PERFORMRx℠

Drug Information Update

May 2024

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NEWLY AVAILABLE GENERICS

Generic Name/ Dosage Form	Brand Name	Manufacturer	Indication
estradiol 0.06% topical gel	EstroGel	Solaris Pharma	• Treatment of moderate to severe vasomotor symptoms due to menopause • Treatment of moderate to severe symptoms of vulvar and vaginal atrophy due to menopause
mirabegron 25 mg, 50 mg extended-release oral tablets	Myrbetriq	Lupin Pharmaceuticals, Zydus Pharmaceuticals	• Treatment of overactive bladder (OAB) in adult patients with symptoms of urge urinary incontinence, urgency, and urinary frequency, either alone or in combination with the muscarinic antagonist solifenacin succinate • Treatment of neurogenic detrusor overactivity (NDO) in pediatric patients aged 3 years and older and weighing 35 kg or more

NEW DRUG ENTITIES/STRENGTHS/COMBINATIONS

Drug Name	Generic Name	Description
Xcopri oral tablet 25 mg	Cenobamate	New strength
Adalimumab-ryvk (2 pen) subcutaneous auto-injector kit 40 mg/0.4ml	Adalimumab-ryvk	Humira biosimilar. Privately labeled version of Simlandi from Evernorth Health Services, which is part of The Cigna Group. Only available in high concentration strengths.
Libervant buccal film 5, 7.5, 10, 12.5, 15 mg	Diazepam	New dosage form. 505(b)(2) approval. Indicated for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy between 2 to 5 years of age.
Anktiva intravesical solution 400 mcg/0.4ml	Nogapendekin alfa inbakic-pmln	New entity. Indicated with Bacillus Calmette-Guérin (BCG) for the treatment of patients with BCG-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS), with or without papillary tumors. First-in-class interleukin (IL)-15 superagonist complex consisting of an IL-15 mutant (IL-15N72D) fused with an IL-15 receptor alpha. Will compete with Keytruda (pembrolizumab) and Adstiladrin (nadofaragene firadenovec-vncg).
Ojemda oral tablet 100 mg Ojemda oral suspension reconstituted 25 mg/ml	Tovorafenib	New entity. Indicated for the treatment of patients 6 months of age and older with relapsed or refractory pediatric low-grade glioma (pLGG) harboring a BRAF fusion or rearrangement, or BRAF V600 mutation. Accelerated approval based on response rate and duration of response. Second therapy approved for BRAF V600E-mutated pLGG. Will compete directly with Mekinist (trametinib) + Tafinlar (dabrafenib), which received approval for the treatment of pLGG with BRAF V600E mutations in March 2023.
Micafungin sodium-nacl intravenous solution 50-0.9 mg/50ml-%	Micafungin	New strength. Indicated for Candidemia and Candidiasis infections for inpatient use.

Drug Name	Generic Name	Description
Micafungin sodium-nacl intravenous solution 100-0.9 mg/100ml-%		
Cyltezo (2 syringe) subcutaneous prefilled syringe kit 40 mg/0.4ml Cyltezo (2 pen) subcutaneous auto-injector kit 40 mg/0.4ml	Adalimumab-adbm	New strength. New high concentration strength of Humira biosimilar. Previously only available in low concentration strengths. Unlike the low concentration strengths which are interchangeable, the high concentration strengths of Cyltezo are currently not interchangeable.
Adalimumab-adbm (2 syringe) subcutaneous prefilled syringe kit 40 mg/0.4ml Adalimumab-adbm (2 pen) subcutaneous auto-injector kit 40 mg/0.4ml	Adalimumab-adbm	New strength. New high concentration strength of Humira biosimilar. Unbranded version of Cyltezo. Previously only available in low concentration strengths. Unlike the low concentration strengths which are interchangeable, the high concentration strengths of Cyltezo are currently not interchangeable.
Tofidence intravenous solution 80 mg/4ml, 200 mg/10ml, 400 mg/20ml	Tocilizumab-bavi	Actemra biosimilar. Second Actemra biosimilar to hit the market. Is approved for only a subset of Actemra's indications, specifically, rheumatoid arthritis (RA) in adults, polyarticular juvenile idiopathic arthritis (PJIA) in patients 2 years of age and older, and systemic juvenile idiopathic arthritis (SJIA) in patients 2 years of age and older. Actemra also has indications for giant cell arteritis (GCA), systemic sclerosis-associated interstitial lung disease (SSc-ILD), cytokine release syndrome (CRS), and coronavirus disease 2019 (COVID-19).
Ingrezza oral capsule sprinkle 40 mg, 60 mg, 80 mg	Valbenazine	New dosage form. Previously only available as regular capsules.
Rextovy nasal liquid 4 mg/0.25ml	Naloxone	505(b)(2) approval. Alternative naloxone nasal spray.

