PERFORMRx℠

Drug Information Update

May 2022

TABLE OF CONTENTS

NEWLY AVAILABLE GENERICS

Generic Name/ Dosage Form	Brand Name	Manufacturer	Indication
K-Phos Original	potassium phosphate, monobasic 500 mg tablets sol	Beach/Redwood	For use in patients with elevated urinary pH. K-PHOS® ORIGINAL helps keep calcium soluble and reduces odor and rash caused by ammoniacal urine. Also, by acidifying the urine, it increases the antibacterial activity of methenamine mandelate and methenamine hippurate.
Velcade	bortezomib 3.5 mg vial	Milennium	• Treatment of adult patients with multiple myeloma • Treatment of adult patients with mantle cell lymphoma
Chantix	varenicline tartrate 0.5 mg (11)-1 mg (42) tab dosepack	Pfizer	For use as an aid to smoking cessation treatment.
Esbriet	Pirfenidone 267 mg, 801 mg tablet	Genentech	For the treatment of idiopathic pulmonary fibrosis (IPF).
Conjupri	Levamlodipine maleate 5 mg tablet	Burke Therapeutics	For the treatment of hypertension in adults and pediatric patients 6 years and older, to lower blood pressure.
Pennsaid	Diclofenac sodium 20 mg/gram per actuation (2 %) pump	Horizon Therapeutics	For osteoarthritis knee pain.
Pentasa	Mesalamine 500 mg ER capsule	Shire US	For the induction of remission and for the treatment of adult patients with mildly to moderately active ulcerative colitis.

NEW DRUG ENTITIES/STRENGTHS/COMBINATIONS

Drug Name	Generic Name	Description	Comments
Norliqva 1 mg/mL oral solution	amlodipine besylate	Amlodipine oral solution for hypertension and CAD.	New Dosage Form and Strength
Camcevi 42 mg subcutaneous syringe	leuprolide mesylate	A gonadotropin-releasing hormone (GnRH) agonist indicated for the treatment of adult patients with advanced prostate cancer. Ready-to-use, 6 month SQ depot formulation. Lupron Depot also available in 6-month formulation. 505(b)2.	New Formulation and Strength
Moderna COVID-19 Vaccine(6mo-5yr)(PF) 25 mcg/0.25 mL IM susp (Unapp)	covid-19 vacc,pedi(moderna)/pf	Unapproved pediatric COVID-19 vaccine	New Age Range; Waiting for FDA review, not available until EUA granted
Moderna COVID-19 Vaccine(6yr-11yr)(PF) 50 mcg/0.5 mL IM susp (Unapp)	covid-19 vacc,pedi(moderna)/pf	Unapproved pediatric COVID-19 vaccine	New Age Range; Waiting for FDA review, not available until EUA granted
valsartan 4 mg/mL oral solution	valsartan	Branded valsartan oral solution, not therapeutically equivalent to tablet version of Diovan	New Dosage Form and Strength
Camzyos 2.5, 5, 10, 15 mg capsule	mavacamten	Allosteric and reversible inhibitor selective for cardiac myosin; approved for the treatment of adults with symptomatic New York Heart Association (NYHA) class II-III obstructive hypertrophic cardiomyopathy (obstructive HCM) to improve functional capacity and symptoms.	New Entity
phytonadione (vitamin K1) 1 mg/0.5 mL injection solution	phytonadione (vit k1)	generic injectable phytonadione; new vial form	New Dosage Form
Igalmi 120, 180 mcg sublingual film	dexmedetomidine hcl	ODT form of dexmedetimidine for acute agitation with schizophrenia/bipolar disorder. Dexmedetomidine is	New Route, Dosage Form, and Strength

Drug Name	Generic Name	Description	Comments
		an alpha 2 adrenergic agonist, which is also used as a sedative in an inpatient setting (Precedex).	
Epsolay 5 % topical cream	benzoyl peroxide	A proprietary cream formulation of benzoyl peroxide, 5%, for the treatment of inflammatory lesions of rosacea in adults.	New GCN
bortezomib 1, 2.5 mg injection powder for solution	bortezomib	Chemotherapy agent; new strength. 505(b)(2) approval	New Strength
Lyvispah 5, 10, 20 mg oral granules in packet	baclofen	Baclofen oral granules form for treatment of spasticity due to MS or spinal cord injuries/diseases. 505(b)(2) approval	New Dosage Form
Multi-Mac 15 mg iron-1,750 mcg DFE tablet	prenatal 181/iron fum/folate	Reformulated Rx prenatal vitamin	New Formulation
Radicava ORS Starter Kit Suspension 105 mg/5 mL oral	edaravone	New sNDA approval for oral formulation of Radicava for ALS	New Route, Dosage Form, and Strength
Radicava ORS 105 mg/5 mL oral suspension	edaravone	New sNDA approval for oral formulation of Radicava for ALS	New Route, Dosage Form, and Strength
Mounjaro 2.5 mg/0.5 mL, 5 mg/0.5 mL, 7.5/0.5 mL, 10 mg/0.5 mL, 12.5 mg/0.5 mL, 15 mg/0.5 mL subcutaneous pen injector	tirzepatide	Once weekly injectable therapy to improve blood sugar control in adults with type 2 diabetes, as an addition to diet and exercise. A novel a glucose-dependent insulinotropic polypeptide (GIP) receptor and glucagon-like peptide-1 (GLP-1) receptor agonist.	New Entity
Mounjaro 12.5 mg/0.5 mL subcutaneous pen injector	tirzepatide	Once weekly injectable therapy to improve blood sugar control in adults with type 2 diabetes, as an addition to diet and exercise. A novel a glucose-dependent insulinotropic polypeptide (GIP) receptor and glucagon-like peptide-1 (GLP-1) receptor agonist.	New Entity

NEW INDICATIONS (EXISTING DRUGS)

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

Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication†
Zerbaxa	ceftolozane and tazobactam for injection, 1.5 g as powder for reconstitution in single-dose vials containing ceftolozan 1 g and tazobactam 0.5 g	Merck	~~Indicated in patients 18 years or older~~ for the treatment of the following infections caused by designated susceptible microorganisms: • Complicated Intra-abdominal infections (cIAI), used in combination with metronidazole, in adult and **pediatric patients (birth to less than 18 years old)**. • Complicated Urinary Tract Infections (cUTI), Including Pyelonephritis, in adult and **pediatric patients (birth to less than 18 years old).** Hospital-acquired Bacterial Pneumonia and Ventilator-associated Bacterial Pneumonia (HABP/VABP), in adult patients 18 years and older.
Veklury	Remdesivir for injection, 100 mg of remdesivir as a lyophilized powder, in a single-dose vial	Gilead	For the treatment of coronavirus disease 2019 (COVID-19) in adults and pediatric patients **(28 days of age and older and weighing at least 3 kg)** ~~(12 years of age and older and weighing at least 40 kg)~~ with positive results of direct SARS-CoV-2 viral testing, who are: • Hospitalized, or Not hospitalized and have mild-to-moderate COVID-19, and are at high risk for progression to severe COVID-19, including hospitalization or death.
Ultomiris	ravulizumab-cwvz injection, 300 mg/30 mL, 300 mg/3 mL, and 1,100 mg/11 mL in single-dose vials	Alexion	• The treatment of adult and pediatric patients one month of age and older with paroxysmal nocturnal hemoglobinuria (PNH) • The 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) **The 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†
Rinvoq	upadacitinib extended-release tablets, 15 mg, 30 mg, 45 mg	AbbVie	• Adults with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to one or more TNF blockers. • Adults with active psoriatic arthritis who have had an inadequate response or intolerance to one or more TNF blockers. • Adults and pediatric patients 12 years of age and older with refractory, moderate to severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies are inadvisable. • Adults with moderately to severely active ulcerative colitis who have had an inadequate response or intolerance to one or more TNF blockers. **Adults with active ankylosing spondylitis who have had an inadequate response or intolerance to one or more TNF blockers.**
Qelbree	viloxazine extended-release capsules, 100 mg, 150 mg, 200 mg	Supernus	For the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in **adults** and pediatric patients **6 years and older** ~~6 to 17 years of age~~
Olumiant	baricitinib oral tablets	Eli Lilly	For the treatment of COVID-19 in hospitalized adults requiring supplemental oxygen, noninvasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).

