PERFORMRx℠

Drug Information Update

July 2024

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NEWLY AVAILABLE GENERICS

Generic Name/ Dosage Form	Brand Name	Manufacturer	Indication
Liraglutide subcutaneous solution pen injector 18mg/3ml	Victoza	Teva	• Adjunct to diet and exercise to improve glycemic control in adults and pediatric patients aged 10 years and older with type 2 diabetes mellitus • To reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus and established cardiovascular disease. Limitations of Use: • Not for treatment of type 1 diabetes mellitus. • Should not be coadministered with other liraglutide-containing products.
Bexagliflozin 20 mg oral tablet	Brenzavvy	Golden State Medical Supply	• Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus Limitation of Use: Not recommended for use to improve glycemic control in patients with type 1 diabetes mellitus.
Edaravone intravenous solution 30 mg/100ml	Radicava	Piramal Critical Care	• For the treatment of amyotrophic lateral sclerosis
Ivabradine oral tablet 5mg, 7.5mg	Corlanor	Camber Pharmaceuticals Ingenus Pharmaceuticals Zydus Pharmaceuticals	• To reduce the risk of hospitalization for worsening heart failure in adult patients with stable, symptomatic chronic heart failure with reduced left ventricular ejection fraction. • For the treatment of stable symptomatic heart failure due to dilated cardiomyopathy in pediatric patients ages 6 months and older.
L-Glutamine Oral Packet 5 GM	Endari	ANI Pharmaceuticals	• To reduce the acute complications of sickle cell disease in adult and pediatric patients 5 years of age and older

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NEW DRUG ENTITIES/STRENGTHS/COMBINATIONS

Drug Name	Generic Name	Description
Scemblix Oral Tablet 100 MG	Asciminib	New strength. Also available in 20mg and 40mg tablets. Kinase inhibitor indicated for the treatment of adults with Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP), previously treated with two or more tyrosine kinase inhibitors (TKIs), and Ph+CML in CP with the T315I mutation.
Adbry Subcutaneous Solution Auto-injector 300 MG/2ML	Tralokinumab-ldrm	New dosage form and strength. Interleukin-13 antagonist indicated for the treatment of moderate-to-severe atopic dermatitis in patients aged 12 years and older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.
Tyenne Subcutaneous Solution Prefilled Syringe 162 MG/0.9ML	Tocilizumab-aazg	New dosage form. Tyenne auto-injector 162/0.9ml recently approved as well. Previously only available as 80 mg/4 ml, 200 mg/10 ml, and 400 mg/20 ml intravenous vials. Actemra biosimilar.
Entresto Oral Capsule Sprinkle 6-6 MG, 15-16 MG	Sacubitril-Valsartan	New dosage strength and form. Hard capsule sprinkles approved in April 2024.
Rystiggo Subcutaneous Solution 420 MG/3ML, 560 MG/4ML, 840 MG/6ML	Rozanolixizumab-noli	New dosage strength. Previously only available as 280 mg/2 mL. Indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive.
Ondansetron Oral Tablet Disintegrating 16 MG	Ondansetron	New strength. Previously only available as 4mg and 8mg ODT.
Ohtuvayre Inhalation Suspension 3 MG/2.5ML	Ensifentrine	New entity. For the maintenance treatment of chronic obstructive pulmonary disease (COPD) in adult patients. First-in-class selective dual inhibitor of the enzymes phosphodiesterase 3 and phosphodiesterase 4 ("PDE3 and PDE4") that combines bronchodilator and non-steroidal anti-inflammatory effects in one molecule. Ohtuvayre is the first inhaled product with a novel mechanism of action available for the maintenance treatment of COPD in more than 20 years.
Sofdra External Gel 12.45 %	Sofpironium Bromide	First drug approved for the treatment of primary axillary hyperhidrosis (PAH). PAH, or excess underarm sweating, affects an estimated 10 million individuals in the U.S. It is

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Drug Name	Generic Name	Description
		the third most common dermatology condition, following acne and atopic dermatitis. Indicated for patients 9 years of age and older.
Kisunla Intravenous Solution 350 MG/20ML	donanemab-azbt	Once monthly infusion for treatment of adults with early symptomatic Alzheimer's disease (AD), which includes people with mild cognitive impairment (MCI) as well as people with the mild dementia stage of AD, with confirmed amyloid pathology. This indication is almost identical to Leqembi, however, major difference is that Kisunla is the first anti-amyloid drug that allows for stopping therapy when amyloid plaques are removed, enabling fewer infusions and lower treatment costs.
Elfabrio Intravenous Solution 5 MG/2.5ML	pegunigalsidase alfa-iwxj	New dosage strength. Elfabrio is a hydrolytic lysosomal neutral glycosphingolipid-specific enzyme indicated for the treatment of adults with confirmed Fabry disease. Already available as 20mg/10ml IV solution.
Acthar Gel Subcutaneous Auto-injector 80 UNIT/ML, 40 UNIT/0.5 ML	Corticotropin	New dosage form. Approved March 2024.
Austedo XR Patient Titration Oral Tablet Extended Release Therapy Pack 12 & 18 & 24 & 30 MG	Deutetrabenazine	New titration pack. Austedo is a vesicular monoamine transporter 2 inhibitor, for the treatment of adults with tardive dyskinesia and chorea associated with Huntington disease. Previously only supplied in 6mg, 12mg, 24mg.
Austedo XR Oral Tablet Extended Release 24 Hour 18 MG	Deutetrabenazine	New strength of Austedo XR.
Zoryve External Cream 0.15 %	Roflumilast	New strength. Indicated for treatment of mild to moderate atopic dermatitis in adult and pediatric patients 6 years of age and older. Also available as 0.3% cream and 0.3% foam.
Clobetasol Propionate Ophthalmic Suspension 0.05 %	Clobetasol Propionate	New entity. Approved March 2024. 505(b)(2) approval. Indicated for the treatment of post-operative inflammation and pain following ocular surgery.
Piasky Injection Solution 340 MG/2ML	Crovalimab-akkz	New entity. Complement C5 inhibitor indicated for the treatment of adult and pediatric patients 13 years and older with paroxysmal nocturnal hemoglobinuria (PNH) and body weight of at least 40 kg. Crovalimab works on a different part of the C5 protein than eclulizumab and ravulizumab, resulting in the ability to treat patients who have a C5 mutation (usually cannot be treated with eclulizumab/ravulizumab). Will compete with Soliris, Ultomiris, and Empaveli as well as Soliris biosimilars that may launch in 2025.

