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Inland Empire Health Plan

PHARMACY TIMES

BY IEHP PHARMACEUTICAL SERVICES DEPARTMENT

January 6, 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
Paroex (chlorhexidine gluconate) 0.12% Oral Rinse, Alcohol Free	NDC: 52376-0021-02; 52376-0021-04	C170FY, C170FZ, C170GA, C170GB, C170GC, C177GP, C177GQ, C177GR Exp 6/30/2022; C191KS, C191KT, C191KU, C191KW, C191KX, C191KY, C198LJ, C198LK, C198LL, C198LM, C205BH, C205BJ, C205BK, C205BL, C205BM, C205BN Exp 7/31/2022; C219DK, C219DL, C219DM, C219DN, C219DP, C219DQ, C219DR, C219DS Exp 8/31/2022; C240GM, C240GP, C240GQ, C240GR Exp 9/30/2022; C191KR Exp 7/31/2020	Class I	Sunstar Americas, Inc.
Clomipramine Hydrochloride 50 mg Capsules	NDC: 59746-0711-30	20P0141 Exp. 02/2022	Class II	Jubilant Cadista Pharmaceuticals, Inc.
Levetiracetam 500 mg Tablets	NDC: 71930-0063-52	LEV5019021A Exp. 10/2021	Class II	EYWA PHARMA INC
Immune Boost with natural strawberry flavor, 8,000 IU, Supports a Healthy and Balanced Immune System, 60 mL bottle	NDC Not Provided	200407, 200413, 200420, 200602, 200608	Class II	Fusion Health and Vitality LLC

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Chlorhexidine Gluconate Oral Rinse USP, 0.12%, Alcohol Free, packaged in 15 mL unit does cups	NDC: 70166-0027-15	T09101A Exp. 01/2021; T08292A, T10011A Exp. 02/2021; T10223A, M10193A Exp. 03/2021	Class I	Lohxa LLC
Regenecare HA (Lidocaine HCL 2%) Topical Anesthetic Hydrogel, Net Wt. 3 oz. (85 g)	NDC: 66977-0107-03	41262 Exp. 01/2021	Class I	MPM Medical LLC
Aripiprazole 15 mg Tablets	NDC: 60429-0449-30	GS026353, GS027150, GS027653, GS028044 Exp. 02/2021	Class II	Golden State Medical Supply Inc.
Aripiprazole 15 mg Tablets per unit dose carton	NDC: 00904-6512-04	T02520, T02637 Exp. 02/2021	Class II	The Harvard Drug Group
Anagrelide 1 mg Capsule	NDC: 13668-0462-01	BFD1G001 Exp. 12/2021	MW	Torrent Pharmaceuticals LTD
Sildenafil 100 mg Tablets	NDC: 42291-0748-01	36884 Exp. 03/2022	MW	AvKare
Trazodone 100 mg Tablets	NDC: 42291-0834-10	36783 Exp. 06/2022	MW	AvKare
Dexmedetomidine HCl in 0.9% Sodium Chloride Injection, 200 mcg / 50 mL (4 mcg / mL), 50 mL Single Dose Bottle	NDC: 63323-0671-05	6123925	Class I	Fresenius Kabi USA, LLC
Busulfan Injection 60 mg/10 mL (6 mg/mL), For Intravenous Infusion Only	NDC: 72485-0210-01; 72485-0210-08	7S10008B Exp. 12/31/2020	Class II	Shilpa Medicare Limited
Azacitidine for Injection 100 mg/Vial, For Subcutaneous and Intravenous Use Only, Rx Only, One Single Dose Vial, Cytotoxic Agent	NDC: 72485-0201-01	7S10115A Exp. 07/31/2021; 7S10143A, 7S10182B Exp. 09/30/2021; 7S10185A Exp. 10/31/2021; 7S10255A, 7S10256A, 7S10263A Exp. 11/30/2021; 7T10028A 12/31/2021; 7T10040A Exp. 01/31/2022	Class II	Shilpa Medicare Limited
Azacitidine for Injection 100 mg/Vial, For Subcutaneous and Intravenous Use Only, Rx Only, One Single Dose Vial, Cytotoxic Agent	NDC: 72606-0558-01	7S10227A Exp. 10/31/2021	Class II	Shilpa Medicare Limited



