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Inland Empire Health Plan

# PHARMACY TIMES

BY IEHP PHARMACEUTICAL SERVICES DEPARTMENT

May 5, 2022

## 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
GONADORELIN (5ML) 0.2 MG/ML INJECTABLE, Packaged in a multi dose 10ML vial, Formula ID132227, APS Pharmacy	NDC Not Provided	745708 BUD: 6/21/2022; 753364 BUD: 7/27/2022; 752508 BUD: 7/24/2022; 750313 BUD: 7/16/2022; 753020 BUD: 7/26/2022; 747712 BUD: 7/4/2022; 747974 BUD: 7/5/2022; 754802 BUD: 8/3/2022; 751158 BUD: 7/19/2022; 756837 BUD: 8/16/2022; 748939 BUD: 7/10/2022; 750842 BUD: 7/18/2022; 755742 BUD: 8/8/2022; 758691 BUD: 8/28/2022; 758432 BUD: 8/27/2022; 758975 BUD: 8/29/2022; 756643 BUD: 8/15/2022	Class II	Drug Depot, Inc., dba APS Pharmacy
(CA) GONADORELIN (4ML) 0.2 MG/ML INJECTABLE, Packaged in a multi dose 10ML vial, Formula ID136345, APS Pharmacy	NDC Not Provided	749842 BUD: 7/13/2022; 749568 BUD: 7/12/2022; 752053 BUD: 7/23/2022; 752817 BUD: 7/25/2022; 757404 BUD: 8/21/2022; 757915 BUD: 8/23/2022; 757321 BUD: 8/20/2022; 753718 BUD: 7/30/2022	Class II	Drug Depot, Inc., dba APS Pharmacy



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TESTOSTERONE CYPIONATE/ANASTROZOLE *GS* OIL 200MG/1MG/ML Injectable, Packaged in a multi dose 10ML vial, as a) 4 ML Formula ID 115387; b) (RM) 10 ML Formula ID 115125; APS Pharmacy	NDC Not Provided	745383 BUD: 6/20/2022; 759295 BUD: 8/30/2022; 745749 BUD: 6/21/2022; 746272 BUD: 6/27/2022	Class II	Drug Depot, Inc., dba APS Pharmacy
TESTOSTERONE CYPIONATE/ ANASTROZOLE *GS* OIL (10ML) 200MG/0.5MG/ML; Packaged in a multi dose 10ML vial, as a) (CA) 4 ML Formula ID 136164; b) (RM) 10 ML Formula ID 115962; APS Phar	NDC Not Provided	Lots: a)750851 BUD: 7/18/2022; b) 754549 BUD: 8/2/2022	Class II	Drug Depot, Inc., dba APS Pharmacy
TESTOSTERONE CYPIONATE/ DHEA *GS* 200/10MG/ML Injectable, Packaged in a multi dose 10ML vial, as a) 5 ML Formula ID 115678; b) 10 ML Formula ID 115498, APS Pharmacy	NDC Not Provided	746000 BUD: 6/26/2022; 751472 BUD: 7/20/2022	Class II	Drug Depot, Inc., dba APS Pharmacy
TESTOSTERONE CYPIONATE/PROPIONATE *SES* Oil (10 ML) 160MG/20MG/ML Injectable, Packaged in a multi dose 10ml vial, Formula ID 115498, APS Pharmacy	NDC Not Provided	759312 BUD: 8/30/2022	Class II	Drug Depot, Inc., dba APS Pharmacy
TESTOSTERONE CYPIONATE *GS* Oil 200 MG/ML Injectable, Packaged in a multi dose 10ML vial, Formula ID 76681, APS Pharmacy	NDC Not Provided	754381 BUD: 8/1/2022	Class II	Drug Depot, Inc., dba APS Pharmacy
TESTOSTERONE CYPIONATE *GS* (2 mL) 80 MG/ML Injectable, Packaged in a multi dose 10ML vial, Formula ID 127492, APS Pharmacy	NDC Not Provided	746269 BUD: 6/27/2022	Class II	Drug Depot, Inc., dba APS Pharmacy