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Drug Name	Generic Name	Description
Vafseo Oral Tablet 150 MG, 300 MG	Vadadustat	New entity. Hypoxia-inducible factor prolyl hydroxylase (HIF-PH) inhibitor indicated for the treatment of anemia due to chronic kidney disease (CKD) in adults who have been receiving dialysis for at least 3 months. Second HIF-PH inhibitor approved after Jesduvroq (daprodustat), which shares the same indication. Includes the same Boxed Warning as Jesduvroq regarding an increased risk for thrombotic vascular events, including major adverse cardiovascular events (MACEs). Approved in March 2024.

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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†
Skyrizi	risankizumab-rzaa 150 mg.ml subcutaneous syringe; 150 mg/ml subcutaneous pen-injector; 180 mg/1.2 ml, 360 mg/2.4 ml subcutaneous cartridge; 600 mg/10 ml intravenous vial	AbbVie	• Treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy • Treatment of active psoriatic arthritis in adults • Treatment of moderately to severely active Crohn's disease in adults • **Treatment of moderately to severely active ulcerative colitis in adults**
Elevidys	delandistrogene moxeparvovec-rokl 1.33 x 10^{13} vector genomes/ml intravenous suspension	Sarepta Therapeutics	**Adeno-associated virus vector-based gene therapy indicated in individuals at least 4 years of age:** • For the treatment of ambulatory ~~pediatric~~ patients ~~aged 4 through 5 years~~ with Duchenne muscular dystrophy (DMD) with a confirmed mutation in the DMD gene[~~1~~] • **For the treatment of DMD in patients who are non-ambulatory and have a confirmed mutation in the DMD gene[1]** [1]~~This~~**The DMD** indication **in non-ambulatory patients** is approved under accelerated approval based on expression of Elevidys micro-dystrophin ~~in skeletal muscle observed in patients treated with Elevidys~~. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.
Wakix	pitolisant 4.45 mg, 17.8 mg oral tablets	Harmony Biosciences	• Treatment of excessive daytime sleepiness (EDS) or cataplexy in adult patients with narcolepsy

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Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication†
			• **Treatment of EDS in pediatric patients 6 years of age and older with narcolepsy**
Vyvgart Hytrulo	efgartigimod alfa and hyaluronidase-qvfc 180 mg-2000 units/ml subcutaneous vial	Argenx	• Treatment of adult patients with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody positive • **Treatment of adult patients with chronic inflammatory demyelinating polyneuropathy (CIDP)**
Krazati	adagrasib 200 mg oral tablets	Mirati Therapeutics	• Treatment of adult patients with KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC), as determined by an FDA approved test, who have received at least one prior systemic therapy[1] • **In combination with cetuximab, for the treatment of adult patients with KRAS G12C-mutated locally advanced or metastatic colorectal cancer (CRC), as determined by an FDA-approved test, who have received prior treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy[1]** [1]~~This~~**These** indication**s** ~~is~~ **are** approved under accelerated approval based on objective response rate (ORR) and duration of response (DOR). Continued approval for ~~this~~ **these** indication**s** may be contingent upon verification and description of a clinical benefit in ~~a~~ confirmatory trial**s**.
Epkinly	epcoritamab-bysp 4mg/0.8ml, 48mg/0.8ml subcutaneous solution	Genmab	• Diffuse Large B-cell Lymphoma and High-grade B-cell Lymphoma: o adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, including DLBCL arising from indolent lymphoma, and high-grade B-cell lymphoma after two or more lines of systemic therapy • **Follicular Lymphoma:**

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Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication†
			○ **adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy** These indications are approved under accelerated approval based on response rate and durability of response. Continued approval for these indications may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).
Zoryve	roflumilast cream 0.15%	Arcutis Biotherapeutics	Zoryve cream is a phosphodiesterase 4 inhibitor: • Zoryve cream, 0.3%, is indicated for the topical treatment of plaque psoriasis, including intertriginous areas, in adult and pediatric patients 6 years of age and older. • **Zoryve cream, 0.15%, is indicated for the topical treatment of mild to moderate atopic dermatitis in adult and pediatric patients 6 years of age and older.**