RECALLS

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
artnaturals hand sanitizer, SCENT FREE HAND SANITIZER (ethyl alcohol 62.5%), 8 fl oz (236 ml) bottles, Dist. By artnaturals, Gardena, CA 90248, UPC: 8 16820 02820 5	Class I	Drugs	Lot: G20127E, G20128A, EXP 5/1/2022;	Chemical Contamination: presence of benzene, acetaldehyde, and acetal.	VIRGIN SCENT INC
Pink Pussycat SENSUAL ENHANCEMENT capsule, 3000mg, 1-count blister card, Manufactured for: Pink Pussycat Products - Chatsworth, CA 91311, UPC 8 91875 00462 6.	Class I	Drugs	Lot: 2009066, Exp: 09/2023	Marketed Without An Approved NDA/ANDA: FDA analysis found the product to contain undeclared sildenafil, an ingredient found in FDA approved products for the treatment of male sexual enhancement, making this an unapproved drug.	Pink Toyz
Insulin Glargine (insulin glargine-yfgn) Injection, 100 units/mL (U-100), packaged in a 10 mL Multiple-Dose vial inside a carton, Rx only, Manufactured by: Mylan Pharmaceuticals Inc., Morgantown, WV 26505, Manufactured for: Mylan Specialty L.P., Morgantown, WV 26505, NDC 49502-393-80	Class I	Drugs	Lot #: BF21002800, Exp 8/2023	Labeling: Missing label on the vial	Mylan Pharmaceuticals Inc
Mickey Mouse Hand Sanitizer, ethyl alcohol 68%, 2.11 oz./to mL bottle, Best Brands Consumer Products, Inc., c/o Best Brands Sales Company LLC, New York, NY NDC 74530-013-02	Class I	Drugs	Lot # 20D21, exp. date 06/30/2022	Chemical Contamination; FDA analysis found product to contain methanol	Best Brands Consumer Products, Inc.
The Mandalorian Hand Sanitizer, ethyl alcohol 68%, 2.11 oz./60 mL bottles, Best Brands Consumer Products, Inc., c/o Best	Class I	Drugs	Lot # 20E21, exp. date 09/30/2022	Chemical Contamination; FDA analysis found product to contain benzene	Best Brands Consumer Products, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Brands Sales Company LLC, New York, NY NDC 74530-012-02					
SyrSpend SF Suspending Base, Cherry Flavored, packaged in a) 500mL bottles (NDC 51552-1123-5) and b) 4L bottles (NDC 51552-1123-9), Rx Only, Manufactured for Fagron, Inc., St. Paul, MN 55120.	Class I	Drugs	Lot #: a) A67185, Exp. Date 08/31/2024; b) Lot #: A67186, Exp. Date 08/31/2024	Microbial Contamination of Non-Sterile Product: Product is contaminated with Burkholderia gladioli.	Fagron, Inc
artnaturals hand sanitizer, SCENT FREE HAND SANITIZER (ethyl alcohol 62.5%), 8 fl oz (236 ml) bottles, Dist. By artnaturals, Gardena, CA 90248, UPC: 8 16820 02820 5	Class II	Drugs	Lot: G20109D, G2019E, G20125E, G20125F, G20125D, G20125A, G20126C, G20126A, G20126D, G20126B, G20126E, G20127C, G20127B, G20127D, G20127A, G20127F, G20127A, G20128B, G20128C, G20128D, G20128E, G20128F, G20129B, G20129A, G20129C, G20129D, G20129E, G20130B, G20130A, G20130C, G20132A, G20132B, G20133A, EXP 5/1/2022; G20133A, EXP 8/1/2022	CGMP Deviations: Other lots recalled because they were manufactured using common ingredients as the contaminated lot	VIRGIN SCENT INC
artnaturals Hand Sanitizer	Class II	Drugs	Lot: G20154A, G20155A, EXP 6/1/2022;	CGMP Deviations: Other lots recalled because they were manufactured using common ingredients as the contaminated lot	VIRGIN SCENT INC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Rifampin for Injection, USP, 600 mg/vial, One Vial per carton, Rx only, Manufactured for: Mylan Institutional LLC, Morgantown, WV 26505 U.S.A., NDC 67457-445-60	Class II	Drugs	Lot #: 7008990, exp. date Dec-2022; 7009025, exp. date Feb-2023; 7009085, 7009086, exp. date Apr-2023	Failed Impurities/Degradation Specifications: High out of specification results obtained for related compound during stability testing.	Mylan Pharmaceuticals Inc
Diclofenac Sodium Topical Solution 1.5% w/w, Generic for Pennsaid, 150 ml bottle, Rx Only, Mfg: Sola Pharmaceutical, Preferred Pharmaceuticals, Inc., The Physicians Solutions, NDC 68788-7918-01	Class II	Drugs	Lots: E1220B, Exp.: 01/31/2023; F0220M, Exp.: 3/31/2023; F2320A, Exp.: 3/31/2023; F3020M, Exp.: 3/31/2023; G0920Q, Exp.: 3/31/2023; C0821M, Exp.: 1/31/2024; J1920, Exp.: 5/31/2023; E2421j, Exp.: 4/30/2024	CGMP Deviations: all products within expiry are being recalled because the manufacturing firm, Teligent Pharma, Inc. is discontinuing its stability study program.	Preferred Pharmaceuticals, Inc.
ARA-290 (Cibinetide Acetate) 6 mg/mL (4 mL) Injection, 4 mL vials, Rx only, Farmakeio 1736 N Greenville Ave Richardson, TX 75081 USA	Class II	Drugs	Lot #: 32618 BUD: 4/4/2022; 34525 BUD: 5/24/2022	Lack of Assurance of Sterility: deviations from Current Good Manufacturing Practices (CGMP) that call into question the sterility of products intended to be sterile.	North American Custom Laboratories, LLC dba FarmaKeio Superior Custom Compounding
BPC-157 2 mg/mL (5 mL) Injection, 5 mL vials, Rx Only, Farmakeio 1736 N Greenville Ave Richardson, TX 75081	Class II	Drugs	Lot #: 32242 BUD: 4/19/2022; 33911 BUD: 6/8/2022	Lack of Assurance of Sterility: deviations from Current Good Manufacturing Practices (CGMP) that call into question the sterility of products intended to be sterile.	North American Custom Laboratories, LLC dba FarmaKeio Superior

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
					Custom Compounding
Ipamorelin Acetate/Sermorelin Acetate (1 mg/1 mg)/mL (10 mL) Injection, 10 mL vials, Rx Only, Farmakeio 1736 N Greenville Ave Richardson, TX 75081	Class II	Drugs	Lot #: 32961 BUD: 5/12/2022	Lack of Assurance of Sterility: deviations from Current Good Manufacturing Practices (CGMP) that call into question the sterility of products intended to be sterile.	North American Custom Laboratories, LLC dba FarmaKeio Superior Custom Compounding
LL-37 2 mg/mL (5 mL) Injection, 5 mL vials, Rx only, Farmakeio 1736 N Greenville Ave Richardson, TX 75081 USA	Class II	Drugs	Lot #: 33444 BUD: 4/26/2022	Lack of Assurance of Sterility: deviations from Current Good Manufacturing Practices (CGMP) that call into question the sterility of products intended to be sterile.	North American Custom Laboratories, LLC dba FarmaKeio Superior Custom Compounding
Melanotan II 1 mg/mL (10 mL) Injection, 10mL vials, Rx only, Farmakeio 1736 N Greenville Ave Richardson, TX 75081 USA	Class II	Drugs	Lot #: 32610 BUD: 4/4/2022; 35126 BUD: 6/7/2022	Lack of Assurance of Sterility: deviations from Current Good Manufacturing Practices (CGMP) that call into question the sterility of products intended to be sterile.	North American Custom Laboratories, LLC dba FarmaKeio Superior Custom Compounding

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
PT-141 (Bremelanotide Acetate) 10 mg/mL (2 mL) Injection, 2mL vials, Rx Only, Farmakeio 1736 N Greenville Ave Richardson, TX 75081	Class II	Drugs	Lot #: 32616 BUD: 4/4/2022; 34527 BUD: 5/24/2022	Lack of Assurance of Sterility: deviations from Current Good Manufacturing Practices (CGMP) that call into question the sterility of products intended to be sterile.	North American Custom Laboratories, LLC dba FarmaKeio Superior Custom Compounding
Sermorelin Acetate 1 mg/mL (6 mL) Injection, 6 mL vials, Rx only, Farmakeio 1736 N Greenville Ave Richardson, TX 75081	Class II	Drugs	Lot #: 32963 BUD: 4/12/2022; 34824 BUD: 5/30/2022; 35130 BUD: 6/7/2022	Lack of Assurance of Sterility: deviations from Current Good Manufacturing Practices (CGMP) that call into question the sterility of products intended to be sterile.	North American Custom Laboratories, LLC dba FarmaKeio Superior Custom Compounding
NAD+ Nicotinamide Adenine Dinucleotide Lyophilized powder for reconstitution, Multi-Dose 500 mg Per Vial, Rx Only, Olympia Pharmaceuticals 6700 Conroy Rd., Ste. 155, Orlando, FL 32835. NDC 73198-0083-00	Class II	Drugs	Lots: E24026 BUD: 5/26/2022, E42112 BUD: 5/12/2022, E48024 BUD: 2/2/2022, F24014 BUD: 6/14/2022, G48028 BUD: 7/28/2022, H24016 BUD: 8/16/2022, H42010 BUD 8/10/2022, H48030 BUD: 8/11/2022, I47003 BUD: 8/11/2022	CGMP Deviations: prior to October 1, 2021, environmental and personnel monitoring Out of Action Limit (OOAL) excursions were not being properly investigated	Olympia Compounding Pharmacy dba Olympia Pharmacy
Diluent for Reconstitution Each ML contains: 1.5% Benzyl Alcohol NF, Sterile Water for	Class II	Drugs	Lots: D41012 BUD 4/12/2022, D41212 BUD:	CGMP Deviations: prior to October 1, 2021, environmental and	Olympia Compounding

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Injection USP, 10 mL Multi-Dose vial, Rx Only, Olympia Pharmaceuticals 6700 Conroy Rd., Ste. 155, Orlando, FL 32835. 73198-0113-10			4/12/2022, D47026 BUD: 4/26/2022, E41017 BUD: 5/17/2022, E41018 BUD: 5/18/2022, E47004 BUD: 5/4/2022, E47024 BUD: 5/24/2022, E47026 BUD: 5/26/2022, E48005 BUD: 5/5/2022, G47014 BUD: 7/14/2022, H48816 BUD: 8/16/2022	personnel monitoring Out of Action Limit (OOAL) excursions were not being properly investigated	Pharmacy dba Olympia Pharmacy
Sermorelin Acetate, Lyophilized powder for reconstitution, Multi-Dose vials, Packaged as a) 3 mg per vial, NDC 73198-0060-00; b) 9 mg NDC 73198-0059-00, Rx Only, Olympia Pharmaceuticals 6700 Conroy Rd., Ste. 155, Orlando, FL 32835.	Class II	Drugs	Lots: a) D41019 BUD: 4/19/2022; b) D41112 BUD: 4/12/2022, D47028 BUD: 4/28/2022, F24009 BUD 3/4/2022, F41001 BUD: 6/1/2022, G48006 BUD: 7/14/2022, G48008 BUD: 7/8/2022, G48012 BUD: 7/12/2022, G48014 BUD: 7/14/2022, G48019 BUD: 7/9/2022, I24009 BUD: 9/9/2022, I41107 BUD: 9/7/2022	CGMP Deviations: prior to October 1, 2021, environmental and personnel monitoring Out of Action Limit (OOAL) excursions were not being properly investigated	Olympia Compounding Pharmacy dba Olympia Pharmacy
QM-2 Papaverine 30 mg/mL. Phentolamine 3 mg/mL . Alprostadil 60 mcg/mL . Atropine 0.2 mg/mL, Multi-Dose 10 mL vial, Rx Only Olympia Pharmaceuticals 6700 Convoy Rd., Ste. 155, Orlando, FL 32835. NDC: 73198-0018-10.	Class II	Drugs	Lots: D41219 BUD: 4/19/2022, I24C13 BUD: 9/13/2022	CGMP Deviations: prior to October 1, 2021, environmental and personnel monitoring Out of Action Limit (OOAL) excursions were not being properly investigated	Olympia Compounding Pharmacy dba Olympia Pharmacy

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
T-105, Papaverine 30mg/mL . Phentolamine 1mg/ml . PGE 10mcg/ml, , Packaged as a) 10 ml Multi-Dose vial, NDC 73198-0005-10; b) 5 ml Multi-Dose vial, NDC 73198-0005-05; c) 2.5 ml Multi-Dose vial, NDC 73198-0005-03; Rx Only, Olympia Pharmaceuticals 6700 Convoy Rd., Ste. 155, Orlando, FL 32835 .	Class II	Drugs	Lots: a) D41412 BUD: 4/22/2022, E41F10 BUD: 5/10/2022, E41G10 BUD: 5/10/2022, F24D21 BUD: 6/21/2022 ; b) D41512 BUD: 4/12/2022; c) F42B21 BUD: 6/21/2022, H42B03 BUD: 8/3/2022, H42C03 BUD: 8/3/2022	CGMP Deviations: prior to October 1, 2021, environmental and personnel monitoring Out of Action Limit (OOAL) excursions were not being properly investigated	Olympia Compounding Pharmacy dba Olympia Pharmacy
Formula F9, Papaverine 0.9mg/ml . Phentolamine 0.1mg/ml . PGE 20mcg/mL Atropine 0.01mg/ml, Multi-Dose 10 ml vial, Rx Only, Olympia Pharmaceuticals 6700 Convoy Rd., Ste. 155, Orlando, FL 32835. NDC: 73198-0004-10	Class II	Drugs	Lots: D41C19 BUD: 4/19/2022, I42C13 BUD: 9/13/2022, I42B13 BUD: 9/13/2022	CGMP Deviations: prior to October 1, 2021, environmental and personnel monitoring Out of Action Limit (OOAL) excursions were not being properly investigated	Olympia Compounding Pharmacy dba Olympia Pharmacy
AT-6, Papaverine 40mg/ml . Phentolamine 4mg/ml . Atropine 0.3mg/ml, Multi-Dose 10 ml vial, Rx Only, Olympia Pharmaceuticals 6700 Convoy Rd., Ste. 155, Orlando, FL 32835. NDC 73198-0040-10	Class II	Drugs	Lots: D41E20 BUD: 4/20/2022, D41F20 BUD: 4/20/2022, G41C13 BUD: 7/13/2022, G41B13 BUD: 7/13/2022	CGMP Deviations: prior to October 1, 2021, environmental and personnel monitoring Out of Action Limit (OOAL) excursions were not being properly investigated	Olympia Compounding Pharmacy dba Olympia Pharmacy
AT-1, Papaverine 8mg/ml . Phentolamine 2mg/ml . Atropine 0.2mg/ml, Multi-Dose 10 ml vial, Rx Only, Olympia Pharmaceuticals 6700 Convoy Rd., Ste. 155, Orlando, FL 32835. NDC 73198-0039-10	Class II	Drugs	Lots: F41C28 BUD: 6/28/2022, F41B28 BUD: 6/28/2022	CGMP Deviations: prior to October 1, 2021, environmental and personnel monitoring Out of Action Limit (OOAL) excursions were not being properly investigated	Olympia Compounding Pharmacy dba Olympia Pharmacy
NB-243, Papaverine 30mg/ml . Phentolamine 3mg/ml . Alprostadil 20mcg/ml, 10ml Multi-Dose vials, Rx Only,	Class II	Drugs	Lots: I24C28 BUD: 9/28/2022, D41I19 BUD: 4/19/2022, F41321 BUD:	CGMP Deviations: prior to October 1, 2021, environmental and personnel monitoring Out of	Olympia Compounding Pharmacy dba

