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# Drug Information Update

October 2021



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## NEWLY AVAILABLE GENERICS

Generic Name/ Dosage Form	Brand Name	Manufacturer	Indication
Verenicline tartrate 0.5 mg, 1 mg tablet	Chantix	Pfizer	<ul style="list-style-type: none"> <li>For use as an aid to smoking cessation treatment</li> </ul>
Ezetimibe/rosuvastatin calcium 10 mg-5 mg, 10 mg-10 mg, 10 mg-20 mg, 10 mg-40 mg tablets	Roszet	Althera	<ul style="list-style-type: none"> <li>For use as an adjunct to diet in patients with primary non-familial hyperlipidemia to reduce low-density lipoprotein cholesterol (LDL-C).</li> <li>For use alone or as an adjunct to other LDL-C-lowering therapies in patients with homozygous familial hypercholesterolemia (HoFH) to reduce LDL-C.</li> </ul>
Everolimus 10 mg tablet	Afinitor	Novartis	<ul style="list-style-type: none"> <li>For the treatment of postmenopausal women with advanced hormone receptor-positive, HER2-negative breast cancer in combination with exemestane, after failure of treatment with letrozole or anastrozole.</li> <li>For the treatment of adult patients with advanced RCC after failure of treatment with sunitinib or sorafenib.</li> <li>For the treatment of adult patients with renal angiomyolipoma and TSC, not requiring immediate surgery.</li> <li>Indicated in adult and pediatric patients aged 1 year and older with TSC for the treatment of SEGA that requires therapeutic intervention but cannot be curatively resected.</li> </ul>
Azathioprine 75 mg, 100 mg tablet	Azasan	Salix	<ul style="list-style-type: none"> <li>For use as an adjunct for the prevention of rejection in renal homotransplantation.</li> <li>For the management of active rheumatoid arthritis to reduce signs and symptoms.</li> </ul>

## NEW DRUG ENTITIES/STRENGTHS/COMBINATIONS

Drug Name	Generic Name	Description	Comments
Lybalvi 5 mg-10 mg, 10 mg-10 mg, 15 mg-10 mg, 20 mg-10 mg tablet	olanzapine/samidorphan Malate	A combination of olanzapine, an atypical antipsychotic, and samidorphan, an opioid antagonist, indicated for the treatment of schizophrenia in adults, bipolar disorder in adults, acute treatment of manic or mixed episodes as monotherapy and as adjunct to lithium or valproate, maintenance monotherapy treatment	New Entity and New Combination
Exkivity 40 mg capsule	mobocertinib Succinate	Oral tyrosine kinase inhibitor conditionally approved as later-line therapy for advanced/metastatic NSCLC with EGFR exon 20 mutations	New Entity
Tivdak 40 mg intravenous solution	tisotumab vedotin-tftv	Conditional approval for use in previously treated recurrent or metastatic cervical cancer; antibody-drug conjugate directed at tissue factor (TF) expressing cancer cells.	New Entity
Opzelura 1.5 % topical cream	ruxolitinib phosphate	First topical JAK inhibitor; FDA approved for treatment of atopic dermatitis.	New Route, Dosage Form, and Strength
Semglee (insulin glargine-yfgn) 100 unit/mL subcutaneous solution, subcutaneous pen	insulin glargine-yfgn	Biosimilar interchangeable insulin to Lantus.	New Entity; Interchangeable with Lantus
Qulipta 10 mg, 30 mg, 60 mg tablet	atogepant	Oral CGRP inhibitor for the preventive treatment of episodic migraine in adults.	New Entity

Drug Name	Generic Name	Description	Comments
Livmarli 9.5 mg/mL oral solution	maralixibat chloride	Oral solution for the treatment of cholestatic pruritus in patients with Alagille syndrome one year of age and older; a minimally absorbed ileal bile acid transporter (IBAT) inhibitor.	New Entity
Diclofenac potassium 25 mg tablet	diclofenac potassium	New strength generic Cataflam	New Strength
Dengvaxia (PF) 10exp4.5-6 CCID50/0.5 mL subcutaneous suspension	dengue vaccine, live, vero(pf)	Prevention of dengue disease; only for those with confirmed previous infection.	New Entity
Sertraline 150 mg, 200 mg capsule	sertraline Hcl	New capsule formulation of sertraline	New Dosage Form and Strength
Skytrofa 3 mg, 3.6 mg, 4.3 mg, 5.2 mg, 6.3 mg, 7.6 mg, 9.1 mg, 11 mg, 13.3 mg subcutaneous cartridge	lonapegsomatropin-tcgd	A once-weekly growth hormone for pediatric patients 1 year and older with growth failure due to endogenous GH deficiency	New Entity
Tecartus 1x10exp6 to 1x10exp8 cell intravenous suspension	brexucabtagene autoleucel	New indication and strength; for relapsed or refractory B-cell precursor acute lymphoblastic leukemia.	New Strength
Tavneos 10 mg capsule	avacopan	Oral selective complement 5a receptor inhibitor, as an adjunctive treatment of adult patients with severe active ANCA vasculitis in combination with standard therapy.	New Entity

## NEW INDICATIONS (EXISTING DRUGS)

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

Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication†
Jakafi	Ruxolitinib phosphate tablets 5mg, 10mg, 15mg, 20mg, 25mg	Incyte Corp	Indicated for the treatment of: <ul style="list-style-type: none"> <li>Intermediate or high-risk myelofibrosis (MF), including primary MF, post-polycythemia vera MF and post-essential thrombocythemia MF in adults</li> <li>Polycythemia vera (PV) in adults who have had an inadequate response to or are intolerant of hydroxyurea</li> <li>Steroid-refractory acute graft-versus-host disease (aGVHD) in adult and pediatric patients 12 years and older</li> <li><b>Chronic graft-versus-host disease (cGVHD) after failure of one or two lines of systemic therapy in adult and pediatric patients 12 years and older</b></li> </ul>
Repatha	Evolocumab injection, 140mg/mL syringe or autoinjector, 420ng/3.5mL on- body infuser with prefilled cartridge	Amgen	Indicated for the treatment of: <ul style="list-style-type: none"> <li>In adults with established cardiovascular disease to reduce the risk of myocardial infarction, stroke, and coronary revascularization</li> <li>As an adjunct to diet, alone or in combination with other low-density lipoprotein cholesterol (LDL-C)-lowering therapies, in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH), to reduce LDL-C</li> <li><b>as an adjunct to diet and other LDL-C-lowering therapies in pediatric patients aged 10 years and older with HeFH, to reduce LDL-C</b></li> </ul>

Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication†
Erbitux	Cetuximab injection, 100mg/50mL, 200mg/100mL in single-dose vials	Bristol-Myers Squibb	<ul style="list-style-type: none"> <li>As an adjunct to other LDL-C-lowering therapies <b>in adults and pediatric patients aged 10 years and older</b> patients with homozygous familial hypercholesterolemia (HoFH), to reduce LDL-C</li> </ul> <p>Indicated for the treatment of:</p> <p><u>Head and Neck Cancer</u></p> <ul style="list-style-type: none"> <li>Locally or regionally advanced squamous cell carcinoma of the head and neck in combination with radiation therapy.</li> <li>Recurrent locoregional disease or metastatic squamous cell carcinoma of the head and neck in combination with platinum based therapy with fluorouracil.</li> <li>Recurrent or metastatic squamous cell carcinoma of the head and neck progressing after platinum-based therapy.</li> </ul> <p><u>Colorectal Cancer</u></p> <ul style="list-style-type: none"> <li>K-Ras wild-type, EGFR-expressing, metastatic colorectal cancer as determined by an FDA-approved test               <ul style="list-style-type: none"> <li>in combination with FOLFIRI for first-line treatment,</li> <li>in combination with irinotecan in patients who are refractory to irinotecan-based chemotherapy,</li> <li>as a single-agent in patients who have failed oxaliplatin- and irinotecan-based chemotherapy or who are intolerant to irinotecan.</li> </ul> </li> </ul> <p><u>Limitations of Use:</u> ERBITUX is not indicated for treatment of Rasmutant colorectal cancer or when the results of the Ras mutation tests are unknown.</p>

Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication†
			<ul style="list-style-type: none"> <li>• <b>BRAF V600E Mutation-Positive Metastatic Colorectal Cancer (CRC) in combination with encorafenib, for the treatment of adult patients with metastatic colorectal cancer (CRC) with a BRAF V600E mutation, as detected by an FDA-approved test, after prior therapy.</b></li> </ul>
Jemperli	Dostarlimab-gxly 500mg/10mL vial	GSK	<p>Indicated for the treatment of:</p> <ul style="list-style-type: none"> <li>• Adult patients with mismatch repair deficient (dMMR) recurrent or advanced endometrial cancer (EC), as determined by an FDA-approved test, that has progressed on or following prior treatment with a platinum-containing regimen, or <b>solid tumors, as determined by an FDA-approved test, that have progressed on or following prior treatment and who have no satisfactory alternative treatment options</b></li> </ul>
Dextenza	Dexamethasone ophthalmic insert, 0.4mg	Ocular Therapeutix	<p>Indicated for the treatment of</p> <ul style="list-style-type: none"> <li>• <b>Ocular itching associated with allergic conjunctivitis.</b></li> </ul>
Verzenio	Ademaciclib tablets, 50mg, 100mg, 150mg, 200mg	Eli Lilly and Company	<p>Indicated for the treatment of:</p> <ul style="list-style-type: none"> <li>• <b>in combination with endocrine therapy (tamoxifen or an aromatase inhibitor) for the adjuvant treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, node-positive, early breast cancer at high risk of recurrence and a Ki-67 score <math>\geq 20\%</math> as determined by an FDA approved test.</b></li> <li>• in combination with an aromatase inhibitor as initial endocrine based therapy for the treatment of postmenopausal women, <b>and men</b>, with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer.</li> </ul>



Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication†
			<ul style="list-style-type: none"> <li>in combination with fulvestrant for the treatment of adult patients <b>(addition of male patients)</b> with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer with disease progression following endocrine therapy.</li> <li>monotherapy for the treatment of adult patients with HR positive, HER2-negative advanced or metastatic breast cancer with disease progression following endocrine therapy and prior chemotherapy in the metastatic setting.</li> </ul>
Tecartus	Brexucabtagene autoleucel suspension for IV infusion, $1 \times 10^6$ CAR-positive viable T cells per kg of body weight, with a maximum of $1 \times 10^6$ CAR-positive viable T cells in approximately 68 mL	Kite Pharma, Inc.	<p>Indicated for the treatment of:</p> <ul style="list-style-type: none"> <li>Adult patients with relapsed or refractory mantle cell lymphoma (MCL).</li> <li><b>Adult patients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL).</b></li> </ul>

## RECALLS

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
X RATED HONEY FOR MEN, packaged in 15g packets, 4 packets per box, UPC 6 13682 41232 2	Class I	Drugs	All lots, Exp. 12/2025	Marketed without an approved NDA/ANDA: Product found to be tainted with Tadalafil.	Phe Inc
Avicel RC-591 NF (MCC/Carboxymethylcellulose Sodium) NF, bulk powder, 80.0 KG drum, Manufactured by: DuPont Nutrition USA, Inc., 1301 Ogletown Road, Newark, DE 19711	Class I	Drugs	Lot # 2173766940	Microbial Contamination of Non-Sterile Product: Out-of-specification results obtained for total aerobic microbial count (TAMC).	DuPont Nutrition USA, Inc
Neutrogena Beach Defense water+sun protection sunscreen spray BROAD SPECTRUM SPF 50, Avobenzone (3%), Homosalate (10%), Octisalate (5%), Octocrylene (10%), NET WT. 6.5 OZ. (184 g) aerosol can, Distributed by: JOHNSON & JOHNSON CONSUMER, INC. Skillman, NJ 08858, UPC 0 86800 11254 9	Class I	Drugs	16621E01, exp 5/2024	Chemical Contamination: product contains benzene levels above the maximum daily exposure limits	Johnson & Johnson Consumer, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Neutrogena Beach Defense water+sun protection sunscreen spray BROAD SPECTRUM SPF 60+, Avobenzone (3%), Homosalate (10%), Octisalate (5%), Octocrylene (10%) NET WT. 8.5 OZ. (240 g) aerosol can, Distributed by: JOHNSON & JOHNSON CONSUMER, INC. Skillman, NJ 08858, UPC 0 86800 11255 6	Class I	Drugs	06320E26, exp 1/2023	Chemical Contamination: product contains benzene levels above the maximum daily exposure limits	Johnson & Johnson Consumer, Inc.
Ruzurgi (amifampridine) Tablets 10 mg, packaged in 100-count bottles, Rx only, Manufactured by: Jacobus Pharmaceutical Company, Inc, P.O. Box 5290, Princeton, New Jersey 08540, NDC 49938-110-01.	Class I	Drugs	Lot #: 18038, 18039, Exp 03/2023; 18079, Exp 05/2023	Microbial contamination of non-sterile products: Firm's testing found lots to exceed specification for aerobic bacteria, yeast, and mold counts.	Jacobus Pharmaceutical Company Inc.
ALPHA MALE+ Male Enhancer, fruit chew strips, 1 strip per foil pouch, Distributed by Umbrella Labs, Made in the USA, UPC 8 60003 03770 6. Also manufactured for and distributed	Class I	Drugs	All lots within expiry	Marketed Without an Approved NDA/ANDA: FDA analysis determined the presence of tadalafil	Alpha-Tek LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
by: Alpha Male Plus, Tucson, AZ UPC 8 60003 74518 2 (pouch), UPC 8 60003 74512 0(carton)					
Firvanq (vancomycin hydrochloride for oral solution), Vancomycin 50 mg/mL Kit, Each Kit Includes: 1 bottle containing 7.7 g Vancomycin Hydrochloride USP, powder for oral solution and 1 bottle containing 145 mL Grape Flavored Diluent for reconstitution per carton, Rx only, Manufactured for: Azurity pharmaceuticals, Wilmington, MA 01887, NDC 65628-206-05.	Class I	Drugs	Lot # 21035, Exp 7/31/2022	Product Mix-up: Incorrect diluent component included in the kit.	Azurity Pharmaceuticals, Inc.
Glucagon Emergency Kit for Low Blood Sugar, Glucagon for Injection, 1 mg per vial; Diluent for Glucagon, 1 mL syringe. Rx only, Marketed by: Lilly USA, LLC, Indianapolis, IN 46285; Glucagon, NDC: 0002-8031-01	Class I	Drugs	Lot #: D239382D, Exp. Date April 2022	SUBPOTENT DRUG: Vial contained a liquid substance, instead of the expected powder substance. There was also a lack of full drug effect upon administration.	Eli Lilly & Company
Chantix (varenicline) tablets 0.5mg/1mg, 56 Tablets, Rx only,	Class II	Drugs	Lots 00018522, 00018523, 00018739, 00018740,	CGMP Deviations: Presence of the N-	Pfizer Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Distributed by Pfizer Labs, Division of Pfizer Inc. NY, NY 10017, Made in Ireland, NDC 00069-0471-03. carton containing one blister pack of 11 0.5 mg tablets and one blister pack containing 42.1 mg tablets.			00020231, 00020232, 00020357, 00020358, 00020716, 00020813, 00021288, 00021289, 00021420, 00021687, 00021688, 00021788, 00021789, 00021790, 00021791, 00021792, 00022819, 00022851, 00023136, 00023137, 00023190, 00023448, DM0275, DM0276, DM0277, DY4470, EC5911, EC5912, ED6814, ET1600, ET1603, ET1607, ET1609, ET1611 EXPIRATION DATE: August 2021 January 2023	nitroso-varenicline impurity above FDA s acceptable interim acceptable intake limit	
Chantix (varenicline) tablets 0.5mg, 56 Tablets, Rx only, Distributed by Pfizer Labs, Division of Pfizer Inc. NY, NY 10017, Made in Ireland, NDC 0069-0468-56.	Class II	Drugs	Lots , CY6861, DM9007, DM9008, EN5725, EN8362, EN8467 EXPIRATION DATE: January 2022 - May 2023	CGMP Deviations: Presence of the N-nitroso-varenicline impurity above FDA s acceptable interim acceptable intake limit	Pfizer Inc.
Chantix (varenicline) tablets 1 mg, 56 Tablets, Rx only,	Class II	Drugs	Lots 00018777, 00019289, 00019593, 00019682,	CGMP Deviations: Presence of the N-	Pfizer Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Distributed by Pfizer Labs, Division of Pfizer Inc. NY, NY 10017, Made in Ireland, NDC 0069-0469-56.			00019846, 00019977, 00020295, 00020448, 00020458, 00020480, 00021024, 00021073, 00021074, CW1565, CW1566, CW1567, CW1568, CW1569, CW1570, CW1571, CW1572, CW1573, CW1574, CW1575, CW1578, CW1579, CW1581, DF5277, DF5278, DF5279, DF5280, DF5281, DF5282, DR5086, DR5092, DR5093, DR5094, DT3885, DW4148, DW4152, DY7987, EC9841, EC9842, EC9847, EC9848, EE1011, EM1069, EM1070, EN5694, EN5695, EP1717, EP1718, EP1719, EW2012, EW3854, EW3865, EX2102, EX2103 EXPIRATION DATE: September 2021 December 2023	nitroso-varenicline impurity above FDA s acceptable interim acceptable intake limit	
Chantix (varenicline) tablets 1 mg, Carton containing 4 blister packs of 14 tablets each,, Rx only,	Class II	Drugs	Lots 00019431, 00019542, 00019543, 00019544, 00020814, 00020815,	CGMP Deviations: Presence of the N-nitroso-varenicline	Pfizer Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Distributed by Pfizer Labs, Division of Pfizer Inc. NY, NY 10017, Made in Ireland, NDC 0069-0469-03. EXPIRATION DATE: September 2021 June 2023			00020907, 00020965, 00021421, 00021422, 00021423, 00022136, 00022174, 00022175, 00022176, 00022177, 00022765, 00022766, 00023134, 00023135, 00023747, 00023748, DL3896, DL7779, DR2614, DX4576, DX5870, DX5871, DX5872, DX5873, DX7805, DY6078, DY7060, DY9367, DY9473, DY9475, DY9476, DY9505, EC5910, EC5913, EE9391, EF2346, EM4805, EM4807, EN2005, ET1601, ET1605, ET1606 EXPIRATION DATE: September 2021 December 2023	impurity above FDA s acceptable interim acceptable intake limit	
Betadine Solution Swabstick Povidone-Iodine Solution USP, 10 % single and three count Antispetic Non-Sterile Solution Avrio Health LP Stamford, CT	Class II	Drugs	Lot # 11901232, Exp. Date 09/30/2021 11901549, Exp. Date 11/30/2021 12000585, Exp. Date 03/31/2022 12000964, Exp. Date 5/31/2022 12001457, Exp.	Subpotent Drug	AVRIO HEALTH L.P

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
06901-3431 NDC 67618-153-01, NDC 67618-153-03			Date 7/31/2022 12002142, Exp. Date 12/31/2022 12100407, Exp. Date 03/31/2023 11901231, Exp. Date 09/30/2021 11901548, Exp. Date 11/30/2021 12000584, Exp. Date 03/31/2022 12000963, Exp. Date 05/31/2022 12001185, Exp. Date 06/30/2022 12001456, Exp. Date 07/31/2022 12002150, Exp. Date 12/31/2022 12100406, Exp. Date 03/31/2023		
Carbamazepine 200mg Tablets, USP, 200 mg, 100 Count Unit Dose Cartons, Rx only, Manufactured by: Torrent Pharmaceuticals Ltd., Bharuch- 392130, India; Manufactured for: Torrent Pharma, Inc., Basking Ridge, NJ 07920; Distributed by: MAJOR PHARMACEUTICALS, 17177 N. Laurel Park Dr., Suite	Class II	Drugs	Lot R01562; Exp. 10/2022	Failed Dissolution Specifications	The Harvard Drug Group



