PERFORMRx℠

Drug Information Update

October 2023

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NEWLY AVAILABLE GENERICS

Generic Name/ Dosage Form	Brand Name	Manufacturer	Indication
Clindamycin phosphate/benzoyl peroxide 1.2-3.75% topical gel w/pump	Onexton	Taro, Oceanside Pharmaceuticals	Topical treatment of acne vulgaris in patients 12 years of age and older.
Amphetamine-dextroamphetamine extended release 12.5 mg, 25 mg, 37.5 mg, 50 mg oral capsules	Mydayis	Teva Pharmaceuticals	Treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients 13 years and older.
Pazopanib 200 mg oral tablet	Votrient	Apotex, Sun Pharmaceuticals	Treatment of adults with advanced renal cell carcinoma (RCC) and treatment of adults with advanced soft tissue sarcoma (STS) who have received prior chemotherapy.

NEW DRUG ENTITIES/STRENGTHS/COMBINATIONS

Drug Name	Generic Name	Description
Adalimumab-adbm 10 mg/0.2 ml, 20 mg/0.4 ml, 40 mg/0.8 ml, subcutaneous syringe; 40 mg/0.8 mL subcutaneous auto-injector	adalimumab-adbm	New unbranded Cyltezo, a biosimilar Humira, made by BI. Interchangeable with original concentration Humira.
Pokonza oral packet 10 meq	potassium chloride	New dosage form of potassium chloride.
Hyrimoz subcutaneous solution auto-injector and prefilled syringe 40 mg/0.8ml	adalimumab-adaz	New strength of Humira biosimilar. Low concentration strength.
Trientine HCl oral capsule 500 mg	trientine	New strength. Indicated for the treatment of patients with Wilson's disease who are intolerant of penicillamine.
Carboprost tromethamine intramuscular solution prefilled syringe 250 mcg/ml	carboprost tromethamine	New dosage form. Previously only available as a vial.
Kepivance intravenous solution reconstituted 5.16 mg	palifermin	New strength.
Pombiliti intravenous solution reconstituted 105 mg	cipaglucosidase alfa-atga	New entity. Indicated to be used in combination with Opfolda (miglustat) for the treatment of adult patients with late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency) weighing ≥40 kg and who are not improving on their current enzyme replacement therapy.

Drug Name	Generic Name	Description
Opfolda oral capsule 65 mg	miglustat	New entity. Indicated to be used in combination with Pombiliti for the treatment of adult patients with late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency) weighing ≥40 kg and who are not improving on their current enzyme replacement therapy.
Motpoly XR oral capsule extended release 24 hour 100 mg, 150 mg, 200 mg	lacosamide	New dosage form. New extended-release formulation of lacosamide indicated for the treatment of partial-onset seizures in adults and in pediatric patients weighing at least 50 kg.
Cosentyx intravenous solution 125 mg/5ml	secukinumab	New dosage form. Previously only available as a subcutaneous syringe and auto-injector. Can only be used for the following indications: active psoriatic arthritis, active ankylosing spondylitis, and active non-radiographic axial spondyloarthritis with objective signs of inflammation.
Kalydeco oral packet 5.8 mg	ivacaftor	New strength. Indicated for the treatment of cystic fibrosis (CF) in patients age 1 month and older who have at least one mutation in the CFTR gene that is responsive to ivacaftor based on clinical and/or in vitro assay data.
Entyvio subcutaneous solution pen-injector 108 mg/0.68ml	vedolizumab	New dosage form. Previously only available as an intravenous vial. Can only be used for moderately to severely active ulcerative colitis indication, while Entyvio IV can also be used for moderately to severely active Crohn's disease.
First pantoprazole oral suspension 4 mg/ml	pantoprazole	New compound kit for pantoprazole oral suspension.
Glipizide oral tablet 2.5 mg	glipizide	New strength.
Likmez oral suspension 500 mg/5ml	metronidazole	New strength and dosage form. Metronidazole oral suspension indicated for trichomoniasis in adults, amebiasis in adults and pediatric patients, and anaerobic bacterial infections in adults. Approved under 505(b)(2) approval pathway.

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†
Jardiance	empagliflozin 10 mg, 25 mg tablets	Boehringer Ingelheim	• To reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure • **To reduce the risk of sustained decline in eGFR, end-stage kidney disease, cardiovascular death, and hospitalization in adults with chronic kidney disease at risk of progression** • To reduce the risk of cardiovascular death in adults with type 2 diabetes mellitus and established cardiovascular disease • As an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients aged 10 years and older with type 2 diabetes mellitus
Bosulif	bosutinib 100 mg, 400 mg, 500 oral tablets; 50 mg, 100 mg oral capsules	Pfizer	• Treatment of adult **and pediatric patients 1 year of age and older** with chronic phase Ph+ chronic myelogenous leukemia (CML), newly-diagnosed or resistant or intolerant to prior therapy • Treatment of adult patients with accelerated, or blast phase Ph+ CML with resistance or intolerance to prior therapy
Zoryve	roflumilast 0.3% topical cream	Arcutis Biotherapeutics	• Topical treatment of plaque psoriasis, including intertriginous areas, in patients ~~12~~ **6** years of age and older
Braftovi	encorafenib 75 mg oral capsules	Pfizer	• To be used in combination with binimetinib, for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, as detected by an FDA-approved test

Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication†
			• To be used in combination with cetuximab, for the treatment of adult patients with metastatic colorectal cancer (CRC) with a BRAF V600E mutation, as detected by an FDA-approved test, after prior therapy • **To be used in combination with binimetinib, for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) with a BRAF V600E mutation, as detected by an FDA-approved test**
Mektovi	binimetinib 15 mg oral tablets	Pfizer	• To be used in combination with encorafenib, for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, as detected by an FDA-approved test • **To be used in combination with encorafenib, for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) with a BRAF V600E mutation, as detected by an FDA-approved test**
Opdivo	nivolumab 40 mg/4 ml, 100 mg/10 ml, 120 mg/12 ml, 240 mg/24 ml intravenous vials	Bristol-Myers Squibb	• Adjuvant treatment of adult and pediatric patients 12 years and older with ~~melanoma with involvement of lymph nodes or metastatic disease who have undergone complete resection~~ **completely resected Stage IIB, Stage IIC, Stage III, or Stage IV melanoma** *Note: Opdivo has many other approved indications not mentioned here; see full prescribing information for details.*
Keytruda	pembrolizumab 100 mg/4 ml intravenous vial	Merck	• **Treatment of patients with resectable (tumors ≥4 cm or node positive) non-small cell lung cancer (NSCLC) in combination with platinum-containing chemotherapy as neoadjuvant treatment, and then continued as a single agent as adjuvant treatment after surgery**

Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication†
			Note: Keytruda has many other approved indications not mentioned here; see full prescribing information for details.
Voxzogo	vosoritide 0.4 mg, 0.56 mg, 1.2 mg subcutaneous vials	BioMarin Pharmaceutical	• To increase linear growth in pediatric patients with achondroplasia ~~who are 5 years of age and older~~ with open epiphyses This indication is approved under accelerated approval based on an improvement in annualized growth velocity. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

RECALLS

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Dr. Berne's MSM DROPS 5% Solution, 30 mL/1.014 OZ bottle, Distributed by: Dr. Berne's Whole Health Products, Tesuque, NM, 87574, hello@drsamberne.com, UPC 00854582001111.	Class I	Drugs	Lot: 6786, Exp: 03/31/25	Non-Sterility	Dr. Berne's Whole Health Products
BREXAFEMME (Ibrexafungerp) tablets 150 mg, 4 count cartons, Rx Only, Manufactured for and distributed by SCYNEXIS, Inc., Jersey City, NJ 07302 NDC 75788-115-04	Class I	Drugs	Lot# LF21000008, Exp. 11/30/2023 Lot# LF22000051, Exp. 11/30/2025	Cross Contamination with Other Products: Potential cross-contamination of ibrexafungerp citrate drug substance with ezetimibe (a non-antibacterial beta-lactam compound).	Scynexis, Inc.
TheraBreath for Kids! Oral Rinse, sodium fluoride 0.05% (0.02% w/v fluoride ion), 16 fl. oz. 473 mL bottles, Strawberry Splash, UPC 6 97029 70000 6, manufactured for Church & Dwight Co, Inc., Ewing, NJ 08628	Class I	Drugs	Lot # PA3083011, Exp 3/31/2025	Microbial contamination of Non-Sterile Product; presence of yeast identified as Candida parapsilosis	Church & Dwight Inc
Sucralfate Oral Suspension, 1g per 10mL, 16 oz (414 mL) PET bottle (12 bottles per case), Rx Only, Manufactured and Distributed by: VistaPharm, Inc. Largo, FL 33771 USA, NDC 66689-305-16	Class I	Drugs	Lot#: 810300, Exp 10/2023	Microbial Contamination of Non-Sterile Products: identified as Bacillus cereus.	VistaPharm LLC
Betaxolol Tablets, USP 10 mg, Rx Only, 100 count bottles, Mfd by: KVK Tech Inc., Newtown, PA 18940, Made in USA, NDC# 10702-013-01.	Class I	Drugs	Lot # 17853A, Exp. 06/30/2027	Presence of Foreign Tablets/Capsules: There is a potential presence of oxycodone HCl tablets, USP 5 mg in bottles.	KVK-Tech, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Florbetaben F-18 (Neuraceq¿) Injection Solution 1.4 to 135 mCi/mL, 50 mL in 1 multi-dose glass vial, Diagnostic-For Intravenous Use Only, Manufactured by SOFIE Co dba SOFIE, Dulles, VA 20166 for Life Molecular Imagining Ltd., NDC 54828-001-50	Class II	Drugs	Batch # FBBVA123082201, EOS: 22 Aug 2023/08:25, EXP: 22 Aug 2023/18:25	Lack of Assurance of Sterility: out-of-specification test results observed for Filter Integrity Test (FIT).	Sofie Co dba Sofie
Dr. Berne's MSM DROPS 15% Solution, 30 mL/1.014 OZ bottle, Distributed by: Dr. Berne's Whole Health Products, Tesuque, NM, 87574, hello@drsamberne.com, UPC 00854582001036	Class II	Drugs	Lots: 6486, Exp: 11/23; 6536, Exp: 01/24; 6549, Exp: 02/24; 6561, Exp: 03/24; 6623, Exp: 06/24; 6630, Exp: 06/24; 6646, Exp: 07/24; 6675, Exp: 09/24; 6686, Exp: 09/24; 6695, Exp: 10/24; 6738, Exp: 11/24; 6767, Exp: 01/25; 6787, Exp: 03/25; 6799, Exp: 04/25; 6832 Exp: 05/25; 6844, Exp: 05/25; 6857, Exp: 06/25; 6888, Exp: 07/25.	CGMP Deviations	Dr. Berne's Whole Health Products
Dr. Berne's MSM MIST 15% Solution, 30 mL/1.014 OZ bottle, Distributed by: Dr. Berne's Whole Health Products, Tesuque, NM, 87574, hello@drsamberne.com.	Class II	Drugs	Lot: 6617, Exp. 05/24; 6623, Exp 06/24; 6646, Exp 07/24; 6675, Exp 09/24; 6716, Exp 11/24.	CGMP Deviations	Dr. Berne's Whole Health Products