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Olympia Pharmaceuticals 6700 Convoy Rd., Ste. 155, Orlando, FL 32835. NDC 73198-0009-10			6/21/2022, I24128 BUD: 9/28/2022	Action Limit (OOAL) excursions were not being properly investigated	Olympia Pharmacy
T-106, Papaverine 30 mg/mL . Phentolamine 1 mg/mL . Alprostadil 25 mcg/mL, Packaged as a) 10 mL Multi-Dose vial, NDC: 73198-0013-10; b) 5 mL Multi-Dose vial, NDC 73198-0013-05; Rx Only, Olympia Pharmaceuticals 6700 Convoy Rd., Ste. 155, Orlando, FL 32835.	Class II	Drugs	Lots: a) E24510 BUD: 5/10/2022, E24610 BUD: 5/10/2022; b) H42H03 BUD: 8/3/2022, E24810 BUD: 5/10/2022, H42203 BUD: 8/3/2022	CGMP Deviations: prior to October 1, 2021, environmental and personnel monitoring Out of Action Limit (OOAL) excursions were not being properly investigated	Olympia Compounding Pharmacy dba Olympia Pharmacy
T-101, Papaverine 17.65 mg/mL . Phentolamine 0.59 mg/mL . Alprostadil 5.9 mcg/mL. Packaged as a) 10 mL Multi-Dose vial, NDC 73198-0014-10; b) 5 mL Multi-Dose vial, NDC 73198-0014-05; Rx Only, Olympia Pharmaceuticals 6700 Convoy Rd., Ste. 155, Orlando, FL 32835.	Class II	Drugs	Lots: a) E41B10 BUD: 5/10/2022; b) E41B08 BUD: 5/10/2022, I41C08 BUD: 9/8/2022, I41D08 BUD: 9/8/2022, E41C10 BUD: 5/10/2022	CGMP Deviations: prior to October 1, 2021, environmental and personnel monitoring Out of Action Limit (OOAL) excursions were not being properly investigated	Olympia Compounding Pharmacy dba Olympia Pharmacy
SB-4, Papaverine 30 mg/mL . Phentolamine 3 mg/mL . Alprostadil 40 mcg/mL, 10 mL Multi-Dose vial, Rx Only, Olympia Pharmaceuticals 6700 Convoy Rd., Ste. 155, Orlando, FL 32835. NDC 73198-0023-10.	Class II	Drugs	Lots: E41C18 BUD: 5/18/2022, E41D18 BUD: 5/18/2022, G42D20 BUD: 7/20/2022, G42B20 BUD: 7/20/2022	CGMP Deviations: prior to October 1, 2021, environmental and personnel monitoring Out of Action Limit (OOAL) excursions were not being properly investigated	Olympia Compounding Pharmacy dba Olympia Pharmacy
SB-5, Papaverine 30 mg/mL . Phentolamine 3 mg/mL . PGE 50 mcg/mL, 10 mL, Multi-Dose vial, Rx Only, Olympia Pharmaceuticals 6700 Convoy Rd., Ste. 155, Orlando, FL 32835. NDC 73198-0024-10.	Class II	Drugs	Lots: E48B18 BUD: 5/18/2022, E48D18 BUD; 5/18/2022, H24D31 BUD: 8/31/2022; E48C18 BUD: 5/18/2022	CGMP Deviations: prior to October 1, 2021, environmental and personnel monitoring Out of Action Limit (OOAL) excursions were not being properly investigated	Olympia Compounding Pharmacy dba Olympia Pharmacy

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
SB-6, Papaverine 30 mg/mL . Phentolamine 3 mg/mL . PGE 60 mcg/mL, Multi-Dose 10 mL vial, Rx Only, Olympia Pharmaceuticals 6700 Convoy Rd., Ste. 155, Orlando, FL 32835. NDC 73198-0025-10.	Class II	Drugs	Lots: E41H18 BUD: 5/18/2022, G41319 BUD: 7/19/2022	CGMP Deviations: prior to October 1, 2021, environmental and personnel monitoring Out of Action Limit (OOAL) excursions were not being properly investigated	Olympia Compounding Pharmacy dba Olympia Pharmacy
ST-1, Papaverine 30 mg/mL . Phentolamine 1.5 mg/mL . Alprostadil 50 mcg/ml, 10 mL Multi-Dose vial, Rx Only, Olympia Pharmaceuticals 6700 Convoy Rd., Ste. 155, Orlando, FL 32835. NDC 73198-0011-10.	Class II	Drugs	Lots: H24F03 BUD: 8/3/2022, H24E03 BUD: 8/3/2022	CGMP Deviations: prior to October 1, 2021, environmental and personnel monitoring Out of Action Limit (OOAL) excursions were not being properly investigated	Olympia Compounding Pharmacy dba Olympia Pharmacy
ST-2, Papaverine 30 mg/mL . Phentolamine 3 mg/mL . Alprostadil 100 mcg/mL, 10 mL Multi-Dose vial, Rx Only, Olympia Pharmaceuticals 6700 Convoy Rd., Ste. 155, Orlando, FL 32835. NDC 73198-0012-10.	Class II	Drugs	Lots: F41C21 BUD: 6/21/2022, G42013 BUD: 7/13/2022, H41C31 BUD: 8/31/2022, F41D21 BUD: 6/21/2022	CGMP Deviations: prior to October 1, 2021, environmental and personnel monitoring Out of Action Limit (OOAL) excursions were not being properly investigated	Olympia Compounding Pharmacy dba Olympia Pharmacy
QM-3, Papaverine 30 mg/mL . Phentolamine 3 mg/mL . Alprostadil 150 mcg/mL . Atropine 0.2 mg/mL, 10 mL Multi-Dose vial, Rx Only, Olympia Pharmaceuticals 6700 Convoy Rd., Ste. 155, Orlando, FL 32835. NDC 73198-0019-10.	Class II	Drugs	Lots: E42B12 BUD: 5/12/2022, E42C12 BUD: 5/12/2022, E42D12 BUD: 5/12/2022, H24B23 BUD: 8/23/2022, H24C23 BUD: 8/23/2022, H24D23 BUD: 8/23/2022	CGMP Deviations: prior to October 1, 2021, environmental and personnel monitoring Out of Action Limit (OOAL) excursions were not being properly investigated	Olympia Compounding Pharmacy dba Olympia Pharmacy
QM-4, Papaverine 30 mg/mL . Phentolamine 3 mg/mL . Alprostadil 300 mcg/mL . Atropine 0.2 mg/mL, 10 mL Multi-Dose vial, Rx Only, Olympia Pharmaceuticals 6700	Class II	Drugs	Lots: E41027 BUD: 5/27/2022, I24E13 BUD: 9/13/2022	CGMP Deviations: prior to October 1, 2021, environmental and personnel monitoring Out of Action Limit (OOAL) excursions	Olympia Compounding Pharmacy dba Olympia Pharmacy

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Convoy Rd., Ste. 155, Orlando, FL 32835. NDC 73198-0020-10.				were not being properly investigated	
RE-1, Papaverine 30 mg/mL . Phentolamine 3 mg/mL . Alprostadil 200 mcg/mL, Packaged in a) 10 mL Multi-Dose vial, NDC 73198-0015-10; b) 2.5 mL Multi-Dose vial, NDC 73198-0015-03; Rx Only, Olympia Pharmaceuticals 6700 Convoy Rd., Ste. 155, Orlando, FL 32835.	Class II	Drugs	Lots: a) E47B18 BUD: 5/18/2022; b) E47C18 BUD: 5/18/2022, H24G31 BUD: 8/31/2022	CGMP Deviations: prior to October 1, 2021, environmental and personnel monitoring Out of Action Limit (OOAL) excursions were not being properly investigated	Olympia Compounding Pharmacy dba Olympia Pharmacy
RE-2, Papaverine 30 mg/mL . Phentolamine 3 mg/mL . Alprostadil 300 mcg/mL, Multi-Dose 10 mL vial, Rx Only, Olympia Pharmaceuticals 6700 Convoy Rd., Ste. 155, Orlando, FL 32835. NDC 73198-0016-10.	Class II	Drugs	Lots: E42G11 BUD: 5/11/2022, H41003 BUD: 8/3/2022; H41B03 BUD: 8/3/2022	CGMP Deviations: prior to October 1, 2021, environmental and personnel monitoring Out of Action Limit (OOAL) excursions were not being properly investigated	Olympia Compounding Pharmacy dba Olympia Pharmacy
BIMIX-3, Papaverine 30 mg/mL . Phentolamine 3 mg/mL, 10 mL Multi-Dose vial, Rx Only, Olympia Pharmaceuticals 6700 Convoy Rd., Ste. 155, Orlando, FL 32835. NDC 73198-0027-10.	Class II	Drugs	Lot: F24C10 BUD: 6/10/2022	CGMP Deviations: prior to October 1, 2021, environmental and personnel monitoring Out of Action Limit (OOAL) excursions were not being properly investigated	Olympia Compounding Pharmacy dba Olympia Pharmacy
FA, Papaverine 20 mg/mL . Phentolamine 2 mg/mL . Alprostadil 20 mcg/mL . Atropine 0.2 mg/mL, 10 mL Multi-Dose vial, Rx Only, Olympia Pharmaceuticals 6700 Convoy Rd., Ste. 155, Orlando, FL 32835. NDC 73198-0006-10.	Class II	Drugs	Lots: F41414 BUD: 6/14/2022, F41C14 BUD: 6/14/2022, I24E28 BUD: 9/28/2022, I24F28 BUD: 9/28/2022	CGMP Deviations: prior to October 1, 2021, environmental and personnel monitoring Out of Action Limit (OOAL) excursions were not being properly investigated	Olympia Compounding Pharmacy dba Olympia Pharmacy
PGE-1, Alprostadil 40 mcg/mL, 10ml Multi-Dose vial, Rx Only, Olympia Pharmaceuticals	Class II	Drugs	Lots: I24028 BUD: 9/28/2022,F47C30 BUD:	CGMP Deviations: prior to October 1, 2021, environmental and personnel monitoring Out of	Olympia Compounding Pharmacy dba

