



Inland Empire Health Plan

PHARMACY TIMES

BY IEHP PHARMACEUTICAL SERVICES DEPARTMENT

October 28, 2021

URGENT: Recalls, Market Withdrawals, & Safety Alerts

Dear IEHP Providers,

According to the FDA recall guidance, Title 21 Code of Federal Regulations Part 7 (21 CFR part 7), recalled products must be promptly removed or corrected. In an effort to promote health and wellness of our members, please review your records and notify members who may have been impacted by these recalls and market withdrawals.

Product Name	Product Code	Lot # and Exp. Date	Classification	Recalling Firm
Atovaquone 750 mg/5 mL Oral Suspension, 210 mL bottle	NDC: 10702-0223-21	16653A, 16654A, Exp 12/2022	Class I	KVK-Tech, Inc.
Sodium Bicarbonate in 5% Dextrose Injection, 150 mEq per 1,000 mL (12.6 mg per mL), 1,000 mL bags	NDC: 70324-0326-01	BUP Exp. 03/23/2022	Class I	SterRx, LLC
Erythromycin 2% Topical Solution, 60mL bottle	NDC: 52565-0027-59	14892 Exp. 01/2022	Class II	Teligent Pharma, Inc.
Sodium Bicarbonate in 5% Dextrose Injection, 150 mEq per 1,000 mL (12.6 mg per mL), 1,000 mL bags	NDC Not Provided	BTW Exp. 03/08/2022; BUI Exp. 03/16/2022	Class II	SterRx, LLC
Micafungin 50 mg/vial for Injection, Single-Dose Vial	NDC: 70594-0036-01	467111 Exp. 01/2023	Class II	XELLIA PHARMACEUTICALS USA, LLC
Micafungin 100 mg/vial for Injection, Single-Dose Vial	NDC: 70594-0037-01	467111 Exp. 01/2023	Class II	XELLIA PHARMACEUTICALS USA, LLC
Sodium Phenylbutyrate Powder, 250 grams bottle	NDC: 42794-0086-14	1813001, 1813101, 1813201 Exp. 05/2023; 1822601, 1822701 Exp. 11/2023; 1905701, 1905801, 1906501, 1906601, 1906701 Exp. 05/2024	Class II	SigmaPharm Laboratories LLC
Fludarabine Phosphate 50 mg per vial for Injection, Single dose vial	NDC: 24201-0237-01	31327913C Exp. 10/2022	Class II	Custopharm, Inc.

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Trulicity (dulaglutide), 0.75 mg/0.5 mL, 4 Single-Dose Pens per box	NDC: 00002-1433-80	D396436C	Class II	Eli Lilly & Company
Carvedilol 25 mg Tablets	NDC: 70518-1826-01	B1273286-071521 Exp. 07/31/2022	Class II	RemedyRepack Inc.
Aminosyn II, 15%, An Amino Acid Injection, Sulfite	NDC: 00409-7171-17	4989094 Exp. 04/01/2022	MW	ICU Medical, Inc.
Firvanq® (Vancomycin Hydrochloride for Oral Solution), Vancomycin 50 mg/mL Kit, Due to a Mix-Up of the Diluent Included in the Kit	NDC: 65628-0206-05	21035 Exp. 07/31/2022	MW	Azurity Pharmaceuticals, Inc.
China_Gel (Camphor 3.00%, Menthol 5.00%) a Topical Pain Reliever	NDC: 76305-0300-13; 76305-0300-02; 76305-0300-03; 76305-0300-04; 76305-0300-03; 76305-0300-06	C030HS, C002KF Exp. 02/2021; B100JS, C100AH Exp. 04/2021; B122DY, B122DX Exp. 05/2021; B183GN, B183GP, B183GQ Exp. 07/2021; B262BF, B262BE, B255KZ Exp. 09/2021; C002KF Exp. 01/2022; C030HT Exp. 02/2022; C094LT Exp. 04/2022; C338CH Exp. 05-2022; C156FF Exp. 06/2022; C247JB, C247JF Exp. 09/2022; C275CW Exp. 10/2022; C275CW, C330BG, C338CH, C330BG Exp. 12/2022;	Class II	China Gel Inc
China_Gel White (Camphor 3.00%, Menthol 5.00%) a Topical Pain Reliever	NDC: 76305-0301-13; 76305-0301-02; 76305-0301-03; 76305-0301-04; 76305-0301-05; 76305-0301-06	B100JS Exp. 04/2021; B183GQ Exp. 07-2021; B183GQ, B255KZ Exp. 09-2021; C030HS Exp. 02-2022; C030HS Exp. 04-2022; C100AH Exp. 06-2022; C247JF Exp. 09-2022; C247JF Exp. 10-2022;	Class II	China Gel Inc