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Glycopyrrolate 1 mg Tablets	NDC: 13107-0014-01	01421008A1, Exp 03/2023	Class II	Aurolife Pharma, LLC
Lansoprazole 15 mg Delayed-Release Capsules	NDC: 55111-0398-30; 55111-0398-90	C2103093, C2103092 Exp. 12/2023	Class II	Dr. Reddy's Laboratories, Inc.
Lansoprazole 30 mg Delayed-Release Capsules	NDC: 55111-0399-90	C2102911 Exp. 12/2023	Class II	Dr. Reddy's Laboratories, Inc.
Insulin Glargine (Insulin glargine-yfgn) Injection, 100 units/mL (U-100), 10 mL vial	NDC: 49502-0393-80	BF21002800 Exp. 08/2023	MW	Mylan Pharmaceuticals, Inc. a Viatrix Company
Symjepi (epinephrine injection) 0.3 mg, (0.3 mg/0.3 mL), Two Pre-Filled Single-Dose Syringes per carton	NDC: 78670-0130-02	21041W Exp. 8/31/2022; 21081W Exp. 11/30/2022; 21102W Exp. 2/28/2023	Class I	Adamis Pharmaceuticals Corporation
Symjepi (epinephrine injection) 0.15 mg (0.15 mg/0.3 mL), Two Pre-Filled Single-Dose Syringes per carton	NDC: 78670-0131-02	21101Y Exp. 11/30/2022	Class I	Adamis Pharmaceuticals Corporation
Orphenadrine Citrate 100 mg Extended-Release Tablets	NDC: 00185-0022-01	JX6411, JX6413 Exp. 05/2022; KC0723, KC3303 Exp. 08/2022; KE4348, KE7169, KE4349 Exp. 11/2022; KL3199, KM0072, KS3939 Exp. 03/2023; LA7704, LA7703, LA9243 Exp. 11/2023	Class II	Sandoz, Inc
Tetracaine 1% Tetracaine HCl Injection, 20mg/2mL (10mg/mL), 10 x 2ml Single Use Vials per box	NDC: 42494-0437-10	21VTHI017, 21VTHI018, 21VTHI019 Exp. 05/31/2023	Class II	Vitae Enim Vitae Scientific, Inc.
Papaverine Hydrochloride 60 mg/2mL (30 mg/mL) Injection	NDC: 72516-0024-25; 72516-0024-10	20VPHI037, 20VPHI038, 20VPHI039 Exp. 12/31/2022; 21VPHI021, 21VPHI022, 21VPHI023 Exp. 06/30/2023; 21VPHI047, 21VPHI048 Exp. 10/31/2023;	Class II	Vitae Enim Vitae Scientific, Inc.



