



Drug Information Update

October 2024



Table of Contents

Table of Contents	1
Newly Available Generics.....	2
New Drug Entities/Strengths/Combinations	3
New Indications (Existing Drugs).....	5
Recalls.....	6
Current Drug Shortages	14

Newly Available Generics

Generic Name/ Dosage Form	Brand Name	Manufacturer	Indication
oxyCODONE HCl oral tablet abuse-deterrent 5mg, 10mg, 30mg	RoxyBond	Ohemo Life Sciences	<ul style="list-style-type: none"> • For the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.
Octreotide acetate intramuscular kit 20mg, 30mg	Sandostatin LAR Depot	Teva	<ul style="list-style-type: none"> • Treatment in patients who have responded to and tolerated octreotide acetate injection subcutaneous injection for: <ul style="list-style-type: none"> ○ Acromegaly ○ Severe diarrhea/flushing episodes associated with metastatic carcinoid tumors ○ Profuse watery diarrhea associated with Vasoactive Intestinal Peptide (VIP) secreting tumors
Hydrocortisone Sod Suc (PF) Injection Solution Reconstituted 100 MG	Solu-Cortef	Cipla USA	<ul style="list-style-type: none"> • For the treatment of allergic states, dermatologic diseases, endocrine disorders, gastrointestinal disease, hematologic disorders, neoplastic diseases, nervous system conditions, ophthalmic diseases, renal diseases, respiratory diseases, rheumatic disorders.

New Drug Entities/Strengths/Combinations

Drug Name	Generic Name	Description
Cobenfy Oral Capsule 50-20 MG, 100-20 MG, 125-30 MG, starter pack	xanomeline and trospium chloride	New entity. Oral first-in-class muscarinic agonist for the treatment of schizophrenia in adults. First new mechanism of action in 30 years, selectively targets muscarinic M1 and M4 receptors in the brain without blocking D2 receptors. Cobenfy did not cause weight gain or extrapyramidal symptoms in the clinical trial program, and does not carry the same black box warning as traditional atypical antipsychotics.
Truqap Oral Tablet Therapy Pack 160 MG, 200 MG	capivasertib	New dosage form. Indicated to be used in combination with Faslodex (fulvestrant) for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer with one or more gene biomarker alterations (PIK3CA, AKT1, or PTEN) as detected by an FDA-approved test, and have progressed on at least one endocrine-based regimen in the metastatic setting or recurrence on or within 12 months of completing adjuvant therapy. Competes with other available targeted therapies in second-line HER2-negative breast cancer, most notably Piqray (alpelisib), which specifically targets activated PIK3CA mutations.
Lumryz Starter Pack Oral Therapy Pack 4.5 & 6 & 7.5 GM	sodium oxybate	New starter pack. Central nervous system depressant indicated for the treatment of cataplexy or excessive daytime sleepiness (EDS) in adults with narcolepsy.
Audenz Intramuscular Prefilled Syringe 0.5 ML, vial	influenza A (H5N1) subunit adj	Inactivated vaccine indicated for active immunization for the prevention of disease caused by the influenza A virus H5N1 subtype contained in the vaccine.
Aqneursa Oral Packet 1 GM	levacetylleucine	New entity. Second approved product for treatment of neurological manifestation of Niemann-Pick Disease Type C (NPC) in adults and pediatric patients 15 kg or greater. Aqneursa is the only FDA-approved stand-alone therapy indicated for the treatment of NPC. Mechanism of action unknown.
Zituvimet XR Oral Tablet Extended Release 24 Hour 50-500 MG, 50-1000 MG, 100-1000 MG	sitagliptin / metformin hydrochloride	New dosage form. Approved in July 2024, just now launching. Fixed-dose combination of sitagliptin and metformin that is used to treat type 2 diabetes in adults. Zituvimet (IR) was first approved in 2023.
Vyalev Subcutaneous Solution 240-12 MG/ML	foscarbidopa and foslevodopa	First and only subcutaneous 24-hour infusion of levodopa-based therapy for the treatment of motor fluctuations in adults with advanced Parkinson's disease. Administered via pump and provides a continuous delivery of levodopa. 505b2 approval.