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Dr. Berne's Organic Castor Oil Eye Drops, Net WT 30 mL/1 fl oz bottle, Distributed by: Dr. Berne's Whole Health Products, Tesuque, NM, 87574, hello@drsamberne.com, Certified Organic by Organic Certifiers.	Class II	Drugs	Lot: 6666, Exp. 11/30/25	CGMP Deviations	Dr. Berne's Whole Health Products
Dr. Berne's MSM DROPS 5% Solution, 30 mL/1.014 OZ bottle, Distributed by: Dr. Berne's Whole Health Products, Tesuque, NM, 87574, hello@drsamberne.com, UPC 00854582001111.	Class II	Drugs	Lot: 6485, Exp: 11/23: 6562, Exp: 03/24; 6624, Exp: 06/24; 6669, Exp: 08/24; 6688, Exp: 09/24; 6727, EXP: 11/24; 6771, Exp: 02/25; 6830, Exp: 03/25; 6887, Exp: 07/25.	CGMP Deviations	Dr. Berne's Whole Health Products
Oxybutynin Chloride Extended-Release Tablets USP 10 mg, a) 100 tablets (NDC 68382-256-01) and b) 500 tablets (NDC 68382-256-05) bottles, Rx Only, Manufactured by: Cadila Healthcare Ltd., Ahmedabad, India, Distributed by: Zydus Pharmaceuticals (USA) Inc., Pennington, NJ 08534	Class II	Drugs	Lot#: M300652 and M300651, exp. Dec 2024	Failed Dissolution Specifications	Zydus Pharmaceuticals (USA) Inc
Triamcinolone Acetonide Injectable Suspension, USP, 400 mg per 10 mL (40mg/mL), 10 mL Multiple Dose Vial, Rx Only, For Intramuscular or Intra-articular use only, Shake Well, Not for IV/ID, intraocular, epidural, or intrathecal use, Mfd. in India for Auromedics Pharma LLC., E Windsor, NJ, 08520, NDC 55150-385-01.	Class II	Drugs	Lot #: 3TC22010, Exp 11/30/2024	Presence of Particulate Matter: A product complaint of a piece of glass was identified in a vial. The piece of glass appears to be roughly 1 cm x 0.5 cm inside the vial.	Eugia US LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Bevacizumab 1.25 MG/0.05 ML Solution for Injection, 1 mL syringes, Rx only, Compounded by Pine Pharmaceuticals 355 Riverwalk Parkway, Tonawanda, NY 14150.	Class II	Drugs	Lot #: 68861, Exp. Date 10/13/2023; 69105, Exp. Date 10/25/2023; 70204, Exp. Date 11/24/2023; 70218, Exp. Date 11/25/2023; 68620 Exp. Date 10/3/2023; 68632 Exp. Date 10/4/2023; 68789 Exp. Date 10/12/2023; 68822 Exp. Date 10/12/2023; 68914 Exp. Date 10/17/2023; 68952, 68954 Exp. Date 10/18/2023; 69105 Exp. Date 10/25/2023; 69731 Exp. Date 11/7/2023; 69991 Exp. Date 11/15/2023; 70142 Exp. Date 11/22/2023; 70233 Exp. Date 11/28/2023; 70258 Exp. Date 11/29/2023; 70297 Exp. Date 11/30/2023; 70355 Exp. Date 12/5/2023; 70404 Exp. Date 12/6/2023; 70516	Lack of Assurance of Sterility	Pine Pharmaceuticals, LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			Exp. Date 12/12/2023; 70579 Exp. Date 12/14/2023; 70659, 70664 Exp. Date 12/19/2023; 70700 Exp. Date 12/20/2023; 68757, Exp. Date 10/10/2023; 68912, Exp. Date 10/17/2023; 69071, Exp. Date 10/24/2023; 69725, Exp. Date 10/31/2023; 69749, Exp. Date 11//2023; 69841, Exp. Date 11/8/2023; 69961, Exp. Date 11/14/2023; 70112, Exp. Date 11/21/2023; 70228, Exp. Date 11/28/2023; 70353, Exp. Date 12/5/2023; 70403, Exp. Date 12/9/2023; 70513, Exp. Date 2/12/2023; 70569, 70570 Exp. Date 12/14/2023; 70692, Exp. Date 12/20/2023; 70726, Exp. Date 12/21/2023; 70853, Exp. Date		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			12/27/2023; 68757, Exp. Date 10/10/2023; 68912, Exp. Date 10/17/2023; 69071, Exp. Date 10/24/2023; 69725, Exp. Date 10/31/2023; 69749, Exp. Dat e1/7/2023; 69841, Exp. Date 11/8/2023; 69961, Exp. Date 11/14/2023; 70112, Exp. Date 11/21/2023; 70228, Exp. Date 11/28/2023; 70353, Exp. Date 12/5/2023; 70403, Exp. Date 12/9/2023; 70513, Exp. Date 12/12/2023; 70569,70570, Exp. Date 12/14/2023; 70 692, Exp. Date 12/20/2023; 70726, Exp. Date 12/21/2023; 70853, Exp. Date 12/27/2023; 69749, Exp. Date 11/7/2023; 69841, Exp. Date 11/8/2023 67538, Exp. Date 10/11/2023;		