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RECALLS

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
RAM IT, Horny Goat Weed, dietary supplement capsules, 1000 mg, packaged in a box containing a 10-count blister card, Distributed By: Integrity Products, 1710 Fenpark Dr., Fenton, MO 63026	Class I	Drugs	Lot HGW221116 (Batch 020123-1), Exp 5/31/2025	Marketed Without an Approved NDA/ANDA: Products contain undeclared sildenafil.	Integrity Products
To the Moon Capsules, Horny Goat Weed, 1000 mg, packaged in a box containing a 10-count blister card, Distributed By: Integrity Products, 1710 Fenpark Dr., Fenton, MO 63026	Class I	Drugs	Lot HGW221116 (Batch 022123-1), Exp 5/31/2025	Marketed Without an Approved NDA/ANDA: Products contain undeclared sildenafil.	Integrity Products
suntegrity, (Zinc Oxide 15%) IMPECCABLE SKIN sunscreen foundation, BUFF, Broad Spectrum SPF30, Net WT 2OZ (56.7 g), Suntegrity Skincare, Las Vegas, NV 89128, NDC: 69949-152-01 UPC 854245006187	Class I	Drugs	Lot#: 115BU, Exp: 06/30/2025;	Microbial Contamination of Non-Sterile Products: Presence of Aspergillus Sydowii (Mold)	SYNCHRONICITY SPA INC, DBA SUNTE
Potassium Chloride Extended-Release Capsules, USP, (750 mg) 10 mEq K, 100-count bottle, Rx Only, Manufactured by: Glenmark Pharmaceuticals Ltd. Plot No. 2, Phase-2, Pharma Zone SEZ, Pithampur, Dist.-Dhar, Madhya Pradesh 454 775, India, Manufactured for: Glenmark Pharmaceuticals Inc, USA, Mahwah, NJ 07430. NDC 68462-357-01	Class I	Drugs	Lot#: 17221446, 17221445, Exp May-31-24; 17221393, 17221403, 17221405, 17221503, 17221508, Exp Jun-30-24; 17221567, 17221566, 17221719, 17221731, Exp Jul-31-24; 17221891, 17221892, 17221900, 17221992, 17222022, Exp Aug-31-24; 17222056,	Failed Dissolution Specifications	Glenmark Pharmaceuticals Inc., USA

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Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			17222043, 17222068, 17222079, 17222099, 17222103, 17222114, 17222119, 17222188, 17222199, 17222209, 17222200, Exp Sep-30-24; 17222265, 17222269, Exp Oct-31-24; 17222527, 17222530, 17222583, 17222586, 17230051, 17230075, 17230067, Exp Nov-30-24;		
Potassium Chloride Extended-Release Capsules, USP, (750 mg) 10 mEq K, 500-count bottle, Rx Only, Manufactured by: Glenmark Pharmaceuticals Ltd. Plot No. 2, Phase-2, Pharma Zone SEZ, Pithampur, Dist.-Dhar, Madhya Pradesh 454 775, India, Manufactured for: Glenmark Pharmaceuticals Inc, USA, Mahwah, NJ 07430. NDC 68462-357-05	Class I	Drugs	Lot #: 17221197, 17221386, 17221385, Exp May-31-24; 17221489, 17221504, 17221530, Exp Jun-30-24; 17221561, 17221579, 17221568, 17221702, 17221704, Exp Jul-31-24; 17221898, 17221993, 17222029, Exp Aug-31-24; 17222300, 17222304, 17222278, 17222609, 17222395, Exp Oct-31-24; 17222589, 17222605,	Failed Dissolution Specifications	Glenmark Pharmaceuticals Inc., USA

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Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			17222613, Exp Nov-30-24;		
STELLALIFE VEGA Oral Care, Spray, Unflavored, 1 fl oz (30 ml) bottles, Distributed by: StellaLife, 22875 NE 191 Street, Suite 500, Aventura, FL 33180, NDC 69685-121-01	Class I	Drugs	Lot # 2552, exp. date 02-28-2026	Microbial Contamination of Non-Sterile Products: multiple Bacillus species organisms	Homeocare Laboratories, Inc.
Duloxetine Delayed-Release Capsules, USP, 30mg, Rx Only, a) 30 capsules bottles, NDC 60429-165-30; b) 90 capsules bottles, NDC 60429-165-90, Mfr. by: Towa Pharmaceutical Europe, S.L. Martorelles, (Barcelona), Spain, Packaged by GSMS, Incorporated, Camarillo, CA 93012.	Class II	Drugs	Lot: a) GS045371, Exp: 01/31/2025; b) GS045910, Exp. 01/31/2025	CGMP Deviations: Presence of Nitrosamine Drug Substance Related Impurity (NDSRI), N-nitroso-duloxetine, above the proposed interim limit.	Golden State Medical Supply Inc.
Extra Strength Acetaminophen 500 MG Tablets,100-count Bottle, Distributed By: MAJOR PHARMACEUTICALS, 17177 N Laurel Park Drive, Suite 233, Livonia, MI USA 48152, NDC 0904-6730-60, UPC Number 309046730606	Class II	Drugs	Lot#: 368638; Exp. 05/2025	Discoloration: Brownish tablets	Contract Pharmacal Corporation
Buprenorphine Hydrochloride Injection, 0.3 mg base/mL, 1 mL Single-dose Carpuject, Sterile Cartridge Unit with Luer Lock, For Intramuscular or Intravenous Use, Rx Only, Distributed by Hospira, Inc., Lake Forest, IL 60045 USA. NDC: 0409-2012-03	Class II	Drugs	Lot#: HJ3965; Exp 2024/09 Lot#: HJ8546; Exp 2024/10	Lack of Assurance of Sterility-The potential for incomplete crimp seals.	Pfizer Inc.
Labetalol Hydrochloride Injection, USP, 20 mg/4 mL (5 mg/mL), 4 mL Single-dose Carpuject, Sterile Cartridge Unit with Luer Lock, For Intravenous Injection Only, Rx Only, Distributed	Class II	Drugs	Lot#: HJ7566; Exp 2025/05 Lot#: HN8747; Exp 2025/09 Lot#: HN8749; Exp 2025/09	Lack of Assurance of Sterility-The potential for incomplete crimp seals.	Pfizer Inc.

