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Inland Empire Health Plan

PHARMACY TIMES

BY IEHP PHARMACEUTICAL SERVICES DEPARTMENT

June 1, 2018

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
Alka-Seltzer Plus n/a	No NDC Provided	n/a	Class I	Bayer HealthCare Pharmaceuticals, Inc
Ibuprofen Tablets 200mg	NDC 49483-0601-05 53943-0291-15	Exp. 02/18	Class II	Time-Cap Laboratories, Inc.
Ibuprofen Tablets 400mg	NDC 49483-0602-01 42582-0111-18	Exp. 03/18	Class II	Time-Cap Laboratories, Inc.
Ibuprofen Tablets 600mg	NDC 49483-0603-01 42582-0112-10	Exp. 03/18	Class II	Time-Cap Laboratories, Inc.
Ibuprofen Tablets 800mg	NDC 49483-0604-01 42582-0113-10	Exp. 02/18	Class II	Time-Cap Laboratories, Inc.
Ibuprofen Caplets 200mg	NDC 49483-0600-05 53943-0292-15	Exp. 02/18	Class II	Time-Cap Laboratories, Inc.
Morphine Sulfate 2mg/ml	NDC 69623-0129-10	Exp. 06/18	Class II	Premier Pharmacy Labs Inc
Morphine Sulfate 4mg/ml	NDC 69623-0127-10	MOR022318NWDSA, MOR022318NWDSB, MOR022318NWDSC, MOR022318NWDSD, MOR022318NWDSE BUD: 05/18	Class II	Premier Pharmacy Labs Inc
Hydromorphone HCL 1mg/ml	NDC 69623-0249-10	HYD030118IJDSA, HYD030118IJDSB, HYD030118IJDSD, HYD030118IJDSE BUD: 05/18	Class II	Premier Pharmacy Labs Inc
Neostigmine Methylsulfate 1mg/ml	NDC 69623-0234-14	Lot: NEO022218SVDS BUD: 8/18	Class II	Premier Pharmacy Labs Inc
Linezolid Injection 600mg/300ml	NDC 55150-0242-51	Exp. 07/18	Class II	AuroMedics Pharma LLC
Levofloxacin Infusion 250mg	NDC 55150-0243-46	Exp. 08/19	Class II	AuroMedics Pharma LLC
Levetiracetam 5mg/ml	NDC 55150-0246-47	Exp. 10/19	Class II	AuroMedics Pharma LLC

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Levetiracetam 10mg/ml	NDC 55150-0247-47	Exp. 09/18	Class II	AuroMedics Pharma LLC
Levetiracetam 15mg/ml	NDC 55150-0248-47	Exp. 09/18	Class II	AuroMedics Pharma LLC
Levofloxacin 5mg/ml	NDC 55150-0244-47	Exp. 08/19	Class II	AuroMedics Pharma LLC
Humira Pen 40mg/0.8ml	NDC 00074-7339-02 00074-4339-07	All lots remaining within expiry dispensed 12/01/2017 through 02/12/2018	Class II	Kroger Specialty Pharmacy, Inc.
Albuterol 0.00083	NDC 76204-0200-60	All lots remaining within expiry dispensed 12/01/2017 through 02/12/2019	Class II	Kroger Specialty Pharmacy, Inc.
Kalydeco 150mg	NDC 51167-0200-01	All lots remaining within expiry dispensed 12/01/2017 through 02/12/2020	Class II	Kroger Specialty Pharmacy, Inc.
Pediasure Liquid Vanilla n/a	NDC 70074-0558-98	All lots remaining within expiry dispensed 12/01/2017 through 02/12/2021	Class II	Kroger Specialty Pharmacy, Inc.
Polyethylene Glycol 3350 527g	NDC 51991-0457-57	All lots remaining within expiry dispensed 12/01/2017 through 02/12/2022	Class II	Kroger Specialty Pharmacy, Inc.
Pulmicort Respules 0.5mg/2ml	NDC 00186-1989-04	All lots remaining within expiry dispensed 12/01/2017 through 02/12/2023	Class II	Kroger Specialty Pharmacy, Inc.
Otezla 30mg	NDC 59572-0631-06	All lots remaining within expiry dispensed 12/01/2017 through 02/12/2024	Class II	Kroger Specialty Pharmacy, Inc.
Taltz 80mg/ml	NDC 00002-1445-11	All lots remaining within expiry dispensed 12/01/2017 through 02/12/2025	Class II	Kroger Specialty Pharmacy, Inc.
Cosentyx 150mg/ml	NDC 00078-0639-98	All lots remaining within expiry dispensed 12/01/2017 through 02/12/2026	Class II	Kroger Specialty Pharmacy, Inc.
Altera Handset n/a	NDC 83490-0678-05	All lots remaining within expiry dispensed 12/01/2017 through 02/12/2027	Class II	Kroger Specialty Pharmacy, Inc.
Cayston 75mg	NDC 61958-0901-01	All lots remaining within expiry dispensed 12/01/2017 through 02/12/2028	Class II	Kroger Specialty Pharmacy, Inc.
Repatha 140mg/ml	NDC 55513-0760-02	All lots remaining within expiry dispensed	Class II	Kroger Specialty Pharmacy, Inc.

