, LLC
PHENYLephrine HCl 800 mcg/10 mL in 0.9% Sodium Chloride Injection, (Concentration = 80mcg/mL) 10 mL fill 12 mL Syringe, Rx Only,	Class II	Drugs	Lot #: 1223048610 Exp 04/10/24; 1223048611 Exp	Lack of Assurance of Sterility	SCA Pharmaceuticals, LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
SCA Pharmaceuticals, 755 Rainbow Rd., Windsor, CT 06095, NDC 70004-0816-12-K, Bar Code 700040081612. (same finished product as F078140, but with RFID for KitCheck compatibility)			04/10/24; 1223048726 Exp 04/13/24; 1223050163 Exp 06/12/24		
Sodium Citrate 4% 3 mL, Anticoagulation Solution Injection (Concentration = 40/mg/mL) 3mL fill Syringe, Repackaged by SCA Pharma, 755 Rainbow Rd., Windsor, CT 06095, NDC 70004-0900-25, Bar Code 70004090025	Class II	Drugs	Lot #: 1223048444 Exp 11/20/23; 1223049011 Exp 12/12/23; 1223049673 Exp 01/09/24; 1223049771 Exp 01/12/24	Lack of Assurance of Sterility	SCA Pharmaceuticals, LLC
SUCcinylcholine Chloride 200 mg/10mL Injection (Concentration = 20mg/mL), 10 mL fill 12 mL Syringe, Rx only, Repackaged by SCA Pharma, 755 Rainbow Rd., Windsor, CT 06095, NDC 70004-0908-12, Bar Code 70004090812	Class II	Drugs	Lot #: 1223049047 Exp 11/29/23; 1223049221 Exp 12/06/23; 1223049343 Exp 12/12/23; 1223049423 Exp 12/14/23; 1223049451 Exp 12/14/23; 1223049452 Exp 12/14/23; 1223049482 Exp 12/14/23	Lack of Assurance of Sterility	SCA Pharmaceuticals, LLC
SUCcinylcholine Chloride 100 mg/5mL Injection (Concentration = 20mg/mL), 5 mL fill 6 mL Syringe, Rx only, Repackaged by SCA Pharma,	Class II	Drugs	Lot #:1223049085 Exp 11/29/23;	Lack of Assurance of Sterility	SCA Pharmaceuticals, LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
755 Rainbow Rd., Windsor, CT 06095, NDC 70004-0908-09, Bar Code 70004090809			1223049364 Exp 12/12/23		
VANCOMYCIN 1.25 g added to 0.9% Sodium Chloride 250 mL Injection, 250 mL bag, Rx only, SCA Pharmaceuticals, 755 Rainbow Rd., Windsor, CT 06095, NDC 70004-0923-59, Bar Code 70004092359	Class II	Drugs	Lot #: 1223049049 Exp 12/28/23	Lack of Assurance of Sterility	SCA Pharmaceuticals, LLC
Divalproex Sodium Extended-release Tablets, USP 250 mg, Rx Only, 100 tablets, Manufactured by: Amneal Pharmaceuticals Pvt. Ltd. Ahmedabad, INDIA, Distributed by: Amneal Pharmaceuticals LLC, Bridgewater, NJ 08807, NDC 65162-755-10. NDC# 65162-755-10	Class II	Drugs	Lot # AR210704, exp. date 04/2024 AR210706, exp. date 04/2024 AR210707, exp. date 04/2024 AR210708, exp. date 04/2024 AR210709, exp. date 04/2024	Failed dissolution specifications	Amneal Pharmaceuticals of New York, LLC
Tri-Lo-Sprintec (norgestimate and ethinyl estradiol) tablets USP - triphasic regimen, packaged in carton containing 3 Blister Cards, 28 Tablets Each, Rx only, Teva Pharmaceuticals USA, INC, North Wales, PA 19454, NDC 0093-2140-62	Class II	Drugs	Lot # 100039678, Exp 04/31/2024; 100038111, 100042277, Exp 07/31/2024	Failed Dissolution Specifications	Teva Pharmaceuticals USA, Inc
VCF Vaginal Contraceptive Film (nonoxynol-9, 28%), package in a carton with 9 single films, Distributed By: Apothecus Pharmaceutical Corp, Ronkonkoma, NY 11779, NDC 52925-112-01	Class II	Drugs	Lot # 1G008A/1G00804722 , Exp 07/31/25	cGMP Diviations	Apothecus Pharmaceutical Corp.
Phenylephrine HCl, 1000 mcg/10 mL, 10 mL Total Volume per syringe, Intravenous, Rx Only, Hospital/Office Use Only, This is a Compounded Drug - Not for Resale, SSM Health Care Corporation Outsourcing Facility, 1015 Bowles	Class II	Drugs	Lot #s: 20240109-837CB8, Exp. 07-Jul-2024; 20231219-08D09D, Exp. 16-Jun-2024; 20231121-	Lack of Assurance of Sterility: Firm did not perform process validation.	SSM Health Care St. Louis DBA SSM St. Clare Health Center