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Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
by Hospira, Inc., Lake Forest, IL 60045 USA. NDC: 0409-2339-24					
Progesterone 200 mg, Compounded, 90-count bottle, Rx, Dissolve One Sublingual Tablet After Dinner Nightly, AnazaoHealth, 5710 Hoover Blvd, Tampa, Fl 33643, (800)-995-4363. Beyond Use Date: 09/08/2024.	Class II	Drugs	Product lot: 240312JL-629220; Exp. 09/08/2024	Presence of Foreign Substance; Broken metal piece found embedded in tablet.	Coast Quality Pharmacy, LLC dba Anazao Health
Zilretta (triamcinolone acetonide extended-release injectable suspension), 32 mg per vial, Rx only, Manufactured for: Pacira Pharmaceuticals Inc., San Diego, CA 92121, NDC 65250-003-01 (carton) NDC 65250-001-01 (vial) with Diluent 5 mL Sterile single-use vial, Rx Only, Mfd. for: Pacira Pharmaceuticals, Inc. NDC 65250-002-01	Class II	Drugs	Lot 23-9006; Expiry Date: MAR 2025	Failed Dissolution Specifications - did not meet the acceptance criteria for IVR Level 3 testing at 9 months 2-8¿C followed by 6 weeks at 25¿C	PACIRA PHARMACEUTICALS INC
Allopurinol Tablets, USP 300mg, 100 Tablets per bottle, Rx only, Manufactured By: Dr. Reddy's Laboratories LA LLC, Shreveport, LA 71106 USA, NDC 55111-730-01.	Class II	Drugs	L2300594	Presence of foreign substance.	Dr. Reddy's Laboratories, Inc.
Little Moon Essentials, Magical Muscle Oil, (Camphor 1.95%, Menthol 3.75%) packaged as: a) 2 FL OZ (59ML) glass jar, UPC Code 6 73673 88202 2, NDC 70722-246-02; b) 4 FL OZ (118ML) jar, UPC Code 6 73673 88233 6, NDC 70722-246-04; Little Moon Essentials LLC Dania Beach, Fl 33004	Class II	Drugs	lot code No expiration date on product: a) 325240, 320260, 329011, 324021, 328221, 421110, 422120, 423120, 421220, 426220, 428220, b) 329230, 328140, 320290, 328011.	CGMP deviations	Little Moon Essentials LLC

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Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Little Moon Essentials, Crampy Belly Rub (Camphor 1.1%), Packaged as a) 4 FL OZ (118ML) glass jar, UPC Code 6 73673 88260 2, NDC 70722-260-04; b) 2 FL OZ (59ML) glass jar, UPC Code 6 73673 88204 6, NDC 70722-260-02, Little Moon Essentials LLC Dania Beach, Fl 33004	Class II	Drugs	lot code No Expiration Date on product: a) 224010, b) 321260, 322260, 320280, 328080, 325021, 321121, 423010, 427110, 429120, 420220, 422140	CGMP deviations	Little Moon Essentials LLC
Little Moon Essentials, Aching Head Rub (Camphor 3.09%, Menthol 2.55%) , a) 0.5OZ (14G), metal tin, UPC Code 67367388226 8, NDC 70722-203-05; b)1OZ (28G) glass jar, UPC Code 6 73673 88203 9, NDC 70722-203-01; Little Moon Essentials LLC Dania Beach, Fl 33004	Class II	Drugs	lot code No expiration date on product: a) 326070, 420140, b) 322030, 321230, 329230, 321240, 329170, 328280, 326090, 322290, 327021, 323121, 327221, 429210, 424130, 427050	CGMP deviations	Little Moon Essentials LLC
Little Moon Essentials, Dream Cream (Camphor 0.45%, Menthol 5%), Packaged as a) 2OZ (57G) glass jar, UPC Code 6 73673 88214 5, NDC 70722-232-02; b) 4OZ (113G) glass jar, UPC Code 6 73673 88804 8, NDC 70722-232-04; Little Moon Essentials LLC Dania Beach, Fl 33004	Class II	Drugs	lot code no expiration dates on product: a) 328260, 321221, 425120, 427230, b) 327150, 326260, 320270, 321301, 422020	CGMP deviations	Little Moon Essentials LLC
Little Moon Essentials, Vital Vapor Balm, (Camphor 0.6%, Menthol 5.2%) Packaged as a) 0.5OZ (14G) metal tin, UPC Code 6 73673 88231 2, NDC 70722-229-05) b) 2OZ (57G) glass jar, UPC Code 6 73673 88220 6, NDC 70722-229-02;	Class II	Drugs	lot code no expiration date on product: a) 324280, b) 328230, 321170, 321290, 326021, 420220,	CGMP deviations	Little Moon Essentials LLC