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		12/01/2017 through 02/12/2029		
Enbrel PFS 50mg/ml	NDC 58406-0435-04	All lots remaining within expiry dispensed 12/01/2017 through 02/12/2030	Class II	Kroger Specialty Pharmacy, Inc.
Botox 100 units	NDC 00023-1145-01	All lots remaining within expiry dispensed 12/01/2017 through 02/12/2031	Class II	Kroger Specialty Pharmacy, Inc.
Prolia 60mg/1ml	NDC 55513-0710-01	All lots remaining within expiry dispensed 12/01/2017 through 02/12/2032	Class II	Kroger Specialty Pharmacy, Inc.
Kitabis Pack 300mg/5ml	NDC 24492-0850-56	All lots remaining within expiry dispensed 12/01/2017 through 02/12/2033	Class II	Kroger Specialty Pharmacy, Inc.
Orkambi 200mg/125ml	NDC 51167-0809-01	All lots remaining within expiry dispensed 12/01/2017 through 02/12/2034	Class II	Kroger Specialty Pharmacy, Inc.
Orkambi 100mg/125ml	NDC 51167-0700-02	All lots remaining within expiry dispensed 12/01/2017 through 02/12/2035	Class II	Kroger Specialty Pharmacy, Inc.
Bethkis 300mg/4ml	NDC 10122-0820-56	All lots remaining within expiry dispensed 12/01/2017 through 02/12/2036	Class II	Kroger Specialty Pharmacy, Inc.
Pulmozyme 1mg/ml	NDC 50242-0100-40	All lots remaining within expiry dispensed 12/01/2017 through 02/12/2037	Class II	Kroger Specialty Pharmacy, Inc.
Azithromycin 250mg	NDC 50111-0787-66	All lots remaining within expiry dispensed 12/01/2017 through 02/12/2038	Class II	Kroger Specialty Pharmacy, Inc.
Creon DR 24,000 units	NDC 00032-1224-07	All lots remaining within expiry dispensed 12/01/2017 through 02/12/2039	Class II	Kroger Specialty Pharmacy, Inc.
MVW Complete Softgels n/a	NDC 58204-004-00	All lots remaining within expiry dispensed 12/01/2017 through 02/12/2040	Class II	Kroger Specialty Pharmacy, Inc.
MVW Complete Chew Vitamin Grape n/a	NDC 58204-0004-15	All lots remaining within expiry dispensed 12/01/2017 through 02/12/2041	Class II	Kroger Specialty Pharmacy, Inc.