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
6700 Convoy Rd., Ste. 155, Orlando, FL 32835. NDC 73198-0028-10.			6/30/2022, F47B30 BUD: 6/30/2022	Action Limit (OOAL) excursions were not being properly investigated	Olympia Pharmacy
PGE-2, Alprostadil 80 mcg/mL, 10ml Multi-Dose vial, Rx Only, Olympia Pharmaceuticals 6700 Convoy Rd., Ste. 155, Orlando, FL 32835. NDC 73198-0029-10.	Class II	Drugs	Lot: F48102 BUD: 6/2/2022	CGMP Deviations: prior to October 1, 2021, environmental and personnel monitoring Out of Action Limit (OOAL) excursions were not being properly investigated	Olympia Compounding Pharmacy dba Olympia Pharmacy
PGE-3, Alprostadil 150 mcg/mL, 10ml Multi-Dose vial, Rx Only, Olympia Pharmaceuticals 6700 Convoy Rd., Ste. 155, Orlando, FL 32835. NDC 73198-0030-10.	Class II	Drugs	Lot: G24C19 BUD: 7/19/2022	CGMP Deviations: prior to October 1, 2021, environmental and personnel monitoring Out of Action Limit (OOAL) excursions were not being properly investigated	Olympia Compounding Pharmacy dba Olympia Pharmacy
T-50, Papaverine 8 mg/mL . Phentolamine 0.29 mg/mL . Alprostadil 2.9 mcg/mL, 10ml Multi-Dose vial, Rx Only, Olympia Pharmaceuticals 6700 Convoy Rd., Ste. 155, Orlando, FL 32835. NDC 73198-0022-10.	Class II	Drugs	Lots: G24F01 BUD: 7/1/2022, G41316 BUD: 7/16/2022, H24B03 BUD: 8/3/2022, H24C03 BUD: 8/3/2022	CGMP Deviations: prior to October 1, 2021, environmental and personnel monitoring Out of Action Limit (OOAL) excursions were not being properly investigated	Olympia Compounding Pharmacy dba Olympia Pharmacy
Formula F2, Papaverine 9 mg/mL . Phentolamine 1 mg/mL . Alprostadil 10 mcg/mL . Atropine 0.1 mg/mL, 10 mL Multi-Dose vial, Rx Only, Olympia Pharmaceuticals 6700 Convoy Rd., Ste. 155, Orlando, FL 32835. NDC 73198-0002-10.	Class II	Drugs	Lots: G48C20 BUD: 7/20/2022, G48B20 BUD: 7/22/2022	CGMP Deviations: prior to October 1, 2021, environmental and personnel monitoring Out of Action Limit (OOAL) excursions were not being properly investigated	Olympia Compounding Pharmacy dba Olympia Pharmacy
Phenylephrine 1 mg/mL, 5 mL Multi-Dose vial, Rx Only, Olympia Pharmaceuticals 6700	Class II	Drugs	Lot: H47030 BUD: 8/30/2022	CGMP Deviations: prior to October 1, 2021, environmental and personnel monitoring Out of	Olympia Compounding Pharmacy dba

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Convoy Rd., Ste. 155, Orlando, FL 32835. NDC 73198-0021-05.				Action Limit (OOAL) excursions were not being properly investigated	Olympia Pharmacy
Testosterone Cypionate 200 mg/mL (in Grapeseed Oil), Packaged in a) 10 mL Multi-Dose vial, NDC 73198-0054-10; b) 5 mL Multi-Dose vial, NDC 73198-0054-05, Rx Only, Olympia Pharmaceuticals 6700 Convoy Rd., Ste. 155, Orlando, FL 32835.	Class II	Drugs	Lots: a) D48027 BUD: 4/27/2022,E47017 BUD: 5/17/2022, F42007 BUD: 6/7/2022, F42107 BUD: 6/7/2022, F42207 BUD: 6/7/2022, F48009 BUD: 6/9/2022, F48109 BUD: 6/9/2022, H47003 BUD: 8/3/2022; b) F24024 BUD: 6/24/2022	CGMP Deviations: prior to October 1, 2021, environmental and personnel monitoring Out of Action Limit (OOAL) excursions were not being properly investigated	Olympia Compounding Pharmacy dba Olympia Pharmacy
Testosterone Cypionate 200 mg/mL, (in Sesame Oil), Packaged in a) 10 mL Multi-Dose vial, NDC 73198-0055-10; b) 5 mL Multi-Dose vial, NDC 73198-0055-05, Rx Only, Olympia Pharmaceuticals 6700 Convoy Rd., Ste. 155, Orlando, FL 32835.	Class II	Drugs	Lots: a) E48019 BUD: 5/19/2022, F42109 BUD: 6/9/2022, F42C09 BUD: 6/9/2022, G47012 BUD: 7/12/2022, G47112 BUD: 7/12/2022; b) F42B09 BUD: 6/9/2022	CGMP Deviations: prior to October 1, 2021, environmental and personnel monitoring Out of Action Limit (OOAL) excursions were not being properly investigated	Olympia Compounding Pharmacy dba Olympia Pharmacy
Ultratest, Testosterone Cypionate 160 mg/mL, Testosterone Propionate 40 mg/mL, 10 mL Multi-Dose vial, Rx Only, Olympia Pharmaceuticals 6700 Convoy Rd., Ste. 155, Orlando, FL 32835. NDC 73198-0058-10.	Class II	Drugs	Lots: E48020 BUD: 5/20/2022 and G47006 BUD: 7/6/2022	CGMP Deviations: prior to October 1, 2021, environmental and personnel monitoring Out of Action Limit (OOAL) excursions were not being properly investigated	Olympia Compounding Pharmacy dba Olympia Pharmacy
Hydroxocobalamin B12, 1 mg/mL, 30 mL Multi-Dose vial, Rx Only, Olympia Pharmaceuticals 6700 Convoy Rd., Ste. 155, Orlando, FL 32835. NDC 73198-0080-30.	Class II	Drugs	Lots: D48026 BUD: 4/26/2022, E48025 BUD: 5/25/2022, G48B21 BUD:	CGMP Deviations: prior to October 1, 2021, environmental and personnel monitoring Out of Action Limit (OOAL) excursions	Olympia Compounding Pharmacy dba

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			7/21/2022, G48C21 BUD: 7/21/2022	were not being properly investigated	Olympia Pharmacy
Sincalide. Lyophilized powder for reconstitution. 5 mcg per Multi-Dose vial, Rx Only, Olympia Pharmaceuticals 6700 Convoy Rd., Ste. 155, Orlando, FL 32835. NDC 73198-0082-00.	Class II	Drugs	Lots: F24018 BUD: 6/18/2022 and G47021 BUD: 7/21/2022	CGMP Deviations: prior to October 1, 2021, environmental and personnel monitoring Out of Action Limit (OOAL) excursions were not being properly investigated	Olympia Compounding Pharmacy dba Olympia Pharmacy
NAD+ Nicotinamide Adenine Dinucleotide Lyophilized powder for reconstitution, Multi-Dose 500 mg Per Vial, Rx Only, Olympia Pharmaceuticals 6700 Conroy Rd., Ste. 155, Orlando, FL 32835. NDC 73198-0083-00	Class II	Drugs	Lot: F41116 BUD: 6/16/2022,	Failed Reconstitution time	Olympia Compounding Pharmacy dba Olympia Pharmacy
Lidocaine 2.5% and Prilocaine 2.5% Cream, USP, packaged in a) 5 g tubes (NDC 0591-2070-72), b) 30 g tubes (NDC 0591-2070-30), Rx Only, Manufactured by: Teligent Pharma, Inc., Buena, NJ 08310, USA, Distributed by: Actavis Pharma, Inc., Parsippany, NJ 07054, USA	Class II	Drugs	Lot #: a) 16291, Exp. Date 01/2024;16469, Exp. Date 02/2024; b)16255, Exp. Date 11/2022; 16256, 16412 Exp. Date 02/2024; 16257, 16258, Exp. Date12/2022; 16505, 6506, Exp. Date 03/2024; 16627,16786, 16787,16820, Exp. Date 04/2024.	cGMP Deviations	Teva Pharmaceuticals USA Inc
Losartan Potassium 50 mg Tablet, a) 30-count blister card (NDC# 70518-3282-1), b) 60-count blister card (NDC: 70518-3282-0), Rx Only, MFG by: Lupin Pharma, Baltimore, MD 21202.	Class II	Drugs	Lot # B1467803-120621, exp. date 06/30/2022 Lot # J0585793-121721, exp. date 12/31/2022	CGMP Deviations- AZIDO Impurity levels observed to be above acceptable limits.	RemedyRepack Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Losartan Potassium Tab. USP 50mg, Pkg Size: 30, Mfg: Lupin Pharmaceuticals, Inc., Preferred Pharmaceuticals, Inc.	Class II	Drugs	Lot: E1321O, Exp.: 5/31/2023 Lot: E2521H, Exp.: 5/31/2023 Lot: E2621F, Exp.: 5/31/2023	CGMP Deviations- AZIDO Impurity levels observed to be above acceptable limits.	Preferred Pharmaceuticals, Inc.
Zonisamide Capsules USP, 25 mg, packaged in 100-count bottles, Rx Only, Manufactured by: Glenmark Pharmaceuticals, Inc., USA Monroe, NC 28110, Manufactured for: Glenmark Pharmaceuticals Inc., USA Mahwah, NJ 07430, NDC 68462-128-01	Class II	Drugs	Lot #: 29200052, Exp 4/30/2023	cGMP deviations	Glenmark Pharmaceuticals Inc., USA
Zonisamide Capsules, USP, 50 mg, packaged in 100-count bottles, Rx only, Manufactured by: Glenmark Pharmaceuticals, Inc., USA Monroe, NC 28110, Manufactured for: Glenmark Pharmaceuticals Inc., USA Mahwah, NJ 07430, NDC 68462-129-01	Class II	Drugs	Lot #: 29200064, Exp 5/31/2023	cGMP deviations	Glenmark Pharmaceuticals Inc., USA
Zonisamide Capsules, USP, 100 mg, packaged in: a) 100-count bottle (NDC 68462-130-01); b) 500-count bottle (NDC 68462-130-05), Rx only, Manufactured by: Glenmark Pharmaceuticals, Inc., USA Monroe, NC 28110, Manufactured for: Glenmark Pharmaceuticals Inc., USA Mahwah, NJ 07430	Class II	Drugs	a) Lot #: 29200053, Exp 4/30/2023; b) Lot #: 29200054, Exp 4/30/2023	cGMP deviations	Glenmark Pharmaceuticals Inc., USA
TORCO RACING FUELS HAND SANITIZER, Alcohol Antiseptic 80% Topical Solution, Hand Sanitizer Non-Sterile Solution, FDA Approved, 76590-8347-1, 3780 mL, 3.78 Liters (1 Gallon). Torco Race Fuels 2527 W. Dallas Ave. Apache Junction, AZ, 85120	Class II	Drugs	No lot or Expiration date on Product	CGMP Deviations: FDA analysis found product to contain acetaldehyde and acetal above specification limits.	Torco Race Fuels