Drug Name	Generic Name	Description
Vyloy Intravenous Solution Reconstituted 100 MG	zolbetuximab-clzb	For use in combination with fluoropyrimidine- and platinum-containing chemotherapy for the first-line treatment of adults with locally advanced unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-negative gastric or gastroesophageal junction (GEJ) adenocarcinoma whose tumors are claudin (CLDN) 18.2 positive as determined by an FDA-approved test. VYLOY is the first and only CLDN18.2-targeted therapy approved in the U.S. Will compete with other first line combination treatments such as Keytruda and Opdivo, which are used as part of FOLFOX regimen.
carBAMazepine Oral Tablet Chewable 200 MG	carbamazepine	New strength of chewable tab. Also available in 100mg.

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†
Opdivo	nivolumab 40 mg/4 ml, 100 mg/10 ml, 120 mg/12 ml, 240 mg/24 ml intravenous vials	Bristol Myers Squibb	<ul style="list-style-type: none"> • Treatment of adult patients with resectable (tumors \geq4 cm or node positive) non-small cell lung cancer and no known EGFR mutations or ALK rearrangements, for neoadjuvant treatment, in combination with platinum-doublet chemotherapy, followed by single-agent Opdivo as adjuvant treatment after surgery. <p><i>Note: Opdivo has many other approved indications not mentioned here; see full prescribing information for details.</i></p>
Lumryz	sodium oxybate extended-release packets 4.5 g, 6 g, 7.5 g, 9 g	Avadel CNS Pharmaceuticals, LLC	<ul style="list-style-type: none"> • For the treatment of cataplexy or excessive daytime sleepiness (EDS) in adults patients 7 years of age and older with narcolepsy
Botox Cosmetic	onabotulinumtoxinA 50 unit, 100 unit vial	AbbVie	<p>Temporary improvement in the appearance of:</p> <ul style="list-style-type: none"> • Moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity • Moderate to severe lateral canthal lines associated with orbicularis oculi activity • Moderate to severe forehead lines associated with frontalis muscle activity • Moderate to severe platysma bands associated with platysma muscle activity
Abrysvo	Respiratory Syncytial Virus Vaccine	Pfizer	<ul style="list-style-type: none"> • Active immunization of pregnant individuals at 32 through 36 weeks gestational age for the prevention of lower respiratory tract disease (LRTD) and severe LRTD caused by respiratory syncytial virus (RSV) in infants from birth through 6 months of age. • Active immunization for the prevention of LRTD caused by RSV in individuals 60 years of age and older. • Active immunization for the prevention of LRTD caused by RSV in individuals 18 through 59 years of age who are at increased risk for LRTD caused by RSV.