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
233, Livonia, MI 48152 USA. NDC 0904-6172-61					
Fulvestrant Injection 250 mg/5 mL (50 mg/mL) For Intramuscular Use Only Contains 2 single-dose pre-filled syringes Rx only NDC 68462-317-32	Class II	Drugs	Lots: 30200014 Exp. 04/30/2022; 30200015 Exp. 05/31/2022; 30200015 Exp. 05/31/2022; 30200016 Exp. 05/31/2022; 30200036 Exp. 09/30/2022; 30200038 Exp. 09/30/2022; 30200039 Exp. 09/30/2022; 30200040 Exp. 09/30/2022; 30210001 Exp. 12/31/2022; 30210002 Exp. 12/31/2022; 30210003 Exp. 01/31/2023; 30210004 Exp. 01/31/2023; 30210005 Exp. 01/31/2023; 30210006 Exp. 01/31/2023; 30210014 Exp. 02/28/2023; 30210022 Exp. 02/28/2023; 30210028 Exp. 02/28/2023; 30210029 Exp. 02/28/2023; 30210030 Exp. 02/28/2023; 30210031 Exp. 02/28/2023	Lack of Assurance of Sterility	Glenmark Pharmaceuticals Inc., USA

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Naproxen Sodium Tablets, USP 275 mg 100 Tablets Rx Only NDC 68462-178-01 Manufactured by: Glenmark Pharmaceuticals Inc., USA 4147 Goldmine Road Monroe, NC 28110 Manufactured for: Glenmark Pharmaceuticals Inc., USA Mahwah, NJ 07430	Class II	Drugs	Lots: 29190087 Exp. 10/31/2021; 29190088 Exp. 10/31/2021; 29190089 Exp. 10/31/2021; 29200077 Exp. 11/30/2022; 29200078 Exp. 11/30/2022	CGMP Deviations	Glenmark Pharmaceuticals Inc., USA
Naproxen Sodium Tablets, USP 550 mg Rx Only Manufactured by: Glenmark Pharmaceuticals Inc., USA 4147 Goldmine Road Monroe, NC 28110 Manufactured for: Glenmark Pharmaceuticals Inc., USA Mahwah, NJ 07430 a) 100 Tablets NDC 68462-179-01; b) 500 Tablets NDC 68462-179-05	Class II	Drugs	Lots: a) 29190082 Exp. 09/30/2021; 29190083 Exp. 09/30/2021; 29190084 Exp. 10/31/2021; 29190085 Exp. 10/31/2021; 29200001 Exp. 12/31/2021; 29200003 Exp. 01/31/2022; 29200004 Exp. 01/31/2022; 29200005 Exp. 01/31/2022; 29200012 Exp. 02/28/2022; 29200013 Exp. 02/28/2022; b) 29200010 Exp. 02/28/2022	CGMP Deviations	Glenmark Pharmaceuticals Inc., USA
Chlorzoxazone Tablets USP 375 mg 100 Tablets Rx Only NDC 68462-724-01 Manufactured by: Glenmark Pharmaceuticals Inc., USA 4147 Goldmine Road	Class II	Drugs	Lots: 29200022 Exp. 03/31/2022; 29200024 Exp. 03/31/2022; 29200035 Exp. 06/30/2022	CGMP Deviations	Glenmark Pharmaceuticals Inc., USA

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Monroe, NC 28110 Manufactured for: Glenmark Pharmaceuticals Inc., USA Mahwah, NJ 07430					
Chlorzoxazone Tablets USP 750 mg 100 Tablets Rx Only NDC 68462-725-01 Manufactured by: Glenmark Pharmaceuticals Inc., USA 4147 Goldmine Road Monroe, NC 28110 Manufactured for: Glenmark Pharmaceuticals Inc., USA Mahwah, NJ 07430	Class II	Drugs	Lots: 29200023 Exp. 03/31/2022; 29200025 Exp. 03/31/2022; 29200036 Exp. 06/30/2022; 29200056 Exp. 09/30/2022; 29200070 Exp. 11/30/2022	CGMP Deviations	Glenmark Pharmaceuticals Inc., USA
Zonisamide Capsules USP 50 mg 100 Capsules Rx Only NDC 68462-129-01 Manufactured by: Glenmark Pharmaceuticals Inc., USA Monroe, NC 28110 Manufactured for: Glenmark Pharmaceuticals Inc., USA Mahwah, NJ 07430	Class II	Drugs	Lots: 29190043 Exp. 05/31/2022; 29190044 Exp. 05/31/2022; 29190045 Exp. 05/31/2022	CGMP Deviations	Glenmark Pharmaceuticals Inc., USA
Zonisamide Capsules USP 100 mg Rx Only Manufactured by: Glenmark Pharmaceuticals Inc., USA Monroe, NC 28110 Manufactured for: Glenmark Pharmaceuticals Inc., USA	Class II	Drugs	Lots: a) 29200014 Exp. 02/28/2023; 29200015 Exp. 03/31/2023; 29200016 Exp. 03/31/2023; 29200030 Exp. 05/31/2023; 29200031 Exp. 05/31/2023; 29200032 Exp.	CGMP Deviations	Glenmark Pharmaceuticals Inc., USA

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Mahwah, NJ 07430 a) 100 Capsules NDC 68462-130-01; b) 500 Capsules NDC 68462-130-05			05/31/2023; 29200033 Exp. 06/30/2023; 29200037 Exp. 06/30/2023; 29200038 Exp. 06/30/2023; 29200039 Exp. 07/31/2023; 29200041 Exp. 07/31/2023; 29200042 Exp. 07/31/2023; 29200048 Exp. 08/31/2023; 29200049 Exp. 08/31/2023; 29200050 Exp. 08/31/2023; 29200072 Exp. 11/30/2023; 29200073 Exp. 11/30/2023; 29200074 Exp. 11/30/2023; 29200075 Exp. 11/30/2023; 29200076 Exp. 11/30/2023; b) 29200014 Exp. 02/28/2023; 29200015 Exp. 03/31/2023; 29200016 Exp. 03/31/2023		
Arformoterol Tartrate Inhalation Solution 15 mcg*/2 mL For Oral Inhalation Only Rx Only Manufactured by: Glenmark Pharmaceuticals Inc., USA Monroe, NC 28110 Manufactured for: Glenmark Pharmaceuticals	Class II	Drugs	Lots: a) 30210041 Exp. 03/31/2023; 30210045 Exp. 04/30/2023; 30210046 Exp. 04/30/2023; 30210050 Exp. 03/31/2023; 30210051 Exp. 04/30/2023; 30210058 Exp. 04/30/2023; b) 30210042	Lack of Assurance of Sterility	Glenmark Pharmaceuticals Inc., USA

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Inc., USA Mahwah, NJ 07430 a) 60x2 mL Sterile Unit-Dose Vials NDC 68462-833-65; b) 30x2 mL Sterile Unit-Dose Vials NDC 68462-833-35			Exp. 03/31/2023; 30210047 Exp. 04/30/2023; 30210048 Exp. 04/30/2023; 30210052 Exp. 04/30/2023; 30210053 Exp. 04/30/2023; 30210054 Exp. 04/30/2023; 30210059 Exp. 04/30/2023; 30210060 Exp. 04/30/2023; 30210061 Exp. 04/30/2023; 30210062 Exp. 04/30/2023; 30210063 Exp. 04/30/2023; 30210064 Exp. 05/31/2023		
Promethazine Syrup Plain, 6.25 mg/5 mL (Promethazine Hydrochloride Syrup, USP), 1 Pint (473 mL), Rx Only, Manufactured For: Wockhardt USA, LLC, Parsippany, NJ 07054; Manufactured By: Morton Grove Pharmaceuticals, Inc, Morton Grove, IL 60053. NDC: 60432-608-16	Class II	Drugs	Lot #: UV1335; UV1352; and UV1373	CGMP Deviations: Potential concern with products manufactured using liquid sugar batches contaminated with microbial organisms.	Morton Grove Pharmaceuticals, Inc.
Promethazine With Codeine Oral Solution, (Promethazine Hydrochloride 6.25 mg/5mL &	Class II	Drugs	Lot #: UV1198	CGMP Deviations: Potential concern with products	Morton Grove Pharmaceuticals, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Codeine Phosphate 10 mg/5 mL), 1 Pint (473 mL), Rx Only, Manufactured For: Wockhardt USA, LLC, Parsippany, NJ 07054; Manufactured By: Morton Grove Pharmaceuticals, Inc, Morton Grove, IL 60053. NDC: 60432-606-16				manufactured using liquid sugar batches contaminated with microbial organisms.	
Valproic Acid Oral Solution USP, (250 mg/5 mL), 1 Pint (473 mL), Rx Only, Manufactured For: Wockhardt USA, LLC, Parsippany, NJ 07054; Manufactured By: Morton Grove Pharmaceuticals, Inc, Morton Grove, IL 60053. NDC: 60432-621-16	Class II	Drugs	Lot #: UV1159	CGMP Deviations: Potential concern with products manufactured using liquid sugar batches contaminated with microbial organisms.	Morton Grove Pharmaceuticals, Inc.
Entacapone Tablets, USP, 200 mg, Rx only, 30 Tablets per unit dose cartons, Distributed by: Major Pharmaceuticals, 17177 N. Laurel Park Dr., Suite 233, Livonia, MI 48152. NDC 0904-6822-04	Class II	Drugs	Lot, expiry: N00187, 05/2022; N00245, 06/2022; N00273, 07/2022; N00355, 11/2022	Failed Dissolution Specifications	The Harvard Drug Group
Metoprolol Tartrate Tablets USP 100 mg, 1000-count bottles, Rx	Class II	Drugs	Lot: MJ1019025-A, Exp. date 04/2022	Presence of Foreign Substance: Product	Aurobindo Pharma USA Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
only, Distributed by: Aurobindo Pharma USA Inc. 279 Princeton-Hightstown Road East Windsor, NJ 08520, NDC 65862-064-99				complaints received for the presence of metal wire in one tablet.	
Zonisamide 100 mg Capsules, 30-count bottles, Packaged and Distributed By: Direct Rx Dawsonville, GA 30534 Mfg. For Glenmark Pharmaceuticals Inc., USA Mahwah, NJ 07430, NDC 61919-0775-30	Class II	Drugs	Lot #: 17JU2118 Exp. 5/31/23	CGMP deviations: Gaps in the quality system in the Quality Control microbiology laboratory.	Direct Rx
Aveeno Protect + Refresh sunscreen weightless spray with oat SPF 60, Avobenzone (3%), Homosalate (10%), Octisalate (5%), Octocrylene (10%), NET WT. 5.0 (OZ) (141 g) aerosol can, Distributed by: Johnson & Johnson Consumer Inc., Skillman, NJ 08558 UPC 3 8137-119462 9	Class II	Drugs	All lots within expiry.	cGMP Deviations	Johnson & Johnson Consumer, Inc.
Neutrogena COOLDRY SPORT sunscreen spray SPF 30, Avobenzone (3%), Homosalate (8%), Octisalate (5%), Octocrylene (8%), a) Net Wt 5.0	Class II	Drugs	All lots within expiry.	cGMP Deviations	Johnson & Johnson Consumer, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
oz (141g) (UPC 0 86800 10035 5) and b) Net Wt. 8 oz. (226 g) UPC 0 86800 10031 7 aerosol can, Distributed by: JOHNSON & JOHNSON CONSUMER INC., Skillman, NJ 08858,					
Neutrogena Beach Defense water + sun protection sunscreen spray BROAD SPECTRUM SPF 30, Avobenzone (3%), Homosalate (8%), Octisalate (5%), Octocrylene (8%), a) NET WT. 6.5 OZ (184 g) (UPC 0 86800 87273 3) and b) NET WT. 8.5 oz (240 g) (UPC 0 86800 10032 4) aerosol can, Distributed by JOHNSON & JOHNSON CONSUMER, INC. Skillman, NJ 08858	Class II	Drugs	All lots within expiry.	cGMP Deviations	Johnson & Johnson Consumer, Inc.
Neutrogena COOLDRY SPORT sunscreen spray BROAD SPECTRUM SPF 50, Avobenzone (3%), Homosalate (10%), Octisalate (5%), Octocrylene (10%), NET WT 5.0 OZ (141 g) aerosol can, Distributed by:	Class II	Drugs	All lots within expiry.	cGMP Deviations	Johnson & Johnson Consumer, Inc.