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Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
c) 4OZ (113G) glass jar, UPC Code 6 73673 88218 3, NDC 70722-229-04; Little Moon Essentials LLC Dania Beach, Fl 33004			422140, c) 326040, 328170		
Little Moon Essentials, Ass Kisser, Packaged as a) 0.5 OZ (14G) metal tin, UPC Code 6 73673 88228 2, NDC 70722-208-05; b) 3 OZ (85.05G) metal tin, UPC Code 6 73673 88208 4, NDC 70722-208-03; Little Moon Essentials LLC Dania Beach, Fl 33004	Class II	Drugs	lot code no expiration date on product: a) 327140, b) 322170, 325040, 325250	CGMP deviations	Little Moon Essentials LLC
Little Moon Essentials, Asana Kisser, (Camphor 1.35%, Menthol 2.86%), Packaged as a) 0.5 OZ (14G) metal tin, UPC Code 6 73673 88227 5, NDC 70722-216-05; b) 3 OZ (85-05G) metal tin UPC Code 6 73673 88216 9, NDC 70722-216-03; Little Moon Essentials LLC Dania Beach, Fl 33004	Class II	Drugs	lot code no expiration date on product: a) 322230, 424040, b) 322230, 325070, 324080, 325180, 325280, 328290, 426110, 423210, 426120, 422220, 423130, 428230, 325040	CGMP deviations	Little Moon Essentials LLC
Little Moon Essentials, Clear Breeze Plus, Hand Sanitizer (Alcohol 65% v/v) Packaged as a) 2 FL OZ (60ML) spray bottle, UPC Code 6 73673 88797 3, NDC 70722-319-02; b) 4 FL OZ (118ML) spray bottle, UPC Code 6 73673 88798 0, NDC 70722-319-04; Little Moon Essentials LLC Dania Beach, Fl 33004	Class II	Drugs	lot code expiration dates are not on products: a) 023170, b) 023170	CGMP deviations	Little Moon Essentials LLC
Methylphenidate Hydrochloride, Extended-release Tablets, USP, 36mg, 100-count Bottle, Rx Only, Manufactured for: Trigen Laboratories, LLC, Alpharetta, GA 30005, NDC 13811-708-10	Class II	Drugs	Lot 230159M, Exp Date 2/28/2026	Failed dissolution specifications: this product is being recalled due to this batch not	Trigen Laboratories

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Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
				meeting dissolution specifications.	
Venlafaxine Hydrochloride, extended-release capsules, USP, 37.5mg, 10 x 10 blister card in one carton, Rx only, Mfg by: Cadila Healthcare Ltd., Ahmedabad, India, Distributed by: Major Pharmaceutical 17177 N Laurel Park Dr., Suite 233, Livonia, MI 48152, USA, NDC 0904-7075-61, UPC code: 309047075614	Class II	Drugs	Lot code: M04614, Exp 09/30/2024	Failed dissolution specifications: out of specification result obtained during routine stability testing for high dissolution.	The Harvard Drug Group LLC dba Major Pharmaceuticals and Rugby Laboratories
Budesonide, USP (Micronized), 500 mg, White to off-white odorless, crystalline powder, Medisca Inc., Plattsburgh, NY, 12901, USA, NDC: 38779-3097-00.	Class II	Drugs	Lot #s: 202323/G, 202323/H, Exp. 07/31/2026	CGMP Deviations and Presence of Particulate Matter: Glass	Medisca Inc.
Decitabine for Injection 50mg per vial, For intravenous infusion only Cytotoxic Agent, Sterile, Rx Only, Single-Dose Vial, Distributed by: Sun Pharmaceutical Industries, Inc., Cranbury, NJ 08512, Manufactured by: Sun Pharmaceutical Ind. Ltd., Halol-Baroda Highway, Halol-389 350, Gujarat, India, NDC 47335-361-40.	Class II	Drugs	HAD2964A, Exp 7/31/2024	CGMP Deviations: Out of Specification for Total Aerobic Microbial Count (TAMC) test for unfiltered bulk for decitabine for injection.	SUN PHARMACEUTICAL INDUSTRIES INC
suntegrity, (Zinc Oxide 15%) IMPECCABLE SKIN sunscreen foundation, Multiple Shades, Broad Spectrum SPF30, Net WT 2OZ (56.7 g), Suntegrity Skincare, Las Vegas, NV 89128, a) NDC: 69949-151-01, UPC: 854245006170 - IVORY b) NDC: 69949-156-01, UPC: 854245006224 - NUDE c) NDC: 69949-152-01, UPC: 854245006187 - BUFF d) NDC: 69949-153-01, UPC: 854245006194 - SAND e) NDC: 69949-	Class II	Drugs	Lot: a) 107IV, Exp: 04/30/2025 b) 107NU, Exp: 06/30/2025; 109NU, Exp: 10/31/2025 c) 117BU, Exp: 10/31/2025 d) 113SA, Exp: 06/30/2025; 114SA, Exp: 10/31/2025 e) 106BR, Exp:	CGMP Deviations	SYNCHRONICITY SPA INC, DBA SUNTE