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Losartan Potassium Tablets USP, 25 mg, a) 90-count bottles (NDC# 68180-376-03), b) 1000-count bottles (NDC# 68180-376-09), Rx Only, Manufactured By: Lupin Limited, Pithampur, India, MFG For: Lupin Pharmaceuticals, Inc. Baltimore, Maryland 21202, USA.	Class II	Drugs	H001333, exp. date Nov-22 H002786, exp. date Jan-23 H101282, exp. date Feb-23 H001189, exp. date Nov-22 H002955, exp. date Jan-23 H101285, exp. date Feb-23 H001714, exp. date Dec-22 H000523, exp. date Jan-23 H101989, exp. date Mar-23 H001940, exp. date Dec-22 H003080, exp. date Jan-23 H101789, exp. date Mar-23 H002388, exp. date Jan-23 H100109, exp. date Feb-23 H002389, exp. date Jan-23 H100642, exp. date Feb-23 H000848, exp. date Nov-22, H002002, exp. date Dec-22 H100110, exp. date Feb-23 H001190, exp. date Nov-22 H002003, exp. date Dec-22 H100111, exp. date Feb-23 H001191, exp. date Nov-22 H002489, exp. date Jan-23 H100146,	CGMP Deviations- AZIDO Impurity levels observed to be above acceptable limits	Lupin Pharmaceuticals Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			exp. date Feb-23 H001192, exp. date Nov-22 H002390, exp. date Jan-23 H100147, exp. date Feb-23 H001058, exp. date Nov-22 H002486, exp. date Jan-23 H101283, exp. date Feb-23 H000985, exp. date Nov-22 H002487, exp. date Jan-23 H101284, exp. date Feb-23 H001059, exp. date Nov-22 H002488, exp. date Jan-23 H100643, exp. date Feb-23 H001275, exp. date Nov-22 H002787, exp. date Jan-23 H100644, exp. date Mar-23 H001715, exp. date Dec-22 H002957, exp. date Jan-23 H100869, exp. date Mar-23 H001716, exp. date Dec-22 H002958, exp. date Jan-23 H101990, exp. date Mar-23 H001717, exp. date Dec-22 H003079, exp. date Jan-23 H101991, exp. date Mar-		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			23 H001718, exp. date Dec-22 H003121, exp. date Feb-23 H101992, exp. date Mar-23 H001941, exp. date Dec-22 H003122, exp. date Feb-23 H000847, exp. date Nov 2022		
Losartan Potassium Tablets USP, 50 mg, a) 90-count bottles (NDC# 68180-377-03), b) 1000-count bottles (NDC# 68180-377-09), Rx Only, Manufactured By: Lupin Limited, Pithampur, India, MFG For: Lupin Pharmaceuticals, Inc. Baltimore, Maryland 21202, USA.	Class II	Drugs	H903720, exp. date Oct-22 H001876, exp. date Dec-22 H003002, exp. date Jan-23 H903774, exp. date Oct-22 H001877, exp. date Dec-22 H003003, exp. date Feb-23 H000849, exp. date Nov-22 H002127, exp. date Dec-22 H003004, exp. date Feb-23 H001412, exp. date Nov-22 H002128, exp. date Dec-22 H003123, exp. date Feb-23 H001413, exp. date Nov-22 H002643, exp. date Jan-23 H003124, exp. date Feb-23 H001414, exp. date Nov-22 H002644, exp. date Jan-23 H101129, exp. date Feb-23	CGMP Deviations- AZIDO Impurity levels observed to be above acceptable limits	Lupin Pharmaceuticals Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			H001430, exp. date Nov-22 H002645, exp. date Jan-23 H101147, exp. date Mar-23 H001526, exp. date Dec-22 H002839, exp. date Jan-23 H102139, exp. date Mar-23 H001652, exp. date Dec-22 H002840, exp. date Jan-23 H102158, exp. date Mar-23 H000605, exp. date Jan-23 H001599, exp. date Dec-22 H100148, exp. date Feb-23 H001401, exp. date Nov-22 H001875, exp. date Dec-22 H102043, exp. date Mar-23 H001063, exp. date Nov-22 H002126, exp. date Dec-22 H101495, exp. date Mar-23 H001188, exp. date Nov-22 H002838, exp. date Jan-23 H001455, exp. date Nov-22 H002642, exp. date Jan-23		
Losartan Potassium Tablets USP, 100 mg, a) 90-count bottles (NDC# 68180-378-03), b) 1000-count bottles (NDC# 68180-378-09),	Class II	Drugs	H903573, exp. date Oct-22 H002311, exp. date Dec-22 H100713, exp. date	CGMP Deviations- AZIDO Impurity levels observed to be above acceptable limits	Lupin Pharmaceuticals Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Rx Only, Manufactured By: Lupin Limited, Pithampur, India, MFG For: Lupin Pharmaceuticals, Inc. Baltimore, Maryland 21202, USA.			Mar-23 H001060, exp. date Nov-22 H002620, exp. date Jan-23 H100714, exp. date Mar-23 H001456, exp. date Nov-22 H002313, exp. date Jan-23 H100934, exp. date Mar-23 H001457, exp. date Nov-22 H002490, exp. date Jan-23 H100935, exp. date Mar-23 H001470,, exp. date Nov-22 H002842, exp. date Jan-23 H101081, exp. date Mar-23 H001484, exp. date Dec-22 H002843, exp. date Jan-23 H101148, exp. date Mar-23 H001485, exp. date Dec-22 H002995, exp. date Jan-23 H101639, exp. date Mar-23 H001708, exp. date Dec-22 H003199, exp. date Feb-23 H101480, exp. date Mar-23 H002314, exp. date Dec-22 H003200, exp. date Feb-23 H101822, exp. date Mar-		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			23 H001709, exp. date Dec-22 H100028, exp. date Feb-23 H101481, exp. date Mar-23 H002001, exp. date Dec-22 H100712, exp. date Feb-23 H102288, exp. date Mar-23 H001991, exp. date Dec-22 H100221, exp. date Feb-23 H002000, exp. date Dec-22 H100222, exp. dateFeb-23 H903582, exp. date Oct-22 H001707, exp. dateDec-22 H100220, exp. date Feb-23 H000556,, exp. date Nov-22 H003045, exp. date Dec-22 H100901, exp. date Mar-23 H000557, exp. date Nov-22 H002391, exp. date Dec-22 H101078, exp. date Mar-23 H001061, exp. date Nov-22 H002312, exp. date Jan-23 H101479, exp. date Mar-23 H001062, exp. date Nov-22 H002517, exp. date Jan-23 H101496,		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			exp. date Mar-23 H001431, exp. date Nov-22 H002841, exp. date Jan-23 H101821, exp. date Mar-23 H002341, exp. date Nov-22 H003044, exp. date Feb-23 H102286, exp. date Mar-23 H001706, exp. date Dec-22 H003198, exp. date Feb-23 H102287, exp. date Mar-23		
Losartan Potassium and Hydrochlorothiazide Tablets USP, 50 mg/12.5 mg a) 30-count bottles (NDC# 68180-215-06) b) 90-count bottles (NDC# 68180-215-09), Rx Only, Manufactured By: Lupin Limited, Pithampur, India, MFG For: Lupin Pharmaceuticals, Inc. Baltimore, Maryland 21202, USA.	Class II	Drugs	Lot # H001149 4/30/2022 68180-215-06 H001602 5/31/2022 68180-215-06 H001884 6/30/2022 68180-215-06 H002539 8/31/2022 68180-215-06 H100944 4/30/2023 68180-215-06 H101054 4/30/2023 68180-215-06 H001150 4/30/2022 68180-215-09 H001151 4/30/2022 68180-215-09 H001152 4/30/2022 68180-215-09 H001532 5/31/2022 68180-215-09 H001533 5/31/2022 68180-215-09 H001534	CGMP Deviations- AZIDO Impurity levels observed to be above acceptable limits	Lupin Pharmaceuticals Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			5/31/2022 68180-215-09 H001535 5/31/2022 68180-215-09 H001536 5/31/2022 68180-215-09 H001603 5/31/2022 68180-215-09 H001604 5/31/2022 68180-215-09 H001605 5/31/2022 68180-215-09 H001606 5/31/2022 68180-215-09 H001607 5/31/2022 68180-215-09 H001608 5/31/2022 68180-215-09 H001885 6/30/2022 68180-215-09 H001886 6/30/2022 68180-215-09 H001887 6/30/2022 68180-215-09 H001888 6/30/2022 68180-215-09 H002171 7/31/2022 68180-215-09 H002172 7/31/2022 68180-215-09 H002173 7/31/2022 68180-215-09 H002174 7/31/2022 68180-215-09 H002175 7/31/2022 68180-215-09 H002540 8/31/2022 68180-215-09 H002541 8/31/2022 68180-215-09 H002542		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			8/31/2022 68180-215-09 H002543 8/31/2022 68180-215-09 H002544 8/31/2022 68180-215-09 H002545 8/31/2022 68180-215-09 H002976 10/31/2022 68180-215-09 H002977 10/31/2022 68180-215-09 H002978 10/31/2022 68180-215-09 H003131 11/30/2022 68180-215-09 H003132 11/30/2022 68180-215-09 H003133 11/30/2022 68180-215-09 H003134 11/30/2022 68180-215-09 H003135 11/30/2022 68180-215-09 H003136 11/30/2022 68180-215-09 H100302 1/31/2023 68180-215-09 H100303 1/31/2023 68180-215-09 H100304 1/31/2023 68180-215-09 H100340 1/31/2023 68180-215-09 H100341 1/31/2023 68180-215-09 H100657 2/28/2023 68180-215-09 H100658 2/28/2023 68180-215-09 H100659		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			2/28/2023 68180-215-09 H100660 2/28/2023 68180-215-09 H100661 2/28/2023 68180-215-09 H100662 2/28/2023 68180-215-09 H100945 4/30/2023 68180-215-09 H100946 4/30/2023 68180-215-09 H101051 4/30/2023 68180-215-09 H101052 4/30/2023 68180-215-09 H101053 4/30/2023 68180-215-09 H101055 4/30/2023 68180-215-09 H101056 4/30/2023 68180-215-09 H101057 4/30/2023 68180-215-09 H101058 4/30/2023 68180-215-09 H101286 5/31/2023 68180-215-09 H101287 5/31/2023 68180-215-09 H101288 5/31/2023 68180-215-09 H101289 5/31/2023 68180-215-09 H101581 6/30/2023 68180-215-09 H101582 6/30/2023 68180-215-09 H101583 6/30/2023 68180-215-09 H101584		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			7/31/2023 68180-215-09 H101585 7/31/2023 68180-215-09 H101790 7/31/2023 68180-215-09 H101791 7/31/2023 68180-215-09 H102078 8/31/2023 68180-215-09 H102079 8/31/2023 68180-215-09 H102080 9/30/2023 68180-215-09 H102118 9/30/2023 68180-215-09 H102119 9/30/2023 68180-215-09 H102120 9/30/2023 68180-215-09 H102125 9/30/2023 68180-215-09 H102126 9/30/2023 68180-215-09		
Losartan Potassium and Hydrochlorothiazide Tablets USP, 100 mg/25 mg a) 30-count bottles (NDC# 68180-217-06) b) 90-count bottles (NDC# 68180-217-09), Rx Only, Manufactured By: Lupin Limited, Pithampur, India, MFG For: Lupin Pharmaceuticals, Inc. Baltimore, Maryland 21202, USA	Class II	Drugs	Lot # H001156 4/30/2022 68180-217-06 H001627 5/31/2022 68180-217-06 H001947 6/30/2022 68180-217-06 H002242 8/31/2022 68180-217-06 H101826 7/31/2023 68180-217-06 H001155 4/30/2022 68180-217-09 H001355 5/31/2022 68180-217-09 H001356 5/31/2022 68180-217-09	CGMP Deviations- AZIDO Impurity levels observed to be above acceptable limits	Lupin Pharmaceuticals Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			H001357 5/31/2022 68180-217-09 H001358 5/31/2022 68180-217-09 H001359 5/31/2022 68180-217-09 H001371 5/31/2022 68180-217-09 H001372 5/31/2022 68180-217-09 H001373 5/31/2022 68180-217-09 H001374 5/31/2022 68180-217-09 H001375 5/31/2022 68180-217-09 H001628 5/31/2022 68180-217-09 H001629 5/31/2022 68180-217-09 H001630 6/30/2022 68180-217-09 H001645 6/30/2022 68180-217-09 H001646 6/30/2022 68180-217-09 H001647 6/30/2022 68180-217-09 H001798 6/30/2022 68180-217-09 H001799 6/30/2022 68180-217-09 H001882 6/30/2022 68180-217-09 H001883 6/30/2022 68180-217-09 H001948 6/30/2022 68180-217-09 H001949 6/30/2022 68180-217-09		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			H001985 6/30/2022 68180-217-09 H001986 6/30/2022 68180-217-09 H001987 7/31/2022 68180-217-09 H001988 7/31/2022 68180-217-09 H001989 7/31/2022 68180-217-09 H001990 7/31/2022 68180-217-09 H002243 8/31/2022 68180-217-09 H002244 8/31/2022 68180-217-09 H002245 8/31/2022 68180-217-09 H002315 8/31/2022 68180-217-09 H002316 8/31/2022 68180-217-09 H002317 8/31/2022 68180-217-09 H002318 8/31/2022 68180-217-09 H002319 8/31/2022 68180-217-09 H002320 8/31/2022 68180-217-09 H002321 8/31/2022 68180-217-09 H002322 8/31/2022 68180-217-09 H002323 8/31/2022 68180-217-09 H002324 8/31/2022 68180-217-09 H002632 9/30/2022 68180-217-09		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			H002633 9/30/2022 68180-217-09 H002634 9/30/2022 68180-217-09 H002635 9/30/2022 68180-217-09 H002636 9/30/2022 68180-217-09 H002765 9/30/2022 68180-217-09 H002766 9/30/2022 68180-217-09 H002767 9/30/2022 68180-217-09 H002768 9/30/2022 68180-217-09 H002769 9/30/2022 68180-217-09 H002770 9/30/2022 68180-217-09 H003194 11/30/2022 68180-217-09 H003195 11/30/2022 68180-217-09 H100009 12/31/2022 68180-217-09 H100010 12/31/2022 68180-217-09 H100021 12/31/2022 68180-217-09 H100022 12/31/2022 68180-217-09 H100023 12/31/2022 68180-217-09 H100029 12/31/2022 68180-217-09 H100030 12/31/2022 68180-217-09 H100342 1/31/2023 68180-217-09		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			H100343 1/31/2023 68180-217-09 H100344 1/31/2023 68180-217-09 H100345 1/31/2023 68180-217-09 H100346 1/31/2023 68180-217-09 H100374 1/31/2023 68180-217-09 H100375 1/31/2023 68180-217-09 H100376 1/31/2023 68180-217-09 H100377 1/31/2023 68180-217-09 H100378 1/31/2023 68180-217-09 H100452 1/31/2023 68180-217-09 H100453 1/31/2023 68180-217-09 H100454 2/28/2023 68180-217-09 H100458 2/28/2023 68180-217-09 H100459 2/28/2023 68180-217-09 H100652 2/28/2023 68180-217-09 H100653 2/28/2023 68180-217-09 H100654 2/28/2023 68180-217-09 H100655 2/28/2023 68180-217-09 H100656 2/28/2023 68180-217-09 H100687 2/28/2023 68180-217-09		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			H100688 2/28/2023 68180-217-09 H100689 2/28/2023 68180-217-09 H100703 2/28/2023 68180-217-09 H100704 2/28/2023 68180-217-09 H100891 3/31/2023 68180-217-09 H100892 3/31/2023 68180-217-09 H100902 3/31/2023 68180-217-09 H100903 3/31/2023 68180-217-09 H100904 3/31/2023 68180-217-09 H100905 3/31/2023 68180-217-09 H100936 3/31/2023 68180-217-09 H100937 3/31/2023 68180-217-09 H100938 3/31/2023 68180-217-09 H101153 5/31/2023 68180-217-09 H101154 5/31/2023 68180-217-09 H101155 5/31/2023 68180-217-09 H101156 5/31/2023 68180-217-09 H101157 5/31/2023 68180-217-09 H101158 5/31/2023 68180-217-09 H101159 5/31/2023 68180-217-09		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			H101294 5/31/2023 68180-217-09 H101295 5/31/2023 68180-217-09 H101296 5/31/2023 68180-217-09 H101297 5/31/2023 68180-217-09 H101325 5/31/2023 68180-217-09 H101326 6/30/2023 68180-217-09 H101327 6/30/2023 68180-217-09 H101328 6/30/2023 68180-217-09 H101349 6/30/2023 68180-217-09 H101350 6/30/2023 68180-217-09 H101351 6/30/2023 68180-217-09 H101352 6/30/2023 68180-217-09 H101482 6/30/2023 68180-217-09 H101483 6/30/2023 68180-217-09 H101606 7/31/2023 68180-217-09 H101618 7/31/2023 68180-217-09 H101619 7/31/2023 68180-217-09 H101620 7/31/2023 68180-217-09 H101621 7/31/2023 68180-217-09 H101827 7/31/2023 68180-217-09		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			H101828 7/31/2023 68180-217-09 H101829 7/31/2023 68180-217-09 H101857 7/31/2023 68180-217-09 H101858 7/31/2023 68180-217-09 H101911 7/31/2023 68180-217-09 H101912 7/31/2023 68180-217-09 H101913 7/31/2023 68180-217-09 H102455 10/31/2023 68180-217-09 H102456 10/31/2023 68180-217-09 H102457 10/31/2023 68180-217-09 H102458 10/31/2023 68180-217-09 H102485 10/31/2023 68180-217-09 H102489 10/31/2023 68180-217-09 H102490 10/31/2023 68180-217-09 H102491 10/31/2023 68180-217-09		
Losartan Potassium and Hydrochlorothiazide Tablets USP, 100 mg/12.5 mg a) 30-count bottles (NDC# 68180-216-06) b) 90-count bottles (NDC# 68180-216-09), Rx Only, Manufactured By: Lupin Limited, Pithampur, India, MFG For: Lupin Pharmaceuticals, Inc. Baltimore, Maryland 21202, USA	Class II	Drugs	Lot # H001878 6/30/2022 68180-216-06 H002178 7/31/2022 68180-216-06 H002626 9/30/2022 68180-216-06 H102149 9/30/2023 68180-216-06 H001600 5/31/2022	CGMP Deviations- AZIDO Impurity levels observed to be above acceptable limits	Lupin Pharmaceuticals Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			68180-216-09 H001601 5/1/2022 68180-216-09 H001625 5/31/2022 68180-216-09 H001626 5/31/2022 68180-216-09 H001794 6/30/2022 68180-216-09 H001795 6/30/2022 68180-216-09 H001796 6/30/2022 68180-216-09 H001797 6/30/2022 68180-216-09 H001879 6/30/2022 68180-216-09 H001880 6/30/2022 68180-216-09 H001881 6/30/2022 68180-216-09 H001942 6/30/2022 68180-216-09 H001943 6/30/2022 68180-216-09 H001944 6/30/2022 68180-216-09 H001945 6/30/2022 68180-216-09 H001946 6/30/2022 68180-216-09 H002179 7/31/2022 68180-216-09 H002180 7/31/2022 68180-216-09 H002181 8/31/2022 68180-216-09 H002182 8/31/2022 68180-216-09 H002183 8/31/2022		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			68180-216-09 H002237 8/31/2022 68180-216-09 H002238 8/31/2022 68180-216-09 H002239 8/31/2022 68180-216-09 H002240 8/31/2022 68180-216-09 H002241 8/31/2022 68180-216-09 H002627 9/30/2022 68180-216-09 H002628 9/30/2022 68180-216-09 H002629 9/30/2022 68180-216-09 H002630 9/30/2022 68180-216-09 H002631 9/30/2022 68180-216-09 H002979 11/30/2022 68180-216-09 H002980 11/30/2022 68180-216-09 H002981 11/30/2022 68180-216-09 H002982 11/30/2022 68180-216-09 H002983 11/30/2022 68180-216-09 H100112 12/31/2022 68180-216-09 H100113 12/31/2022 68180-216-09 H100114 12/31/2022 68180-216-09 H100115 12/31/2022 68180-216-09 H100116 12/31/2022		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			68180-216-09 H100156 12/31/2022 68180-216-09 H100157 12/31/2022 68180-216-09 H100622 2/28/2023 68180-216-09 H100623 2/28/2023 68180-216-09 H100624 2/28/2023 68180-216-09 H100625 2/28/2023 68180-216-09 H100626 2/28/2023 68180-216-09 H100627 2/28/2023 68180-216-09 H100628 2/28/2023 68180-216-09 H100629 2/28/2023 68180-216-09 H100939 4/30/2023 68180-216-09 H100940 4/30/2023 68180-216-09 H100941 4/30/2023 68180-216-09 H100942 4/30/2023 68180-216-09 H100943 4/30/2023 68180-216-09 H101094 5/31/2023 68180-216-09 H101095 5/31/2023 68180-216-09 H101096 5/31/2023 68180-216-09 H101097 5/31/2023 68180-216-09 H101098 5/31/2023		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			68180-216-09 H101151 5/31/2023 68180-216-09 H101152 5/31/2023 68180-216-09 H101290 5/31/2023 68180-216-09 H101291 5/31/2023 68180-216-09 H101292 5/31/2023 68180-216-09 H101293 5/31/2023 68180-216-09 H101323 5/31/2023 68180-216-09 H101324 5/31/2023 68180-216-09 H101823 7/31/2023 68180-216-09 H101824 7/31/2023 68180-216-09 H101825 7/31/2023 68180-216-09 H101853 8/31/2023 68180-216-09 H101854 8/31/2023 68180-216-09 H101855 8/31/2023 68180-216-09 H101856 8/31/2023 68180-216-09 H102127 9/30/2023 68180-216-09 H102128 9/30/2023 68180-216-09 H102129 9/30/2023 68180-216-09 H102130 9/30/2023 68180-216-09 H102150 9/30/2023		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			68180-216-09 H102151 9/30/2023 68180-216-09 H102152 9/30/2023 68180-216-09 H102153 9/30/2023 68180-216-09 H102154 9/30/2023 68180-216-09 H102155 9/30/2023 68180-216-09 H102201 9/30/2023 68180-216-09 H102223 9/30/2023 68180-216-09 H102268 9/30/2023 68180-216-09 H102269 9/30/2023 68180-216-09 H102270 9/30/2023 68180-216-09 H102271 9/30/2023 68180-216-09		
Halobetasol Propionate Ointment 0.05% Net Wt., 50 gram tube, Rx Only, Manufactured by: Teligent Pharma, Inc. Buena, NJ 08310, Distributed by: McKesson Corporation dba Sky Packaging 4071 Southridge Blvd., Suite 101 Memphis, TN 38141, NDC 63739-998-67	Class II	Drugs	Lots: 15720, Exp.: 06/30/2022; 16449 Exp.: 02/28/2023; 16450, Exp.: 02/26/2023	CGMP Deviations: all products within expiry are being recalled because the manufacturing firm, Teligent Pharma, Inc.is discontinuing its stability study program.	McKesson Corporation dba McKesson Drug Company
Lidocaine Hydrochloride Topical Solution USP 4% (40 mg/mL), 50 mL bottle, Rx only, Manufactured by: Teligent Pharma, Inc. Buena, NJ 08310 Distributed by: McKesson Corporation dba Sky Packaging 4071 Southridge Blvd., Suite 101 Memphis, TN 38141, NDC 63739-977-64	Class II	Drugs	Lots: 15597, Exp.: 05/31/2023; 16305, Exp.: 12/23/2023; 16334, Exp.: 01/31/2024; 16340, Exp.: 01/31/2024; 16346 Exp.: 01/31/2024; 16356, Exp.:	CGMP Deviations: all products within expiry are being recalled because the manufacturing firm, Teligent Pharma, Inc.is discontinuing its stability study program.	McKesson Corporation dba McKesson Drug Company