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Ave, Fenton, MO 63026-2394. NDC: 60652-0104-1			20F8BB, Exp. 19-May-2024; 20231115-2FF64D, Exp. 13-May-2024; 20231101-09C52B, Exp. 29-Apr-2024; 20231010-3D0B35, Exp. 07-Apr-2024; 20230912-847E0C, Exp. 10-Mar-2024.		
FentaNYL citrate, 10 mcg in 0.9% Sodium Chloride 1 mL Vial (10 mcg/mL), 1.5 mL Total Volume per Vial, Intravenous, Rx Only, Hospital/Office Use Only, SSM Health Care Corporation Outsourcing Facility, 1015 Bowles Ave, Fenton, MO 63026-2394. NDC: 60652-9010-1	Class II	Drugs	Lot: 20231031-0C91D9, Exo 29-Feb-2024.	Lack of Assurance of Sterility: Firm did not perform process validation.	SSM Health Care St. Louis DBA SSM St. Clare Health Center
Lactated Ringer's Injection USP, 1000mL, EXCEL CONTAINER, Rx only, B.Braun Medical Inc., Bethlehem, PA 18018, NDC 0264-7750-00	Class II	Drugs	Lot #: J3N023, Exp: 31 March 2026	Lack of assurance of sterility: bags have the potential to leak..	B. Braun Medical Inc
fentaNYL Citrate 2,500 mcg/50mL in Sterile Water, 50 mL CADD for Injection, IntegraDose Compounding Services, LLC, 719 Kasota Ave SE, Minneapolis, MN. NDC 71139-6030-1	Class II	Drugs	Lot#: 20231020FEN-1, Exp: 04/17/2024	Lack of Assurance of Sterility: leaking bags	IntegraDose Compounding Services LLC
Diltiazem Hydrochloride Extended-Release Capsules, USP 120 mg, Twice-a-Day Dosage, 100 Capsules per bottle, Rx Only, Manufactured for: Glenmark Pharmaceuticals Inc., USA Mahwah, NJ, 07430, Product of India, NDC 68462-562-01	Class II	Drugs	Lot #: 17230304, Exp. 12/31/2024.	Failed Dissolution Specifications: Out of Specification (OOS) was reported in test of dissolution at the 12th	Glenmark Pharmaceuticals Inc., USA