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			68535, Exp. Date 10/4/2023; 68611, 68613 Exp. Date 10/3/2023; 68612, 68633, 68637 Exp. Date 10/4/2023; 68638, 68673, 68674,68675, Exp. Date 10/5/2023; 68634, 68699, 68700, 68701, 68702, 68709 Exp. Date 10/6/2023; 68703, 68708, 68728, 68729, 68736, 68737, 68738, 68739, Exp. Date 10/7/2023; 68758, 68759, Exp. Date 10/10/2023; 68784, 68785, 68786, 68787, 68788, Exp. Date 10/11/2023; 68821, 68823, 68824,Exp. Date 10/12/2023; 68843, 68844, 68850, 68851, 68852, 10/13/2023;68853, Exp. Date 10/13/2023; 68877, 68878, 68879, exp. date		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			10/14/2023; 68880, exp. date 10/14/2023; 68886, exp. date 10/14/2023; 68896, exp. date 10/13/2023; 68897, exp. date 10/13/2023; 68913, exp. date 10/17/2023; 68915, exp. date 10/17/2023; 68922, exp. date 10/18/2023; 68923, exp. date 10/17/2023; 68953, exp. date 10/18/2023; 68959, exp. date 10/20/2023; 68976, exp. date 10/18/2023; 68977, exp. date 10/19/2023; 68978, exp. date 10/19/2023; 68979, exp. date 10/19/2023; 68980, exp. date		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			10/18/2023; 68981, exp. date 10/19/2023; 68982, exp. date 10/20/2023; 69016, exp. date 10/20/2023; 69017, exp. date 10/20/2023; 69018, exp. date 10/21/2023; 69019, exp. date 10/20/2023; 69047, exp. date 10/21/2023; 69048, exp. date 10/21/2023; 69049, exp. date 10/21/2023; 69050, exp. date 10/21/2023; 69051, exp. date 10/21/2023; 69052, exp. date 10/21/2023; 69056, exp. date 10/21/2023; 69072, exp. date 10/24/2023; 69073, exp. date		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			10/24/2023; 69074, exp. date 10/24/2023; 69075, exp. date 10/24/2023; 69101, exp. date 10/28/2023; 69102, exp. date 10/25/2023; 69103, exp. date 10/25/2023; 69104, exp. date 10/25/2023; 69109, exp. date 10/25/2023; 69127, exp. date 10/26/2023; 69128, exp. date 10/27/2023; 69129, exp. date 10/26/2023; 69130, exp. date 10/28/2023; 69131, exp. date 10/28/2023; 69132, exp. date 10/28/2023; 69142, exp. date 10/27/2023; 69143, exp. date		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			10/28/2023; 69144, exp. date 10/28/2023; 69166, exp. date 10/28/2023; 69167, exp. date 10/28/2023; 69168, exp. date 10/28/2023; 69169, exp. date 10/28/2023; 69170, exp. date 10/28/2023; 69171, exp. date 10/28/2023; 69726, exp. date 10/31/2023; 69727, exp. date 10/31/2023; 69745, exp. date 11/4/2023; 69746, exp. date 11/2/2023; 69748, exp. date 11/2/2023; 69750, exp. date 11/2/2023; 69751, exp. date 11/4/2023; 69754, exp. date 11/3/2023; 69755, exp. date 11/3/2023; 69768, exp. date		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			11/3/2023; 69770, exp. date 11/3/2023; 69779, exp. date 11/4/2023; 69780, exp. date 11/4/2023; 69781, exp. date 11/4/2023; 69782, exp. date 11/4/2023; 69783, exp. date 11/4/2023; 69784, exp. date 11/4/2023; 69793, exp. date 11/4/2023; 69794, exp. date 11/7/2023; 69839, exp. date 11/8/2023; 69863, exp. date 11/9/2023; 69864, exp. date 11/18/2023; 69865, exp. date 11/9/2023; 69866, exp. date 11/9/2023; 69867, exp. date 11/9/2023; 69868, exp. date 11/14/2023; 69890, exp. date 11/10/2023; 69892, exp. date 11/10/2023; 69893, exp. date		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			11/10/2023; 69894, exp. date 11/10/2023; 69895, exp. date 11/10/2023; 69896, exp. date 11/10/2023; 69897, exp. date 11/10/2023; 69928, exp. date 11/11/2023; 69929, exp. date 11/11/2023; 69930, exp. date 11/11/2023; 69931, exp. date 11/11/2023; 69932, exp. date 11/11/2023; 69933, exp. date 11/11/2023; 69962, exp. date 11/18/2023; 69963, exp. date 11/16/2023; 69964, exp. date 11/14/2023; 69965, exp. date 11/15/2023; 69987, exp. date		

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			11/15/2023; 69988, exp. date 11/15/2023; 69990, exp. date 11/15/2023; 69998, exp. date 11/18/2023; 70011, exp. date 11/18/2023; 70031, exp. date 11/16/2023; 70032, exp. date 11/16/2023; 70033, exp. date 11/16/2023; 70034, exp. date 11/16/2023; 70035, exp. date 11/21/2023; 70066, exp. date 11/17/2023; 70067, exp. date 11/17/2023; 70094, exp. date 11/18/2023; 70095, exp. date 11/18/2023; 70113, exp. date 11/21/2023; 70114, exp. date		

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			11/21/2023; 70115, exp. date 11/21/2023; 70116, exp. date 11/22/2023; 70138, exp. date 11/22/2023; 70139, exp. date 11/22/2023; 70140, exp. date 11/22/2023; 70147, exp. date 11/22/2023; 70163, exp. date 11/23/2023; 70164, exp. date 11/23/2023; 70165, exp. date 11/23/2023; 70166, exp. date 11/23/2023; 70167, exp. date 11/23/2023; 70168, exp. date 11/23/2023; 70193, exp. date 11/24/2023; 70194, exp. date 11/24/2023; 70195, exp. date		

