
To: All IEHP PCPs, All IEHP Pharmacy Providers
From: IEHP Pharmaceutical Services
Date: June 30, 2023
Subject: **URGENT: Recalls, Market Withdrawals & Safety Alerts, June 2023**

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.

Included in this correspondence are the Class I and Class II products that have been recalled during this timeframe.

The Recalls, Market Withdrawals & Safety Alerts notifications are available on our website under IEHP Safety Resources: <https://www.iehp.org/en/providers/pharmacy-services/safety-resources>

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 Plan Updates (Correspondence):
<https://www.iehp.org/en/providers/plan-updates>
4. IEHP Pharmacy Times Notices:
<https://www.iehp.org/en/providers/pharmacy-services/provider-communications---pharmacy>

If you have any questions or comments regarding this recall, please email IEHP Clinical Pharmacy Program team at ClinicalPharmacyPrograms@iehp.org .

Sincerely,
IEHP Pharmaceutical Services

Product Name	Product Code	Lot # and Exp. Date	Classification	Recalling Firm
Alcohol Antiseptic 80%, Topical Solution, Hand Sanitizer	Not provided	All batches with Date of Manufacture: 26MAR2020; 01APR2020; 02APR2020; 27APR2020; 04MAY2020; 13MAY2020; 04AUG2020.	Class I	Jarman's Midwest Cleaning Systems, Inc.
G-Supress DX (Dextromethorphan HBr Guaifenesin Phenylephrine HCl) Pediatric Drops Cough Suppressant Expectorant Nasal Decongestant Cherry Flavor Sugar & Alcohol Free	NDC 52083-0655-01	Lot: D20911, Exp. Oct/25	Class I	Novis PR, LLC dba Kramer Novis
SOFT HANDS Alcohol Antiseptic 80%, Topical Solution, HAND SANITIZER	Not provided	All product with Date of Manufacture: 26MAR2020; 01APR2020; 02APR2020; 04APR2020; 27APR2020; 04MAY2020; 07MAY2020; 13MAY2020; 04AUG2020.	Class I	Jarman's Midwest Cleaning Systems, Inc.
Acetaminophen & Codeine Phosphate Oral Solution	ALL NDCs	All Lots	Class II	Akorn, Inc.
Acetic Acid Otic Solution	ALL NDCs	All Lots	Class II	Akorn, Inc.
Acyclovir Oral Suspension 200mg/5mL	ALL NDCs	All Lots	Class II	Akorn, Inc.
AK-POLY-BAC (bacitracin Zinc and Polymyxin B Sulfate) Ophthalmic Ointment	ALL NDCs	All Lots	Class II	Akorn, Inc.
Albuterol Sulfate Syrup 2mg	ALL NDCs	All Lots	Class II	Akorn, Inc.
Amantadine Hydrochloride Oral Solution 50mg/5mL	ALL NDCs	All Lots	Class II	Akorn, Inc.
Apraclonidine Ophthalmic Solution 0.5%	ALL NDCs	All Lots	Class II	Akorn, Inc.
Artificial Tears Ointment 3.5 gram tubes	ALL NDCs	All Lots	Class II	Akorn, Inc.
Artificial Tears Solution Polyvinyl Alcohol 1.4%	ALL NDCs	All Lots	Class II	Akorn, Inc.
ASCORBIC ACID PRESERVED INJECTION SOLUTION, 500 mg/mL, 30 mL Sterile Multiple-Dose Vial	NDC 72627-2405-01	Lot: 606775 BUD: 09/25/2023	Class II	Empower Clinic Services LLC dba Empower Pharmacy
Atropine Sulfate Ophthalmic Solution 1%	ALL NDCs	All Lots	Class II	Akorn, Inc.