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
JOHNSON & JOHNSON CONSUMER, INC. Skillman, NJ 08858, UPC 0 86800 10036 2					
Neutrogena COOLDRY SPORT sunscreen spray BROAD SPECTRUM SPF 70, Avobenzone (3%), Homosalate (15%), Octisalate (5%), Octocrylene (10%), NET WT. 5.0 OZ (141 g) aerosol can, Distributed by: JOHNSON & JOHNSON CONSUMER, INC. Skillman, NY 08858, UPC 0 86800 10037 9	Class II	Drugs	All lots within expiry.	cGMP Deviations	Johnson & Johnson Consumer, Inc.
Neutrogena Ultra Sheer body mist sunscreen BROAD SPECTRUM SPF 30, Avobenzone (3%), Homosalate (8%), Octisalate (5%), Octocrylene (8%), Net Wt. 5.0 OZ (141 g) aerosol can, Distributed by: JOHNSON & JOHNSON CONSUMER, INC. Skillman, NY 08858 UPC 0 86800 10038 6	Class II	Drugs	All lots within expiry	cGMP Deviations	Johnson & Johnson Consumer, Inc.
Neutrogena Ultra Sheer body mist sunscreen BROAD	Class II	Drugs	All lots within expiry.	cGMP Deviations	Johnson & Johnson Consumer, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
SPECTRUM SPF 45, Avobenzone (3%), Homosalate (10%), Octisalate (5%), Octocrylene (10%), a) Net Wt. 5 OZ (141 g) (UPC 0 86800 10039 3) and b) Net Wt. 8.0 oz. (226 g) (UPC 0 86800 11134 4) aerosol can, Distributed by: JOHNSON & JOHNSON CONSUMER, INC. Skillman, NJ, 08858,					
Neutrogena Ultra Sheer body mist sunscreen BROAD SPECTRUM SPF 70, Avobenzone (3%), Homosalate (15%), Octisalate (5%), Octocrylene (10%), NET WT. 5.0 OZ (141 g) aerosol can, Distributed by: JOHNSON & JOHNSON CONSUMER, INC. Skillman, NJ 08858, UPC 0 86800 10040 9	Class II	Drugs	All lots within expiry.	cGMP Deviations	Johnson & Johnson Consumer, Inc.
Neutrogena Ultra Sheer body mist sunscreen BROAD SPECTRUM SPF 100+, Avobenzone (3%), Homosalate (15%), Octisalate (5%),	Class II	Drugs	All lots within expiry.	cGMP Deviations	Johnson & Johnson Consumer, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Octocrylene (10%), Oxybenzone (15%), NET WT. 5.0 OZ (141 g) aerosol can, Distributed by: JOHNSON & JOHNSON CONSUMER INC. Skillman, NJ 08858, UPC 0 86800 10041 6					
Neutrogena COOLDRY SPORT sunscreen spray BROAD SPECTRUM SPF 100, Avobenzone (3%), Homosalate (15%), Octisalate (5%), Octocrylene (10%), Oxybenzone (6%) aerosol can, NET WT. 5.0 OZ (141 g) Distributed by: JOHNSON & JOHNSON CONSUMER, INC. Skillman, NJ 08858, UPC 0 86800 10143 7	Class II	Drugs	All lots within expiry.	cGMP Deviations	Johnson & Johnson Consumer, Inc.
Neutrogena Beach Defense water+sun protection sunscreen spray BROAD SPECTRUM SPF 100, Avobenzone (3%), Homosalate (15%), Octisalate (5%), Octocrylene (10%), Oxybenzone (6%), NET WT. 6.5 OZ (184 g) aerosol can,	Class II	Drugs	All lots within expiry.	cGMP Deviations	Johnson & Johnson Consumer, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Distributed by: JOHNSON & JOHNSON CONSUMER, INC. Skillman, NJ 08858, UPC 0 86800 10144 4					
Neutrogena COOLDRY SPORT WITH MICROMESH SUNSCREEN SPRAY Broad Spectrum SPF 50, Avobenzone 2.7%, Homosalate 5%, Octisalate 4.5%, Octocrylene 6%, Oxybenzone 4.5%. NET WT. 5.5 OZ. (155 g) aerosol can, Distributed by: JOHNSON & JOHNSON CONSUMER, INC. Skillman, NJ 08858, UPC 0 86800 11033 0	Class II	Drugs	All lots within expiry.	cGMP Deviations	Johnson & Johnson Consumer, Inc.
Neutrogena Invisible Daily defense body spray sunscreen BROAD SPECTRUM SPF 60+, Avobenzone (3%), Homosalate (10%), Octisalate (5%), Octocrylene (10%), NET WT. 5.0 OZ. (141 g) aerosol can, Distributed by: JOHNSON & JOHNSON CONSUMER, INC.	Class II	Drugs	All lots within expiry.	cGMP Deviations	Johnson & Johnson Consumer, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Skillman, NJ 08858, UPC 0 86800 11154 2					
Neutrogena Beach Defense water+sun protection sunscreen spray BROAD SPECTRUM SPF 70, Avobenzone (3%), Homosalate (15%), Octisalate (5%), Octocrylene (10%), a) NET WT. 6.5 OZ. (184 g) (UPC 0 86800 87274 0) and b) NET WT. 8.5 OZ. (240 g) (UPC 0 86800 10048 5) aerosol can, Distributed by: JOHNSON & JOHNSON CONSUMER, INC. Skillman, NJ 08858	Class II	Drugs	All lots within expiry	cGMP Deviations	Johnson & Johnson Consumer, Inc.
Neutrogena Ultra Sheer body mist sunscreen BROAD SPECTRUM SPF 30, Avobenzone (3%), Homosalate (8%), Octisalate (5%), Octocrylene (8%), Net Wt. 8.0 oz. (226 g) aerosol can, Distributed by: JOHNSON & JOHNSON CONSUMER, INC. Skillman, NY 08858 UPC 0 86800 11133 7	Class II	Drugs	All lots within expiry	cGMP Deviations	Johnson & Johnson Consumer, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Neutrogena Beach Defense water+sun protection sunscreen spray BROAD SPECTRUM SPF 70, Avobenzone (3%), Homosalate (15%), Octisalate (5%), Octocrylene (10%), NET WT. 8.5 OZ. (240 g) aerosol can, Distributed by: JOHNSON & JOHNSON CONSUMER, INC. Skillman, NJ 08858 UPC 0 86800 10048 5	Class II	Drugs	All lots within expiry	cGMP Deviations	Johnson & Johnson Consumer, Inc.
Neutrogena Beach Defense water+sun protection sunscreen spray BROAD SPECTRUM SPF 50, Avobenzone (3%), Homosalate (10%), Octisalate (5%), Octocrylene (10%), NET WT. 6.5 OZ. (184 g) aerosol can, Distributed by: JOHNSON & JOHNSON CONSUMER, INC. Skillman, NJ 08858, UPC 0 86800 11254 9	Class II	Drugs	All lots within expiry	cGMP Deviations	Johnson & Johnson Consumer, Inc.
Neutrogena Beach Defense water+sun protection sunscreen spray BROAD SPECTRUM SPF	Class II	Drugs	All lots within expiry	cGMP Deviations	Johnson & Johnson Consumer, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
60+, Avobenzone (3%), Homosalate (10%), Octisalate (5%), Octocrylene (10%) NET WT. 8.5 OZ. (240 g) aerosol can, Distributed by: JOHNSON & JOHNSON CONSUMER, INC. Skillman, NJ 08858, UPC 0 86800 11255 6					
Aconitum nap Fear* 87% Alcohol HPUS: 5X, 7X, 18X, 30X, packaged in 30 mL containers, Aconitum nap Fear* 87% Alcohol HPUS: 24X, packaged in 50 mL containers, WHP Homeopathic Medicine, Washington Homeopathic Products 260 JR Hawvermale Way, Berkeley Springs, WV 25411.	Class II	Drugs	Lot # 26198	Out-of-specification test results obtained for identification testing based on HPTLC analysis.	Washington Homeopathic Products, Inc.
ZTE-105 Formula Gentle Detoxing. Contents 1000 mL, RX Only, REMEDY: Bryoni Alba 10X, Chelidonium Majus 10X, Carduus Marianus 10X, Dolichos Pruriens 10X, Solidago Vigaurea 10X, Alfalfa 10X, Boldo 10X, Cynara	Class II	Drugs	Lot # 25950, 26933, Exp 8/17/2026	Out-of-specification test results obtained for identification testing based on HPTLC analysis.	Washington Homeopathic Products, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
<p>Scolymus 10X, Zincum Muriaticum 13X, Chromium Sulphuricum 10X, Manganum Metallicum 10X, Dilution Alcohol 20%. WHP Homeopathic Medicine. For Manufacturing Use Only, Manufactured for Optimal Health Dimensi. Manufactured By: Washington Homeopathic Products, 260 JR Hawvermale Way, Berkeley Springs, WV, 25411.</p>					
<p>Ocular Allergy Blend 87% Alcohol; In Equal Parts of Apis Mellifica 7x Allium Cepa 7x Euphrasia Officinalis 7X Sabadilla 7X, WHP Homeopathic Medicine For Manufacturing Only, 500 ml. Manufactured by Washington Homeopathic Products 260JR Hawvermale Way, Berkeley Springs WV 25411</p>	Class II	Drugs	Lot # 30148	Out-of-specification test results obtained for identification testing based on HPTLC analysis.	Washington Homeopathic Products, Inc.
<p>Yeast Guard Blend, Calcarea Carbonica 6X, Collinsonia Canadensis 3X, Kali Muriaicum</p>	Class II	Drugs	Lot # 29782	Out-of-specification test results obtained for identification	Washington Homeopathic Products, Inc.