Drug Name	Generic Name	Description
Xolremdi oral capsule 100 mg	Mavorixafor	New entity. Selective CXC chemokine receptor 4 (CXCR4) antagonist indicated for use in patients 12 years of age and older with warts, hypogammaglobulinemia, infections, and myelokathexis (WHIM) syndrome to increase the number of circulating mature neutrophils and lymphocytes. First FDA-approved treatment specifically indicated in patients with WHIM syndrome.
Omvoh subcutaneous solution prefilled syringe 100 mg/ml	Mirikizumab-mrkz	New dosage form. Indicated for the treatment of moderately to severely active ulcerative colitis in adults. Previously available as a 300 mg/15 ml intravenous vial and 100 mg/ml subcutaneous pen.
Beqvez intravenous suspension therapy pack 4 x 1 ml, 5 x 1 ml, 6 x 1 ml, 7 x 1 ml	Fidanacogene elaparvovec-dzkt	New entity. One-time gene therapy for the treatment of moderate to severe hemophilia B among adult patients who currently use factor IX prophylaxis therapy, have current or historical life-threatening hemorrhage, or have repeated, serious spontaneous bleeding episodes, and do not have neutralizing antibodies to adeno-associated virus serotype Rh74var (AAVRh74var) capsid as detected by an FDA-approved test. Second gene therapy approved for hemophilia B, after Hemgenix (etranacogene dezaparvovec-drlb), which was approved in November 2022.
Fasenra subcutaneous solution prefilled syringe 10 mg/0.5ml	Benralizumab	New strength. Previously only available as a 30 mg/ml subcutaneous syringe and auto-injector. Intended for new age expansion in pediatric patients 6 to 11 years of age.

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†
Tivdak	tisotumab vedotin-tftv 40 mg intravenous vial	Seagen Inc.	• Treatment of adult patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy ~~This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.~~
Otezla	apremilast 10 mg, 20 mg, 30 mg oral tablets	Amgen	Inhibitor of phosphodiesterase 4 (PDE4) that is indicated for the treatment of: • Adult patients with active psoriatic arthritis • Adult patients with plaque psoriasis who are candidates for phototherapy or systemic therapy • **Pediatric patients 6 years of age and older and weighing at least 20 kg with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy** • Adult patients with oral ulcers associated with Behçet's Disease