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
				month time point in long term stability study.	
Rifampin Capsules USP, 300mg, 30-count bottles, Rx only, Manufactured for: Lupin Pharmaceuticals, Inc. Baltimore, Maryland 21202, Manufactured by: Lupin Limited Aurangabad 431 210 India, NDC 6818-0659-06	Class II	Drugs	Lot #: A201064, Exp. Date March 2024	Subpotent Drug	Lupin Pharmaceuticals Inc.
Isotretinoin Capsules, USP 40mg, 30-count 3x10 blister packs per carton, Rx Only, Manufactured For: Teva Pharmaceuticals USA, Inc., Parsippany, NJ 07054. Blister Pack NDC 0591-2436-45, Carton NDC 0591-2436-15	Class II	Drugs	Lot #: 100044259, Exp 06/30/2025.	Superpotent Drug: The 3-month stability result for assay was found to be above specification limit	Teva Pharmaceuticals USA, Inc
Lansoprazole Delayed-Release Capsules USP, 15 mg, Acid reducer 24 Hour, Treats Frequent Heartburn, 14 capsules per bottle, Manufactured by: Natco Pharma Limited Kothur- 509 228, India, Distributed by: Rising Pharma Holdings, Inc. East Brunswick, NJ. 08816. NDC 16571-742-41	Class II	Drugs	Lot#: 411988, Exp date: 05/31/2025	CGMP Deviations	NATCO Pharma Limited
Sterile Diluent, HUMALOG U-100 (insulin lispro injection), HUMULIN R U-100 REGULAR (insulin human injection), Insulin Lispro Injection u-100, 10 mL, Use ONLY with Insulins listed on carton, Marketed by: Lilly USA, LLC, Indianapolis, IN 46285. NDC: 0002-0800-01	Class II	Drugs	Batch number: D608951C, exp 4/10/2025	CGMP Deviations	Eli Lilly & Company
S.P.Labs, Thyroid, Full Strength, Rx only, For Manufacturing, Processing or Repackaging Use Only, Specialty Process Labs, Phoenix, AZ 85034, NDC 81305-500-01.	Class II	Drugs	Lot #: H22212-FSV, Exp: 11/21/2024 1.0 kg pack size.	Failed Stability Specifications	Specialty Process Labs LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
S.P Labs, Thyroid, USP, Rx only, For Manufacturing, Processing or Repackaging Use only, Specialty Process Labs, Phoenix, AZ, NDC #'s a) 81305-100-01, b)81305-100-02, c)81305-100-03	Class II	Drugs	Lot #: L13152-1XV, Exp: 11/21/2024; a)1.00 kg, b)0.5 kg, c)100g pack sizes. Lot #: B10383-1XV, Exp: 02/14/2025, a)1 kg, b)0.5 kg, c)100g pack sizes. Lot #: B10453-1X, Exp: 02/15/2025, a)1.00 kg, b)0.5 kg, c)100g pack sizes. Lot #: C10803-1X, Exp: 03/23/2025, a)1.00 kg, c)100g pack sizes. Lot #: E11363-1X, Exp: 05/18/2025, a)1.00 kg, b)0.5 kg, c)100g pack sizes. Lot #: K12753-1X, Exp: 10/12/2025, a)1.00 kg pack sizes. Lot #: L13103-1X, Exp: 11/13/2025, a)1 kg, b)0.5 kg, c)100g pack sizes.	Failed Stability Specifications	Specialty Process Labs LLC
Digoxin Tablets, USP 125mcg, (0.125 mg), 1000-count bottle, Rx Only, Manufactured by: Novitium Pharma LLC., 70 Lake Drive, East Windsor, New Jersey 08520, NDC 70954-201-20	Class III	Drugs	Lot #: M23172A, Exp 01/31/2025	Cross Contamination with Other Products:(mycophenolate mofetil).	Novitium Pharma LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
IPOL Polio Vaccine 40 Unit - 8 Unit - 32 Unit / 0.5 mL Injection Multiple-Dose Vial 5 mL MMS Item no. 327341 Catalog No. 860-10	Class III	Biologics	Lot No. W1A101M NDC No. 49281086010	McKesson Medical Surgical (MMS) Phoenix, AZ Distribution Center experienced a critical temperature excursion in the Walk-In refrigerator due to mechanical failures, causing temperatures to fall below the validated range for up to 60 minutes. This incident led to stored medical products being exposed to temperatures as low as 25oF, averaging 28oF over the hour-long period. MMS has initiated a voluntary recall for products negatively impacted by this excursion.	Mckesson Medical-Surgical Inc. Corporate Office
Adacel Tdap Vaccine Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine, Adsorbed, Preservative Free Injection Single-Dose Vial 0.5 mL MMS Item no. 562083 Catalog No. 49281040010	Class III	Biologics	Lot No. 2CA61C1 NDC No. 49281040010	McKesson Medical Surgical (MMS) Phoenix, AZ Distribution Center experienced a critical temperature excursion in the Walk-In refrigerator due to mechanical failures, causing temperatures to fall below the validated range for up to 60 minutes. This incident led to stored	Mckesson Medical-Surgical Inc. Corporate Office

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
				medical products being exposed to temperatures as low as 25oF, averaging 28oF over the hour-long period. MMS has initiated a voluntary recall for products negatively impacted by this excursion.	
Twinrix Hepatitis A and Hepatitis B Vaccine 720 Unit - 20 mcg / mL Injection Prefilled Syringe 1 mL MMS Item no. 769020 Catalog No. 58160081552	Class III	Biologics	Lot No. H7RF2 NDC No. 58160081552	McKesson Medical Surgical (MMS) Phoenix, AZ Distribution Center experienced a critical temperature excursion in the Walk-In refrigerator due to mechanical failures, causing temperatures to fall below the validated range for up to 60 minutes. This incident led to stored medical products being exposed to temperatures as low as 25oF, averaging 28oF over the hour-long period. MMS has initiated a voluntary recall for products negatively impacted by this excursion.	Mckesson Medical-Surgical Inc. Corporate Office
ENGERIX-B Hepatitis B Vaccine 20 mcg / mL Injection Prefilled Syringe 1 mL MMS Item no. 769341 Catalog No. 58160082152	Class III	Biologics	Lot No. 4T39P NDC No. 58160082152	McKesson Medical Surgical (MMS) Phoenix, AZ Distribution Center	Mckesson Medical-Surgical Inc. Corporate Office