Recalls

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Hard Steel Capsules packaged in 1 count blister packs in boxes of 10, 20 and 30, Manufactured in U.S.A.	Class I	Drugs	All lots	Marketed without an approved NDA/ANDA: FDA analysis found products to be tainted with undeclared acetaminophen and sildenafil.	Supercore Products Group Inc.
Gold Hard Steel Plus Liquid, 2 FL OZ bottles, UPC 787188873199	Class I	Drugs	All lots	Marketed without an approved NDA/ANDA: FDA analysis found products to be tainted with undeclared acetaminophen and sildenafil.	Supercore Products Group Inc.
Veklury (remdesivir) for injection, 100 mg/vial, Single-Dose Vial, Rx only, Manufactured for: Gilead Sciences, Inc., Foster City, CA 94404, NDC 61958-2901-2	Class I	Drugs	Lot: 47035CFA, Exp. 11/2025	Presence of Particulate Matter: Presence of glass particle.	Gilead Sciences, Inc.
Vail-Bon Jie Yang Wan capsules, 30-count bottle, Vall Boon Medical Factory Sdn. Bhd., No 1, Lorong Mengkudu, Taman Mengkudu, 14100 Juru, Malaysia.	Class I	Drugs	All lots within expiry	Marketed without an approved NDA/ANDA: Product found to be tainted with undeclared dexamethasone and chlorpheniramine.	123Herbals
Atovaquone Oral Suspension, USP 750 mg/5 mL, 210 mL bottle, Rx only, Distributed by: Bionpharma Inc., Princeton, NJ 08540, NDC # 69452-252-87.	Class I	Drugs	Lot # 2310083, Exp. 09/30/2025	Microbial Contamination of a Non-sterile Product: The product was found to be contaminated with Cohnella bacteria.	Bionpharma Inc.
Infla-650 Herbal Dietary Supplement, 700mg, packaged in pouches containing 60 capsules, Distributed by: Guru Inc., 4370 Lawrenceville Hwy NW, P.O. Box 2204, Lilburn, GA 30047-1100, USA. Ph.: 872 216 1566, http://www.dalayurevda.com , Made in India, UPC: 042535355019	Class II	Drugs	Batch # IN-032, Exp 11/30/2027	Marketed without an approved NDA/ANDA: FDA analysis found product to be tainted with undeclared acetaminophen, diclofenac, and phenylbutazone.	Guru Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Mycophenolic Acid Delayed-Release Tablets USP, 360 mg, Rx Only, 120 Tablets per bottle, Manufactured by Alkem Laboratories, LTD, INDIA; Distributed by Ascend Laboratories, LLC, Parsippany, NJ 07054, NDC 67877-427-12.	Class II	Drugs	Lots 22123437, 22123438, 22123535, Exp Date 9/30/24; 22123536, 22123537, 22123538, 22123646, 22123647, Exp Date 10/31/24; 23120529, 23120530, Exp Date 1/31/25; 23120703, 23120705, Exp Date 2/28/25; 23121429, 23121726, 23122049, 23122097, Exp Date, 4/30/25; 23121984, 23121985, 23121986, Exp Date 5/31/25; 23122325, 23122329, 23122330, 23122331, Exp Date 6/30/26; 23122776, 23122852, 23122853, 23123154, 23123155, Exp Date 8/31/26; 23123458, Exp Date 9/30/26.	Failed Dissolution Specifications	Ascend Laboratories, LLC
Mupirocin Ointment, USP, 2%, 22 g, Rx only, Manufactured by: Glenmark Pharmaceuticals, Ltd., Colvale-Bardez, Goa 403513, India. Manufactured for: Glenmark Pharmaceuticals Inc., USA, Mahwah, NJ, 07430, NDC 68462-180-22.	Class II	Drugs	Lot #: 19223615, 19223537, 19223544, 19223568, 19223593, 19223641, Exp. Date 08/2024; 19224055, 19224281, 19224307, 19224321, 19224341, 19224467, Exp. Date 09/2024; 19224525, 19224542, 19224560, 19224580, Exp. Date 10/2024; 19224990, 19224998, 19225014, 19225033, 19225293,	Subpotent Drug	Glenmark Pharmaceuticals Inc., USA