RECALLS

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Spanish Fly 22K capsules, 2-count box, UPC 0 664979 979455	Class I	Drugs	All lots	Marketed without an approved NDA/ANDA: Products found to contain undeclared sildenafil and/or tadalafil.	Pyramids Wholesale Inc.
Weiner Boner Honey, 12g packet, 100% Organic Formula.	Class I	Drugs	All lots	Marketed without an approved NDA/ANDA: Products found to contain undeclared sildenafil and/or tadalafil.	Pyramids Wholesale Inc.
Flower Power, CBD infused Female Enhancement, 59 ml bottle, UPC 0 678741 351646.	Class I	Drugs	All lots	Marketed without an approved NDA/ANDA: Products found to contain undeclared sildenafil and/or tadalafil.	Pyramids Wholesale Inc.
Samurai-X Honey 6800, UPC 2 56891 27553 3.	Class I	Drugs	All lots	Marketed without an approved NDA/ANDA: Products found to contain undeclared sildenafil and/or tadalafil.	Pyramids Wholesale Inc.
Pink Pussycat Honey, net wt: 20gx12 sachets, UPC 7 918750 046557	Class I	Drugs	All Lots	Marketed without an approved NDA/ANDA: Products found to contain undeclared sildenafil and/or tadalafil.	Pyramids Wholesale Inc.
GoHARD 25000, Male Sexual Enhancement, Honey, 100% Natural, UPC: N/A.	Class I	Drugs	All lots	Marketed without an approved NDA/ANDA:	Pyramids Wholesale Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
				Products found to contain undeclared sildenafil and/or tadalafil.	
libigrow RED DRAGON+, Maximum Strength Formula, 2 capsules per box, UPC 7 05105 83073 5.	Class I	Drugs	All lots	Marketed without an approved NDA/ANDA: Products found to contain undeclared sildenafil and/or tadalafil.	Pyramids Wholesale Inc.
SILVERBACK XXX POWER MALE ENHANCEMENT, 2 fl. oz., UPC 8 700470 032762	Class I	Drugs	All lots	Marketed without an approved NDA/ANDA: Products found to contain undeclared sildenafil and/or tadalafil.	Pyramids Wholesale Inc.
The GOAT SUBLINGUAL STRIP, MALE ENHANCEMENT, 2 Pack, Distributed by Hombres LLC, 130 Maccormick Ave, Suite 105, Costa Mesa, A, UPC 6 61631 26363 1.	Class I	Drugs	All lots	Marketed without an approved NDA/ANDA: Products found to contain undeclared sildenafil and/or tadalafil.	Pyramids Wholesale Inc.
ALPHASTRIP MALE PERFORMANCE ENHANCER, The fastest acting sublingual, Serving Size (1 strip), Distributed by: GALT INT'L	Class I	Drugs	All lots	Marketed without an approved NDA/ANDA: Products found to contain undeclared sildenafil and/or tadalafil.	Pyramids Wholesale Inc.
HONEY MANUKA BUNNY LOVE, 12g, All Natural Sexual Enhancement, UPC: N/A	Class I	Drugs	All lots	Marketed without an approved NDA/ANDA: Products found to contain undeclared sildenafil and/or tadalafil.	Pyramids Wholesale Inc.
Alcoholada Gel, Pain Relieving Gel, 0.5% Lidocaine Hydrochloride, packaged in (a) 8.5 fl	Class I	Drugs	Lot, expiry: (a) 25253, Exp 5/1/2024; 25976,	Chemical Contamination: Product manufactured with	Aruba Aloe Balm N.V.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
oz (251 mL) plastic bottle UPC 0 82252 03120 9 (b) 2.2 fl oz (65 mL) plastic bottle, UPC 0 82252 34030 1 , Manufactured in Aruba by Aruba Aloe Balm Inc., Pitastraat 115, Aruba, Dutch Caribbean.			Exp 8/11/2024; 26150, Exp 9/11/2024; 26473, Exp 11/25/2024; 26553, Exp 12/11/2024; 27318, Exp 5/10/2025; 27481, Exp 6/15/2025; 27660, Exp 7/15/2025; 27839, Exp 8/5/2025; 28121, Exp 10/7/2025; 28152, Exp 10/18/2025; 28355, Exp 12/17/2025; 28761, Exp 2/22/2026; 29088, Exp 4/1/2026; 29510, Exp 5/11/2026; 29558, Exp 5/13/2026; 29728, Exp 6/3/2026; 30339, Exp 9/13/2026; 30563, Exp 10/27/2026. (b) 25253, Exp 5/1/2024; 25976, Exp 8/11/2024; 26150, Exp 9/11/2024; 26553, Exp	ethanol API that contains methanol	