Azelastine Hydrochloride Nasal Spray 0.15%	ALL NDCs	All Lots	Class II	Akorn, Inc.
Calcipotriene Topical Solution 0.005% (Scalp Solution)	ALL NDCs	All Lots	Class II	Akorn, Inc.
Calcitriol Injection 1 mcg/mL 1 mL ampules	ALL NDCs	All Lots	Class II	Akorn, Inc.
Calcitriol Injection 2 mcg/mL 1 mL ampules	ALL NDCs	All Lots	Class II	Akorn, Inc.
Cetrorelix Acetate for Injection 0.25 mg	ALL NDCs	All Lots	Class II	Akorn, Inc.
Ciclopirox Topical Solution 8% (Nail Lacquer)	ALL NDCs	All Lots	Class II	Akorn, Inc.
Cimetidine HCl Oral Solution 300mg/5mL	ALL NDCs	All Lots	Class II	Akorn, Inc.
Clobetasol Propionate Cream 0.05%	ALL NDCs	All Lots	Class II	Akorn, Inc.
Clobetasol Propionate Ointment 0.05% 15 g tubes	ALL NDCs	All Lots	Class II	Akorn, Inc.
Clobetasol Propionate Shampoo 0.05% 4oz (118 mL) bottles	ALL NDCs	All Lots	Class II	Akorn, Inc.
Colic Calm Colic Gas & Reflux Homeopathic Medicine 2 Fl. Oz (59 ml) bottle	Not provided	Lot: 8290V, Exp: 10-2023	Class II	Denison Pharmaceuticals, LLC
Cromolyn Sodium Ophthalmic Solution 4% 10 mL bottles	ALL NDCs	All Lots	Class II	Akorn, Inc.
DetomiSed (detomidine hydrochloride) packaged in vials	ALL NDCs	All Lots	Class II	Akorn, Inc.
Dicyclomine Hydrochloride Injection 20 mg/2 mL (10 mg/mL) 2 mL ampules	ALL NDCs	All Lots	Class II	Akorn, Inc.
Diuril (chlorothiazide sodium) Injection 500mg/vial Single-Dose Vial	ALL NDCs	All Lots	Class II	Akorn, Inc.
DOCU LIQUID (docusate sodium 50 mg/5 mL)	ALL NDCs	All Lots	Class II	Akorn, Inc.
Ephedrine Sulfate Injection 50 mg/mL 1mL Single Dose Ampules	ALL NDCs	All Lots	Class II	Akorn, Inc.
Extended Phenytoin Sodium Capsules, USP, 100 mg	NDC 65162-0212-10	Lot # HL00721A, Exp. 12/2023	Class II	Amneal Pharmaceuticals of New York, LLC
Fentanyl Citrate Injection 100 mcg/2mL (50 mcg/mL)	ALL NDCs	All Lots	Class II	Akorn, Inc.
Ferrous Sulfate Iron Supplement Drops	ALL NDCs	All Lots	Class II	Akorn, Inc.

Fluticasone Propionate Nasal Spray 50mcg	ALL NDCs	All Lots	Class II	Akorn, Inc.
Gonak Hypromellose Ophthalmic Solution 25mg/mL	ALL NDCs	All Lots	Class II	Akorn, Inc.
Granisetron HCl Injection 1 mg/mL packaged	ALL NDCs	All Lots	Class II	Akorn, Inc.
Guaiatussin AC Sugar-Free	ALL NDCs	All Lots	Class II	Akorn, Inc.
Guaifenesin Oral Solution, 300 mg/ 15 mL, Sugar Free/Alcohol Free	ALL NDCs	All Lots	Class II	Akorn, Inc.
HydrALAZINE HCl Injection 20 mg/mL 1 mL Single Dose vials	ALL NDCs	All Lots	Class II	Akorn, Inc.
Hydrocortisone and Acetic Acid Otic Solution	ALL NDCs	All Lots	Class II	Akorn, Inc.
HYDROMORPHONE HCl 10 mg in 0.9% Sodium Chloride 50 mL syringe (0.2 mg/mL)	NDC 60652-0600-02	Lot: 20230222-45AB24, BUD: 8/21/2023; Lot: 20230110-058361, BUD: 7/9/2023; Lot: 20221208-0F5483, BUD: 6/6/2023; Lot: 20221109-45BA60, BUD: 5/8/2023; Lot: 20220929-523FD5, BUD: 3/28/2023; Lot: 20220914-5D5AE0, BUD: 3/13/2023; Lot: 220502-024, BUD: 10/29/2022; Lot: 220510-035, BUD: 11/6/2022; Lot: 220526-015, BUD: 11/22/2022; Lot: 220811-010, BUD: 2/7/2023	Class II	SSM Health Care St. Louis DBA SSM St. Clare Health Center
Hydromorphone Hydrochloride Injection 50mg/5mL (10 mg/mL)	ALL NDCs	All Lots	Class II	Akorn, Inc.
IC-Green (indocyanine green for injection) 25 mg/10 mL Kit	ALL NDCs	All Lots	Class II	Akorn, Inc.
Isopropyl Alcohol Antiseptic 75%, Topical Solution, Hand Sanitizer Non-sterile Solution	NDC 74663-0002-01	All batches with Date of Manufacture: 24MAR2020; 12DEC2020.	Class II	Jarman's Midwest Cleaning Systems, Inc.
Ketorolac Tromethamine Ophthalmic Solution 0.5% Sterile	ALL NDCs	All Lots	Class II	Akorn, Inc.
Lactulose Solution (For oral or rectal administration)	ALL NDCs	All Lots	Class II	Akorn, Inc.
Lactulose Solution (Oral) 10g/15 mL	ALL NDCs	All Lots	Class II	Akorn, Inc.
Levetiracetam Oral Solution 100 mg/mL (100 mg/mL)	ALL NDCs	All Lots	Class II	Akorn, Inc.
Levocarnitine Oral Solution	ALL NDCs	All Lots	Class II	Akorn, Inc.