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Sodium Chloride 0.03	NDC 00487-9003-60	All lots remaining within expiry dispensed 12/01/2017 through 02/12/2042	Class II	Kroger Specialty Pharmacy, Inc.
Xolair 150mg	NDC 50242-0040-62	All lots remaining within expiry dispensed 12/01/2017 through 02/12/2043	Class II	Kroger Specialty Pharmacy, Inc.
Vosevi 400/100/100mg	NDC 61958-2401-01	All lots remaining within expiry dispensed 12/01/2017 through 02/12/2044	Class II	Kroger Specialty Pharmacy, Inc.
Dupixent 300mg/2ml	NDC 00024-5914-01	All lots remaining within expiry dispensed 12/01/2017 through 02/12/2045	Class II	Kroger Specialty Pharmacy, Inc.
Boost VHC Oral Liquid n/a	NDC 43900-0182-15	All lots remaining within expiry dispensed 12/01/2017 through 02/12/2046	Class II	Kroger Specialty Pharmacy, Inc.
Stelara 90mg/ml	NDC 57894-0061-03	All lots remaining within expiry dispensed 12/01/2017 through 02/12/2047	Class II	Kroger Specialty Pharmacy, Inc.
Cimzia 200mg/ml	NDC 50474-0710-79	All lots remaining within expiry dispensed 12/01/2017 through 02/12/2048	Class II	Kroger Specialty Pharmacy, Inc.
Praluent 75mg	NDC 00024-5901-02	All lots remaining within expiry dispensed 12/01/2017 through 02/12/2049	Class II	Kroger Specialty Pharmacy, Inc.
Copaxone 20mg, 40mg	NDC 68546-0325-12 68546-0317-30	All lots remaining within expiry dispensed 12/01/2017 through 02/12/2050	Class II	Kroger Specialty Pharmacy, Inc.
Tecfidera 240mg	NDC 64406-0006-02	All lots remaining within expiry dispensed 12/01/2017 through 02/12/2051	Class II	Kroger Specialty Pharmacy, Inc.
Pomalyst 3mg	NDC 59572-0503-21	All lots remaining within expiry dispensed 12/01/2017 through 02/12/2052	Class II	Kroger Specialty Pharmacy, Inc.
Xtandi 40mg	NDC 00469-0125-99	All lots remaining within expiry dispensed 12/01/2017 through 02/12/2053	Class II	Kroger Specialty Pharmacy, Inc.
Promacta 50mg	NDC 00078-0686-15	All lots remaining within expiry dispensed 12/01/2017 through 02/12/2054	Class II	Kroger Specialty Pharmacy, Inc.



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Revlimid 5mg, 10mg, 15mg, 20mg, 25mg	NDC 59572-0410-28 59572-0415-21 59572-0420-21 59572-0405-28 59572-425-21	All lots remaining within expiry dispensed 12/01/2017 through 02/12/2055	Class II	Kroger Specialty Pharmacy, Inc.
Avonex 30mcg/0.5ml	NDC 59627-0222-05	All lots remaining within expiry dispensed 12/01/2017 through 02/12/2056	Class II	Kroger Specialty Pharmacy, Inc.
Ibrance 125mg	NDC 00069-0189-21	All lots remaining within expiry dispensed 12/01/2017 through 02/12/2057	Class II	Kroger Specialty Pharmacy, Inc.
Glatiramer Acetate 40mg/ml	NDC 00378-6961-12	All lots remaining within expiry dispensed 12/01/2017 through 02/12/2058	Class II	Kroger Specialty Pharmacy, Inc.
Xalkori 250mg	NDC 00069-8140-20	All lots remaining within expiry dispensed 12/01/2017 through 02/12/2059	Class II	Kroger Specialty Pharmacy, Inc.
Temozolomide 20mg	NDC 43975-0253-05	All lots remaining within expiry dispensed 12/01/2017 through 02/12/2060	Class II	Kroger Specialty Pharmacy, Inc.
Temozolomide 250mg	NDC 43975-0257-05	All lots remaining within expiry dispensed 12/01/2017 through 02/12/2061	Class II	Kroger Specialty Pharmacy, Inc.
Gleevec 100mg	NDC 00078-0401-34	All lots remaining within expiry dispensed 12/01/2017 through 02/12/2062	Class II	Kroger Specialty Pharmacy, Inc.
Sprycel 80mg, 100mg	NDC 00003-0855-22 00003-0852-22	All lots remaining within expiry dispensed 12/01/2017 through 02/12/2063	Class II	Kroger Specialty Pharmacy, Inc.
Cyclophosphamide 50mg	NDC 00054-0383-25	All lots remaining within expiry dispensed 12/01/2017 through 02/12/2064	Class II	Kroger Specialty Pharmacy, Inc.
Dexamethasone 4mg	NDC 49884-0087-01	All lots remaining within expiry dispensed 12/01/2017 through 02/12/2065	Class II	Kroger Specialty Pharmacy, Inc.
Sutent 37.5mg, 50mg	NDC 00069-0830-38 00069-0550-38	All lots remaining within expiry dispensed 12/01/2017 through 02/12/2066	Class II	Kroger Specialty Pharmacy, Inc.
Imatinib Mesylate 400mg	NDC 60505-2901-03	All lots remaining within expiry dispensed	Class II	Kroger Specialty Pharmacy, Inc.