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Phenobarbital Sodium 65mg/mL Injection	NDC: 42494-0415-25; 42494-0415-03	20VPSI007 Exp. 03/31/2022; 20VPSI015 Exp. 05/30/2022; 20VPSI018 Exp. 06/1/2022; 20VPSI032 Exp. 11/30/2022; 21VPSI002, 21VPSI003 Exp. 01/31/2023; 21VPSI006 Exp. 03/31/2023; 21VPSI012, 21VPSI020 Exp. 05/31/2023; 21VPSI035 Exp. 07/31/2023; 21VPSI037, 21VPSI038 Exp. 08/31/2023; 21VPSI043, 21VPSI044 Exp. 10/31/2023; 21VPSI050, 21VPSI051 Exp. 11/30/2023; 22VPSI004 Exp. 07/31/2024; 22VPSI006 Exp. 08/31/2024; 20VPSI008 Exp. 03/31/2022; 20VPSI019 Exp. 06/30/2022; 21VPSI050 Exp. 11/30/2023,	Class II	Vitae Enim Vitae Scientific, Inc.
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Phenobarbital Sodium 130 mg/mL Injection	NDC: 42494-0416-25; 42494-0416-03	20VPSI011 Exp. 04/30/2022; 20VPSI014 Exp. 05/31/2022; 20VPSI020, 20VPSI022, 20VPSI023 Exp. 07/31/2022; 21VPSI007 Exp. 03/31/2023; 21VPSI013 Exp. 05/31/2023; 21VPSI027 Exp. 06/30/2023; 21VPSI039 Exp. 08/31/2023; 21VPSI042 Exp. 10/31/2023; 21VPSI049 Exp. 11/30/2023; 21VPSI052 Exp. 12/31/2023; 22VPSI005 Exp. 07/31/2024; 22VPSI007 Exp. 08/31/2024; 22VPSI007 Exp. 08/31/2024; 20VPSI009 Exp. 03/31/2022; 20VPSI020 Exp. 07/31/2022; 21VPSI039 Exp. 08/31/2023; 22VPSI005 Exp. 07/31/2024	Class II	Vitae Enim Vitae Scientific, Inc.
Sucralfate 1g/10ml Oral Suspension	NDC: 69339-0148-17; 69339-0148-19	376908P40, 376908P100 Exp. 02/28/2023	Class II	DASH Pharmaceuticals LLC
Accuretic (quinapril HCl/hydrochlorothiazide) 10 mg/12.5 mg Tablets	NDC: 00071-3112-23	FG5379 Exp. 08/2024	Class II	Pfizer Inc.
Accuretic (quinapril HCl/hydrochlorothiazide) 10 mg/12.5 mg Tablets	NDC: 00071-0222-23	EA6686 Exp. 04/2022	Class II	Pfizer Inc.



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Accuretic (quinapril HCl/hydrochlorothiazide) 20 mg/12.5 mg Tablets	NDC: 00071-0220-23	EA6665, CN0640 Exp. 04/2022	Class II	Pfizer Inc.
Accuretic (quinapril HCl/hydrochlorothiazide) 20 mg/25 mg Tablets	NDC: 00071-0223-23	ET6974 Exp. 02/2023	Class II	Pfizer Inc.
Quinapril and hydrochlorothiazide 20 mg/25 mg Tablets	NDC: 59762-5225-09	FE3714 Exp. 02/2023	Class II	Pfizer Inc.
Quinapril HCl/hydrochlorothiazide 20 mg/12.5 mg Tablets	NDC: 59762-0220-01	DN6931, ED3904, ED3905 Exp. 03/2023	Class II	Pfizer Inc.
Quinapril HCl/hydrochlorothiazide 20 mg/25 mg Tablets	NDC: 59762-0223-01	DP3414 Exp. 02/2023	Class II	Pfizer Inc.
Accuretic (quinapril HCl/hydrochlorothiazide) 20 mg/12.5 mg Tablets	NDC: 00071-5212-23	FG5381 Exp. 08/2024	Class II	Pfizer Inc.
Janumet (sitagliptin and metformin HCl) 50 mg/500 mg Tablets, Sample-Not For Sale	NDC: 00006-0575-02; 00006-0575-03	U015824 Exp. 09/2022	Class II	MERCK SHARP & DOHME CORP
Travoprost 0.004% Ophthalmic Solution, 2.5 mL bottle	NDC: 00378-9651-32	TV11W101 Exp. 03/2023	Class II	Mylan Pharmaceuticals Inc
Idarubicin Hydrochloride Injection 5mg/5mL (1mg/mL), 5mL Single Dose Vial	NDC: 00703-4154-11	31329657B Exp. 08/2023	Class I	Teva Pharmaceuticals USA Inc
Clobetasol Propionate Lotion 0.05%, Generic for Temovate, 118 mL bottle	NDC: 68788-7768-01	A0721O, A1421Y, A2121G, A2821D, B0421H, B0421I, B0521U, B1121G, B1921C, C0421B, C1821N, L0120F, L2320O, L3020T Exp. 04/30/2022; B2521A, C1121S, C2521U, D0121S, D0921B, D1421B, D2921C, E0721A Exp. 10/31/2022; D2221A Exp. 12/31/2022	Class II	Preferred Pharmaceuticals, Inc.
Econazole Nitrate Cream, 1%, Generic for Spectazole, 30 gm tube	NDC: 68788-7406-03	A1122P, G1421N Exp. 01/01/2023	Class II	Preferred Pharmaceuticals, Inc.