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			19225304, 19225320, 19225349, 19225367, 19225379, 19225401, Exp. Date 11/2024; 19230115, 19230123, 19230132, 19230137, 19230167, 19230170, Exp. Date 12/2024; 19230572, 19230607, 19230614, 19230628, 19230631, Exp. Date 1/2025; 19230874, 19230925, 19230941, 19230957, 19230976, 19231232, 19231238, 19231282, 19231285, Exp. Date 02/2025.		
Pyridoxine HCL (B6) Injection Solution, 100mg/mL, 30 mL Sterile Multiple-Dose Vial, For IM or IV use only, RX Only, Compounded by: Empower Pharmacy 5980 W Sam Houston Pkwy N Ste 300, Houston, TX 77041 NDC 72627-2424-1.	Class II	Drugs	Product lot number: 609763 Beyond Use Date: 04/18/2025	Lack of Assurance of Sterility	Empower Pharmacy
Refresh P.M., (Mineral Oil 42.5%, White Petrolatum 57.3%) Lubricant Eye Ointment, Net wt, 0.12 oz (3.5g) Tube, Distributed by: Allergen, an AbbVie company, Madison, NJ 07940, UPC code: 300230667043,	Class II	Drugs	Lot: 387392, 387393, 387394, Exp. Feb 25; 387395, 388729, 388730, 388731, 388732, 390391, 390404, Exp. Apr 25; 391688, 391734, Exp. Oct 25; 392616, 392620, Exp. Dec 25; 392987, 393560, Exp. Jan 26; 394816, 394821, Exp. Nov 25; 394927, 394929, Exp. Feb 26; 395713, 395992,	Lack of Assurance of Sterility: The impacted lots may contain a breach in the tube seal.	AbbVie Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			396815, Exp. Mar 26; 396816, 397248, 397315, Exp. Apr 26; 397316, 397774, 397775, 397776, 398436, 398437, Exp. May 26; 398621, 398643, 398739, 398944, 399001, 399255, 399270, 399271, Exp. Jun 26; 399798, 399806, 400003, Exp. Jul 26; 408668, 408723, 408737, 408853, 408895, Exp. Apr 27; 409121, 409142, Exp. May 27; 409261, Exp. Apr 27; T4534, T4535, T4591, T4592, Exp. Dec 24; T4660, T4661, T4696, T4697, T4709, T4772, T4773, Exp. Jan 25; T4844, T4845, Feb 25		
Refresh LACRI-LUBE, (42.5% Mineral Oil, 57.3% White Petrolatum) Lubricant Eye Ointment, Net wt, 0.12 oz (3.5g) Tube, Distributed by: Allergen, an AbbVie company, Madison, NJ 07940, UPC code: 300230312042	Class II	Drugs	Lot: 387489, Exp. Oct 24; 387490, Exp. Jun 25; 390422, Exp. Nov 24; 390424, Exp. Oct 24; 391692, Exp. Jun 25; 391893, Exp. Nov 25; 394822, Exp. Feb 26; 395991, Exp. Mar 26; 397905, 397973, 397974, Exp May 26; 399019, 399254, Exp. Jun 26; 399922, Exp. Jul 26; 408738, Exp. Mar 27; T3911, Exp. Sep 24; T4015, T4031, T4032, T4033, T4108, Exp. Oct 24.	Lack of Assurance of Sterility: The impacted lots may contain a breach in the tube seal.	AbbVie Inc.
Proparacaine Hydrochloride Ophthalmic Solution, USP 0.5% (sterile), 15 mL bottle,	Class II	Drugs	Lot # 476261, 479751, 479741, Exp 3/31/2026	Temperature abuse: Products exposed to improper	Mckesson Medical-Surgical Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Rx only, MFG: Bausch & Lomb, NDC 24208-730-06				temperature above drug label specifications.	Corporate Office
Vivier Sheer SPF 30 Mineral With Antioxidants (titanium dioxide 10% and zinc oxide 8%) packaged in 60 ml/2 fl oz, Vivier Canada Inc. / Mfd. for Vivier Pharma, Vaudereull-Dorion OC Canada, J7V 5V5, Champlain, NY USA 12919, Made in Canada, NDC 67226-2232-6. SKU 10-160-ZZ-80059-R	Class II	Drugs	Lot #: 91771, Exp. Date 09/2025	Microbial Contamination of Non-Sterile Product	Vivier Pharma, Inc.
EnviroClean Hand Sanitizer Gel (isopropyl alcohol 70% v/v), 473 mL (16 fl. oz.) bottles, EnviroServe Chemicals Inc., 603 South Wilson Avenue, Dunn NC, 28334, NDC 76563-3010-1	Class II	Drugs	Lot #: 042224-L1, Exp. Date 04/22/2025	CGMP deviations	EnviroServe Chemicals Inc.
Ryaltris (olopatadine hydrochloride and mometasone fluorate) Nasal Spray, 665 mcg/25 mcg per spray, 240 Metered Sprays/bottle, 29 g net fill weight, Distr. by Hikma Specialty USA Inc., Columbus, OH 43328, hikma, Glenmark Specialty SA. NDC 59467-700-27.	Class II	Drugs	Lots 14230425, Exp Date, Nov-25; 14240024, Exp Date Dec-25; 14240029, Exp Date Dec-25; 14240076, Exp Date Jan-26; 14240082 Exp Date, Jan-26, 14240090, Exp Date Jan-26; and 14240100, Exp Date Jan-26	Defective Delivery System: The dip tube is clogged causing the spray not to work.	Glenmark Pharmaceuticals Inc., USA
Atorvastatin Calcium Tablets, USP, 40mg, Rx only, 1000 Tablets per bottle, Manufactured for: Nivagen Pharmaceuticals, Inc. Sacramento, CA 95827, USA, Manufactured by: Umedica Laboratories Pvt Ltd., Vapi Gujarat 396195, India, NDC: 75834-257-01.	Class II	Drugs	Lot #: U24T0408A, Exp: 03/31/2026	Presence of Foreign Tablets/Capsules: A Carbamazepine Extended-Release 400 mg tablet was found in a 1000-count bottle of Atorvastatin Calcium Tablets, USP 40 mg.	Nivagen Pharmaceuticals Inc
Pluvicto, 1000 MBq/mL (27 mCi/mL), lutetium, LU 177, vipivotide tetraxetan injection, Single-dose vial, Sterile,	Class II	Drugs	Lot#: LPS240919B-16, 24-Sep-2024 Lot#: LPS240920B-16,	CGMP deviations	Advanced Accelerator