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Imatinib Mesylate 100 mg Tablets	NDC: 72485-0202-90	7S10033B, 7S10033A, 7S10031A Exp. 02/28/2021	Class II	Shilpa Medicare Limited
Imatinib Mesylate 400 mg Tablets	NDC: 72485-0203-30	7S10032A, 7S10034A Exp. 02/28/2021	Class II	Shilpa Medicare Limited
Docetaxel Injection USP 160 mg/8mL (20 mg/mL), For Intravenous Infusion Only, Rx Only, 8 mL Single Use Vial, Cytotoxic Agent	NDC: 72485-0216-08	7S10185A Exp. 10/31/2021	Class II	Shilpa Medicare Limited
Trazodone Hydrochloride 100 mg Tablets	NDC: 42291-0834-10	36783 Exp. 06/2022	Class I	AVKARE Inc.
CJC-1295, 2000 mcg/mL, 5 mL Vial	NDC Not Provided	1029202004 Exp. 11/29/2020; 1102202001, 102202009 Exp. 12/08/2020; 1105202009 Exp. 12/20/2020; 1110202003 Exp. 12/10/2020; 1112202004 Exp. 12/12/2020	Class II	Advanced Nutraceuticals, LLC
FGL, 10 MG/mL, 3 mL Vial	NDC Not Provided	1112202006 Exp. 12/12/2020	Class II	Advanced Nutraceuticals, LLC
PT-141, 10 mg/mL, 2 mL Vial	NDC Not Provided	1112202006 Exp. 12/12/2020	Class II	Advanced Nutraceuticals, LLC
AOD-9604, 1200 mcg/mL, 5 mL Vial	NDC Not Provided	1029202003 Exp. 11/29/2020; 1110202002 Exp. 12/10/2020; 1112202001 Exp. 12/12/2020	Class II	Advanced Nutraceuticals, LLC
BPC-157, 2000 mcg/mL, 5 mL Vial	NDC Not Provided	1102202009 Exp. 12/08/2020; 1105202009 Exp. 12/20/2020; 1110202001 Exp. 12/15/2020; 1112202004 Exp. 12/12/2020	Class II	Advanced Nutraceuticals, LLC
Thymosin Alpha, 2000 mcg/mL, 5 mL Vial	NDC Not Provided	1102202000, 1102202009 Exp. 12/09/2020; 1105202009 Exp. 12/20/2020; 1110202008 Exp. 12/10/2020	Class II	Advanced Nutraceuticals, LLC