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			11/24/2023; 70196, exp. date 11/24/2023; 70197, exp. date 11/24/2023; 70198, exp. date 11/24/2023; 70211, exp. date 11/25/2023; 70212, exp. date 11/25/2023; 70213, exp. date 11/25/2023; 70214, exp. date 11/25/2023; 70220, exp. date 11/25/2023; 70229, exp. date 11/28/2023; 70231, exp. date 11/28/2023; 70232, exp. date 11/28/2023; 70234, exp. date 11/28/2023; 70254, exp. date 11/29/2023; 70255, exp. date 11/29/2023; 70256, exp. date		

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			11/29/2023; 70257, exp. date 11/29/2023; 70261, exp. date 11/29/2023; 70262, exp. date 11/29/2023; 70263, exp. date 11/29/2023; 70264, exp. date 11/30/2023; 70265, exp. date 12/1/2023; 70314, exp. date 12/1/2023; 70315, exp. date 12/1/2023; 70324, exp. date 12/7/2023; 70325, exp. date 12/2/2023; 70326, exp. date 12/2/2023; 70339, exp. date 12/7/2023; 70340, exp. date 12/15/2023; 70358, exp. date 12/5/2023; 70397, exp. date 12/6/2023; 70398, exp. date 12/6/2023; 70399, exp. date 12/6/2023; 70445, exp. date 12/7/2023;		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			70462, exp. date 12/8/2023; 70463, exp. date 12/8/2023; 70465, exp. date 12/8/2023; 70466, exp. date 12/8/2023; 70467, exp. date 12/8/2023; 70494, exp. date 12/9/2023; 70495, exp. date 12/9/2023; 70497, exp. date 12/9/2023; 70523, exp. date 12/12/2023; 70544, exp. date 12/13/2023; 70549, exp. date 12/13/2023; 70552, exp. date 12/13/2023; 70553, exp. date 12/13/2023; 70571, exp. date 12/14/2023; 70572, exp. date 12/14/2023; 70573, exp. date 12/14/2023; 70585, exp. date 12/14/2023; 70605,		

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			exp. date 12/15/2023; 70606, exp. date 12/15/2023; 70608, exp. date 12/15/2023; 70609, exp. date 12/15/2023; 70635, exp. date 12/16/2023; 70636, exp. date 12/16/2023; 70660, exp. date 12/19/2023; 70661, exp. date 12/19/2023; 70662, exp. date 12/19/2023; 70663, exp. date 12/19/2023; 70672, exp. date 12/20/2023; 70693, exp. date 12/20/2023; 70694, exp. date 12/20/2023; 70695, exp. date 12/20/2023; 70696, exp. date 12/20/2023; 70702,		