Levofloxacin Injection 500mg/20 mL (25 mg/mL) For Intravenous Infusion	ALL NDCs	All Lots	Class II	Akorn, Inc.
Levofloxacin Ophthalmic Solution 0.5%	ALL NDCs	All Lots	Class II	Akorn, Inc.
Levofloxacin Oral Solution 25 mg/mL	ALL NDCs	All Lots	Class II	Akorn, Inc.
Levsin injection (hyoscyamine sulfate injection, USP), 0.5 mg per ml in water for Injection, 1 ml ampule	NDC 00037-9001-05	Lot #: 101241A, Exp 10/23	Class II	Viartis Inc
Lidocaine 2.5% & Prilocaine 2.5% Cream	ALL NDCs	All Lots	Class II	Akorn, Inc.
Lidocaine HCl Jelly 2%	ALL NDCs	All Lots	Class II	Akorn, Inc.
Lidocaine Hydrochloride Oral Topical Solution (Viscous) 2%	ALL NDCs	All Lots	Class II	Akorn, Inc.
Lidocaine Ointment 5% 1 1/4 oz tubes	ALL NDCs	All Lots	Class II	Akorn, Inc.
Lorazepam Injection USP 2 mg/mL vial	ALL NDCs	All Lots	Class II	Akorn, Inc.
Lorazepam Oral Concentrate 2mg per mL	ALL NDCs	All Lots	Class II	Akorn, Inc.
Megestrol Acetate Oral Suspension 40 mg/mL	ALL NDCs	All Lots	Class II	Akorn, Inc.
Midazolam Injection 2mg/2mL (1 mg/mL) For Intramuscular or Intravenous Use Only	ALL NDCs	All Lots	Class II	Akorn, Inc.
Midazolam Injection 50 mg/10mL (5mg/mL) For Intramuscular or Intravenous Use Only 10 mL vials	ALL NDCs	All Lots	Class II	Akorn, Inc.
Moxifloxacin HCl Ophthalmic Solution 0.5%	ALL NDCs	All Lots	Class II	Akorn, Inc.
Naloxone Injection USP 0.4 mg/mL For Intravenous Intramuscular or Subcutaneous Use	ALL NDCs	All Lots	Class II	Akorn, Inc.
Neomycin & Polymyxin B Sulfates and Bacitracin Zinc Ophthalmic Ointment	ALL NDCs	All Lots	Class II	Akorn, Inc.
Olopatadine HCl Nasal Spray 665 mcg	ALL NDCs	All Lots	Class II	Akorn, Inc.
Olopatadine HCl Ophthalmic Solution 0.1%	ALL NDCs	All Lots	Class II	Akorn, Inc.