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Ipamorelin, 2000 mcg/mL, 5 mL Vial	NDC Not Provided	1029202005 Exp. 11/29/2020; 1102202014 Exp. 12/08/2020; 1112202002 Exp. 12/12/2020	Class II	Advanced Nutriceuticals, LLC
GHRP, 2000 mcg/mL, 5 mL Vial	NDC Not Provided	1112202008 Exp. 12/11/2020	Class II	Advanced Nutriceuticals, LLC
Nandrolone, 200 mcg/mL, 2 mL	NDC Not Provided	1113202002 Exp. 01/13/2021; 1102202005 Exp. 12/08/2020	Class II	Advanced Nutriceuticals, LLC
B12 for Injection, 2 mg/mL, 10 mL Vial	NDC Not Provided	1111202001 Exp. 01/11/2021	Class II	Advanced Nutriceuticals, LLC
DSIP, 1000 mcg/mL, 5 mL Vial	NDC Not Provided	1111202002 Exp. 12/11/2020	Class II	Advanced Nutriceuticals, LLC
Cerebrolysin, 107.5 MG/mL, 10 mL Vial	NDC Not Provided	1110202004 Exp. 12/10/2020	Class II	Advanced Nutriceuticals, LLC
Thymosin Beta - 4, 2000 mcg/mL, 5 mL Vial	NDC Not Provided	1110202005 Exp. 12/10/2020; 1102202015 Exp. 12/08/2020; 1105202009 Exp. 12/20/2020	Class II	Advanced Nutriceuticals, LLC
GHK-CU, 10 MG/mL, 5 mL Vial	NDC Not Provided	1030202010 Exp. 11/30/2020	Class II	Advanced Nutriceuticals, LLC
High Dose E B12, 10 mg/mL, 10 mL Vial	NDC Not Provided	1029202007 Exp. 12/29/2020	Class II	Advanced Nutriceuticals, LLC
LL-37, 2000 mcg/mL, 2 mL Vial	NDC Not Provided	1105202006 Exp. 12/18/2020	Class II	Advanced Nutriceuticals, LLC
Pentosan Polysulfate, 300 mg/mL, 5 mL Vial	NDC Not Provided	1110202006 Exp. 12/10/2020	Class II	Advanced Nutriceuticals, LLC
Kollidon CL-M Crosprovidone Ph.Eur.Type B, USP/NF, JP, micronized, packaged in 30 kg plastic drums	NDC Not Provided	18472036, 18472041	Class II	BASF Corporation
CVS Health Athlete's Foot Cream, Clotrimazole 1% Cream , Antifungal, (28.4 g)	NDC: 59779-0305-03	A873430336 Exp. 12/2020	Class II	Taro Pharmaceuticals U.S.A., Inc.



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Equate Athlete's Foot, Clotrimazole 1%, Antifungal Cream, (14.2g), (60g)	NDC: 49035-0812-27; 49035-0812-01	A873430371 Exp. 12/2020; B870030918 Exp. 01/2021; C868330918 Exp. 02/2021; A873430406, A873530406, A873630406 Exp. 12/2020; B870030635, B870130867 Exp. 01/2021; C868330867 Exp. 02/2021	Class II	Taro Pharmaceuticals U.S.A., Inc.
H-E-B - Athlete's Foot Cream Clotrimazole 1% Cream, (14.2 g)	NDC: 37808-0305-01	A873630558 Exp. 12/2020; D867331276 Exp. 03/2021	Class II	Taro Pharmaceuticals U.S.A., Inc.
Kaiser Permanente Clotrimazole 1% Cream, Antifungal Cream, (28.4 g)	NDC: 00179-8014-30	A873630634 Exp. 12/2020; B870030634 Exp. 01/2021	Class II	Taro Pharmaceuticals U.S.A., Inc.
Kroger Athlete's Foot Cream, Clotrimazole 1% Cream, Antifungal, (15g)	NDC: 30142-0305-01	A873430372 Exp. 12/2020; D867331278 Exp. 03/2021	Class II	Taro Pharmaceuticals U.S.A., Inc.
Kroger Jock Itch Cream, Clotrimazole 1% Cream, Antifungal Cream, (15 g)	NDC: 30142-0510-01	A873630557 Exp. 12/2020	Class II	Taro Pharmaceuticals U.S.A., Inc.
RiteAid Pharmacy Ringworm Cream, Clotrimazole 1% Cream, Antifungal (14.2g)	UPC: 0 11822 53812 1	A873630559 Exp. 12/2020	Class II	Taro Pharmaceuticals U.S.A., Inc.
Best Choice, Clotrimazole 1% Cream, Antifungal, (14.2g)	UPC: 0-70038-20355-1	D867331087 Exp. 03/2021	Class II	Taro Pharmaceuticals U.S.A., Inc.
TopCare Health, Athlete's Foot Cream, Clotrimazole 1% Cream, Antifungal, (14.2 g)	NDC: 36800-0495-69	D867331277 Exp. 03/2021	Class II	Taro Pharmaceuticals U.S.A., Inc.
Athlete's Foot Cream, Clotrimazole 1% Cream, Antifungal Cream, (30 g)	UPC: 3 51672 20022 0	B870130838 Exp. 01/2021	Class II	Taro Pharmaceuticals U.S.A., Inc.