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			01/31/2024; 16357, Exp.: 01/31/2024		
Lidocaine Prilocaine Cream USP, 2.5%/2.5% Net Wt. 30 gram tube, Rx Only, Distributed by: McKesson Corporation dba Sky Packaging 4971 Southridge Blvd., Suite 101 Memphis, TN 38141 Manufactured by: Teligent Pharma, Inc., Buena, NJ 08310, NDC 63739-054-66	Class II	Drugs	Lot: 16876, Exp.: 05/31/2023	CGMP Deviations: all products within expiry are being recalled because the manufacturing firm, Teligent Pharma, Inc.is discontinuing its stability study program.	McKesson Corporation dba McKesson Drug Company
Betamethasone Dipropionate Ointment USP, 0.05%* (Augmented) (Potency expressed as betamethasone), 15 gram tube, Rx Only, Manufactured by: Teligent Pharma, Inc. Buena, NJ 08310, Distributed by: McKesson Corporation dba Sky Packaging 4971 Southridge Blvd., Suite 101 Memphis, TN 38141, NDC 63739-996-65	Class II	Drugs	Lot: 15644, Exp.: 05/31/2022	CGMP Deviations: all products within expiry are being recalled because the manufacturing firm, Teligent Pharma, Inc.is discontinuing its stability study program.	McKesson Corporation dba McKesson Drug Company
Erythromycin Topical Gel USP, 2%, Net Wt 60 g tube, Rx only, Manufactured by: Teligent Pharma, Inc. Buena, NJ 08310 Distributed by: McKesson Corporation dba Sky Packaging 4971 Southridge Blvd., Suite 101 Memphis, TN 38141, NDC 63739-053-68	Class II	Drugs	Lot: 15723, Exp.: 06/30/2022	CGMP Deviations: all products within expiry are being recalled because the manufacturing firm, Teligent Pharma, Inc.is discontinuing its stability study program.	McKesson Corporation dba McKesson Drug Company
Pantoprazole Sodium Delayed-Release Tablets, USP, 20 mg, Rx Only, 90 tablets per bottle, Manufactured by: Torrent Pharmaceuticals Ltd., Indrad-382 721, India, Manufactured for: Torrent Pharma Inc., Levittown, PA 19057, NDC# 13668-096-90.	Class II	Drugs	Lot #s: BA34G021, BA34G022, Exp. 09/2022	CGMP deviations: tablets cracking	Torrent Pharma Inc