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Lansoprazole (Generic for Prevacid) 15mg Delayed-Release Capsules	NDC: 68788-6390-09	H0221R, D3021T, D2221J, D1321X Exp. 12/31/2023.	Class II	Preferred Pharmaceuticals, Inc.
Accupril® (Quinapril HCl Tablets), 10 mg	NDC: 00071-0530-23	DR9639 Exp. 03/31/2023	MW	Pfizer
Accupril® (Quinapril HCl Tablets), 20 mg	NDC: 00071-0532-23	DX8682 Exp. 03/31/2023 DG1188 Exp. 03/31/2022	MW	Pfizer
Accupril® (Quinapril HCl Tablets), 40 mg	NDC: 00071-0535-23	DX6031 Exp. 03/31/2023 CK6260 Exp. 03/31/2023	MW	Pfizer
Rifampin for Injection, 600 mg/vial, One Vial per carton	NDC: 67457-0445-60	7008990 Exp. 12/2022; 7009025 Exp. 02/2023; 7009085, 7009086 Exp. 04/2023	Class II	Mylan Pharmaceuticals Inc
Diclofenac Sodium (Generic for Pennsaid) Topical Solution 1.5% w/w, 150 ml bottle	NDC: 68788-7918-01	E1220B Exp. 01/31/2023; F0220M, F2320A, F3020M, G0920Q Exp. 03/31/2023; C0821M Exp. 01/31/2024; J1920 Exp. 05/31/2023; E2421 Exp. 04/30/2024	Class II	Preferred Pharmaceuticals, Inc.
ARA-290 (Cibinetide Acetate) 6 mg/mL (4 mL) Injection, 4 mL vials	NDC Not Provided	32618 BUD: 04/4/2022; 34525 BUD: 05/24/2022	Class II	North American Custom Laboratories, LLC dba FarmaKeio Superior Custom Compounding
BPC-157 2 mg/mL (5 mL) Injection, 5 mL vials	NDC Not Provided	32242 BUD: 04/19/2022; 33911 BUD: 06/8/2022	Class II	North American Custom Laboratories, LLC dba FarmaKeio Superior Custom Compounding
Ipamorelin Acetate/Sermorelin Acetate (1 mg/1 mg)/mL (10 mL) Injection, 10 mL vials	NDC Not Provided	32961 BUD: 05/12/2022	Class II	North American Custom Laboratories, LLC dba FarmaKeio Superior Custom Compounding
LL-37 2 mg/mL (5 mL) Injection, 5 mL vials	NDC Not Provided	33444 BUD: 04/26/2022	Class II	North American Custom Laboratories, LLC dba FarmaKeio Superior Custom Compounding



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Melanotan II 1 mg/mL (10 mL) Injection, 10mL vials	NDC Not Provided	32610 BUD: 04/4/2022; 35126 BUD: 06/7/2022	Class II	North American Custom Laboratories, LLC dba FarmaKeio Superior Custom Compounding
PT-141 (Bremelanotide Acetate) 10 mg/mL (2 mL) Injection, 2mL vials	NDC Not Provided	32616 BUD: 04/4/2022; 34527 BUD: 05/24/2022	Class II	North American Custom Laboratories, LLC dba FarmaKeio Superior Custom Compounding
Sermorelin Acetate 1 mg/mL (6 mL) Injection, 6 mL vials	NDC Not Provided	32963 BUD: 04/12/2022; 34824 BUD: 05/30/2022; 35130 BUD: 06/7/2022	Class II	North American Custom Laboratories, LLC dba FarmaKeio Superior Custom Compounding

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