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Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
155-01, UPC: 854245006217 - BRONZE f) NDC: 69949-157-01, UPC: 854245006446 - MOCHA			04/30/2025; f) 101MO, Exp: 05/31/2025		
Blemfree All Day Lotion (salicylic acid 0.5% w/w), packaged in a) 1 oz. 29 ML tube NDC:53228-003-01 b) 4 OZ 118ML plastic bottle, UPC 7 01450 90008 6, NDC # 53228-002-01, Equibal Labs, Inc	Class II	Drugs	Lot # a) BF063221, exp. date 03/04/2025, BF097221, exp. date 04/07/2025, b) BF097221 exp date 04/07/2025	CGMP Deviations: Manufactured without following Current Good Manufacturing Practises.	Equibal Inc
Dianeal Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with 2.5% Dextrose, For Intraperitoneal Administration Only, 6000 mL per bag, Rx Only, Baxter Healthcare Corporation, Deerfield, IL 60015 USA. NDC: 0941-0457-01	Class II	Drugs	Lot R24B25FA; Exp. 2/28/2026	Lack of Assurance of Sterility: Potential presence of leaks originating from the Connector Assembly component.	Baxter Healthcare Corporation
buPROPion Hydrochloride Extended-release Tablets USP (XL) Once-Daily, 150 mg, 100 Tablets (10 x 10) per carton, Rx Only, Distributed by: American Health Packaging, Columbus, Ohio 43217, NDC: 60687-782-01.	Class II	Drugs	Lot 1017343, Exp. 12/31/2025	Failed Dissolution Specifications; the product is dissolving faster than the specified limits.	Amerisource Health Services LLC
Lidocaine HCL Injection, USP 2% 200mg/10mL (20mg/mL) and EPINEPHRINE HCl 1:200,000, 10 ml Single Dose Vial, Rx only, Compounded drug by Medivant Healthcare, 158 S Kyrene Rd, Chandler, AZ 85226, NDC 81483-0038-0, UPC 3 81483 00380 2	Class II	Drugs	Lot Number: 2311003, Expiration Date: 11/13/2024	Subpotent Drug: reduced efficacy for epinephrine	TAILSTORM HEALTH INC
Cardura XL (doxazosin) extended release tablets 4mg, 30-count bottles, Rx Only, Made in Singapore, Distributed by Roerig Division of Pfizer Inc, NY, NY 10017 NDC 0049-2040-10	Class II	Drugs	Lot #: 8147040; Exp. June 2024 Lot #: 8163764; Exp. March 2025	Failed Impurities/Degradation Specifications	Viatris Inc

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Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Cardura XL (doxazosin) extended release tablets 8mg, 30-count bottles, Rx Only Made in Singapore, Distributed by Roerig Division of Pfizer Inc, NY, NY 10017 NDC 0049-2080-10	Class II	Drugs	Lot#: 8147041; Exp. June 2024 Lot#: 8163765; Exp. March 2025	Failed Impurities/Degradation Specifications	Viatris Inc
Potassium Chloride Extended-Release Capsules, USP, (750 mg) 10 mEq K, 100-count bottle, Rx Only, Manufactured by: Glenmark Pharmaceuticals Ltd. Plot No. 2, Phase-2, Pharma Zone SEZ, Pithampur, Dist.-Dhar, Madhya Pradesh 454 775, India, Manufactured for: Glenmark Pharmaceuticals Inc, USA, Mahwah, NJ 07430. NDC 68462-357-01	Class II	Drugs	Lot #: 17230074, 17230221, Exp Dec-31-24; 17230468, 17230479, 17230553, 17230543, 17230561, Exp Jan-31-25; 17230619, 17230624, Exp Feb-28-25; 17230879, 17230890, 17230918, 17230984, 17230996, 17231002, 17231081, Exp Mar-31-25; 17231102, 17231135, 17231329, Exp Apr-30-25; 17231369, 17231513, Exp May-31-24; 17231516, 17231713, Exp Jun-30-25; 17231909, 17231903, Exp Jul-31-25; 17231943, Exp Aug-31-25; 17232166, 17232179, Exp Sep-30-25.	CGMP Deviations	Glenmark Pharmaceuticals Inc., USA

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Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Potassium Chloride Extended-Release Capsules, USP, (750 mg) 10 mEq K, 500-count bottle, Rx Only, Manufactured by: Glenmark Pharmaceuticals Ltd. Plot No. 2, Phase-2, Pharma Zone SEZ, Pithampur, Dist.-Dhar, Madhya Pradesh 454 775, India, Manufactured for: Glenmark Pharmaceuticals Inc, USA, Mahwah, NJ 07430. NDC 68462-357-05	Class II	Drugs	Lot #: 17230186, 17230192, 17230213, 17230278, 17230399, Exp Dec-31-24; 17230406, 17230412, 17230427, 17230444, 17230453, 17230495, Exp Jan-31-25; 17230574, 17230585, 17230608, 17230629, Exp Feb-28-25; 17230883, 17230921, Exp Mar-31-25; 17231087, 17231339, Exp Apr-30-25; 17231360, Exp May-31-25; 17231711, 17231745, Exp Jun-30-25; 17231819, 17231820, 17231936, 17231957, Exp Jul-31-25; 17231998, 17232012, Aug-31-25; 17232110, Exp Sep-30-25; 17232114, Exp Aug-31-25; 17232119, 17232343, Exp Sep-30-25.	CGMP Deviations	Glenmark Pharmaceuticals Inc., USA
STELLALIFE ADVANCED FORMULA Peppermint, VEGA Oral Care, Rinse, 16 fl oz (473 ml),	Class II	Drugs	Lot # 2550, exp. date 02-28-2026	Microbial Contamination of Non-Sterile Products:	Homeocare Laboratories, Inc.