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Manufacturer Advanced Accelerator Applications, 57 E. Willow Street, NJ 07041, Millburn USA. NDC 69488-0010-61			25-Sep-2024 Lot#: LPS240920C-16, 25-Sep-2024		Applications USA, Inc.
Dapsone Gel 7.5%, 60 gram pump, Rx Only, Manufactured by: Zydus Lifesciences Ltd., Ahmedabad, India, Distributed by: Viona Pharmaceuticals Inc., Cranford, NJ 07016, NDC 72578-094-02.	Class II	Drugs	Lot #: T400512, Exp 02/28/2026	Crystallization	VIONA PHARMACEUTICALS INC
First Aid Antiseptic Ointment, Povidone Iodine USP 10%, Inactive Ingredients: mineral oil, petrolatum. NET Wt. 1 OZ (28.4 g) per tube, Distributed by: Rugby Laboratories, Indianapolis, IN 46268. Made in China. NDC: 0536-1271-80	Class II	Drugs	Lot, expiry: Lot 220901, Exp. 09/30/2024; Lot 230701, Exp. 07/31/2026; Lot 230301, Exp. 03/31/2026; Lot 230401, Exp. 04/30/2026; Lot 230501, Exp. 05/31/2026; Lot 230801, Exp. 08/31/2026; Lot 240301, Exp. 03/31/2027; Lot 240501, Exp. 04/30/2027.	Incorrect/Undeclared Excipients: The inactive ingredients labeled on the product boxes and tubes are listed as "mineral oil , petrolatum ". The inactive ingredients in the actual product are polyethylene glycol 400 , polyethylene glycol 4000.	Zhejiang Jingwei Pharmaceutical Co., Ltd.
Cisplatin Injection, 100mg/100mL (1mg/mL), For Intravenous Use, 100 mL Multiple Dose Vial, Rx Only, Manufactured for: Accord Healthcare Inc., Durham, NC 27703. Manufactured by: Intas Pharmaceuticals Limited, Pharmez, Ahmedabad 382 213, India. Mfg. Lic. No.: G/28/1336, NDC 16729-288-38	Class II	Drugs	Lot #: P2202009, Exp. Date: 03/2025	Failed Impurities/Degradation Specifications.	ACCORD HEALTHCARE, INC.
Duloxetine Delayed-Release Capsules, USP, 20mg, Rx Only, 500-count bottles, Mfr. by: Towa Pharmaceutical Europe, S.L. Distributed by: BPI, NDC 51991-746-05.	Class II	Drugs	Lot #: 220128, Exp. Date 12/2024	CGMP Deviations: Presence of Nitrosamine Drug Substance Related Impurity (NDSRI), N-nitroso-duloxetine, above the proposed interim limit.	Breckenridge Pharmaceutical , Inc
Phenylephrine HCl 0.9% Sodium Chloride Injection USP, 20 mg per 250 mL, Single	Class II	Drugs	Lot# C274-000039006, exp. date 19-Jan-25	CGMP violations	Fresenius Kabi Compounding, LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Dose Bag, Rx only, Fagron Sterile Services, Canton, MA NDC 71506-002-58					
Phenylephrine HCl 0.9% Sodium Chloride Injection USP, 20 mg per 250 mL, Single Dose Bag, Rx only, Fagron Sterile Services, Canton, MA NDC 71506-024-58	Class II	Drugs	Lot # C274-000037046, exp. date 13-Oct-24	cGMP violations	Fresenius Kabi Compounding, LLC
Phenylephrine HCl 0.9% Sodium Chloride Injection USP, 10 mg per 250 mL, Single Dose Bag, Rx only, Fagron Sterile Services, Canton, MA NDC 71506-010-58	Class II	Drugs	Lot #C274-000037039, exp. date 9-Oct-24 C274-000037239, exp. date 21-Oct-24	cGMP violations	Fresenius Kabi Compounding, LLC