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Aulief (Organic Camphor 3.00% Organic Menthol 5.00%), Topical Pain Relief	NDC: 76305-0302-01; 76305-0302-02; 76305-0302-03	B136HN, B136HN, B136HN Exp. 05/2021	Class II	China Gel Inc
Cyclobenzaprine Hydrochloride 7.5mg Tablets	NDC: 00591-3330-01	1408821A Exp. 08/2023 (labeler - Teva)	Class II	Teva Pharmaceuticals USA
Cyclobenzaprine Hydrochloride 7.5mg Tablets	NDC: 70199-0014-01	1408822A Exp. 08/2023 (labeler - Casper)	Class II	Teva Pharmaceuticals USA
Cyclobenzaprine Hydrochloride 7.5mg Tablets	NDC: 57237-0266-01	1408824A Exp. 08/2023	Class II	Teva Pharmaceuticals USA
Clopidogrel 75 mg Tablets	NDC: 33342-0060-15	BCA82021A Exp. 06/2023	Class II	Macleods Pharma Usa Inc
Naproxen Sodium 220 mg Tablets (Caplet)	NDC: 62207-0762-36	7620060a	Class II	Granules USA, Inc.
Artificial Tears Ointment, Lubricant Eye Ointment, Net Wt. 3.5 g (1/8 oz.) per tube	NDC: 17478-0062-35	9G01A Exp. 06/2022; 9H32A Exp. 07/2022; 9K82A, 9K82B Exp. 09/2022	Class II	Akorn, Inc.
Ruzurgi® (amifampridine) 10 mg Tablets	NDC: 49938-0110-01	18038, 18039 Exp. 03/2023 18079 Exp. 05/2023	MW	Jacobus Pharmaceutical Company Inc.
Chantix 0.5 mg Tablets	NDC: 00069-0468-56	00019213, DM9007, EC6994, EN8362, CY6861, DM9008, EN5725, EN8467 Exp. 01/2022 to 05/2023	MW	Pfizer



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Chantix 1 mg Tablets	NDC: 00069-0469-56	00018777, 00021024, CW1572, DF5280, DY7987, EN5694, 00019289, 00021073, CW1573, DF5281, EA6080, EN5695, 00019593, 00021074, CW1574, DF5282, EC9841, EP1717, 00019682, CW1565, CW1575, DR5086, EC9842, EP1718, 00019846, CW1566, CW1578, DR5092, EC9843, EP1719, 00019977, CW1567, CW1579, DR5093, EC9847, EW2012, 00020295, CW1568, CW1581, DR5094, EC9848, EW3854, 00020448, CW1569, DF5277, DT3885, EE1011, EW3865, 00020458, CW1570, DF5278, DW4148, EM1069, EX2102, 00020480, CW1571, DF5279, DW4152, EM1070, EX2103 Exp. 09/2021 to 12/2024; 00019431, 00021421, 00022765, DR2614, DY7060, EE9391, 00019542, 00021422, 00022766, DX4576, DY9367, EF2346, 00019543, 00021423, 00023134, DX5870, DY9473, EM4805, 00019544, 00022136, 00023135, DX5871, DY9475, EM4807, 00020814, 00022174, 00023747, DX5872, DY9476, EN2005, 00020815, 00022175, 00023748, DX5873, DY9505, ET1601, 00020907, 00022176, DL3896, DX7805, EC5910, ET1605, 00020965, 00022177, DL7779, DY6078, EC5913, ET1606 Exp. 09/2021 to 06/2023	MW	Pfizer
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Chantix 0.5/1 mg Tablets	NDC: 00069-0471-03	00018522, 00020358, 00021688, 00022851, DM0277, ET1607, 00018523, 00020716, 00021788, 00023136, DY4470, ET1609, 00018739, 00020813, 00021789, 00023137, EC5911, ET1611, 00018740, 00021288, 00021790, 00023190, EC5912, 00020231, 00021289, 00021791, 00023448, ED6814, 00020232, 00021420, 00021792, DM0275, ET1600, 00020357, 00021687, 00022819, DM0276, ET1603 Exp. 08/2023 to 01/2023	MW	Pfizer
Cefazolin 2 gram in 20 mL syringe for injection	NDC: 71139-7087-10	20210803CEF-1 Exp. 09/17/2021 20210805CEF-3 Exp. 09/19/2021 20210806CEF-1, 20210806CEF-2 Exp. 09/20/2021 20210809CEF-1, 20210809CEF-2 Exp. 09/23/2021 20210810CEF-1 Exp. 09/24/2021 20210811CEF-1 Exp. 09/25/2021 20210812CEF-1 Exp. 09/26/2021	MW	IntegraDose Compounding Services, LLC
Cefazolin 3 gram in 100 mL 0.9% sodium chloride bag for injection	NDC: 71139-7053-10	20210722CEF-2 Exp. 09/20/2021; 20210728CEF-1 Exp. 09/26/2021	MW	IntegraDose Compounding Services, LLC
Lidocaine Hydrochloride 4% Topical Solution, 50 mL glass bottles	NDC: 52565-0009-50	14218, Exp. 08/2022	Class I	Teligent Pharma, Inc.