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			exp. date 12/20/2023; 70727, exp. date 12/21/2023; 70728, exp. date 12/21/2023; 70729, exp. date 12/21/2023; 70730, exp. date 12/21/2023; 70731, exp. date 12/21/2023; 70759, exp. date 12/22/2023; 70760, exp. date 12/22/2023; 70762, exp. date 12/22/2023; 70763, exp. date 12/22/2023; 70786, exp. date 12/23/2023; 70787, exp. date 12/26/2023; 70788, exp. date 12/23/2023; 70789, exp. date 12/23/2023; 70790, exp. date 12/26/2023; 70791,		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			exp. date 12/23/2023; 70832, exp. date 1/4/2024; 70835, exp. date 12/26/2023; 70851, exp. date 1/4/2024; 70852, exp. date 12/27/2023; 70860, exp. date 12/27/2023; 70871, exp. date 12/28/2023; 70874, exp. date 12/28/2023 68622 Exp. Date 10/3/2023 68699 Exp. Date 10/6/2023 68704 Exp. Date 10/6/2023 68706 Exp. Date 10/6/2023 68726 Exp. Date 10/7/2023 68740 Exp. Date 10/7/2023 68784 Exp. Date 10/11/2023 68647 Exp. Date 10/10/2023 68843 Exp. Date 10/13/2023 68891 Exp. Date 10/14/2023 68980 Exp. Date 10/18/2023 68983		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			Exp. Date 10/21/2023 69042 Exp. Date 10/21/2023 69077 Exp. Date 10/26/2023 69793 Exp. Date 11/4/2023 69796 Exp. Date 11/9/2023 69872 Exp. Date 11/9/2023 69928 Exp. Date 11/11/2023 69950 Exp. Date 11/11/2023 69988 Exp. Date 11/15/2023 69963 Exp. Date 11/16/2023 70163 Exp. Date 11/23/2023 70167 Exp. Date 11/23/2023 70191 Exp. Date 11/24/2023 70197 Exp. Date 11/24/2023 70208 Exp. Date 11/25/2023 70214 Exp. Date 11/25/2023 70220 Exp. Date 11/25/2023 70277 Exp. Date 11/29/2023 70291 Exp. Date 11/30/2023 70300 Exp. Date 11/30/2023 70333		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			Exp. Date 12/2/2023 70338 Exp. Date 12/2/2023 70341 Exp. Date 12/2/2023 70399 Exp. Date 12/6/2023 70409 Exp. Date 12/6/2023 70410 Exp. Date 12/6/2023 70462 Exp. Date 12/8/2023 70493 Exp. Date 12/9/2023 70494 Exp. Date 12/9/2023 70497 Exp. Date 12/9/2023 70501 Exp. Date 12/9/2023 70419 Exp. Date 12/12/2023 70514 Exp. Date 12/12/2023 70523 Exp. Date 12/12/2023 70552 Exp. Date 12/13/2023 70503 Exp. Date 12/14/2023 70605 Exp. Date 12/15/2023 70607 Exp. Date 12/15/2023 70619 Exp. Date 12/15/2023 70636 Exp. Date 12/16/2023 70731		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			Exp. Date 12/21/2023 70744 Exp. Date 12/21/2023 70760 Exp. Date 12/22/2023 70762 Exp. Date 12/22/2023 70789 Exp. Date 12/23/2023 70833 Exp. Date 12/27/2023 70868 Exp. Date 12/28/2023 70869 Exp. Date 12/28/2023 70870 Exp. Date 12/28/2023 68890 Exp. Date 10/14/2023 69012 Exp. Date 10/20/2023 70093 Exp. Date 11/18/2023 70275 Exp. Date 11/29/2023 70259 Exp. Date 12/1/2023 70299 Exp. Date 12/1/2023 70406 Exp. Date 12/6/2023 70450 Exp. Date 12/7/2023 70613 Exp. Date 12/15/2023 70422 Exp. Date 12/9/2023 70569 Exp. Date 12/14/2023		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Vancomycin 1 MG/0.1 ML Solution for Intraocular Injection, 0.8 ML Single Dose Vial, Rx only, Compounded by: Pine Pharmaceuticals 355 Riverwalk Parkway, Tonawanda, NY 14150.	Class II	Drugs	Lot #: 69985, exp. date 11/15/2023	Lack of Assurance of Sterility	Pine Pharmaceuticals, LLC
Endophth Kit (Vancomycin 1mg/0.1 mL - Ceftazidime 2.25mg/0.1 mL), Rx only, Compounded by Pine Pharmaceuticals 355 Riverwalk Parkway, Tonawanda, NY 14150.	Class II	Drugs	Lot #: 69986, Exp. Date 11/15/2023	Lack of Assurance of Sterility	Pine Pharmaceuticals, LLC
Calcium Gluconate Ophthalmic Irrigation Solution 1%, 500 mL bags, Rx only, Compounded by Pine Pharmaceuticals 355 Riverwalk Parkway, Tonawanda, NY 14150.	Class II	Drugs	Lot #: 69802, Exp. Date 02/28/2024	Lack of Assurance of Sterility	Pine Pharmaceuticals, LLC
Calcium Gluconate 2.5% solution for inhalation, 5mL pre-filled syringes, Rx only, Compounded by Pine Pharmaceuticals 355 Riverwalk Parkway, Tonawanda, NY 14150.	Class II	Drugs	Lot #: 70363, Exp. Date 03/20/2024	Lack of Assurance of Sterility	Pine Pharmaceuticals, LLC
Tropi-Phen (Tropicamide 1% phenylephrine HCl 2.5%) ophthalmic solution, 15 mL multi-use Droppers, Rx only, Compounded by Pine Pharmaceuticals 355 Riverwalk Parkway, Tonawanda, NY 14150.	Class II	Drugs	Lot #: 67008, Exp. Date 10/04/2023; 67685, Exp. Date 10/21/2023; 67853, Exp. Date 10/25/2023; 69967, Exp. Date 01/13/2024	Lack of Assurance of Sterility	Pine Pharmaceuticals, LLC
Moxifloxacin in Balanced Salt Solution, Solution for Intraocular Injection, 600 mcg/0.4mL (150 mcg/0.1mL) Syringe, Rx only, Compounded by: Pine Pharmaceuticals 355 Riverwalk Parkway, Tonawanda, NY 14150.	Class II	Drugs	Lot #: 67480, Exp. Date 10/9/2023; 68640,Exp. Date 12/3/2023; 68769, Exp. Date 12/9/2023; 68760, Exp. Date 12/10/2023; 68925,	Lack of Assurance of Sterility	Pine Pharmaceuticals, LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			Exp. Date 12/16/2023;70119, Exp. Date 1/20/2024		
Cefuroxime 4mg /0.4 mL (10 mg/mL), 1mL syringe, Rx only, Compounded by: Pine Pharmaceuticals 355 Riverwalk Parkway, Tonawanda, NY 14150.	Class II	Drugs	Lot #: 67918, Exp. Date 10/29/2023; 68033, Exp. Date 11/4/2023; 68515, Exp. Date 11/26/2023; 68528, Exp. Date 11/27/2023; 68618, Exp. Date 12/2/2023; 68651, Exp. Date 12/3/2023; 68767, Exp. Date 12/9/2023; 68829, Exp. Date 12/11/2023; 69820, Exp. Date 1/9/2024; 70733, Exp. Date 2/19/2024; 71068, Exp. Date 3/9/2024; 67345, Exp. Date 10/3/2023	Lack of Assurance of Sterility	Pine Pharmaceuticals, LLC