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			12/11/2024; 26696, Exp 1/8/2025; 27318, Exp 5/10/2025; 27481, Exp 6/15/2025; 27660, Exp 7/15/2025; 27839, Exp 8/5/2025; 28281, Exp 11/30/2025; 28355, Exp 12/17/2025; 28761, Exp 2/22/2026; 29088, Exp 4/1/2026; 29728, Exp 6/3/2026; 30086, Exp 7/26/2026; 30339, Exp 9/13/2026; 30563, Exp 10/27/2026.		
Aruba Aloe Hand Sanitizer Gel, 80% Alcohol, 12 fl oz (355 mL) plastic bottle, Manufactured in Aruba by Aruba Aloe Balm Inc., Pitastraat 115, Aruba, Dutch Caribbean. UPC 0 82252 03300 5	Class I	Drugs	Lot #: 25160, Exp 4/16/2024; 25344, Exp 5/20/2024, 25580, Exp 6/15/2024; 25828, Exp 7/28/2024; 26057, Exp 8/25/2024; 26195, Exp 9/18/2024; 26471, Exp 11/25/2024; 26754, Exp 1/20/2025;	Chemical Contamination: Product manufactured with ethanol API that contains methanol	Aruba Aloe Balm N.V.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			26821, Exp 2/2/2025; 27005, Exp 3/11/2025; 27518, Exp 6/22/2025; 27927, Exp 8/26/2025; 28176, Exp 10/22/2025; 28392, Exp 12/31/2025.		
ForeverMen Natural Energy Boost Capsules, packaged in a box containing a 10-count blister card.	Class I	Drugs	All lots within expiry	Marketed Without an Approved NDA/ANDA: Product was found to contain undeclared sildenafil, an ingredient found in FDA approved products for the treatment of male sexual enhancement, making this unapproved drug.	FA Online Inc
Javygtor (sapropterin dihydrochloride) Powder for Oral Solution 100mg, 30 individual packets per carton, Rx Only, Distributor: Dr. Reddy's Laboratories Inc., Princeton, NJ 08540 Made in India, NDC 43598-097-30.	Class I	Drugs	Lot #: T2202812, Exp. 07/31/2025; T2204053, Exp. 10/31/2025; T2300975, T2300976, Exp. 02/28/2026; T2304356, Exp. 08/31/2026.	Sub-potent Drug; powder discoloration associated with decreased potency	Dr. Reddy's Laboratories, Inc.
Sapropterin Dihydrochloride Powder for Oral Solution 100mg, 30 individual packets per carton, Rx Only, Distributor: Dr. Reddy's	Class I	Drugs	Lot # T2200352, Exp. 12/31/2024	Sub-potent Drug; powder discoloration associated with decreased potency	Dr. Reddy's Laboratories, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Laboratories Inc., Princeton, NJ 08540, Made in India, NDC 43598-477-30.					
Schwinnng Herbal Dietary Supplement Capsules, packaged in 10-count boxes, distributed by VSD Productions Inc., Las Vegas, NV.	Class I	Drugs	Lot 2108; EXP 10/31/2024	Marketed Without An Approved NDA/ANDA	Stop Clopez Corp
Ipratropium Bromide and Albuterol Sulfate Inhalation Solution USP, 0.5 mg & 3mg/3mL unit-dose vials, packaged in carton containing 30 vials (6 pouches of 5 - 3 mL vials), Rx only, Manufactured by: Cipla Ltd., Indore SEZ, Pithampur, India, Manufactured for: Cipla USA, Inc., 10 Independence Boulevard, Suite 300, Warren, NJ 07059, NDC 69097-173-53	Class II	Drugs	Lot # IA30390, Exp 4/30/2025, IA30517, Exp 6/30/ 2025	Short fill: Complaints received of less fill volume in respule and few drops of liquid observed in the intact pouch.	Cipla USA, Inc.
Eyesaline, Saline Eyewash Solution, Cartridge for Fendall 2000, Net contents: 7.9 gal per cartridge, Sperian Eye & Face Protection, Inc., 825 East Highway 151, Platteville, WI 53818. NDC: 0498-0631-37	Class II	Drugs	Manufacturer's Product Number/ Catalog Number: 32-002050-0000; Exp 06/21/2025	CGMP Deviations	HONEYWELL INC
Diltiazem Hydrochloride Extended-Release Capsules, USP 120 mg, Twice-a-Day Dosage, 100 Capsules per bottle, Rx Only, Manufactured for: Glenmark Pharmaceuticals Inc., USA Mahwah, NJ, 07430, Product of India, NDC 68462-562-01.	Class II	Drugs	Lot #: 17221312, Exp. 5/31/2024	Failed Dissolution Specifications	Glenmark Pharmaceuticals Inc., USA
Cloderm (clocortolone pivalate) Cream, 0.1%, Rx Only, For Topical Use Only, Net Wt 45g, Manufactured for: EPI Health, LLC, Charleston, SC 29403, NDC 71403-804-90	Class II	Drugs	lot SDFC- exp. 5/31/2024 lot TFBW- exp. 5/31/2025	CGMP Deviation: Discontinuation of the Quality program by manufacturer that would assure product meet the identity, strength, quality,	EPI Health, LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
				and purity characteristics that they are purported or represented to possess.	
minolira (minocycline hydrochloride) extended-release tablets, 105mg 30-count Bottle, Rx Only, Mfg by: Dr Reddy's Laboratories Limited, INDIA, Manufactured for: EPI Health, LLC, Charleston, SC 29403, NDC 71403-101-30.	Class II	Drugs	lot # T2300765- exp. 11/30/2025 lot# T2201702A-exp. 02/28/2025 lot# T2201699- exp. 2/28/2025 lot# T2201698- exp. 2/28/2025	CGMP Deviation: Discontinuation of the Quality program by manufacturer that would assure product meet the identity, strength, quality, and purity characteristics that they are purported or represented to possess.	EPI Health, LLC
minolira (minocycline hydrochloride) extended-release tablets, 135mg 30-count Bottle, Rx Only, Mfg by: Dr Reddy's Laboratories Limited, INDIA, Manufactured for: EPI Health, LLC, Charleston, SC 29403, NDC 71403-102-30.	Class II	Drugs	lot# T2201700- exp. 02/28/2025 lot# T2201701- exp. 02/28/2025	CGMP Deviation: Discontinuation of the Quality program by manufacturer that would assure product meet the identity, strength, quality, and purity characteristics that they are purported or represented to possess.	EPI Health, LLC
GloStrips, Fluorescein Sodium Ophthalmic Strips USP (0.6 mg Fluorescein), Rx Only, a) 100 strips per carton, NDC 51801-003-40; b) 300 strips per carton, NDC 51801-003-50, Nomax, Inc., St. Louis, MO 63123.	Class II	Drugs	Lot #s: a) 14904, Exp. 06/30/2024; Lot 14938, Exp. 07/31/2024; b) Lot 14931, Exp. 06/30/2024	Failed Impurities/Degradation Specifications: The Active Pharmaceutical Ingredient (API) used in the product is not being manufactured to the current USP monograph in regard to Unspecified Impurities.	Nomax Inc