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Lansoprazole Delayed-Release 15 mg Orally Disintegrating Tablets	NDC: 68382-0771-77	M915744 Exp. 10/2021; M904770 Exp. 02/2021	Class II	Zydus Pharmaceuticals (USA) Inc
Lansoprazole Delayed-Release 30 mg Orally Disintegrating Tablets	NDC: 68382-0772-77	M900412 Exp. 12/2020; M904772 Exp. 02/2021; M915745 Exp. 10/2021	Class II	Zydus Pharmaceuticals (USA) Inc
Sildenafil 100 mg Tablets	NDC: 42291-0748-01	36884 Exp. 03/2022	Class II	AVKARE Inc.
Vumerity (diroximel fumarate) 231 mg Delayed-Release Capsule	NDC: 64406-0020-01	101801 Exp 5/31/2021; 102826 Exp. 6/21/2021; 101799 Exp. 5/31/2021; 102362 Exp. 6/21/2021	Class II	Biogen MA Inc.
Sodium Chloride 0.9% Injection, 0.308 mOsmol/mL, 2mL Single Dose Vial	NDC: 00641-0497-17	048315 Exp. 4/2021; 068320 Exp. 6/2021; 128302 Exp. 12/2021; 099349 Exp 9/2022	Class II	Hikma Pharmaceuticals USA Inc.
Azacitidine for Injection 100 mg/Vial For Subcutaneous and Intravenous Use Only Single-Dose Vial	NDC: 69097-0805-40	7S10182A Exp. 9/2021	Class II	CIPLA
Paroex Chlorhexidine Gluconate 0.12% Oral Rinse	NDC: 52376-0021-02	All Lots with expiration 12/31/2020 to 09/30/2022	MW	Sunstar Americas, Inc.
Hydroxyzine Hydrochloride 10 mg/5 mL Oral Solution (Syrup)	NDC: 60432-0150-04; 60432-0150-16	UU1207 Exp. 07/2021; UU1326 Exp. 09/2021; UU1328, UU1327 Exp. 10/2021	Class II	Morton Grove Pharmaceuticals, Inc.
Auryxia (ferric citrate) 210 mg Tablets	NDC: 59922-0631-01	9062 Exp. 02/2021	Class II	Akebia Therapeutics dba Keryx Biopharmaceuticals, Inc
Sensorcaine-MPF (Bupivacaine HCl and Epinephrine Injection), 0.5%, 150 mg per 30 mL (5 mg per mL), 30 mL Single Dose Vial	NDC: 63323-0462-01; 63323-0462-37	6123760 Exp. 02/2022	Class II	Fresenius Kabi USA, LLC
Vasopressin 20 Units added to 0.9% Sodium Chloride 100 mL	Bar Code: 70004093232	1120025012 BUD: 01/13/2021; 1120025015 BUD: 01/15/2021; 1120025272 BUD: 01/28/2021	Class II	SCA Pharmaceuticals, Inc.



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Paroex Chlorhexidine Gluconate 0.12% Oral Rinse, 15 mL unit dose cups	NDC: 68094-0028-61; 68094-0028-62	502037, 502040, 502043 Exp. 01/31/2021; 502494, 502757 Exp. 08/31/2021; 502677 Exp. 09/30/2021; 502693,502728, 502759 Exp. 10/31/2021; 502771, 502784 Exp. 11/30/2021; 502824 Exp. 12/31/2021; 502925 Exp. 02/28/2022	MW	Precision Dose Inc.
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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