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Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Distributed by: StellaLife, 2875 NE 191 Street, Suite 500, Aventura, FL 33180, NDC 69685-143-16				presence of Terribacillus species organism	
DELFLEX PERITONEAL DIALYSIS SOLUTION With LOW MAGNESIUM / LOW CALCIUM 4.25% DEXTROSE and attached stay "safe Exchange Set, 2500mL (Approx. 50 mL excess), Single Dose Container Sterile and Non-Pyrogenic, For Intraperitoneal Administration Only, Fresenius Medical Care NA Waltham, MA 02451, 1-800-323-5188 NDC 49230-212-94	Class II	Drugs	24AU03024, exp. date 07/31/2025	This product is being recalled due to the tube weld failure presents itself as a slow leak and can be difficult to detect.	Fresenius Medical Care Holdings, Inc.
Potassium Chloride Micro 10mEq K (750 mg) Extended Release Capsules, 30-count blister card, Rx only, MFG: Glenmark, Mahwah, NJ 07430, Repackaged by: RemedyRepack Inc., Indiana, PA 15701, NDC 70518-1203-03	Class II	Drugs	Lot #: J0758674-021824, Exp 03/31/2025; J0751898-011424, Exp 01/31/2025	CGMP Deviations: Out of specification for dissolution	RemedyRepack Inc.
Oatmeal Daily Moisturizing Body Lotion (1.3% Dimethicone), 8 fl oz (236mL), packaged in an HDPE bottle 12 bottles per case, Manufactured By:/Fabrique Par: , Brands International Corp., Newmarket, ON, L3X 2S2, Made in Canada.	Class II	Drugs	Lot# 24092009, Exp 03/27; 24094010, Exp 04/27	Microbial Contamination of Non-Sterile Products: confirmed presence of mold contamination	Brands International Corporation
Pravastatin Sodium Tablets, USP 80mg, packaged in a) 90-count bottle, NDC 68462-198-90; b) 500-count bottle, NDC 68462-198-05, Rx only, Manufactured by: Glenmark Pharmaceuticals Limited Pithampur, Madhya Pradesh 454775, India, Manufactured for: Glenmark Pharmaceuticals Inc., USA, Mahwah, NJ 07430,	Class II	Drugs	Lot#: a) 17211249, 17211264, 17211266,17211286, Exp 6/30/24; 17211525, 17211535, 17211549, Exp 7/31/24; 17211787, 17211801, 8/31/24; 17212041, 9/30/24; 17212088, 17212106,	Failed Dissolution Specifications: results below specifications	Glenmark Pharmaceuticals Inc., USA

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Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			Exp 10/31/24; 17212346, 17212345, 11/30/24; 17220053, 17220054, 17220055 12/31/24; 17220309, 17220310, Exp 1/31/25; b) 17211290, 6/30/2024		
Fludrocortisone Acetate Tablets, USP 0.1mg, Rx Only, 100 Tablets per bottle, Manufactured in Canada By: Patheon, Inc., Mississauga, ON, Canada L5N 7K9, Manufactured For: Teva Pharmaceuticals USA, Inc., North Wales, PA 19454, NDC 0555-0997-02.	Class II	Drugs	Lot #s: CNSDH, Exp. 6/30/2024; CNWVM, CNWWH, Exp. 07/31/2024; CNXKW, CNXKY, CNXMB, CNXMH, Exp. 09/30/2024; CPBTP, CPBTV, Exp. 11/30/2024.	Failed Impurities/Degradation Specifications: Product is being recalled due to API related substances and unknown impurities that are above the specification limits.	Teva Pharmaceuticals USA, Inc
Cyanocobalamin Injection, USP, 1,000mcg/mL, 1 mL Multiple-Dose Vial, Rx Only, Manufactured for: Northstar Rx LLC, Memphis, TN, 38141, Mfd. in India, NDC 16714-165-01.	Class II	Drugs	Lot #: L200253, L200281, L200301, Exp 07/31/2024	Presence of particulate matter: glass	Zydus Pharmaceuticals (USA) Inc
Nitrofurantoin Capsules, USP (Macrocrystals), 100 mg, Rx Only, 100 capsules per bottle, Manufactured by: Sidmak Laboratories (India) Pvt. Ltd. Plot No. 20, Pharmacity, Selaqui Industrial Area, Dehradun - 248-197, Uttarakhand, India. Distributed by: Sun Pharmaceutical Industries, Inc. Cranbury, NJ 08512, NDC 57664-233-88.	Class II	Drugs	Lot #s: 231067, 231069, Exp 04/30/2025	Failed Dissolution Specifications	SUN PHARMACEUTICAL INDUSTRIES INC
SinuFrin Decongestant (oxymetazoline HCl) Nasal Solution Nasal Decongestant,	Class III	Drugs	Lot: SD134; Exp: 10/31/2026	Sub-potent Drug	Neilmed Pharmaceuticals Inc