Phenylephrine HCl 0.9% Sodium Chloride Injection USP, 10 mg per 250 mL, Single Dose Bag, Rx only, Fagron Sterile Services, Canton, MA NDC 71506-029-58	Class II	Drugs	Lot # C274-000038499, exp. date 21-Dec-24	cGMP violations	Fresenius Kabi Compounding, LLC
Vancomycin HCl 750 mg per 250 mL 0.9% Sodium Chloride Injection USP, Single Dose Bag, Rx only, Fagron Sterile Services, Canton, MA NDC 71506-014-58	Class II	Drugs	Lot # C274-000038004, exp. date 27-Nov-24	cGMP violations	Fresenius Kabi Compounding, LLC
NORpinephrine Bitartrate 0.9% Sodium Chloride Injection USP, 4 mg per 250 mL, Single Dose Bag, Rx only, Fagron Sterile Services, Canton, MA NDC: 71506-025-58	Class II	Drugs	Lot # C274-000038582, exp. date 29-Nov-24	cGMP violations	Fresenius Kabi Compounding, LLC
NORpinephrine Bitartrate 0.9% Sodium Chloride Injection USP, 8 mg per 250 mL, Single Dose Bag, Rx only, Fagron Sterile Services, Canton, MA NDC: 71506-027-58	Class II	Drugs	Lot # C274-000038404, exp. date 18-Nov-24	cGMP violations	Fresenius Kabi Compounding, LLC
Oxytocin 0.9% Sodium Chloride Injection USP, 30 units per 500 mL Single Dose Bag, Rx only, Fagron Sterile Services, Canton, MA NDC: 71506-028-59	Class II	Drugs	Lot # C274-000038801, exp. date 9-Oct-24 C274-000039045, exp. date 24-Oct-24 C274-000039240, exp. date 31-Oct-24	cGMP violations	Fresenius Kabi Compounding, LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
EPINEPHrine 0.9% Sodium Chloride Injection USP, 8 mg per 250 mL Single Dose Bag, Rx only, Fagron Sterile Services, Canton, MA NDC: 71506-060-58	Class II	Drugs	Lot # C274-000038958, exp. date 17-Oct-24 C274-000039206, exp. date 23-Oct-24	cGMP violations	Fresenius Kabi Compounding, LLC
Thiamine HCl 0.9% Sodium Chloride Injection USP, 500 mg per 100 mL, Single Dose Bag, Rx only, Fagron Sterile Services, Canton, MA NDC: 71506-079-56	Class II	Drugs	Lot # C274-000037436, exp. date 30-Oct-24 C274-000038893, exp. date 7-Jan-25	cGMP violations	Fresenius Kabi Compounding, LLC
OneLAX Docusate Sodium Liquid (docusate sodium 50 mg/5 mL) Stool Softener Laxative, 16 FL OZ (473 mL) bottle, Akron Pharma, Manufactured for: Akron Pharma, Inc., Fairfield, NJ 07004, NDC 71399-0039-06.	Class II	Drugs	Lot #ODS230001A, ODS230002A, Exp. 10/2025; ODS230003A, Exp. 11/2025.	CGMP Deviations	Akron Pharma, Inc.
AK Forte Ortiga y Omega 3 Cont. Neto 100 Tabletas, 400 mg,	Class II	Drugs	All Lots	Marketed without an Approved NDA/ANDA: FDA analysis found the product to be tainted with undeclared diclofenac and acetaminophen.	C & A Naturistics
Ciclopirox Gel 0.77%, For Dermatologic Use Only, Not for Use in Eyes, Rx Only, a) 30 gm Tube, NDC 68462-0455-35; b) 45 gm Tube, NDC 68462-0455-47; c) 100 gm Tube, NDC 68462-0455-94, Manufactured by: Glenmark Pharmaceuticals, Ltd., Colvale-Bardez, Goa 403513, India, Manufactured for: Glenmark Pharmaceuticals Inc., USA, Mahwah, NJ 07430.	Class III	Drugs	Lot #: a) 19242028, Exp. 04/30/2026; b) 19242028, Exp. 04/30/2026; c) 19242028, Exp. 04/30/2026	Defective Container: Firm received complaints of broken tube at the seal.	Glenmark Pharmaceuticals Inc., USA

