



A Public Entity

Inland Empire Health Plan

PHARMACY TIMES

BY IEHP PHARMACEUTICAL SERVICES DEPARTMENT

August 04, 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
Topotecan 4 mg/4 mL (1 mg/mL) Injection	NDC: 00703-4714-71; 00703-4714-01	31328962B Exp. 04/2022	MW	Teva Pharmaceuticals
Compounded Lypophilized Injectable Semorelin / Ipamorelin 3mg	NDC Not Provided	SIP210 Exp. 12/15/2021; SIP215 Exp. 01/14/2022; SIP220 Exp. 01/23/2022	MW	Innoveix Pharmaceuticals, Inc.
Compounded Lypophilized Injectable AOD-9604 3mg	NDC Not Provided	AOD205 Exp. 11/09/2021; AOD210 Exp. 11/18/2021; AOD 215 Exp. 12/15/2021; AOD202 Exp. 11/09/2021	MW	Innoveix Pharmaceuticals, Inc.
Topotecan 4 mg/4mL (1 mg/mL) Injection, Single-Dose vial	NDC: 00703-4714-01; 00703-4714-71	31328962B Exp. 04/2022	Class I	Teva Pharmaceuticals USA
Buprenorphine and Naloxone Sublingual Film 2mg/0.5mg, 30 pouches each containing 1 sublingual film	NDC: 47781-0355-03	36924 Exp. 06/2021	Class II	Alvogen, Inc
Xolair (omalizumab) Injection, 150 mg/1 mL, 1 prefilled syringe.	NDC: 50242-0215-01	Lot No.: 3352758, Exp. Date Aug 2021; Lot No.: 3352759, Exp. Date Aug 2021	Class II	Genentech Inc
Xylocaine-MPF with Epinephrine 1:200,000, (Lidocaine HCl and Epinephrine Injection, USP), 1%, 300 mg/30 mL, (10 mg/mL), 30 mL Single Dose Vial	NDC: 63323-0487- 07; 63323-0487-37	6123435 Exp. 01/2022; 6124730, 6124731 Exp. 07/2022	Class II	Fresenius Kabi USA LLC

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Chantix (varenicline) 0.5 mg Tablets	NDC: 00069-0468-56	19213 Exp. 01/2022; EC6994 Exp. 05/2023:	MW	Pfizer
Chantix (varenicline) 1 mg Tablets	NDC: 00069-0469-56	EA6080, EC9843 Exp. 03/2023	MW	Pfizer
Chantix (varenicline) 0.5/1 mg Tablets	NDC: 00069-0471-03	00020231 Exp. 09/2021; 00020232 Exp. 11/2021; 00020357 Exp. 12/2021; 00020358, 00020716 Exp. 01/2022; ET1600, ET1607, ET1609 Exp. 01/2023;	MW	Pfizer
Solifenacin Succinate 10 mg Tablets	NDC: 69097-0261-02	GG90819 Exp. 06/2021	Class II	CIPLA
Nifedipine 30 mg Extended-Release Tablets	NDC: 00904-7080-61; 00904-7080-06	N00418, N00417 Exp. 09/2022	Class II	The Harvard Drug Group
Compounded Lyophilized Semorelin/Ipamorelin 3 mg For subcutaneous or intramuscular injection, Compounded by: Innoveix Addison	NDC Not Provided	SIP215 Exp. 01/14/2022; SIP220 Exp. 01/23/2022; SIP210 Exp. 12/15/2021	Class II	Innoveix Pharmaceuticals Inc
Compounded Lyophilized AOD-9604, 3 mg For subcutaneous or intramuscular injection, Compounded by: Innoveix Addison	NDC Not Provided	Lot #: AOD205 Exp. 11/09/2021; AOD210 Exp. 11/18/2021; AOD215 Exp. 12/15/2021; AOD220 Exp. 01/20/2022.	Class II	Innoveix 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