Moxifloxacin in Balanced Salt Solution 400 mcg/0.4 mL (100 mcg/0.1 mL) 1 mL syringes, Rx only, Compounded by: Pine Pharmaceuticals 355 Riverwalk Parkway, Tonawanda, NY 14150.	Class II	Drugs	Lot #: 67623, Exp. Date 10/15/2023; 67919, Exp. Date 10/29/2023; 68917, Exp. Date 12/16/2023; 69079, Exp. Date 12/23/2023; 69120, Exp. Date 12/24/2023	Lack of Assurance of Sterility	Pine Pharmaceuticals, LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Lidocaine-phenylephrine 1%-1.5% 1mL Single Dose Vial, Rx only, Compounded by Pine Pharmaceuticals 355 Riverwalk Parkway, Tonawanda, NY 14150.	Class II	Drugs	Lot #: 67849, Exp. Date 10/25/2023; 67887, Exp. Date 10/28/2023; 68260, Exp. Date 11/14/2023; 68534, Exp. Date 11/27/2023; 68816, Exp. Date 12/12/2023; 69046, Exp. Date 12/20/2023; 69971, Exp. Date 1/13/2024	Lack of Assurance of Sterility	Pine Pharmaceuticals, LLC
TPC Drops (tropicamide 1%- phenylephrine 2.5%- cyclopentolate HCl 1% ophthalmic solution, 5 mL droppers, Rx only, Compounded by Pine Pharmaceuticals 355 Riverwalk Parkway, Tonawanda, NY 14150.	Class II	Drugs	Lot #: 68184, Exp. Date 10/9/2023; 68623, Exp. Date 11/2/2023	Lack of Assurance of Sterility	Pine Pharmaceuticals, LLC
Calcium chloride Solution for Intravenous Injection, 20 mg/mL, 500 mL bags, Rx only, Compounded by Pine Pharmaceuticals 355 Riverwalk Parkway, Tonawanda, NY 14150.	Class II	Drugs	Lot #: 70101, Exp. Date 1/17/2024	Lack of Assurance of Sterility	Pine Pharmaceuticals, LLC
Lidocaine HCl 4% ophthalmic solution, 3 mL single-use dropper, Rx only, Compounded by Pine Pharmaceuticals 355 Riverwalk Parkway, Tonawanda, NY 14150.	Class II	Drugs	Lot #: 67443, Exp. Date 10/8/2023; 68775, Exp. Date 12/9/2023	Lack of Assurance of Sterility	Pine Pharmaceuticals, LLC
Tropi-Phen (tropicamide 1%, phenylephrine 2.5%) ophthalmic solution, 5mL multi-use dropper, Rx only, Compounded by Pine Pharmaceuticals 355 Riverwalk Parkway, Tonawanda, NY 14150.	Class II	Drugs	Lot #: 67659, Exp. Date 10/16/2023; 70316, Exp. Date 1/30/2024	Lack of Assurance of Sterility	Pine Pharmaceuticals, LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Lidocaine HCL 2% and Oxymetazoline HCl 0.025% Solution for intranasal administration, 2 mL syringes, Rx only, Compounded by Pine Pharmaceuticals 355 Riverwalk Parkway, Tonawanda, NY 14150.	Class II	Drugs	Lot #: 67808, Exp. Date 10/23/2023	Lack of Assurance of Sterility	Pine Pharmaceuticals, LLC
Foscarnet Sodium 2.4mg/0.1 mL solution for injection, 0.2 mL single-dose Staclear Luer Slip Syringe, Rx only, Compounded by Pine Pharmaceuticals 355 Riverwalk Parkway, Tonawanda, NY 14150.	Class II	Drugs	Lot #: 68680, Exp. Date 12/4/2023	Lack of Assurance of Sterility	Pine Pharmaceuticals, LLC
Certain Over-The-Counter (OTC) drug products sold by Family Dollar retail stores.	Class II	Drugs	Certain drug products sold by Family Dollar retail stores located in AL, AR, AZ, CA, CO, FL, GA, ID, KS, LA, MS, MT, ND, NE, NM, NV, OK, OR, SD, TX, UT, WA, and WY.	CGMP Deviations: OTC products were stored outside of labeled temperature requirements.	Dollar Tree Distribution, Inc.
Doxil (doxorubicin hydrochloride liposome injection) 50 mg in 25 mL (2 mg/mL), Single-Dose Vial, Rx only, Manufactured for: Baxter Healthcare Corporation, Deerfield, IL 60015. NDC 0338-0067-01	Class II	Drugs	Lot# MKZSU02, Exp 6/30/2024	CGMP Deviations: Product was exposed to temperatures exceeding the labeled storage conditions during transportation were released by mistake.	Baxter Healthcare Corporation
Clearasil Rapid Rescue Deep Treatment Pads (Salicylic Acid 2%), packaged in 90-count plastic jar, further packaged in case of 6 jars per case, Distributed by RB Health (US), Parsippany, NJ 07054, NDC 63824-431-90	Class III	Drugs	Lot # KT220211, Exp 07/2024	Labeling: Label Error on Declared Strength: The incorrect label on the back of the product packaging.	RB Health (US) LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Eligard (leuprolide acetate) for injectable suspension, 7.5 mg every month, Sterile, Rx Only, Must be reconstituted before use, NDC 62935-753-75, Manufactured by: Tolmar Inc., Fort Collins, CO 80526, For Tolmar Therapeutics Inc., Fort Collins, CO 80526.	Class III	Drugs	Lot: 13635A1, Exp. 07/31/2024	Superpotent Drug - Higher than expected levels of leuprolide acetate in the constituted product.	Tolmar, Inc.
HydrALAZINE Hydrochloride Tablets, USP, 10 mg, 100 Tablets (10 x 10) per carton, Rx Only, Distributed by: American Health Packaging, Columbus, Ohio 43217. Carton NDC#: 68084-447-01; Individual Dose NDC: 68084-447-11	Class III	Drugs	Lot#: 1007002, Exp 12/31/2023	Failed Impurities/Degradation Specifications: Out of Specification results in the repackaged product for impurities at the 12-month time point.	Amerisource Health Services LLC
Epinephrine-Lidocaine HCl (0.25mg/mL and 7.5mg/mL) 1mL Single Use Intraocular injection Preservative Free NDC 71384-640-01 Not for resale. Office use only. Lot: 23APR018 Date Compounded: 24APR2023 Expires on: 17APR2024. In case of adverse event contact: www.fda.gov/medwatch or (800)-FDA-1088 Imprimis NJOF, LLC. 1705 Route 46 West, Unit 6B, Ledgewood, NJ, 07852 (844) 446-6979	Class III	Drugs	23APR018	Subpotent: Failing Test Results for Epinephrine	Imprimis NJOF, LLC
MYDRIATIC-4: Tropicamide - Proparacaine - Phenylephrine - Ketorolac Sterile Ophthalmic Solution Drops 1% - 0.5% - 2.5% - 0.5%, 5mL bottle, Imprimis, NJOF, 1705 Route 46 West, Unit 6B, Ledgewood, NJ 07852 (844)-446-6979, NDC:71384-632-05	Class III	Drugs	Lot#s: 22DEC065 (MDU), exp: 09/29/2023; 23JAN024 (MDU), exp: 10/13/2023; 23FEB024 (SDU), exp: 11/09/2023; 23MAR013 (SDU),	Subpotent: Out of Specification result observed for Ketorolac assay levels, below the 90.0-110.0% of label claim.	Imprimis NJOF, LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			exp: 12/01/2023; 23MAR033 (SDU), exp: 12/16/2023; 23MAY044 (SDU), exp: 03/23/2024;		
Bupropion Hydrochloride Extended-Release Tablets USP (SR), 150 mg, 60 tablets 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 47335-737-86	Class III	Drugs	Lot #: HAD0360A, Exp. 12/2023	Failed Dissolution Specifications	SUN PHARMACEUTICAL INDUSTRIES INC