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Lansoprazole Delayed-Release Orally Disintegrating Tablets, 30 mg, 10 Packs of 10 Tablets each, 100 Tablets per blister pack, Rx Only, Distributed by: Dr. Reddy's Laboratories, Inc., Princeton, NJ 08540, Made in India, NDC 43598-561-78.	Class II	Drugs	Lot #: T2000645, Exp 07/2022	Failed Dissolution Specifications	Dr. Reddy's Laboratories, Inc.
Losartan Potassium Tablets, USP, 25 mg, a) 90-count bottles (NDC # 33342-044-10), b) 1000-count bottles (NDC # 33342-044-44), Rx Only, MFR: Macleods Pharma USA, Inc. Plainsboro, NJ 08536	Class II	Drugs	Lot # BLH2002A, exp. date 11/2022 BLH2003B, exp. date 11/2022 BLH2004A, exp. date 11/2022	CGMP Deviations- AZIDO Impurity levels observed to be above acceptable limits	Macleods Pharma Usa Inc
Losartan Potassium Tablets, USP, 50 mg, a) 30-count bottles (NDC # 33342-045-07), b) 90-count bottles (NDC # 33342-045-10), c) 1000-count bottles (NDC # 33342-045-44), Rx Only, MFR: Macleods Pharma USA, Inc. Plainsboro, NJ 08536	Class II	Drugs	Lot # BLI2002A, exp. date 11/2022 BLI2004A, exp. date 11/2022 BLI2104B, exp. date 05/2023	CGMP Deviations- AZIDO Impurity levels observed to be above acceptable limits	Macleods Pharma Usa Inc
Losartan Potassium Tablets, USP, 100 mg, a) 30-count bottles (NDC # 33342-046-07), b) 90-count bottles (NDC # 33342-046-10), c) 1000-count bottles (NDC # 33342-046-44), Rx Only, MFR: Macleods Pharma USA, Inc. Plainsboro, NJ 08536	Class II	Drugs	Lot # BLI2107B, exp. date 06/2023 BLI2101A, exp. date 12/2022 BLI2103A, exp. date 12/2022 BLI2105A, exp. date 05/2023	CGMP Deviations- AZIDO Impurity levels observed to be above acceptable limits	Macleods Pharma Usa Inc
Losartan Potassium & Hydrochlorothiazide Tablets, USP, 50 mg/12.5 mg, a) 30-count bottles (NDC# 33342-050-07), b) 90-count bottles (NDC # 33342-050-10) c) 1000-count bottles (NDC # 33342-050-44), Rx Only, MFR: Macleods Pharma USA, Inc. Plainsboro, NJ 08536	Class II	Drugs	Lot # BLK2107B, exp. date 05/2023 BLK2101A, exp. date 01/2025 BLK2102A, exp. date 02/2025 BLK2103B, exp. date 02/2023 BLK2103C, exp. date 02/2023	CGMP Deviations- AZIDO Impurity levels observed to be above acceptable limits	Macleods Pharma Usa Inc

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			BLK2104A, exp. date 05/2023		
Losartan Potassium & Hydrochlorothiazide Tablets, USP, 100 mg/25 mg, a) 30-count bottles (NDC# 33342-052-07), b) 90-count bottles (NDC # 33342-052-10) c) 1000-count bottles (NDC # 33342-052-44), Rx Only, MFR: Macleods Pharma USA, Inc. Plainsboro, NJ 08536	Class II	Drugs	Lot # BLM2106B, exp. date 05/2023 BLM2101A, exp. date 01/2025 BLM2102A, exp. date 02/2023 BLM2106A, exp. date 05/2023 BLM2103B, exp. date 02/2023 BLM2104A, exp. date 05/2023 BLM2110A, exp. date 06/2023	CGMP Deviations- AZIDO Impurity levels observed to be above acceptable limits	Macleods Pharma Usa Inc
Losartan Potassium & Hydrochlorothiazide Tablets, USP, 100 mg/12.5 mg, a) 30-count bottles (NDC# 33342-051-07), b) 90-count bottles (NDC # 33342-051-10) c) 1000-count bottles (NDC # 33342-051-44), Rx Only, MFR: Macleods Pharma USA, Inc. Plainsboro, NJ 08536	Class II	Drugs	Lot # BLL2107B, exp. date 05/2023 BLL2101A, exp. date 01/2025 BLL2102A, exp. date 02/2025 BLL2103B, exp. date 02/2023 BLL2104A, exp. date 05/2023	CGMP Deviations- AZIDO Impurity levels observed to be above acceptable limits	Macleods Pharma Usa Inc
alprazolam XR extended-release tablets, 3 mg, 60-count bottle, Rx only, Distributed by: Greenstone LLC, Peapack, NJ 07977, NDC 59762-0068-1.	Class II	Drugs	Lot # EH8348, exp. date August 2023	Failed Dissolution Specifications: low out-of-specification dissolution test results observed.	Viatris Inc
Norepinephrine 8mg in 0.9% Sodium Chloride 250 mL bag, Rx only, SCA Pharmaceuticals Windsor, CT 06095, NDC 70004-078-40	Class II	Drugs	Lot #: 1222035815, Exp. Date 10-Jul-22	CGMP Deviations	SCA Pharmaceuticals
Fentanyl 2mcg/ml and Bupivacaine 0.125% in 0.9% Sodium Chloride 100 mL bags, Rx	Class II	Drugs	Lot #: 1222035837, Exp. Date 22-Jul-22 Lot #:	CGMP Deviations	SCA Pharmaceuticals