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
GloStrips, Fluorescein Sodium Ophthalmic Strips USP (1.0 mg Fluorescein), Rx Only, 100 Sterile Strips per carton, Nomax, Inc., St. Louis, MO 63123, NDC 51801-009-40.	Class II	Drugs	Lot #: 14708, Exp. 04/30/2024.	Failed Impurities/Degradation Specifications: The Active Pharmaceutical Ingredient (API) used in the product is not being manufactured to the current USP monograph in regard to Unspecified Impurities.	Nomax Inc
FUL-GLO, Fluorescein Sodium Sterile Ophthalmic Strips USP (0.6 mg Fluorescein), 300 sterile strips per carton, Manufactured for: Akorn, Inc., Lake Forest, IL 60045, NDC 17478-403-03.	Class II	Drugs	Lot 14842, Exp. 6/30/2024	Failed Impurities/Degradation Specifications: The Active Pharmaceutical Ingredient (API) used in the product is not being manufactured to the current USP monograph in regard to Unspecified Impurities.	Nomax Inc
FUL-GLO, Fluorescein Sodium Ophthalmic Strips USP 1 mg, 100 sterile strips per carton, Manufactured for: Akorn, Inc., Lake Forest, IL 60045, NDC 17478-404-01.	Class II	Drugs	Lot #: 14776, Exp. 05/31/2024.	Failed Impurities/Degradation Specifications: The Active Pharmaceutical Ingredient (API) used in the product is not being manufactured to the current USP monograph in regard to Unspecified Impurities.	Nomax Inc
Methylergonovine Maleate Tablets, USP, 0.2mg, 12-count bottle, Rx Only, Distributed by:	Class II	Drugs	Lot #: BJ01922A, exp. date 03/2024	Failed Dissolution Specifications	Amneal Pharmaceuticals of New York, LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Amneal Pharmaceuticals, LLC, Bridgewater, NJ 08807, NDC # 69238-1605-2.					
Prednisolone Sodium Phosphate-Moxifloxacin-Bromfenac Sterile Ophthalmic Solution 1%, 0.5%, 0.075%, 8mL, Compounded By: Imprimis NJOF, LLC. 1705 Route 46 West, Unit 6B Ledgewood, NJ 07852, NDC 71384-340-08	Class II	Drugs	Lot #: 23JUN031; Exp. 07/03/2024	Subpotent Drug	Imprimis NJOF, LLC
EYLEA, (aflibercept) Injection, 2 mg (0.05mL of a 40mg/mL solution), Single-dose Pre-filled Syringe, Rx only, Manufactured by: Regeneron Pharmaceuticals, Inc., 777 Old Saw Mill River Road, Tarrytown, NY 10591, NDC 61755-005-01	Class II	Drugs	Lot # 8231500321, Exp 10/31 24; 8231500335, 8231500333, 8231500334, 8231500339, 8231500347, Exp 1/30/25	Lack of Assurance of Sterility: Complaints of syringe breakage	Regeneron Pharmaceuticals Inc
Amphotericin B Liposome for Injection, 50mg vials, Rx only, Distributed by: Sun Pharmaceutical Industries, Inc. Cranbury, NJ 08512, Manufactured by: Sun Pharmaceutical Medicare Limited, Baska Ujeti Road, Ujeti Halol-389350, Gujarat, India. NDC 62756-233-01	Class II	Drugs	Lot #: BAE0055A, BAE0056A, BAE0068A, Exp. Date 03/2026	Out of specification for assay	SUN PHARMACEUTICAL INDUSTRIES INC
Timolol Maleate Ophthalmic Solution, USP, 0.5%, packaged in a) 5mL bottles (NDC 64980-514-05), and b) 15 mL bottles (NDC 64980-514-15), Rx only, Manufactured by: FDC Limited, Maharashtra, India, Distributed by: Rising Pharmaceuticals, Inc, NJ	Class II	Drugs	Lot #: a) 083H008, Exp. Date 07/2025; 083G003, Exp. Date 06/2025; 083J017, Exp. Date 09/2025; b) 083I013, Exp. Date 08/2025.	Defective Container: yellow-colored spike from cap lodged in the nozzle. Firm received several complaints from customers.	FDC Limited
traMADol Hydrochloride Tablets, USP 50 mg, 1000-count bottle, Rx Only, Distributed by:	Class II	Drugs	Lot #: 230774HI, Exp 4/30/2026	Presence of Foreign Tablets: Pharmacist reported a	Rubicon Research Private Limited