*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

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

Chloroprocaine Hydrochloride Injection

Clindamycin Phosphate Injection

Clonazepam Tablet

Conivaptan Hydrochloride Injection



Cromolyn Sodium Concentrate

Cyclopentolate Hydrochloride Ophthalmic Solution

Dacarbazine Injection

Desmopressin Acetate Spray

Dexamethasone Sodium Phosphate Injection

Dexmedetomidine Hydrochloride Injection

Dextrose Monohydrate 10% Injection

Dextrose Monohydrate 25% Injection

Dextrose Monohydrate 5% Injection

Dextrose Monohydrate 50% Injection

Dextrose Monohydrate 70% Injection

Dextrose Monohydrate, Lidocaine Hydrochloride Anhydrous Injection

Dobutamine Hydrochloride Injection

Dopamine Hydrochloride Injection

Dulaglutide Injection

Echothiophate Iodide Ophthalmic Solution

Epinephrine Bitartrate, Lidocaine Hydrochloride Injection

Etomidate Injection

Fentanyl Citrate Injection

Flurazepam Hydrochloride Capsule

Furosemide Injection

Heparin Sodium Injection



Hydrocortisone Sodium Succinate Injection
Hydromorphone Hydrochloride Injection
Hydroxypropyl Cellulose (1600000 Wamw) Insert
Indocyanine Green Injection
Isoniazid Tablet
Ketamine Hydrochloride Injection
Ketorolac Tromethamine Injection
Lactated Ringers 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

Parathyroid Hormone Injection

Penicillin G Benzathine Injection

Peritoneal Dialysis Solution

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

Somatropin Injection

Sterile Water Injection

Sterile Water Irrigant

Streptozocin Powder, For Solution

Sufentanil Citrate Injection

Technetium Tc-99m Pyrophosphate Kit Injection

Technetium Tc-99m Sodium Pertechnetate Generator

Triamcinolone Acetonide Injection

Triamcinolone Hexacetonide Injection

Valproate Sodium Injection

Vecuronium Bromide Injection