Olopatadine HCl Ophthalmic Solution 0.2% 5mL bottles	ALL NDCs	All Lots	Class II	Akorn, Inc.
Oxcarbazepine Oral Suspension 300 mg/5 mL	ALL NDCs	All Lots	Class II	Akorn, Inc.
Pilocarpine Hydrochloride Ophthalmic Solution 1%	ALL NDCs	All Lots	Class II	Akorn, Inc.
Pilocarpine Hydrochloride Ophthalmic Solution 2%	ALL NDCs	All Lots	Class II	Akorn, Inc.
Pilocarpine Hydrochloride Ophthalmic Solution 4%	ALL NDCs	All Lots	Class II	Akorn, Inc.
Pin-Away PYRENTAL PAMOATE (Pyrantel base 50 mg / mL) Pinworm Treatment	NDC 70309-0080-02	Lot: 8640, Exp: 11/2023	Class II	Denison Pharmaceuticals, LLC
Prednisolone Oral Solution 15 mg/5 mL	ALL NDCs	All Lots	Class II	Akorn, Inc.
Promethazine HCl & Codeine Phosphate Oral Solution 6.25mg/10mg per 5 mL	ALL NDCs	All Lots	Class II	Akorn, Inc.
Promethazine HCl Oral Solution 6.25 mg/5mL	ALL NDCs	All Lots	Class II	Akorn, Inc.
Proparacaine HCl Ophthalmic Solution 0.5%	ALL NDCs	All Lots	Class II	Akorn, Inc.
Rifampin Capsules 150 mg	ALL NDCs	All Lots	Class II	Akorn, Inc.
Rifampin Capsules 300 mg	ALL NDCs	All Lots	Class II	Akorn, Inc.
Ropivacaine Hydrochloride Injection 0.2% 200mg/100 mL (2 mg/mL) 100 mL Vial	ALL NDCs	All Lots	Class II	Akorn, Inc.
Ropivacaine Hydrochloride Injection 0.5%, 150mg/30 mL (5 mg/mL) 30 mL Single-dose Vial	ALL NDCs	All Lots	Class II	Akorn, Inc.
Safe tussin DM DAY TIME Cough Relief (Dextromethorphan HBr 10mg Guaifenesin 100mg)	Not provided	Lot: 8314, Exp: 04/2023, 8753, 8753A, Exp: 10/2023; 8659, Exp: 08-2023	Class II	Denison Pharmaceuticals, LLC
Safe tussin PM NIGHT TIME Cough Relief (Dextromethorphan HBr 7.5mg Doxylamine Succinate 3.125mg)	Not provided	Lot: 8639, Exp: 8/2023	Class II	Denison Pharmaceuticals, LLC
Sodium Chloride 0.9% Injection	NDC 49230-0300-10	Lot: 23AU05030, Exp 01/13/2024; 23AU05035, Exp 01/15/2024	Class II	Fresenius Medical Care Holdings, Inc.
Sodium Chloride Ophthalmic Ointment 5%	ALL NDCs	All Lots	Class II	Akorn, Inc.
Sodium Chloride Ophthalmic Solution 5%, 50mg/mL	ALL NDCs	All Lots	Class II	Akorn, Inc.

Sodium DIURIL (chlorothiazide sodium) 0.5g/vial Single-dose vial	ALL NDCs	All Lots	Class II	Akorn, Inc.
Sufenta (Sufentanil Citrate Injection) 50 mcg/mL For Intravenous and Epidural Use	ALL NDCs	All Lots	Class II	Akorn, Inc.
Sulfamethoxazole & Trimethoprim Oral Suspension 200mg/40mg per 5mL Cherry Flavor	ALL NDCs	All Lots	Class II	Akorn, Inc.
Timolol Maleate Ophthalmic Solution 0.5%	ALL NDCs	All Lots	Class II	Akorn, Inc.
Tobramycin Inhalation Solution 300 mg/5 mL 4 single-dose ampules	ALL NDCs	All Lots	Class II	Akorn, Inc.
Tobramycin Ophthalmic Solution 0.3% 5mL bottles	ALL NDCs	All Lots	Class II	Akorn, Inc.
Travoprost Ophthalmic Solution, USP (Ionic Buffered Solution), 0.004%	NDC 51407-0731-25, NDC 51407-0731-05	Lot #: a) GS049666, GS049807, Exp: 03/31/2024; b) GS049667, GS051447, Exp: 09/30/2024.	Class II	Golden State Medical Supply Inc.
Trihexyphenidyl Hydrochloride Oral Solution 2mg/5mL	ALL NDCs	All Lots	Class II	Akorn, Inc.
Tropicamide Ophthalmic Solution 0.1%	ALL NDCs	All Lots	Class II	Akorn, Inc.
Tropicamide Ophthalmic Solution USP 0.5% 15 mL bottles	ALL NDCs	All Lots	Class II	Akorn, Inc.
Valproic Acid Oral Solution 250mg/5mL	ALL NDCs	All Lots	Class II	Akorn, Inc.
Vitamin D Supplement Drops 400 IU Cherry Flavored	ALL NDCs	All Lots	Class II	Akorn, Inc.
XOPENEX (levalbuterol HCl) Inhalation Solution Concentrate 1.25mg/3mL	ALL NDCs	All Lots	Class II	Akorn, Inc.

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