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Aminosyn II 15% An Amino Acid Injection, Sulfite-Free, 2000 mL in flexible containers	NDC: 00409-7171-17	4989094 Exp. 04/01/2022	Class I	ICU Medical Inc
Betamethasone Dipropionate 0.05% Lotion (Augmented)	NDC: 61748-0480-30; 61748-0480-60	372286, 372289, 372286, 372289 Exp. 01/31/2022	Class II	Akorn, Inc.
Oxycodone Hydrochloride 10 mg Tablets	NDC: 42858-0002-01	WP5K0Y Exp. 02/28/2023	Class II	Rhodes Pharmaceuticals, L.P.
Spirolactone Ophthalmic Solution 0.005 mg/mL, 15 mL bottles, Compound	NDC Not Provided	03012021@35; 04132021@10; 05102021@12; 06012021@28; 07012021@25; 03012021@36; 04132021@12; 05102021@11; 06012021@29; 07132021@14; 03152021@9; 06162021@21; 07132021@16; 03152021@10; 06162021@22	Class II	Prescription Labs Inc dba Greenpark
MIC+Methyl B12 injection Methionine Inositol Choline+Methylcobalamin 25 mg/50 mg/50 mg/1 mg/mL, 10 mL vial sterile	NDC Not Provided	06152021@2 Exp 09/13/2021	Class II	Promise Pharmacy, LLC
Glucagon Emergency Kit	NDC: 00002-7529-01	D239382D Exp. 04/2022	MW	Eli Lilly and Company
Avicel RC-591 NF (MCC/Carboxymethylcellulose Sodium) NF, bulk powder, 80.0 KG drum	NDC Not Provided	2173766940	Class I	DuPont Nutrition USA, Inc
Chantix (varenicline) 0.5mg/1mg Tablets, 56 Tablets	NDC: 00069-0471-03	00018522, 00018523, 00018739, 00018740, 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 Exp. 08/2021 and 01/2023;	Class II	Pfizer Inc.



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Chantix (varenicline) 0.5mg Tablets, 56 Tablets	NDC: 00069-0468-56	CY6861, DM9007, DM9008, EN5725, EN8362, EN8467 Exp. 01/2022 to 05/2023;	Class II	Pfizer Inc.
Chantix (varenicline) 1 mg Tablets, 56 Tablets	NDC: 00069-0469-56	00018777, 00019289, 00019593, 00019682, 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 Exp. 09/2021 to 12/2023	Class II	Pfizer Inc.
Chantix (varenicline) 1 mg Tablets	NDC: 00069-0469-03	00019431, 00019542, 00019543, 00019544, 00020814, 00020815, 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 Exp. 09/2021 to 12/2023	Class II	Pfizer Inc.



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Betadine Solution Swabstick Povidone-Iodine Solution USP, 10 % single	NDC: 67618-0153-03	11901232, 11901231 Exp. 09/30/2021; 11901549, 11901548 Exp. 11/30/2021; 12000585, 12000584 Exp. 03/31/2022; 12000964, 12000963 Exp. 05/31/2022; 12001185 Exp. 06/30/2022; 12001457, 12001456 Exp. 07/31/2022 ; 12002142, 12002150, 12100406 Exp. 12/31/2022; 12100407, Exp. 03/31/2023;	Class II	AVRIO HEALTH L.P
Carbamazepine 200 mg Tablets	NDC: 00904-6172-61	R01562 Exp. 10/2022	Class II	The Harvard Drug Group
Fulvestrant Injection 250 mg/5 mL (50 mg/mL) For Intramuscular Use Only Contains 2 single-dose pre- filled syringes Rx only	NDC: 68462-0317-32	30200014 Exp. 04/30/2022; 30200015, 30200016 Exp. 05/31/2022; 30200036, 30200038, 30200039, 30200040 Exp. 09/30/2022; 30210001, 30210002 Exp. 12/31/2022; 30210003, 30210004, 30210005, 30210006 Exp. 01/31/2023; 30210014, 30210022, 30210028, 30210029, 30210030, 30210031 Exp. 02/28/2023	Class II	Glenmark Pharmaceuticals Inc., USA
Naproxen Sodium 275 mg Tablets	NDC: 68462-0178-01	29190087, 29190088, 29190089 Exp. 10/31/2021; 29200077, 29200078 Exp. 11/30/2022	Class II	Glenmark Pharmaceuticals Inc., USA