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Advagen Pharma Limited, 666 Plainsboro Road Suite 605, Plainsboro, NJ, 08536, USA, Manufactured by: Rubicon Research, Private Limited, Ambernath, Dist. Thane, 421506 India NDC 72888-080-00				tablet of baclofen in a bottle of 1000-count tramadol	
Duloxetine Delayed-Release Capsules, USP, 30mg, Rx Only, (a) 90-count bottles (NDC 51991-747-90), (b) 1000-count bottles (NDC 51991-747-10), Mfr. by: Towa Pharmaceutical Europe, S.L. Martorelles, (Barcelona), Spain, Dist. by: Breckenridge Pharmaceuticals, Inc., Berkeley Heights, NJ 07922.	Class II	Drugs	220265: Exp. Feb 2025 220088: Exp. Nov 2024 220267: Exp. Feb 2025 220256: Exp. Feb 2025 220225: Exp. Jan 2025 220269: Exp. Feb 2025	CGMP Deviations: Presence of Nitrosamine Drug Substance Related Impurity (NDSRI), N-nitroso-duloxetine, above the proposed interim limit.	Breckenridge Pharmaceutical, Inc
Duloxetine Delayed-Release Capsules, USP, 20 mg, , 500-count bottles, Rx Only, Mfr. by: Towa Pharmaceutical Europe, S.L. Martorelles, (Barcelona), Spain, Dist. by: Breckenridge Pharmaceuticals, Inc., Berkeley Heights, NJ 07922, NDC 51991-746-05.	Class II	Drugs	220456: Exp. Feb 2025	CGMP Deviations: Presence of Nitrosamine Drug Substance Related Impurity (NDSRI), N-nitroso-duloxetine, above the proposed interim limit.	Breckenridge Pharmaceutical, Inc
Duloxetine Delayed-Release Capsules, USP, 60 mg, 90-count bottles, Rx Only, Mfr. by: Towa Pharmaceutical Europe, S.L. Martorelles, (Barcelona), Spain, Dist. by: Breckenridge Pharmaceuticals, Inc., Berkeley Heights, NJ 07922, NDC: 51991-748-90.	Class II	Drugs	230028C: Exp. Nov 2025 230106C: Exp. Dec 2025 230170C: Exp. Dec 2025 220039: Exp. Dec 2024 220363: Exp. Feb 2025	CGMP Deviations: Presence of Nitrosamine Drug Substance Related Impurity (NDSRI), N-nitroso-duloxetine, above the proposed interim limit.	Breckenridge Pharmaceutical, Inc
Clorazepate Dipotassium Tablets, USP, 3.75 mg, a) 100 tablets per bottle, NDC 13107-282-01 b) 500 tablets per bottle, NDC 13107-282-05, Rx Only, Distributed by Aurobindo Pharma USA,	Class II	Drugs	Lot #s: a) CZA124001B, CZA124002B, CZA124003B, Exp.	Discoloration: Dotted and yellow spots on tablets	Aurobindo Pharma USA Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Inc., 279 Princeton-Hightstown Road, East Windsor, NJ 08520, Made in India.			12/31/2025; b) CZA124001A, CZA124003A, Exp. 12/31/2025.		
Clorazepate Dipotassium Tablets, USP, 7.5 mg, a) 100 tablets per bottle, NDC 13107-283-01, b) 500 tablets per bottle, NDC 13107-283-05, Rx Only, Distributed by Aurobindo Pharma USA, Inc., 279 Princeton-Hightstown Road, East Windsor, NJ 08520, Made in India.	Class II	Drugs	Lot #s: a) CZB124001B, CZB124002B, CZB124003B, Exp. 12/31/2025; b) CZB124001A, CZB124003A, Exp. 12/31/2025.	Discoloration: Dotted and yellow spots on tablets	Aurobindo Pharma USA Inc.
Gordofilm Wart Remover (salicylic acid 16.7% USP) packaged in 15 cc glass jars, Gordon Laboratories, Upper Darby PA 19082, NDC 10481-3009-01	Class II	Drugs	Lot #: F135, Exp. Date March 2025; F146, Exp. Date April , 2025; G103, Exp. Date January 2026; G194, Exp. Date September 2026	cGMP Deviations	Dercher Enterprises, Inc., DBA Gordon Laboratories
MethylPREDNISolone Acetate Injectable Suspension, USP, 400 mg per 10 mL (40 mg per mL), 1 x 10 mL Multi-Dose Vial, Rx only, Mfd. for SAGENT Pharmaceuticals, Schaumburg, IL 60195, Made in India. NDC: 25021-820-10	Class II	Drugs	Lots 5100186, 5100187, 5100188, 5100189, Exp 01/31/2025	Presence of Particulate Matter: Potential for black particulates in the drug product.	Sagent Pharmaceuticals
Cefdinir for Oral Suspension USP 250 mg/5 mL (60 mL when reconstituted), 60 mL bottle, Rx only, Manufactured for: Lupin Pharmaceuticals, Inc., Baltimore, Maryland 21202, United States, Manufactured by: Lupin Limited, Mandideep 462 046, India, NDC 68180-723-04	Class II	Drugs	Lot # F305442, Exp 8/30/2025	Presence of foreign substance: Product complaint of foreign material in reconstituted bottle.	Lupin Pharmaceuticals Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Cefdinir for Oral Suspension USP 125 mg/5 mL (60 mL when reconstituted), 60 mL bottle, Rx only, Manufactured for: Lupin Pharmaceuticals, Inc., Baltimore, Maryland 21202, United States, Manufactured by: Lupin Limited, Mandideep 462 046, India, NDC 68180-722-04	Class II	Drugs	Lot # F305292, Exp 8/30/2025	Presence of foreign substance: Product complaint of foreign material in reconstituted bottle.	Lupin Pharmaceuticals Inc.