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
				experienced a critical temperature excursion in the Walk-In refrigerator due to mechanical failures, causing temperatures to fall below the validated range for up to 60 minutes. This incident led to stored medical products being exposed to temperatures as low as 25oF, averaging 28oF over the hour-long period. MMS has initiated a voluntary recall for products negatively impacted by this excursion.	
Boostrix Tdap Booster Vaccine Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine, Adsorbed Injection Prefilled Syringe 0.5 mL MMS Item no. 772678 Catalog No. 58160084252	Class III	Biologics	Lot No. P5SR5 NDC No. 58160084252	McKesson Medical Surgical (MMS) Phoenix, AZ Distribution Center experienced a critical temperature excursion in the Walk-In refrigerator due to mechanical failures, causing temperatures to fall below the validated range for up to 60 minutes. This incident led to stored medical products being exposed to temperatures as low as 25oF, averaging 28oF	Mckesson Medical-Surgical Inc. Corporate Office

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
				over the hour-long period. MMS has initiated a voluntary recall for products negatively impacted by this excursion.	
Thrombin-JMI Thrombin (Bovine) 5,000 Units Vial MMS Item no. 916386 Catalog No. 60793021505	Class III	Biologics	Lot No. N/A NDC No. 60793021505	McKesson Medical Surgical (MMS) Phoenix, AZ Distribution Center experienced a critical temperature excursion in the Walk-In refrigerator due to mechanical failures, causing temperatures to fall below the validated range for up to 60 minutes. This incident led to stored medical products being exposed to temperatures as low as 25oF, averaging 28oF over the hour-long period. MMS has initiated a voluntary recall for products negatively impacted by this excursion.	Mckesson Medical-Surgical Inc. Corporate Office
TDVAX Td Vaccine Tetanus and Diphtheria Toxoids Adsorbed Injection Single-Dose Vial 0.5 mL MMS Item no. 981867 Catalog No. 13533013101	Class III	Biologics	Lot No. A146A1 NDC No. 13533013101	McKesson Medical Surgical (MMS) Phoenix, AZ Distribution Center experienced a critical temperature excursion in the Walk-In refrigerator due	Mckesson Medical-Surgical Inc. Corporate Office

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
				to mechanical failures, causing temperatures to fall below the validated range for up to 60 minutes. This incident led to stored medical products being exposed to temperatures as low as 25oF, averaging 28oF over the hour-long period. MMS has initiated a voluntary recall for products negatively impacted by this excursion.	
Shingrix Shingles Vaccine Zoster Vaccine Recombinant, Adjuvanted 50 mcg / 0.5 mL Injection Single-Dose Vial 0.5 mL MMS Item no. 1081079 Catalog No. 58160082311	Class III	Biologics	Lot No. MG5EJ NDC No. 58160082311	McKesson Medical Surgical (MMS) Phoenix, AZ Distribution Center experienced a critical temperature excursion in the Walk-In refrigerator due to mechanical failures, causing temperatures to fall below the validated range for up to 60 minutes. This incident led to stored medical products being exposed to temperatures as low as 25oF, averaging 28oF over the hour-long period. MMS has initiated a voluntary recall for products	Mckesson Medical-Surgical Inc. Corporate Office

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
				negatively impacted by this excursion.	
Retacrit Epoetin Alfa-epbx 3,000 U / mL Injection Single-Dose Vial 1 mL MMS Item no. 1144894 Catalog No. 69130610	Class III	Biologics	Lot No. N/A NDC No. 69130610	McKesson Medical Surgical (MMS) Phoenix, AZ Distribution Center experienced a critical temperature excursion in the Walk-In refrigerator due to mechanical failures, causing temperatures to fall below the validated range for up to 60 minutes. This incident led to stored medical products being exposed to temperatures as low as 25oF, averaging 28oF over the hour-long period. MMS has initiated a voluntary recall for products negatively impacted by this excursion.	Mckesson Medical-Surgical Inc. Corporate Office
Retacrit Epoetin Alfa-epbx 10,000 U /mL Injection Single-Dose Vial 1 mL MMS Item no. 1144897 Catalog No. 69130810	Class III	Biologics	Lot No. N/A NDC No. 69130810	McKesson Medical Surgical (MMS) Phoenix, AZ Distribution Center experienced a critical temperature excursion in the Walk-In refrigerator due to mechanical failures, causing temperatures to fall below the validated range	Mckesson Medical-Surgical Inc. Corporate Office