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
3X, WHP Homeopathic Medicine, For Manufacturing Use Only. 1.957 kg Lactose, Manufactured by Wasington Homeopathic Products 260 JR Hawvermale Way, Berkeley Springs WV 25411.				testing based on HPTLC analysis.	
Haloderm Homeopathic Blend, For Manufacturing Use Only, 1,000 ml 20% Alcohol, Contains: Dulcamara 10x, Nitricum Acidum 12x, Thuja Occidentalis 10x, Antimonium Crudum 12x, Calcarea Cadbonica 12x, Silicea 12x, WHP Homeopathic Medicine, FOr Manufacturing Use Only. 1.957 kg Lactose Manufactured by Wasington Homeopathic Products 260 JR Hawvermale Way, Berkeley Springs WV 25411. Marketed by: Health Specialty	Class II	Drugs	Lot # 30308	Out-of-specification test results obtained for identification testing based on HPTLC analysis.	Washington Homeopathic Products, Inc.
Cedar Fever Drops, 20% USP ALCOHOL, 30 mL, homeopathic drug for symptoms of cider allergies, Manufactured for	Class II	Drugs	Lot # 25586, 27410	Out-of-specification test results obtained for identification	Washington Homeopathic Products, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Peoples RX, 3801 S Lamar, Austin, TX 78704. UPC 7 40640 64166 8				testing based on HPTLC analysis.	
Althaea Officinalis 4X, Irritable Bladder* packaged as Sucrose/Lactose Pills, 4 Dram, WHP Homeopathic Medicine, Washington Homeopathic Products, 260 JR Hawvermale Way, Berkeley Springs, WV 25411.	Class II	Drugs	Lot # 29377, Exp 8/17/2026	Out-of-specification test results obtained for identification testing based on HPTLC analysis.	Washington Homeopathic Products, Inc.
Cinnamomum 6X, Flatulence* Sucrose/Lactose Pills, Packaged as a) 4 Dram, b) 1 oz, and Cinnamomum 30X, Flatulence* Sucrose/Lactose Pills, Packaged as 4 Dram, WHP Homeopathic Medicine, Washington Homeopathic Products 260 JR Hawvermale Way, Berkeley Springs WV 25411	Class II	Drugs	Lot # 28626, Exp 8/17/2026	Out-of-specification test results obtained for identification testing based on HPTLC analysis.	Washington Homeopathic Products, Inc.
Cistus Canadensis 6X, 10X, 15X, 30X, Coldness* Sucrose/Lactose Pills, 6X Packaged as a) 1 OZ, UPC 7 40640 28177 2, b) 4 dr, UPC 7 40640 28173 4; 10X Packaged as	Class II	Drugs	Lot # 28638, EXP 08/17/2026	Out-of-specification test results obtained for identification testing based on HPTLC analysis.	Washington Homeopathic Products, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
c) 4 dr; 15X Packaged as d) 1 OZ; 30X Packaged as e) 2 Dram, UPC 7 40640 28171 0, f) 4 dr, UPC 7 40640 28175 8; WHP Homeopathic Medicine, Washington Homeopathic Products 260 JR Hawvermale Way, Berkeley Springs WV 25411					
Humulus 6X, 15X, Sucrose/Lactose Pills, 6X Packaged as a) 4dr, UPC 7 40640 33969 5; 15X Packaged as b) 4 dr; WHP Homeopathic Medicine. Washington Homeopathic Products, 260 JR Hawvermale Way, Berkeley Springs, WV 25411.	Class II	Drugs	Lot # 29298, Exp 8/17/2026	Out-of-specification test results obtained for identification testing based on HPTLC analysis.	Washington Homeopathic Products, Inc.
Quebracho 4C, 5C, 6C, 12C, 30C, Fever*, Sucrose/Lactose Pills, 5C Packaged as a) 4dr; 6C Packaged as b) 4 Dram UPC 7 40640 44092 6; c) 2 oz UPC 7 40640 44100 8; 12C Packaged as d) 4 Dram; e) 2 oz; 30C Packaged as f) 2 dr UPC 7 40640 44090 2; g) 4 Dram, UPC 7	Class II	Drugs	Lot # 28930, Exp 8/17/2026	Out-of-specification test results obtained for identification testing based on HPTLC analysis.	Washington Homeopathic Products, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
40640 44094 0; h) 1 oz, UPC 7 40640 44098 8; i) 2 oz, UPC 7 40640 44102 2; WHP Homeopathic Medicine, Washington Homeopathic Products, 260 JR Hawvermale Way, Berkeley Springs, WV 25411.					
Verbena Officinalis 6X, Nervousness* Sucrose/Lactose Pills, Packaged 2 Dram, WHP Homeopathic Medicine, Washington Hoemopathis Producers, 260 JR Hawvermale Way, Berkeley Springs, WV 25411.	Class II	Drugs	Lot # 29060, Exp 8/17/2026	Out-of-specification test results obtained for identification testing based on HPTLC analysis.	Washington Homeopathic Products, Inc.
Viola Odorata 4X, 10X, 12X, Bee Stings*, Sucrose/Lactose Pills, 4X Packaged in a) 2 Dram; 10X Packaged in b) 2 Dram; 12X Packaged in c) 2 Dram; d) 4 Dram; WHP Homeopathic Medicine, Washington Homeopathic Products, 260 JR	Class II	Drugs	Lot # 29057, Exp 8/17/2026	Out-of-specification test results obtained for identification testing based on HPTLC analysis.	Washington Homeopathic Products, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Hawvermale Way, Berkeley Springs, WV, 25411.					
La Core LCL-2-0191 Blend, 149,980ml 20% Alcohol, WHP Homeopathic Medicine, For Manufacturing Only, Liter LCL-2-0191-Bend: 12% Lycopodium Clavatum 10X, 12% Carbo Vegetabilis 16X, 12% Natrum Muriaticum 9X, 12% Calcareo Carbonica 12X, 10% Hypothalamus 30X, 6% Pituitarum Posterium 12X, 6% Pituitarum Posterium 30C, 3% Natrum Phosphoricum 12X, 3% Graphites 30X, 3# Agnus Castus 6X, 3% Thiosinaminum 8X, 3% Phytolacca Decandra 12X, 3% Magnesia Phosphorica 10X, 3% Ornithogalum Umbellatum 6X, 3% Chelidonium Majus 6X, 3% Quercus Robur 14X, 3% Nux Vomica 30X, Manufactured by Washington Homeopathic Products 260 JR Hawvermale	Class II	Drugs	Lot # 27861, Exp 8/17/2026	Out-of-specification test results obtained for identification testing based on HPTLC analysis.	Washington Homeopathic Products, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Way, Berkeley Springs, WV, 25411.					
Kali Sulphuricum 3X, 960ml 20% Alcohol, WHP Homeopathic Medicine, For Manufacturing Use Only. Manufactured by Washington Homeopathic Products 260JR hawvermale Way Berkeley Springs WV 25411.	Class II	Drugs	Lot # 29475, Exp 8/17/2026	Out-of-specification test results obtained for identification testing based on HPTLC analysis.	Washington Homeopathic Products, Inc.
Althaea Officinalis 6X, Irritable Bladder* Sucrose/Lactose Pills, packaged as 4 Dram, WHP Homeopathic Medicine, Washington Homeopathic Products, 260 JR Hawvermale Way, Berkeley Springs, WV 25411.	Class II	Drugs	Lot # 29377, Exp 8/17/2026	Out-of-specification test results obtained for identification testing based on HPTLC analysis.	Washington Homeopathic Products, Inc.
Althaea 6X, Irritable Bladder* Sucrose/Lactose Pills, packaged as 1 OZ, WHP Homeopathic Medicine, Washington Homeopathic Products, 260 JR Hawvermale Way, Berkeley Springs, WV 25411.	Class II	Drugs	Lot # 29377, Exp 8/17/2026	Out-of-specification test results obtained for identification testing based on HPTLC analysis.	Washington Homeopathic Products, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Althaea 6X, Irritable Bladder* 20% Alcohol, Drops, packaged as 15 ml, WHP Homeopathic Medicine, Washington Homeopathic Products, 260 JR Hawvermale Way, Berkeley Springs, WV 25411.	Class II	Drugs	Lot # 29377, Exp 8/17/2026	Out-of-specification test results obtained for identification testing based on HPTLC analysis.	Washington Homeopathic Products, Inc.
Althaea 30X, Irritable Bladder* Sucrose/Lactose Pills, packaged as 4 Dram, WHP Homeopathic Medicine, Washington Homeopathic Products, 260 JR Hawvermale Way, Berkeley Springs, WV 25411.	Class II	Drugs	Lot # 29377, Exp 8/17/2026	Out-of-specification test results obtained for identification testing based on HPTLC analysis.	Washington Homeopathic Products, Inc.
Cistus Canadensis 5X Coldness* 20% Alcohol drops, Packaged in a) 15ml; b) 50 ml; WHP Homeopathic Medicine, Washington Homeopathic Products 260 JR Hawvermale Way, Berkeley Springs WV 25411	Class II	Drugs	Lot # 28638, Exp 8/17/2026	Out-of-specification test results obtained for identification testing based on HPTLC analysis.	Washington Homeopathic Products, Inc.
Quebracho 4C, Fever*, 20% Alcohol, Packaged as 100ml, WHP Homeopathic Medicine, Washington Homeopathic	Class II	Drugs	Lot # 28930, Exp 8/17/2026	Out-of-specification test results obtained for identification	Washington Homeopathic Products, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Products, 260 JR Hawvermale Way, Berkeley Springs, WV 25411.				testing based on HPTLC analysis.	
Viola od 6X, 30X, Bee Stings*, Sucrose/Lactose Pills, 6X Packaged in a) 4 Dram, UPC 7 40640 50139 9; 30X Packaged in b) 4 dr, UPC 7 40640 50141 2; c) 2 oz, UPC 7 40640 50149 8; WHP Homeopathic Medicine, Washington Homeopathic Products, 260 JR Hawvermale Way, Berkeley Springs, WV, 25411.	Class II	Drugs	Lot # 29057, Exp 8/17/2026	Out-of-specification test results obtained for identification testing based on HPTLC analysis.	Washington Homeopathic Products, Inc.
Z-103 GU DETOXING. Contents 1000ml 20% Alcohol. WHP Homeopathic Medicine. For Manufacturing Use Only, REMEDY: Agrimonia Eupatoria 24X, Alfalfa 24X, Althaea Officinalis 24X, Avena Sativa 24X, Boldo 24X, Carduus Marianus 24X, Chioanathus Virginica 24X, Cynara Scolymus 24X, Iria Versicolor 24X, Millefolium 24X,	Class II	Drugs	Lot # 26364, Exp 8/17/2026	Out-of-specification test results obtained for identification testing based on HPTLC analysis.	Washington Homeopathic Products, Inc.