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Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Decongestant Relief for up to 12 Hours, 12 Hour Relief, 0.5 fl oz (15 ml) bottle, Manufactured by NeilMed Pharmaceuticals Inc, 602 Aviation Blvd, Santa Rosa, CA 95403 877-477-8633; NDC 13709-325-01; UPC 7 05928 09001 9.					
Eszopiclone Tablets, USP 1mg CIV, 30-count bottle, Rx only, Mfd. By: Dr. Reddy's Laboratories Limited, Bachupally - 500 090 INDIA, NDC 55111-629-30	Class III	Drugs	Lot#: C2302598, Exp 2/29/2025	Failed Impurities/Degradation Specifications: Related Substances	Dr. Reddy's Laboratories, Inc.
Dodex Injectable (Cyanocobalamin Injection) USP, 1,000mcg/mL, 1mL multiple dose vial, Rx only, Manufactured for: Accord Healthcare, Inc., Durham, NC 27703, Manufactured by: Intas Pharmaceuticals Limited, Ahmedabad-382 210, India, NDC 16729-533-08, UPC Code: 031672953308	Class III	Drugs	Lot# R2200834, R2200835, R2200841, R2200958, Exp 06/30/2024; R2201044 R2201045 R2201046, R2201047, R2201095, R2201142, R2201143, R2201144, Exp 07/31/2024; M2215870, M2215918, Exp 10/2024	Subpotent drug: out of specification results	Accord Healthcare, Inc.
Diflorasone Diacetate Ointment, USP, 0.05%, 60g tube, Rx only, Mfd. By: Lyne Laboratories, Inc., Brockton, MA 02301; Mfd. For: Rising Pharmaceuticals, Inc., East Brunswick, NJ 08816 NDC 64980-124-60	Class III	Drugs	Lot #, DI2303B, Exp 12/31/2024	Failed Impurities/Degradation Specifications: The impurity results at 12 months stability testing,did not conform to the specification limit.	Rising Pharma Holding, Inc.
Verapamil Hydrochloride Injection, USP 5 mg / 2mL(2.5 mg/mL), packaged as (a) 25x2 mL Single-Dose Vial per carton, Vial NDC: 70710-1643-1; Carton NDC 70710-1643-7; (b) 5x2 mL	Class III	Drugs	Lot# (a) Lots L300255, L300262, Exp Date 07/31/2025;	Cross contamination with other products.	Zydus Pharmaceuticals (USA) Inc

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Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Single-Dose Vial per carton, Vial NDC: 70710-1643-1; Carton NDC 70710-1643-5; Rx Only, Manufactured by: Zydus Lifesciences Ltd. Vadodara, India, Distributed by: Zydus Pharmaceuticals (USA)Inc., Pennington, NJ 08534,			(b)L300263, Exp Date 08/31/2025		
Verapamil Hydrochloride Injection, USP 10 mg/4 mL (2.5 mg/mL), 5 x 4 mL Single-Dose Vial per carton, Rx Only, Manufactured by: Zydus Lifesciences Ltd. Vadodara, India, Distributed by: Zydus Pharmaceuticals (USA)Inc., Pennington, NJ 08534, Vial NDC: 70710-1644-1, Carton NDC: 70710-1644-5.	Class III	Drugs	Lot L300269, Exp Date 07/31/2025	Cross contamination with other products.	Zydus Pharmaceuticals (USA) Inc
Micafungin for injection, USP, 100 mg/vial, Single-Dose Vial, Rx Only, Manufactured by: Zydus Lifesciences Ltd., Vadodara, India, Distributed by: Zydus Pharmaceuticals (USA) Inc., Pennington, NJ 08534, NDC 70710-1725-01 (vial), NDC 70710-1725-06 (outer box).	Class III	Drugs	Lot #: L300220, Exp. 05/31/2025.	Cross contamination with other products	Zydus Pharmaceuticals (USA) Inc
Micafungin for injection, USP, 100 mg/vial, Single-Dose Vial, Rx Only, Manufactured for: Northstar Rx LLC, Memphis, TN 38141, Manufactured by: Zydus Lifesciences Ltd., Vadodara, India, NDC 16714-301-01 (vial), NDC 16714-301-10 (outer box).	Class III	Drugs	Lot #: L300217, Exp. 04/31/2025.	Cross contamination with other products	Zydus Pharmaceuticals (USA) Inc

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

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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

Carboplatin Injection

Cefotaxime Sodium Injection

Cefotetan Disodium Injection

Chloroprocaine Hydrochloride Injection

Clindamycin Phosphate Injection

Clonazepam Tablet

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Conivaptan Hydrochloride Injection

Cromolyn Sodium Concentrate

Cyclopentolate Hydrochloride Ophthalmic Solution

Cytarabine Injection

Dacarbazine Injection

Desmopressin Acetate Spray

Dexamethasone Sodium Phosphate Injection

Dexmedetomidine Hydrochloride Injection

Dextrose Monohydrate Injection

Dextrose Monohydrate, Lidocaine Hydrochloride Anhydrous Injection

Diltiazem Hydrochloride Injection

Dobutamine Hydrochloride Injection

Dopamine Hydrochloride Injection

Dulaglutide Injection

Echothiophate Iodide Ophthalmic Solution

Epinephrine Bitartrate, Lidocaine Hydrochloride Injection

Epinephrine Injection, Syringes

Etomidate Injection

Fentanyl Citrate Injection

Flurazepam Hydrochloride Capsule

Furosemide Injection

Heparin Sodium Injection

Hydrocortisone Sodium Succinate Injection

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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

Methylphenidate Hydrochloride Tablet, Extended Release

Methylprednisolone Acetate Injection

Metronidazole Injection

Midazolam Hydrochloride Injection

Morphine Sulfate Injection

Naltrexone Hydrochloride Tablet

Nitroglycerin Injection

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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

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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

Vitamin A Palmitate Injection

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