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
				for up to 60 minutes. This incident led to stored medical products being exposed to temperatures as low as 25oF, averaging 28oF over the hour-long period. MMS has initiated a voluntary recall for products negatively impacted by this excursion.	
MenQuadfi Meningitis Vaccine Meningococcal (Groups A, C, Y, and W-135) Conjugate Vaccine, Preservative Free 10 mcg / 0.5 mL Injection Single-Dose Vial 0.5 mL MMS Item no. 1191780 Catalog No. 49281059005	Class III	Biologics	Lot No. U7852AB NDC No. 49281059005	McKesson Medical Surgical (MMS) Phoenix, AZ Distribution Center experienced a critical temperature excursion in the Walk-In refrigerator due to mechanical failures, causing temperatures to fall below the validated range for up to 60 minutes. This incident led to stored medical products being exposed to temperatures as low as 25oF, averaging 28oF over the hour-long period. MMS has initiated a voluntary recall for products negatively impacted by this excursion.	Mckesson Medical-Surgical Inc. Corporate Office

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
FluMist Quadrivalent 2023 - 2024 Flu Vaccine 10E6.5 - 7.5 FFU Intranasal Sprayer 0.2 mL MMS Item no. 1220929 Catalog No. 66019031010	Class III	Biologics	Lot No. TJ2944 NDC No. 66019031010	McKesson Medical Surgical (MMS) Phoenix, AZ Distribution Center experienced a critical temperature excursion in the Walk-In refrigerator due to mechanical failures, causing temperatures to fall below the validated range for up to 60 minutes. This incident led to stored medical products being exposed to temperatures as low as 25oF, averaging 28oF over the hour-long period. MMS has initiated a voluntary recall for products negatively impacted by this excursion.	Mckesson Medical-Surgical Inc. Corporate Office
Cyclophosphamide for Injection, USP, 500mg/vial, Lyophilized, Cytotoxic Agent, Single Dose Vial for Intravenous Use, Rx Only, Manufactured for: XGen Pharmaceuticals DJB, Inc. Big Flats, NY 14814, NDC # 39822-0250-01.	Class III	Drugs	Lot #: CIC1-23001 A, Exp. 08/30/2026	Labeling: Incorrect or missing Package Insert: There is an error on the Package Insert (PI), section 2.3, Preparation, Handling, and Administration. The concentration of the reconstituted product is listed as '20 mg per vial.' This information should read: '20 mg per mL'.	X-Gen Pharmaceuticals Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Cyclophosphamide for Injection, USP, 1g/vial, Lyophilized, Single Dose Vial, Discard unused solution, Cytotoxic Agent, After Reconstitution: For direct intravenous injection or must be further diluted before intravenous infusion, Rx Only, Manufactured for: XGen Pharmaceuticals DJB, Inc., Big Flats, NY 14814, NDC # 39822-0255-01.	Class III	Drugs	Lot #: CIC2-23001 A, Exp. 11/30/2026	Labeling: Incorrect or missing Package Insert: There is an error on the Package Insert (PI), section 2.3, Preparation, Handling, and Administration. The concentration of the reconstituted product is listed as '20 mg per vial.' This information should read: '20 mg per mL'.	X-Gen Pharmaceuticals Inc.
Digoxin Tablets, USP 62.5 mcg (0.0625 mg), 100-count bottles, Rx Only, Manufactured by: Novitium Pharma LLC, 70 Lake Drive, East Windsor, New Jersey 08520, NDC 70954-200-10	Class III	Drugs	Lot M23011A; Exp. 12/2024	Failed Impurities/Degradation Specifications	Novitium Pharma LLC
NEXLIZET (bempedoic acid and ezetimibe) tablets, 180 mg/10 mg, 30-count bottle, Rx only, Manufactured for: Esperion Therapeutics, Ann Arbor, MI 48108, NDC 72426-818-03	Class III	Drugs	Lot #, 1990305, Exp 08-31-2025	Failed dissolution specifications: out-of-specification bempedoic acid dissolution at the 0-month timepoint.	Esperion