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
<p>Rumex Crispus 24X, Selenium Metallicum 12X, Selenium Metallicum 60X, Solidago Virgaurea 12X, Solidago Virgaurea 24X, Solidago Virgaurea 60X, Spiraea Ulmaira 24X, Taraxacum Officinale 24X, Urtica Dioica 24X, Uva-Ursi 24X, Zincum Muriaticum 13X, Zincum Mruiatricum 30X, Dilution Alcohol 20%. Manufactured for Optimal Health Dimensi. RX Only, Manufactured by Washington Homeopathic Products, 260 JR Hawvermale Way, Berkeley Springs, WV, 25411.</p>					
<p>Z-107 Formula Soft Tissue Healing. Contents 1000ml. For Manufacturing Use Only, REMEDY: Amygdalus Persica 10X, Arnica Montana 10X, Bellis Perennis 10X, Chromium Sulphuricum 10X, Citrus Vulgaris 10X, Derris Pinnata 13X, Franciscea Uniflora 13X,</p>	Class II	Drugs	Lot # 27668, Exp 8/17/2026	Out-of-specification test results obtained for identification testing based on HPTLC analysis.	Washington Homeopathic Products, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
<p>Hamamelis Virginiana 10X, Manganum Metallicum 10X, Ruta Graveolens 10X, Sarsaparilla 10X, Zincum Muriaticum 13X, Dilution Alcohol 20%. Manufactured for Optimal Health Dimensi. RX Only, Manufactured by Washington Homeopathic Products, Inc. 260 JR Hawvermale Way, Berkeley Springs, WV, 25411.</p>					
<p>ZTE-1020 Formula. Contents 1000ml. WHP Homeopathic Medicine, For Manufacturing Use Only, REMEDY: Aurum Metallicum 10X, Crataegus Oxyacantha 10X, Baryta Carbonica 10X, Digitalis Purpurea 10X, Zincum Muriaticum 13X, Chromium Sulphuricum 10X, Manganum Metallicum 10X, Dilution Alcohol 20%. Manufactured for Optimal Health Dimensions. RX Only, Manufactured by Washington Homeopathic Products, Inc. 260</p>	Class II	Drugs	Lot # 25740, Exp 8/17/2026	Out-of-specification test results obtained for identification testing based on HPTLC analysis.	Washington Homeopathic Products, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
JR Hawvermale Way, Berkeley Springs, WV, 25411.					
Z-1020 Formula. Contents 1000ml 20% Alcohol. WHP Homeopathic Medicine, For Manufacturing Use Only, REMEDY: Aurum Metallicum 10X, Baryta Carbonica 10X, Chromium Sulphuricum 10X, Crataegus Oxyacantha 10X, Digitalis Purpurea 10X, Manganum Metallicum 10X, Zincum Muriaticum 13X, Dilution Alcohol 20%. Manufactured for Optimal Health Dimensions. Manufactured by Washington Homeopathic Products, Inc. 260 JR Hawvermale Way, Berkeley Springs, WV, 25411.	Class II	Drugs	Lot # 26529, Exp 8/17/2026	Out-of-specification test results obtained for identification testing based on HPTLC analysis.	Washington Homeopathic Products, Inc.
Z-1050 Formula Hepatodetox. Contents 1000ml. WHP Homeopathic Medicine, For Manufacturing Use Only, REMEDY: Cholesterinum 10X, Avena Sativa 12X, Cynara	Class II	Drugs	Lot # 26071, 28180, Exp 8/17/2026	Out-of-specification test results obtained for identification testing based on HPTLC analysis.	Washington Homeopathic Products, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
<p>Scolymos 12X, Phosphorus 12X, Oroticum Acidum 13X, Aesculus Hippocastanum 24X, Carduus Marianus 24X, Chelidonium Majus 24X, Cimicifuga Racemosa 24X, Cinchona Officinalis 24X, Colocynthis 24X, Histaminum Hydrochloricum 24X, Lycopodium Clavatum 24X, Sulphur 24X, Tataxatum Officinale 24X, Veratrum Album 24X, Sepia 30X, Strontium Carbonicum 30X, Dilution Alcohol 20%.                      Manufactured for Optimal Health Dimensions. RX Only.                      Manufactured by Washington Homeopathic Products, Inc. 260 JR Hawvermale Way, Berkeley Springs, WV, 25411.</p>					
<p>Z-1070 Formula Anxioheal. Contents 1000ml 20% Alcohol. WHP Homeopathic Medicine, For Manufacturing Use Only, REMEDY:Causticum 30X, Conium Maculatum 8X, Conium</p>	Class II	Drugs	Lot # 26007, Exp 8/17/2026	Out-of-specification test results obtained for identification testing based on HPTLC analysis.	Washington Homeopathic Products, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Maculatum 12X, Crataegus Oxyacantha 12X, Crataegus Oxyacantha 30X, Ignatia Amara 24X, Lycopus Virginicus 12X, Phosphoricum Acidum 12X, Phosphoricum Acidum 24X, Rhus Toxicodendron 24X, Secale Cornutum 24X, Secale Cornutum 30X, Sepia 6X, Sepia 24X, Solanum Nigrum 30X, Zincum Valerianicum 8X, Zincum Valerianicum 12X, Dilution Alcohol 20%. Manufactured for Optimal Health Dimensions. RX Only. Manufactured by Washington Homeopathic Products, Inc. 260 JR Hawvermale Way, Berkeley Springs, WV, 25411.					
ZTE-1034 Formula Antimicrobial Bowel. Contents 1000ml. WHP Homeopathic Medicine, For Manufacturing Use Only, REMEDY: Arsenicum Album 10X, Baptisia Tinctoria 10X, Pulsatilla	Class II	Drugs	Lot # 25887, Exp 8/17/2026	Out-of-specification test results obtained for identification testing based on HPTLC analysis.	Washington Homeopathic Products, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
10X, Lachesis Mutus 11X, Rhus Toxicodendron 10X, Belladonna 7X, Colchicum Autumnale 5X, Aconitum Napellus 8X, Astragalus Menziesli 8X, Carbo Vegetabilis 8X, Chamomilla 3X, Hydrastis Canadensis 3X, Echinacea Angustifolia 12X, Pulsatilla 11X, Anas Barariae, Hepatis ET 60C, Anas Barariae, Hepatis ET 100C, Anas Barariae, Hepatis ET 200C, Carduus Marianus 6X, Taraxacum Officinale 4X, Berberis Aquifolium 8X, Zingiber Officinal 8X, Allium Sativum 4X, Dilution Alcohol 20%. Causticum 30X, Conium Maculatum 8X, Conium Maculatum 12X, Crataegus Oxyacantha 12X, Crataegus Oxyacantha 30X, Ignatia Amara 24X, Lycopus Virginicus 12X, Phosphoricum Acidum 12X, Phosphoricum Acidum 24X, Rhus Toxicodendron 24X, Secale Cornutum 24X, Secale Cornutum					

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
<p>30X, Sepia 6X, Sepia 24X, Solanum Nigrum 30X, Zincum Valerianicum 8X, Zincum Valerianicum 12X, Dilution Alcohol 20%. Manufactured for Optimal Health Dimensions. RX Only. Manufactured by Washington Homeopathic Products, Inc. 260 JR Hawvermale Way, Berkeley Springs, WV, 25411.</p>					
<p>ZTE-1035 Formula, Antimicrobial Combination, Contents 1006 ml, REMEDY: Arsenicum Album 10X, Baptista Tinctoria 10X, Phosphorus 10X, Arnica Montana 10X, Bryonia Alba 10X, Antimonium Crudum 10X, Iodium 10X, Lycopodium Clavatum 10X, Pulsatilla 10X, Berberis Vulgaris 10X, Glycyrrhiza Clabra 10X, Condurango 10X, Ginco Biloba 10X, Zincum Muriaticum 13X, Chromium Sulphuricum 10X, Manganum Metallicum 10X,</p>	Class II	Drugs	Lot # 25697, no expiry date	Out-of-specification test results obtained for identification testing based on HPTLC analysis.	Washington Homeopathic Products, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Alfalfa 3X, Dilution Alcohol 20%, Manufactured by: Washington Homeopathic Products 260 JR Hawvernale Way, Berkeley Springs, WV, 225411, Manufactured for Optimal Health Dimensions, Washington Homeopathic Products, Inc. 260 JR Hawvernale Way, Berkeley Springs, WV, 25411,					
ZTE 1013 Formula Antimicrobial - F&M , Contents 1000 ml, REMEDY: Bryonia Alba 10X, Antimonium Crudum 10X, Iodium 10X, Lycopodium Clavatum 10X, Pulsatilla 10X, Berberus Vulgaris 10X, Glycyrrhiza Clabra 10X, Condurango 10X, Ginco Biloba 10X, Chromium Sulphuricum 10X, Manganum Metallicum 10X, Zincum Muriaticum 13X, Dilution Alcohol 20%, WHP Homeopathic Medicine, For Manufacturing Use Only; Manufactured for Optimal Health Dimensions,	Class II	Drugs	Lot # 25738, no expiry date	Out-of-specification test results obtained for identification testing based on HPTLC analysis.	Washington Homeopathic Products, Inc.