CVS Health Magnesium Citrate Saline Laxative Oral Solution DYE FREE Cherry Flavor, 10 fl. oz bottle, Distributed by: CVS Pharmacy, Inc., One CVS Drive, Woonsocket, RI 02895, NDC 51316-881-10.	Class II	Drugs	Lot #: A81506, Exp 12/31/2025	Microbial Contamination of Non-Sterile Products - Presence of Acetobacter nitrogenifigens bacteria	Pharma Nobis LLC
Meijer Magnesium Citrate Saline Laxative Oral Solution Dye Free, Sugar Free Grape, 10 fl. oz bottle, Distributed by: Meijer Distribution Inc., Grand Rapids,MI 49544, NDC 79481-0034-9	Class II	Drugs	Lot #: A81834, Exp 1/31/2026	Microbial Contamination of Non-Sterile Products - Presence of Acetobacter nitrogenifigens bacteria	Pharma Nobis LLC
Losartan Potassium and Hydrochlorothiazide Tablets, USP 50mg /12.5 mg, 1000-count bottle, Rx only, Manufactured for: Macleods Pharma USA, Inc. Princeton, NJ 08540, Manufactured by: Macleods Pharmaceuticals Ltd. Baddi, Himachal Pradesh, INDIA, NDC 33342-050-44	Class II	Drugs	Lot #: BLK2304A, Exp. 07/31/2025	Presence of foreign substance: plastic-like substance.	MACLEODS PHARMA USA, INC
Abilify (aripiprazole), 5 mg tablets, packaged in 30 count bottles, RX only, Otsuka America Pharmaceutical, Inc., NDC 59148-007-13	Class III	Drugs	Lot # AKS00623A, Exp 01/31/2026; AKS00322A, Exp 02/28/2025	Cross Contamination with Other Products	Second Tokushima Factory, Otsuka Pharmaceutical Co., Ltd.
Abilify (aripiprazole), 10 mg tablets, packaged in a) 30 count bottles (NDC 59148-008-13) and b) 7 count blister packs (NDC 59148-008-95), RX only, Otsuka America Pharmaceutical, Inc.	Class III	Drugs	Lot #: a) ALS00422A, Exp 04/30/2025; ALS00523A, Exp 11/30/2025; b)	Cross Contamination with Other Products	Second Tokushima Factory, Otsuka Pharmaceutical Co., Ltd.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			1K77YUD1H1A, Exp 11/30/2024		
Abilify (aripiprazole), 15 mg tablets, packaged in 30 count bottles, RX only, Otsuka America Pharmaceutical, Inc., NDC 59148-009-13	Class III	Drugs	Lot # AMS00223A, Exp 07/31/2025	Cross Contamination with Other Products	Second Tokushima Factory, Otsuka Pharmaceutical Co., Ltd.
Abilify (aripiprazole), 30 mg tablets, packaged in 30 count bottles, RX only, Otsuka America Pharmaceutical, Inc., NDC 59148-011-13	Class III	Drugs	Lot # APS00423A, Exp 07/31/2025; APS00222A, Exp 11/30/2024	Cross Contamination with Other Products	Second Tokushima Factory, Otsuka Pharmaceutical Co., Ltd.
Epinephrine-Lidocaine HCl 0.25 mg/mL and 7.5 mg/mL Preservative-Free, 1 mL Single-Use vials, Rx only, Imprimis NJOF, LLC 1705 Route 46 West, Unit 6B, Ledgewood, NJ, 07852, NDC 71384-640-01	Class III	Drugs	Lot #: 23JUL028, Exp. Date 8/1/2024; 23AUG053, Exp. Date 8/30/2024	Out of specification for assay	Imprimis NJOF, LLC
Valacyclovir Tablets USP, 500 mg, 90 count bottles, Rx Only, Manufactured for: Mylan Pharmaceuticals Inc. Morgantown, WV 26505 USA, NDC 0378-4275-77	Class III	Drugs	Lot #: 3183269, Exp. Date May 2025; 3157326, Exp. date June 2024	Failed Tablet/Capsule Specifications: There is a potential for the imprint, M 122, to be missing on some tablets.	Viatris Inc
Fentanyl 1000mcg/100mL (10mcg/mL) in 0.9% Sodium Chloride Injection, packaged in 100mL bags, Rx only, Compounded by: Hikma Injectables USA Inc. 2 Esterbrook Lane, Cherry Hill, NJ 08003, Distributed by: Hikma Injectables USA Inc. 36 Stults Road, Dayton, NJ 08810, NDC 63037-100-05	Class III	Drugs	Lot #: CH0324001, Exp. Date 3/4/2025	Labeling: Wrong Barcode	Hikma Injectables USA Inc
Sodium Sulfacetamide 10% - Sulfur 5% Cleanser, Rx Only, 6 oz (170.3 g) Bottle, Manufactured for Acela Pharmaceuticals, LLC Alphareta, GA 30005, NDC 42192-136-06	Class III	Drugs	Lot # 22085 Exp. date 08/02/2024	Subpotent drug	Acella Pharmaceuticals, LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm