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Naproxen Sodium 550 mg Tablets	NDC: 68462-0179-01; 68462-0179-05	29190082, 29190083 Exp. 09/30/2021; 29190084, 29190085 Exp. 10/31/2021; 29200001 Exp. 12/31/2021; 29200003, 29200004, 29200005 Exp. 01/31/2022; 29200012, 29200013, 29200010 Exp. 02/28/2022	Class II	Glenmark Pharmaceuticals Inc., USA
Chlorzoxazone 375 mg Tablets	NDC: 68462-0724-01	29200022, 29200024 Exp. 03/31/2022; 29200035 Exp. 06/30/2022	Class II	Glenmark Pharmaceuticals Inc., USA
Chlorzoxazone 750 mg Tablets	NDC: 68462-0725-01	29200023, 29200025 Exp. 03/31/2022; 29200036 Exp. 06/30/2022; 29200056 Exp. 09/30/2022; 29200070 Exp. 11/30/2022	Class II	Glenmark Pharmaceuticals Inc., USA
Zonisamide 50 mg Capsules	NDC: 68462-0129-01	29190043, 29190044, 29190045 Exp. 05/31/2022	Class II	Glenmark Pharmaceuticals Inc., USA
Zonisamide 100 mg Capsules	NDC: 68462-0130-01; 68462-0130-05	29200014 Exp. 02/28/2023; 29200015, 29200016 Exp. 03/31/2023; 29200030, 29200031, 29200032 Exp. 05/31/2023; 29200033, 29200037, 29200038 Exp. 06/30/2023; 29200039, 29200041, 29200042 Exp. 07/31/2023; 29200048, 29200049, 29200050 Exp. 08/31/2023; 29200072, 29200073, 29200074, 29200075, 29200076 Exp. 11/30/2023;	Class II	Glenmark Pharmaceuticals Inc., USA



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Arformoterol Tartrate Inhalation Solution 15 mcg*/2 mL For Oral Inhalation Only	NDC: 68462-833-65; 68462-0833-35	30210041, 30210042, 30210050 Exp. 03/31/2023; 30210045, 30210046, 30210051, 30210058, 30210047, 30210048, 30210052, 30210053, 30210054, 30210059, 30210060, 30210061, 30210062, 30210063 Exp. 04/30/2023; 30210064 Exp. 05/31/2023	Class II	Glenmark Pharmaceuticals Inc., USA
Promethazine Syrup Plain, 6.25 mg/5 mL (Promethazine Hydrochloride Syrup, USP), 1 Pint (473 mL)	NDC: 60432-0608-16	UV1335, UV1352, UV1373	Class II	Morton Grove Pharmaceuticals, Inc.
Promethazine With Codeine Oral Solution, (Promethazine Hydrochloride 6.25 mg/5mL & Codeine Phosphate 10 mg/5 mL), 1 Pint (473 mL)	NDC: 60432-0606-16	UV1198	Class II	Morton Grove Pharmaceuticals, Inc.
Valproic Acid (250 mg/5 mL) Oral Solution USP, 1 Pint (473 mL)	NDC: 60432-0621-16	UV1159	Class II	Morton Grove Pharmaceuticals, Inc.
Entacapone 200 mg Tablets	NDC: 00904-6822-04	N00187 Exp. 05/2022; N00245 Exp. 06/2022; N00273 Exp. 07/2022; N00355 Exp. 11/2022	Class II	The Harvard Drug Group
Metoprolol Tartrate 100 mg Tablets	NDC: 65862-0064-99	MJ1019025-A Exp. 04/2022	Class II	Aurobindo Pharma USA Inc.
Zonisamide 100 mg Capsules	NDC: 61919-0775-30	17JU2118 Exp. 5/31/2023	Class II	Direct Rx

I = Class I Recall, II = Class II Recall, MW = Market Withdrawal

Additional information can be found at:

1. FDA Recalls, Market Withdrawals, & Safety Alerts:
<https://www.fda.gov/Safety/Recalls/default.htm>
2. FDA Enforcement Report:
<http://www.fda.gov/Safety/Recalls/EnforcementReports/default.htm>



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3. IEHP Safety Resources:

<https://ww3.iehp.org/en/providers/pharmaceutical-services/clinical-information/safety-resources/>

If you have any questions or comments regarding this recall, please call IEHP Pharmaceutical Services Department at 909-890-2049, 8am – 5pm (PST), Monday through Friday.

Sincerely,

IEHP Pharmaceutical Services