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		12/01/2017 through 02/12/2067		
Capecitabine 150mg, 500mg	NDC 00378-2511-97 00378-2512-78	All lots remaining within expiry dispensed 12/01/2017 through 02/12/2068	Class II	Kroger Specialty Pharmacy, Inc.
Bendeka 25mg/ml	NDC 63459-0348-04	All lots remaining within expiry dispensed 12/01/2017 through 02/12/2069	Class II	Kroger Specialty Pharmacy, Inc.
Ondansetron 8mg	NDC 57237-0076-30	All lots remaining within expiry dispensed 12/01/2017 through 02/12/2070	Class II	Kroger Specialty Pharmacy, Inc.
Letrozole 2.5mg	NDC 51991-0759-33	All lots remaining within expiry dispensed 12/01/2017 through 02/12/2071	Class II	Kroger Specialty Pharmacy, Inc.
Perjeta 420mg/14ml	NDC 50242-0145-01	All lots remaining within expiry dispensed 12/01/2017 through 02/12/2072	Class II	Kroger Specialty Pharmacy, Inc.
Zarxio 300mcg/0.5ml	No NDC Provided	All lots remaining within expiry dispensed 12/01/2017 through 02/12/2073	Class II	Kroger Specialty Pharmacy, Inc.
Tasigna 150mg	NDC 00078-0592-87	All lots remaining within expiry dispensed 12/01/2017 through 02/12/2074	Class II	Kroger Specialty Pharmacy, Inc.
Opdivo 40mg/4ml	NDC 00005-3772-11	All lots remaining within expiry dispensed 12/01/2017 through 02/12/2075	Class II	Kroger Specialty Pharmacy, Inc.
Kisqali 200mg	NDC 00078-0874-63	All lots remaining within expiry dispensed 12/01/2017 through 02/12/2076	Class II	Kroger Specialty Pharmacy, Inc.
Lupron Depot 22.5mg	NDC 00074-3346-03	All lots remaining within expiry dispensed 12/01/2017 through 02/12/2077	Class II	Kroger Specialty Pharmacy, Inc.
Metoprolol Succinate Extended Release 100mg	NDC 55111-0468-001	Batch # C706254, 08/2019	Class II	Dr. Reddy's Laboratories, Inc.
Macroaggregated Albumin (MAA) 2.5-5mg	No NDC Provided	Lot: MAA-171219BM BUD: 4/18; MAA- 180226BM BUD: 06/18	Class II	Coast Quality Pharmacy LLC
Technetium TC-99M Mebrofenin Preparation Kit 45mg	NDC 455367-0455-01 45567-0455-02	Part Number MEM05 and MEB30 both with expiry date 12/2018	Class II	Pharmalucence, Inc.