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
only, SCA Pharmaceuticals Windsor, CT 06095, NDC 70004-0231-32			1222035804, Exp. Date 25-Jul-22		
Vancomycin HCl 1.5 g in 0.9% Sodium Chloride, 500 mL bags, Rx only, SCA Pharmaceuticals Windsor, CT 06095, NDC 70004-0924-44	Class II	Drugs	Lot #: 1222035839, Exp. Date 09-Aug-22	CGMP Deviations	SCA Pharmaceuticals
Esomeprazole Magnesium Delayed-Release Capsules, USP 20 mg, packaged in Unit Dose Blister Cards of 6 (10 cards of 6 Capsules each per carton), Rx only, Manufactured for: Mylan Pharmaceuticals Inc., Morgantown, WV 26505 USA. NDC 42292-009-16	Class II	Drugs	Lot #: 3112743, Exp. Date 4/30/2023; 3112582, Exp. Date 3/31/2023; 3110438, 3111708, 3111120, Exp. Date 7/31/2022	Failed Impurities/Degradation Specifications: OOS result was obtained for Any Other Individual Impurity at the 12M room temperature time point.	Mylan Institutional, Inc. (d.b.a. UDL Laboratories)
Esomeprazole Magnesium Delayed-Release Capsules, USP 40 mg, packaged in Unit Dose Blister Cards of 6 (10 cards of 6 Capsules each per carton), Rx only, Manufactured for: Mylan Pharmaceuticals Inc., Morgantown, WV 26505 USA. NDC 42292-010-16	Class II	Drugs	Lot #: 3110437, 3111409, 3110785, Exp. Date 7/31/2022; 3112173, Exp. Date 11/30/2022	Failed Impurities/Degradation Specifications: OOS result was obtained for Any Other Individual Impurity at the 12M room temperature time point.	Mylan Institutional, Inc. (d.b.a. UDL Laboratories)
Xanax XR (alprazolam) extended-release tablets, 3 mg, 60-count bottle, Rx only, Distributed by Pharmacia & Upjohn Co, Division of Fizer Inc, NY, NY 10017, NDC 0009-0068-07.	Class II	Drugs	Lot #: DX7983, exp. date 02/28/2023	Failed Dissolution Specifications: low out of specification results for dissolution.	Viatris Inc
MVASI (bevacizumab-awwb), Injection, For Intravenous Infusion After Dilution, 100 mg/4 ml, Single dose vial, Rx only, Manufactured by Amgen Inc. Thousand Oaks, CA 91320-1799, NDC 55513-0206-01	Class II	Drugs	Lots: 1142258, 1143196, Exp. 09/24	Defective container: loose crimp defect, potential loss of container integrity.	Amgen, Inc.
Kill 'Dat Sanitizing Products Hand Sanitizer, 1 gallon (128 fl. oz.) 80% Alcohol, OTC,	Class II	Drugs	Batch 39	CGMP Deviations: FDA analysis found product to contain	Lula Holdings L.L.C.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Manufactured by: Lula Holdings LLC, 15532 St. Charles Avenue, New Orleans, LA, NDC 77348-001-02.				acetaldehyde above specification limits.	
Wal-Tussin DM (dextromethorphan HBr/Guaifenesin), 12 FL OZ (354 mL) bottles, Distributed By: Walgreen Co. 200 Wilmot Rd., Deerfield, IL 60015, NDC 0363-0324-28.	Class III	Drugs	All lots	Incorrect/Undeclared Excipient: Product contains alcohol	AptaPharma Inc.
Cyanocobalamin Injection, USP, 1000 mcg per mL, For Intramuscular or Subcutaneous Use Only, 25 x 1 mL Vials, Rx only, Manufactured by: Eugia Pharma Specialties Limited, Hyderabad India for BluePoint Laboratories. NDC for Carton: 68001-509-60; NDC for vial: 68001-509-59	Class III	Drugs	Lots: CCC210008, CCC210009, Exp. 01/23	Subpotent Drug: Out of specification for assay.	American Health Packaging
Lidocaine Hydrochloride Oral Topical Solution, USP (Viscous) 2%, 100 mL per bottle, Rx only, Manufactured by Hi-Tech Pharmacal Co., Inc. Amityville, NY 11701, NDC 50383-775-04	Class III	Drugs	Lot #: 370978, Exp 9/30/2022	Failed viscosity specification - product was below specificcation	Akorn, Inc.
Nandrolone Decanoate, USP, 100 g per plastic container, Rx Only, For Prescription Compounding, Fagron, Inc. 2400 Pilot Knob Rd., St Paul, MN 55120. NDC 51552-1564-04	Class III	Drugs	Lot #: 18H02-U02-044979, 18H02-U02-046141, Exp. Date 10/31/2022; 18L12-U02-050309,18L12-U02-000953, 18L12-U02-A009829, Exp. Date Sep 2023.	Subpotent Drug	Fagron, Inc
Nandrolone Decanoate, USP, 500 g per plastic container, Rx Only, For Prescription Compounding, Fagron, Inc. 2400 Pilot Knob Rd., St Paul, MN 55120. NDC 51552-1564-05	Class III	Drugs	Lot #: 18H02-U02-044978, 18L12-U02-050018, Exp. Date 10/31/2022 18L12-	Subpotent Drug	Fagron, Inc

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			U02-000952, Exp. Date Sep 2023		
Nandrolone Decanoate, USP, 1 kg per plastic container, Rx Only, For Prescription Compounding, Fagron, Inc. 2400 Pilot Knob Rd., St Paul, MN 55120. NDC 51552-1564-07	Class III	Drugs	Lot #: 18H02-U02-044977, 18H02-U02-046140, 18L12-U02-050572, Exp. Date 10/31/2022; 18L12-U02-050308, 18L12-U02-000951, Exp. Date Sep 2023	Subpotent Drug	Fagron, Inc
Nandrolone Decanoate, USP, 500 g per plastic container, Rx Only, For Prescription Compounding, Distributed by: Humco, 7400 Alumax Road, Texarkana, TX 75501. NDC 0395-8212-56	Class III	Drugs	Lot #: 18L12-U02-050018, Exp. Date 10/31/2022	Subpotent Drug	Fagron, Inc
Nandrolone Decanoate, USP, 1 kg per plastic container, Rx Only, For Prescription Compounding, Distributed by: Humco, 7400 Alumax Road, Texarkana, TX 75501. NDC 0395-8212-43	Class III	Drugs	Lot #: 18L12-U02-050019, Exp. Date 10/31/2022	Subpotent Drug	Fagron, Inc
buPROPion Hydrochloride Extended-Release Tablet, USP (SR), 150 mg packaged in a) 60-count bottle (47335-737-86), b)100-count bottle (47335-737-88), c)500-count bottle (47335-737-13), Rx only Distributed by: Sun Pharmaceutical Industries, Inc. Cranbury, NJ 08512, Manufactured by: Sun Pharmaceutical Industries Limited, Halol-Baroda Highway, Halol-389 350, Gujarat, India	Class III	Drugs	Lot #: a) JKX5126A, JKX5127A, JKX5128A, Exp 10/2022; b) JKX5126B , JKX5128B, Exp 10/2022; c)JKX5126C, JKX5127C, JKX5128C, Exp 10/2022;	Presence Of Foreign Substance: Customer complaint for the presence of dark, gritty substance found within the bottle which was determined to be activated carbon from the desiccant canister inside the bottle.	SUN PHARMACEUTICAL INDUSTRIES INC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
buPROPion Hydrochloride Extended-Release Tablet, USP (SR), 200 mg, 60-count bottle, Rx only Distributed by: Sun Pharmaceutical Industries, Inc. Cranbury, NJ 08512, Manufactured by: Sun Pharmaceutical Industries Limited, Halol-Baroda Highway, Halol-389 350, Gujarat, India, NDC 47335-738-86	Class III	Drugs	Lot #: HAC2237A, exp. date 05/2023	Presence Of Foreign Substance: Customer complaint for the presence of dark, gritty substance found within the bottle which was determined to be activated carbon from the desiccant canister inside the bottle.	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

Acetazolamide Injection
Amifostine Injection
Amino Acids
Amoxapine Tablets
Amphetamine Aspartate; Amphetamine Sulfate; Dextroamphetamine Saccharate; Dextroamphetamine Sulfate Tablets
Amphetamine Oral Suspension, Extended Release
Atropine Sulfate Injection
Azacitidine for Injection
Azithromycin (Azasite) Ophthalmic Solution 1%
Bacteriostatic 0.9% Sodium Chloride Injection
Bacteriostatic Water for Injection
Belatacept (Nulojix) Lyophilized Powder for Injection
Bumetanide Injection
Bupivacaine Hydrochloride and Epinephrine Injection
Bupivacaine Hydrochloride Injection
Calcium Disodium Versenate Injection
Calcium Gluconate Injection
Cefazolin Injection
Cefixime Oral Capsules
Cefotaxime Sodium Injection
Cefotetan Disodium Injection
Chlordiazepoxide Hydrochloride Capsules
Chloroprocaine Hydrochloride Injection
Conivaptan Hydrochloride (Vaprisol) in 5% Dextrose Plastic Container
Continuous Renal Replacement Therapy (CRRT) Solutions
Cortisone Acetate Tablets
Cyclopentolate Ophthalmic Solution
Cysteamine Hydrochloride Ophthalmic Solution
Cytarabine Injection
Dacarbazine Injection
Desmopressin Acetate Nasal Spray
Dexamethasone Sodium Phosphate Injection
Dexmedetomidine Injection
Dextrose 10% Injection
Dextrose 25% Injection
Dextrose 5% Injection
Dextrose 50% Injection

Diflunisal Tablets
Digoxin Injection
Diltiazem Hydrochloride Injection
Disopyramide Phosphate (Norpace) Capsules
Dobutamine Hydrochloride Injection
Dopamine Hydrochloride Injection
Echothiophate Iodide (Phospholine Iodide) Ophthalmic Solution
Enalaprilat Injection
Epinephrine Injection, 0.1 mg/mL
Epinephrine Injection, Auto-Injector
Fentanyl Citrate (Sublimaze) Injection
Floxuridine for Injection
Fludarabine Phosphate Injection
Fluorescein Injection
Fluvoxamine ER Capsules
Furosemide Injection
Gemifloxacin Mesylate (Factive) Tablets
Gentamicin Sulfate Injection
Guanfacine Hydrochloride Tablets
Heparin Sodium and Sodium Chloride 0.9% Injection
Hydrocortisone Tablets
Hydromorphone Hydrochloride Injection
Hydroxypropyl (Lacrisert) Cellulose Ophthalmic Insert
Ibutilide Fumarate Injection
Imipenem and Cilastatin for Injection
Iodixanol (Visipaque) Injection
Iohexol (Omnipaque) Injection
Isoniazid Injection
Ketamine Injection
Ketoprofen Capsules
Ketorolac Tromethamine Injection
Leucovorin Calcium Lyophilized Powder for Injection
Leuprolide Acetate Injection
Lidocaine Hydrochloride (Xylocaine) and Dextrose Injection Solution-Premix Bags
Lidocaine Hydrochloride (Xylocaine) Injection
Lidocaine Hydrochloride (Xylocaine) Injection with Epinephrine
Lipid Injection
Lithium Oral Solution
Lorazepam Injection
Loxapine Capsules
Lutetium Lu 177 Dotatate (LUTATHERA) Injection
Mannitol Injection
Mepivacaine Hydrochloride Injection
Methyldopa Tablets
Methylprednisolone Acetate Injection
Metronidazole Injection

Midazolam Injection
Morphine Sulfate Injection
Multi-Vitamin Infusion (Adult and Pediatric)
Nefazodone Hydrochloride Tablets
Nizatidine Capsules
Paclitaxel Injection (protein-bound particles)
Pantoprazole Sodium for Injection
Parathyroid Hormone (Natpara) Injection
Pentostatin Injection
Physostigmine Salicylate Injection
Potassium Acetate Injection
Potassium Chloride Concentrate Injection
Promethazine (Phenergan) Injection
Propofol Injectable Emulsion
Protamine Sulfate Injection
Rifampin Capsules
Rifampin Injection
Rifapentine Tablets
Ropivacaine Hydrochloride Injection
Sclerosol Intrapleural Aerosol
Semaglutide (WEGOVYÂ®) 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
Sterile Water for Injection
Streptozocin Powder for Injection
Sufentanil Citrate Injection
Sulfasalazine Tablets
Technetium TC-99M Mebrofenin Injection
Technetium Tc99m Succimer Injection (DMSA)
Teprotumumab-trbw
Thiothixene Capsules
Triamcinolone Acetonide Injectable Suspension
Triamcinolone Hexacetonide Injectable suspension
Trimethobenzamide Hydrochloride Capsules
Valproate Sodium Injection
Varenicline Tartrate (Chantix) Tablets
Vecuronium Bromide for Injection