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

CURRENT DRUG SHORTAGES

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

Generic Name or Active Ingredient

Albuterol Sulfate 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
Bazedoxifene Acetate, Estrogens, Conjugated Tablet, Film Coated
Bumetanide Injection
Bupivacaine Hydrochloride Injection
Bupivacaine Hydrochloride, Epinephrine Bitartrate Injection, Solution
Capecitabine Tablet
Carboplatin Injection, Solution
Cefixime Capsule
Cefotaxime Sodium Injection
Cefotetan Disodium Injection
Chloramphenicol Sodium Succinate Injection
Chloroprocaine Hydrochloride Injection
Cisplatin Injection
Clindaymycin Phosphate Injection
Clonazepam Tablet
Collagenase Clostridium Histolyticum Ointment
Conivaptan Hydrochloride Injection
Cyclopentolate Hydrochloride Ophthalmic Solution
Cyclopentolate Hydrochloride, Phenylephrine 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
Diazepam Gel
Difluprednate Emulsion

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
Erythromycin Ointment
Etomidate Injection
Fentanyl Citrate Injection
Fluconazole Injection
Fludarabine Phosphate Injection
Fluorescein Sodium Injection
Flurazepam Hydrochloride Capsule
Furosemide Injection
Gentamicin Sulfate Injection
Heparin Sodium Injection
Hydrocortisone Sodium Succinate Injection
Hydromorphone Hydrochloride Injection
Hydroxypropyl Cellulose (1600000 Wamw) Insert
I.V. Fat Emulsion
Indigotindisulfonate Sodium Injection
Isoniazid Tablet
Ketamine Hydrochloride Injection
Ketorolac Tromethamine Injection
Ketorolac Tromethamine Tablet, Film Coated
Leucovorin Calcium Injection
Lidocaine Hydrochloride Injection
Lidocaine Hydrochloride Solution
Liraglutide Injection
LISDEXAMFETAMINE DIMESYLATE CAPSULE
Lisdexamfetamine Dimesylate Tablet, Chewable
Lorazepam Injection
Mannitol Injection
Mepivacaine Hydrochloride Injection
Methamphetamine Hydrochloride Tablet
Methotrexate Sodium Injection
Methotrexate Sodium Tablet
Methyldopa Tablet, Film Coated
Methylphenidate Hydrochloride Tablet, Extended Release
Methylprednisolone Acetate Injection
Metronidazole Injection
Midazolam Hydrochloride Injection

Morphine Sulfate Injection
Multi-Vitamin Infusion (Adult and Pediatric) Injection
Neomycin Sulfate Tablet
Nitroglycerin Injectable
Nizatidine Capsule
Oxybutynin Chloride Syrup
Parathyroid Hormone Injection
Penicillin G Benzathine Injection
Potassium Acetate Injection
Potassium Chloride Injection
Quinapril Hydrochloride Tablet
Quinapril/Hydrochlorothiazide Tablet
Remifentanil Hydrochloride Injection
Rifampin Capsule
Rifampin Injection
Rifapentine Tablet, Film Coated
Rocuronium Bromide Injection
Rocuronium Bromide Injection, Solution
Rocuronium Bromide Solution
Ropivacaine Hydrochloride Injection
Semaglutide Injection
Sodium Acetate Injection
Sodium Bicarbonate Injection
Sodium Chloride 0.9% Injection
Sodium Chloride 14.6% Injection
Sodium Chloride 23.4% Injection
Sodium Chloride Injection
Sodium Chloride Irrigant
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
Tirzepatide Injection
Triamcinolone Acetonide Injection
Triamcinolone Hexacetonide Injection
Trimethobenzamide Hydrochloride Capsule
Valproate Sodium Injection
Vecuronium Bromide Injection
Vinblastine Sulfate Injection