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Sulfamethoxazole and Trimethoprim Tablets 800mg/160mg	NDC 53489-0146-05	Lot 6848501, EXP 04/20	Class II	Sun Pharmaceutical Industries, Inc.
Amlodipine and Benazapril HCL 5mg/10mg	NDC 00378-6896-01	Lot Numbers# 3083005, 3083006, 3086121, 3086122, Exp. 01/19	Class II	Mylan Pharmaceuticals Inc.
Amlodipine and Benazapril HCL 5mg/40mg	NDC 00378-6899-01	Lot Numbers# 3083008,3086124 Exp. 01/19	Class II	Mylan Pharmaceuticals Inc.
Clindamycin 150mg	NDC 00527-1382-01	Lot # 0130126	Class II	Prescript Pharmaceuticals, Inc.
Acetaminophen w/Codeine Phosphate 300mg/30mg	NDC 13107-0059-99 00406-0484-10	Lot # 0130131, EXP 8/20 Lot # 0130130 EXP 12/20	Class II	Prescript Pharmaceuticals, Inc.
Chlorhexidine 0.0012	NDC 00116-2001-16	Lot # 130128, EXP 08/20	Class II	Prescript Pharmaceuticals, Inc.
Clindamycin 300MG	NDC 00527-1383-01	Lot # 0130132, EXP 3/19	Class II	Prescript Pharmaceuticals, Inc.
Scopolamine Transdermal Therapeutic System 1 mg/3 days	NDC 45802-0580-84 45802-0580-46 45802-0580-62	Lot #: a) 46397, 46457 Exp 03/19; 46621, Exp 04/19; 46894, 46904, 46905, Exp 06/19; 47133, Exp 07/19; 47153, Exp 08/19; 47154, 47213, 47214, Exp 09/19; b) 46695, Exp 04/19; 46994, 47012, Exp 07/19; 47322 10/19; c) 46822, Exp 05/19 ; 47155, 47212, Exp 09/19	Class II	L. Perrigo Company
B Prox 10 Anti-blemish Wash 0.1	No NDC Provided	Lot: # ET507-0, Exp. 5/19; GU894-8, Exp. 7/10	Class II	Milbar Laboratories, Inc.
Solar Defense Sheer Sunscreen Broad Spectrum SPF50	No NDC Provided	Lot #: KU455-2, Exp. 11/20; KU455-6, Exp.11/20	Class II	Milbar Laboratories, Inc.
Naturmetic SPF51	No NDC Provided	Lot #: KU455-4, Exp.10/20	Class II	Milbar Laboratories, Inc.
MD Complete Clarifying Cleanser 0.02	No NDC Provided	Lot #: KU503-6, KU393-6, Exp. 12/20	Class II	Milbar Laboratories, Inc.
Hydrocortisone Ointment 0.025	NDC 45802-0014-02	Lot Numbers: 7AT0283V, exp. 11/18 7AT0284V, exp. 11/18 7AT0285V, exp. 11/18 7FT0460, exp. 05/19 7FT0461, exp. 05/19 7GT0465, exp. 06/19 7GT0466, exp. 06/19 7JT0390, exp. 08/19 7JT0392, exp. 08/19 7KT0588, exp. 09/19 7KT0589, exp. 09/19	Class II	Perrigo New York
Ampicillin and Sulbactam 3g	NDC 55150-0117-20	Lot #AS0317041-A Exp. 08/19	RMS	AuroMedics Pharma LLC



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Pipercillin and Tazobactam 3.375g & 4.5g	No NDC Provided	Exp. 05/18	RMS	AuroMedics Pharma LLC & cApotex Corporation
7K & Poseidon 4500 Dietary Supplements 1000mg	No NDC Provided	Lot #20117BL Exp. 02/17	RMS	7K and Poseidon
Various Homeopathic Products n/a	No NDC Provided	n/a	RMS	MBI Distributing, Inc
Rhino 69 Extreme 50000 n/a	No NDC Provided	All Lots	Class I	AMA Wholesale Inc.
0.9% Sodium Chloride Injection 1000ml	NDC 49230-0300-10	Lot # 17LU05005; Exp. 09/18 Part Number 060- 10109	Class II	Fresenius Medical Care Renal Therapies Group, LLC
Loxapine 25mg, 50mg	NDC 00378-7025-01 00378-7050-01	Lot #: 3083756, 3083757, 3083758, 3083759, 3083760, 3083761, Exp. 3/19	Class II	Mylan Pharmaceuticals Inc.
Screamin Hot Pain Relieving Gel 0.0003	UPC 750263800724 750263800076 750263800762	Lot #: 116002, Exp 01/19; 217003, Exp 02/20; 1217017, Exp 12/20	Class II	Ideaz Llc
Screamin Menthol Pain Relieving Gel 0.04	UPC 750263800625 750263800069 750263800663	Lot #: 1015019, Exp 10/18; 1116011, Exp 11/19	Class II	Ideaz Llc
Diclofenac Sodium and Misoprostol Delayed Release 75mg/0.2mg	NDC 42367-0111-06	Lot: GH70154 Exp. 12/18	Class II	Exela Pharma Sciences LLC
Prednisolone Sodium Phosphate ODT 10mg, 15mg, 30mg	No NDC Provided	Lot #: 3081542, 3081543, 3081544, 3082235 Exp. 08/18 3085903 Exp. 12/18 3088974, 3090445, Exp. 06/19	Class II	Mylan Pharmaceuticals Inc.

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>
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