*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 Solution
Alprostadil Suppository
Amifostine Injection
Amino Acid Injection
Amoxapine Tablet
Amoxicillin Powder, For Suspension
Amphetamine Aspartate Monohydrate, Amphetamine Sulfate, Dextroamphetamine Saccharate, Dextroamphetamine Sulfate Tablet
Atropa Belladonna, Opium Suppository
Atropine Sulfate Injection
Azacitidine Injection
Bumetanide Injection
Bupivacaine Hydrochloride Injection
Bupivacaine Hydrochloride, Epinephrine Bitartrate Injection, Solution
Capecitabine Tablet
Carboplatin Injection
Cefotaxime Sodium Injection
Cefotetan Disodium Injection
Chloroprocaine Hydrochloride Injection
Cisplatin Injection
Clindaymycin Phosphate Injection
Clonazepam Tablet
Collagenase Clostridium Histolyticum Ointment
Conivaptan Hydrochloride Injection
Cromolyn Sodium Concentrate
Cyclopentolate Hydrochloride Ophthalmic Solution
Cytarabine Injection, Solution
Dacarbazine Injection
Desmopressin Acetate Spray
Dexamethasone Sodium Phosphate Injection
Dexmedetomidine Hydrochloride Injection
Dextrose Monohydrate Injection
Dextrose Monohydrate, Lidocaine Hydrochloride Anhydrous Injection
Digoxin Injection
Diltiazem Hydrochloride Injection
Disopyramide Phosphate Capsule
Dobutamine Hydrochloride Injection
Dopamine Hydrochloride Injection

Dulaglutide Injection
Echothiophate Iodide Ophthalmic Solution
Enalaprilat Injection
Epinephrine Bitartrate, Lidocaine Hydrochloride Injection
Epinephrine Injection, Syringes
Erythromycin Ointment
Etomidate Injection
Fentanyl Citrate Injection
Fluconazole Injection
Flurazepam Hydrochloride Capsule
Furosemide Injection
Gentamicin Sulfate Injection
Heparin Sodium Injection
Hydrocortisone Sodium Succinate Injection
Hydromorphone Hydrochloride Injection
Hydroxocobalamin Injection
Hydroxypropyl Cellulose (1600000 Wamw) Insert
Isoniazid Tablet
Ketamine Hydrochloride Injection
Ketorolac Tromethamine Injection
Leucovorin Calcium Injection
Lidocaine Hydrochloride Injection
Lidocaine Hydrochloride Solution
Liraglutide Injection
Lisdexamfetamine Dimesylate Capsule
Lisdexamfetamine Dimesylate Tablet, Chewable
Lorazepam Injection
Methamphetamine Hydrochloride Tablet
Methotrexate Sodium Injection
Methotrexate Sodium Tablet
Methylphenidate Hydrochloride Tablet, Extended Release
Methylprednisolone Acetate Injection
Metronidazole Injection
Midazolam Hydrochloride Injection
Morphine Sulfate Injection
Naltrexone Hydrochloride Tablet
Neomycin Sulfate Tablet
Nitroglycerin Injection
Oxybutynin Chloride Syrup
Parathyroid Hormone Injection
Penicillin G Benzathine Injection
Potassium Acetate Injection
Potassium Chloride Injection
Promethazine Hydrochloride Injection
Propranolol Hydrochloride Injection
Quinapril Hydrochloride Tablet

Quinapril/Hydrochlorothiazide Tablet
Remifentanil Hydrochloride Injection
Rifampin Capsule
Rifampin Injection
Rifapentine Tablet, Film Coated
Riluzole Oral Suspension
Rocuronium Bromide Injection
Ropivacaine Hydrochloride Injection
Semaglutide Injection
Sodium Acetate Injection
Sodium Bicarbonate Injection
Sodium Chloride 0.9% Injection
Sodium Chloride 0.9% Irrigation
Sodium Chloride 14.6% Injection
Sodium Chloride 23.4% Injection
Sodium Phosphate, Dibasic, Anhydrous, Sodium Phosphate, Monobasic, Monohydrate Injection, Solution
Somatropin Injection
Sterile Water Injection
Sterile Water Irrigant
Streptozocin Powder, For Solution
Sucralfate Tablet
Sufentanil Citrate Injection
Sulfasalazine Tablet
Technetium TC-99M Pyrophosphate Kit Injection
Tirzepatide Injection
Triamcinolone Acetonide Injection
Triamcinolone Hexacetonide Injection
Valproate Sodium Injection
Vecuronium Bromide Injection
Vinblastine Sulfate Injection