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

CURRENT DRUG SHORTAGES

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

Generic Name or Active Ingredient

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

Epinephrine Injection, Syringes
Erythromycin Ointment
Etomidate Injection
Fentanyl Citrate Injection
Flurazepam Hydrochloride Capsule
Furosemide Injection
Gentamicin Sulfate Injection
Heparin Sodium Injection
Hydrocortisone Sodium Succinate Injection
Hydromorphone Hydrochloride Injection
Hydroxocobalamin Injection
Hydroxypropyl Cellulose (1600000 Wamw) Insert
Isoniazid Tablet
Ketamine Hydrochloride Injection
Ketorolac Tromethamine Injection
Leucovorin Calcium Injection
Lidocaine Hydrochloride Injection
Lidocaine Hydrochloride Solution
Liraglutide Injection
Lisdexamfetamine Dimesylate Capsule
Lisdexamfetamine Dimesylate Tablet, Chewable
Lorazepam Injection
Mefloquine Hydrochloride Tablet
Methamphetamine Hydrochloride Tablet
Methotrexate Sodium Injection
Methotrexate Sodium Tablet
Methylphenidate Hydrochloride Tablet, Extended Release
Methylprednisolone Acetate Injection
Metronidazole Injection
Midazolam Hydrochloride Injection
Morphine Sulfate Injection
Naltrexone Hydrochloride Tablet
Nitroglycerin Injection
Oxybutynin Chloride Syrup
Parathyroid Hormone Injection
Penicillin G Benzathine Injection
Potassium Acetate Injection
Promethazine Hydrochloride Injection
Propranolol Hydrochloride Injection
Quinapril Hydrochloride Tablet
Quinapril/Hydrochlorothiazide Tablet
Remifentanil Hydrochloride Injection
Rifampin Capsule
Rifampin Injection
Rifapentine Tablet, Film Coated
Riluzole Oral Suspension

Rocuronium Bromide Injection
Ropivacaine Hydrochloride Injection
Semaglutide Injection
Sodium Acetate Injection
Sodium Bicarbonate Injection
Sodium Chloride 0.9% Injection
Sodium Chloride 0.9% Irrigation
Sodium Chloride 14.6% Injection
Sodium Chloride 23.4% Injection
Sodium Phosphate, Dibasic, Anhydrous, Sodium Phosphate, Monobasic, Monohydrate Injection, Solution
Somatropin Injection
Sterile Water Injection
Sterile Water Irrigant
Streptozocin Powder, For Solution
Sucralfate Tablet
Sufentanil Citrate Injection
Technetium TC-99M Pyrophosphate Kit Injection
Tirzepatide Injection
Triamcinolone Acetonide Injection
Triamcinolone Hexacetonide Injection
Valproate Sodium Injection
Vecuronium Bromide Injection
Vinblastine Sulfate Injection