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Manufactured by: Washington Homeopathic Products 260 JR Hawvernale Way, Berkeley Springs, WV, 25411,					
ZTE 1015 Formula, Contents 1000 ml, For Manufacturing Use only, REMEDY: Argentum Nitricum 10X, Rhus Toxicodendron 10X, Aurum Metallicum 10X, Iris Versicolor 10X, Lycopodium Clavatum 10X, Zincum Muriaticum 13X, Chromium Sulphuricum 10X, Manganum Metallicum 10X, Dilution Alcohol 20%, Manufactured for Optimal Health Dimensions, Manufactured by: Washington Homeopathic Products 260 JR Hawvernale Way, Berkeley Springs, WV, 25411,	Class II	Drugs	Lot # 25739, no expiry date	Out-of-specification test results obtained for identification testing based on HPTLC analysis.	Washington Homeopathic Products, Inc.
Strophanthus hisp 30X, Hives*, 20% Alcohol, Packaged in (a) 15 mL, UPC 7 40640 47553 9; (b) 30mL UPC 7 40640 47557 7; (c) 100mL, UPC 7 40640 47565 2;	Class II	Drugs	Lot # 29061	Out-of-specification test results obtained for identification testing based on HPTLC analysis.	Washington Homeopathic Products, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
WHP Homeopathic Medicine, 260 JR Hawvermale Way, Berkeley Springs, WV 25411					
Strophanthus hisp 30X, Hives*, Sucrose/Lactose Pills , Packaged in (a) 2 dr, UPC 7 40640 47533 1; (b) 4 dr UPC 7 40640 47537 9; (c) 1 oz, UPC 7 40640 47541 6; (d) 2 oz, UPC 7 40640 47545 4; WHP Homeopathic Medicine, 260 JR Hawvermale Way, Berkeley Springs, WV 25411	Class II	Drugs	Lot # 29061	Out-of-specification test results obtained for identification testing based on HPTLC analysis.	Washington Homeopathic Products, Inc.
Aconitum Napellus Fear* 20% Alcohol HPUS: 5X, 6X, 26X, 30X, packaged in 15mL containers, Aconitum Napellus Fear* 20% Alcohol HPUS: 6X, 10X, packaged in 30mL containers Aconitum Napellus Fear* 20% Alcohol HPUS: 5X, 10X, 12X, 30X, packaged in 50mL containers Aconitum Napellus Fear* 20% Alcohol HPUS: 5X, packaged in 100mL containers WHP Homeopathic Medicine,	Class II	Drugs	Lot # 26198	Out-of-specification test results obtained for identification testing based on HPTLC analysis.	Washington Homeopathic Products, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Washington Homeopathic Products 260 JR Hawvermale Way, Berkeley Springs, WV 25411.					
Aconitum nap Fear* Sucrose/Lactose Pills HPUS: 4X, 5X, 6X,15X, packaged in 1 oz containers, Aconitum nap Fear* Sucrose/Lactose Pills HPUS: 4X, 7X, 12X, packaged in 2 dr containers, Aconitum nap Fear* Sucrose/Lactose Pills HPUS: 4X, 12X, 20X, packaged in 2 oz containers, Aconitum nap Fear* Sucrose/Lactose Pills HPUS: 4X, 5X, 9X,11X, 24X, packaged in 4 dr containers, Aconitum nap Fear* Sucrose/Lactose Pills HPUS: 6X, 30X, packaged in 4 oz containers, WHP Homeopathic Medicine, Washington Homeopathic Products 260 JR Hawvermale Way, Berkeley Springs, WV 25411.	Class II	Drugs	Lot # 26198	Out-of-specification test results obtained for identification testing based on HPTLC analysis.	Washington Homeopathic Products, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Aconitum Napellus Fear* Sucrose/Lactose Pills HPUS: 8X, 9X, 12X,30X, packaged in 1 oz containers, Aconitum Napellus Fear* Sucrose/Lactose Pills HPUS: 6X, 10X, 15X, 24X, 30X, packaged in 2 dr containers, Aconitum Napellus Fear* Sucrose/Lactose Pills HPUS: 6X, 30X, packaged in 2 oz containers, Aconitum Napellus Fear* Sucrose/Lactose Pills HPUS: 6X, 7X, 8X, 10X, 12X, 15X, 16X, 18X, 30X, packaged in 4 dram containers, WHP Homeopathic Medicine, Washington Homeopathic Products 260 JR Hawvermale Way, Berkeley Springs, WV 25411.	Class II	Drugs	Lot # 26198	Out-of-specification test results obtained for identification testing based on HPTLC analysis.	Washington Homeopathic Products, Inc.
Aconitum nap Fear* 20% Alcohol HPUS: 6X, packaged in 50mL & 8 oz containers Aconitum nap Fear* 20% Alcohol HPUS: 7X, 12X, packaged in 15mL containers WHP Homeopathic Medicine, Washington Homeopathic	Class II	Drugs	Lot # 26198	Out-of-specification test results obtained for identification testing based on HPTLC analysis.	Washington Homeopathic Products, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Products 260 JR Hawvermale Way, Berkeley Springs, WV 25411.					
Aconitum Napellus 12X Fear* 87% Alcohol HPUS: packaged in 30 mL containers; WHP Homeopathic Medicine, Washington Homeopathic Products 260 JR Hawvermale Way, Berkeley Springs, WV 25411.	Class II	Drugs	Lot # 26198	Out-of-specification test results obtained for identification testing based on HPTLC analysis.	Washington Homeopathic Products, Inc.
Lyrica CR (pregabalin) extended release tablets, 330 mg, 30-count bottles, Rx only, Distributed by Parke-Davis Division of Pfizer Inc., NY, NY 10017, NDC 0071-1029-01	Class II	Drugs	Lot #: DN5396, EP9726, EK2417, Exp. Date August 2022	Failed Dissolution Specifications	Viartis
Valproic Acid Oral Solution, USP, 500 mg/10 mL, 100 10 mL unit dose cups per case, Rx Only, Packaged and Distributed by: American Health Packaging, Columbus, Ohio 43217 Case NDC#: 60687-262-56; Individual Dose NDC: 60687-262-42	Class II	Drugs	Lot 1000082; Exp 06/30/2022	CGMP Deviations: Potential concern with products manufactured using liquid sugar batches contaminated with microbial organisms.	American Health Packaging

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Morphine Sulfate Injection, USP, 2 mg per mL, 1 mL single dose vial, Rx only, Fresenius Kabi, Lake Zurich, IL 60047, NDC 63323-452-01. 25 vials per tray packaged 18 trays per shipper	Class II	Drugs	Lot # 6023731, 6023732, Exp 03/2023; 6024172, 6024260, Exp 06/2023	Defective container: Cracked vials leading to lack of sterility assurance	Fresenius Kabi USA LLC
ceFAZolin, 2 G/20 mL in Sterile Water, 20 mL Sterile Syringe for Injection, IntegraDose Compounding Services, LLC, 719 Kasota Ave SE, Minneapolis, MN. NDC 71139-7087-1	Class II	Drugs	Lot, expiry: Lot 20210803CEF-1, exp 09/17/2021; Lot 20210805CEF-3, 09/19/2021; Lots 20210806CEF-1, 20210806CEF-2, exp 09/20/2021; Lots 20210809CEF-1, 20210809CEF-2, exp 09/23/2021; Lot 20210810CEF-1, exp 09/24/2021; Lot 20210811CEF-1, exp 09/25/2021; Lot 20210812CEF-1, exp 09/26/2021	Lack of sterility assurance.	IntegraDose Compounding Services LLC
ceFAZolin 3 G in 0.9% Sodium Chloride, 115 mL Bag for Injection, Sterile Product, IntegraDose Compounding	Class II	Drugs	Lot, expiry: 20210722CEF-2, exp 09/20/2021; 20210728CEF-1, exp 09/26/2021	Lack of sterility assurance.	IntegraDose Compounding Services LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Services, LLC, 719 Kasota Ave SE, Minneapolis, MN. NDC: 71139-7153-1					
Testosterone Cypionate Testosterone Propionate, 180mg/mL, 20mg/mL, 1 mL vial, Rx only, New Vitalis Pharmacy 4139 Cadillac Ct # 201 Louisville, KY 40213	Class II	Drugs	Lot, expiry: Lot #AL07202021@901, Exp 9/18/21; Lot #AL07272021@901, Exp 9/25/21; Lot #AL08032021@901, Exp 10/2/21; Lot #AL08102021@901, Exp 10/9/21; Lot #AL08172021@901, Exp 10/16/21; Lot #AL08242021@901, Exp 10/23/21	Lack of Assurance of Sterility	New Vitalis Pharmacy LLC dba New Vitalis Pharmacy
Sodium Phenylbutyrate Powder, 250 Grams, Rx Only, packaged in 500 cc HDPE bottles and 53 mm CRC caps packed in a carton and then in case packs containing 2 bottles. Sigmapharm Laboratories, LLC, Bensalem, PA 19020, NDC 42794-086-14	Class II	Drugs	Lots 2005401, 2005501, 2005601, 2005701, Exp FEB 2023; Lots 2101401, 2101501, Exp FEB-2024	Failed Impurities/Degradatio n Specifications; Out of Specification impurity results obtained during routine testing.	SigmaPharm Laboratories LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Hydroquinone USP, 4% Skin Bleaching Cream, Rx only, Net Wt 1 oz (28.35g), Manufactured for: Westminster Pharmaceuticals, LLC Nashville, TN 37217 NDC 69367-174-01	Class II	Drugs	Lots: 21FP1743, 21FP1745 Exp. 05/2023	Finished product specification did not meet USP specifications.	Monarch PCM, LLC
Meclizine HCl Tablets, 25 mg, packaged in 100-count HDPE bottle, Distributed by: Rising Pharma Holdings, Inc. East Brunswick, NJ 08816, Manufactured by: Aurex laboratories LLC, East Windsor, NJ 08520, NDC 16571-752-01	Class II	Drugs	Lot # CB21024, Exp 2/2023	Labeling: Incorrect Instructions	RISING PHARMACEUTICALS
Artesunate for Injection, 110 mg/vial, packaged in a) 2x2 pack containing 2 Single-dose vials artesunate (73607-001-01) and 2 vials sterile diluent (NDC 73607-001-02) per carton (NDC 73607-001-11); 4x4 pack containing 4 Single-dose vials artesunate (73607-001-01) and 4 vials sterile diluent (NDC 73607-001-02) per carton (NDC 73607-001-10), Rx	Class II	Drugs	Manufacturer Lot Numbers: AR479E01, exp. date 11/03/2022; AR479E02, exp. date 11/09/2022; AR479E03, exp. date 11/16/2022; Cardinal Health Packaging Solutions Lot Numbers: 7507001 and 7508001	Lack of Assurance of Sterility: Air filter failed post integrity test leading to a lack of sterility assurance.	AMIVAS (US), LLC



Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
only, Mfg for: Amivas, LLC, 1209 Orange St., Wilmington, Delaware 19801.					
Betaxolol Ophthalmic Solution, USP, 0.5%, (Betaxolol HCl 5.6 mg/mL), 5 mL dropper bottle, Rx only, Sterile, Manufactured by: Akorn, Inc., Lake Forest, IL 60045. Carton NDC: 17478-705-10, Bottle NDC 17478-705-11	Class II	Drugs	Lot 0B61A, Exp 01/31/2022	Microbial Contamination of Sterile Products: Confirmed sterility failure identified during stability testing at the 12-month time point.	Akorn, Inc.
Potassium Chloride 40 mEq in 0.9% Sodium Chloride 270 mL NS, 250 mL bag, Rx Only, SSM Health Care Corporation, 1015 Bowles, Fenton, MO. NDC 60652-6429-1	Class II	Drugs	Lot 210806-015, exp 11/4/2021	Lack of Assurance of Sterility	SSM Health Care St. Louis DBA SSM St. Clare Health Center
Potassium Chloride Extended-Release Tablets, USP 10 mEq (750 mg), 500 Tablets, Rx Only, Manufactured by: Strides Shasun Limited, Bengaluru - 562106, India, Distributed by: Strides Pharma In., East Brunswick, NJ 08816, NDC 64380-861-07.	Class II	Drugs	Lot 7240840A, exp. 12/31/2021	Failed Dissolution Specifications	Strides Pharma Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Sodium Sulfacetamide, 10%, Wash, packaged in bottles: a) 6 fl oz (177 mL) NDC 42808-103-06 UPC 3 42808 10306 5; b) 12 fl oz (354.8 mL) NDC 42808-103-12 UPC 3 42808 10312 6, Rx only, Manufactured in the U.S.A. for Exact-Rx, Inc., Melville, NY 11747	Class III	Drugs	Lots: a) 21FP1737 Exp 05/2023; b) 21FP1738 Exp 05/2023	Subpotency: one product for active ingredient assay and another one for preservative assay	Monarch PCM, LLC
Hydroquinone, USP, 4% Skin Bleaching Cream, packaged in 1 oz (28.35g) tube, Rx only, Manufactured for: Westminster Pharmaceuticals, LLC Nashville, TN 37217, NDC 69367-174-01 UPC 3 69367 17401 5	Class III	Drugs	Lot: 21FP1731 Exp 05/2023	Subpotency: one product for active ingredient assay and another one for preservative assay	Monarch PCM, LLC
Sirolimus Tablets 1 mg, 30 Tablets (5 blister cards x 6 unit doses), Rx only, Packaged and Distributed by: American Health Packaging Columbus, OH 43217, NDC 68084-915-25	Class III	Drugs	Lot #: 1000789, Exp. Date 10/31/2022	Failed Impurities/ Degradation Specifications	American Health Packaging
Daytime Severe Cold & Flu Relief 8 Pre-Measured Vials 0.51 FL OZ (15 mL) Each 4.06 FL OZ (120 mL) Total/Nighttime Severe Cold &	Class III	Drugs	Lot: 2021-10159 Exp. 06/08/2023	Subpotent Drug	New Vision Pharmaceuticals LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Flu Relief 8 Pre-Measured Vials 1.01 FL OZ (30 mL) Each 8.12 FL OZ (240 mL) Total Single-Use Vials Mixed Berry Flavor NDC 69842-495-16 UPC 0 50428 64057 9 Distributed by: CVS Pharmacy, Inc. One CVS Drive, Woonsocket, RI 02895					
CVS Health Daytime Severe Cold & Flu Relief Single-Use Vials Mixed Berry Flavor 8 Pre- Measured Vials 0.51 FL OZ (15 mL) Each 4.06 FL OZ (120 mL) Total NDC 69842-499-08 UPC 0 50428 64130 9 Distributed by: CVS Pharmacy, Inc. One CVS Drive Woonsocket, RI 02895	Class III	Drugs	Lots: 2021-10154 Exp. 06/29/2023; 2021-10164 Exp. 06/11/2023	Subpotent Drug	New Vision Pharmaceuticals LLC

\*Please refer to FDA website for further information at: <http://www.fda.gov/Safety/Recalls/default.htm>

## CURRENT DRUG SHORTAGES

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

### Generic Name or Active Ingredient

Acetazolamide Injection  
Amifostine Injection  
Amino Acids  
Amoxapine Tablets  
Amphetamine Aspartate; Amphetamine Sulfate; Dextroamphetamine Saccharate; Dextroamphetamine Sulfate Tablets  
Atropine Sulfate Injection  
Azacitidine for Injection  
Belatacept (Nulojix) Lyophilized Powder for Injection  
Bumetanide Injection  
Bupivacaine Hydrochloride and Epinephrine Injection  
Bupivacaine Hydrochloride Injection  
Calcium Disodium Versenate Injection  
Calcium Gluconate Injection  
Cefazolin Injection  
Cefotaxime Sodium Injection  
Cefotetan Disodium Injection  
Cefoxitin for Injection  
Ceftazidime and Avibactam (AVYCAZÂ®) for Injection, 2 grams/0.5 grams  
Ceftolozane and Tazobactam (Zerbaxa) Injection  
Chlordiazepoxide Hydrochloride Capsules  
Chloroprocaine Hydrochloride Injection  
Continuous Renal Replacement Therapy (CRRT) Solutions  
Cortisone Acetate Tablets  
Cyclopentolate Ophthalmic Solution  
Cysteamine Hydrochloride Ophthalmic Solution  
Cytarabine Injection  
Dacarbazine Injection  
Desmopressin Acetate Nasal Spray  
Dexamethasone Sodium Phosphate Injection  
Dexmedetomidine Injection  
Digoxin Injection  
Diltiazem Hydrochloride Injection  
Disopyramide Phosphate (Norpace) Capsules  
Dobutamine Hydrochloride Injection  
Dopamine Hydrochloride Injection  
Echothiophate Iodide (Phospholine Iodide) Ophthalmic Solution  
Enalaprilat Injection



Epinephrine Injection, 0.1 mg/mL  
Epinephrine Injection, Auto-Injector  
Famotidine Injection  
Famotidine Tablets  
Fentanyl Citrate (Sublimaze) Injection  
Floxuridine for Injection  
Fluvoxamine ER Capsules  
Furosemide Injection  
Gemifloxacin Mesylate (Factive) Tablets  
Gentamicin Sulfate Injection  
Guanfacine Hydrochloride Tablets  
Heparin Sodium and Sodium Chloride 0.9% Injection  
Hydrocortisone Tablets  
Hydromorphone Hydrochloride Injection  
Hydroxocobalamin Injection  
Hydroxypropyl (Lacrisert) Cellulose Ophthalmic Insert  
Imipenem and Cilastatin for Injection  
Isoniazid Injection  
Ketamine Injection  
Ketoprofen Capsules  
Ketorolac Tromethamine Injection  
Kit for the Preparation of Technetium Tc 99m Sulfur Colloid Injection  
Leucovorin Calcium Lyophilized Powder for Injection  
Leuprolide Acetate Injection  
Lidocaine Hydrochloride (Xylocaine) and Dextrose Injection Solution-Premix Bags  
Lidocaine Hydrochloride (Xylocaine) Injection  
Lidocaine Hydrochloride (Xylocaine) Injection with Epinephrine  
Lithium Oral Solution  
Lorazepam Injection  
Loxapine Capsules  
Mannitol Injection  
Mepivacaine Hydrochloride Injection  
Methohexital Sodium (Brevital) Injection  
Methyldopa Tablets  
Midazolam Injection  
Misoprostol Tablets  
Morphine Sulfate Injection  
Multi-Vitamin Infusion (Adult and Pediatric)  
Nefazodone Hydrochloride Tablets  
Nizatidine Capsules  
Ondansetron Hydrochloride Injection  
Paclitaxel Injection (protein-bound particles)  
Pantoprazole Sodium for Injection  
Parathyroid Hormone (Natpara) Injection  
Physostigmine Salicylate Injection  
Pindolol Tablets



Potassium Acetate Injection  
Promethazine (Phenergan) Injection  
Propofol Injectable Emulsion  
Protamine Sulfate Injection  
Rifampin Injection  
Rifapentine Tablets  
Ropivacaine Hydrochloride Injection  
Sclerosol Intrapleural Aerosol  
Sincalide (Kinevac) Lyophilized Powder for Injection  
Sodium Acetate Injection  
Sodium Bicarbonate Injection  
Sodium Chloride 23.4% Injection  
Sodium Chloride Injection USP, 0.9% Vials and Syringes  
Sodium Phosphates Injection  
Sulfasalazine Tablets  
Tacrolimus Capsules  
Technetium Tc99m Succimer Injection (DMSA)  
Teprotumumab-trbw  
Thiothixene Capsules  
Tocilizumab Injection  
Traimcinolone Acetonide Injectionable suspension  
Triamcinolone Hexacetonide Injectable suspension  
Trimethobenzamide Hydrochloride Capsules  
Valproate Sodium Injection  
Varenicline Tartrate (Chantix) Tablets  
Vecuronium Bromide for Injection