

Enforcement Report - Week of June 7, 2023

Class I Drugs Event

Event ID:

92324

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

04/20/2023

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

06/06/2023

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Novis PR, LLC dba Kramer Novis

320 Ave Barbosa

San Juan PR United States

Distribution Pattern:

Puerto Rico

Associated Products

Product Description:

G-Supress DX (Dextromethorphan HBr, Guaifenesin, Phenylephrine HCl) Pediatric Drops Cough Suppressant Expectorant Nasal Decongestant, Cherry Flavor Sugar & Alcohol Free, packaged in a bottle Net Content: 30 mL (1 oz.) further packaged in a carton, Manufactured in the USA for Kramer Novis, San Juan, PR 00917, NDC 52083-655-01

Product Quantity:

9077 bottles

Reason for Recall:

Product mix-up: incorrect product was found inside the G-Supress DX product carton.

Recall Number:

D-0868-2023

Code Information:

Lot: D20911, Exp. Oct/25

Class II Drugs Event

Event ID:

91788

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

04/26/2023

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

06/01/2023

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Akorn, Inc.

5605 Centerpoint Ct Ste A

Gurnee IL United States

Distribution Pattern:

Nationwide in the USA and Puerto Rico

Associated Products

Product Description:

Atropine Sulfate Ophthalmic Solution, USP 1%, For Topical Application To The Eye, packaged in a) 2 mL bottles b) 5 mL bottles, and C) 15 mL bottles, Sterile, Rx only, Distributed by: Akorn Operating Company LLC, Gurnee, IL 60031. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0779-2023

Code Information:

All Lots

Product Description:

Acetaminophen & Codeine Phosphate Oral Solution 120mg/12mg/5mL, packaged in a) 473mL bottles and b) 40 UD cups, Rx only, Distributed by: Akorn Operating Company LLC, Gurnee, IL 60031. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0780-2023

Code Information:

All Lots

Product Description:

Acetic Acid Otic Solution, 15 mL per bottle, Rx only, Distributed by: Akorn Operating Company LLC, Gurnee, IL 60031. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0781-2023

Code Information:

All Lots

Product Description:

Acyclovir Oral Suspension, 200mg/5mL, Rx only, Distributed by: Akorn Operating Company LLC, Gurnee, IL 60031. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0782-2023

Code Information:

All Lots

Product Description:

Albuterol Sulfate Syrup, 2mg (base), 16 fl oz (473 mL) per bottle, Rx only, Distributed by: Akorn Operating Company LLC, Gurnee, IL 60031. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0783-2023

Code Information:

All Lots

Product Description:

Apraclonidine Ophthalmic Solution 0.5%, packaged in a) 5mL and b) 10 mL bottles, Rx only, Sterile, For Topical Ophthalmic Use Only, Distributed by: Akorn Operating Company LLC, Gurnee, IL 60031. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0784-2023

Code Information:

All Lots

Product Description:

Artificial Tears Solution, Polyvinyl Alcohol 1.4%, For Ophthalmic Use Only, Distributed by: Akorn Operating Company LLC, Gurnee, IL 60031. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0785-2023

Code Information:

All Lots

Product Description:

Artificial Tears Ointment, Sterile, For Ophthalmic Use Only, 3.5 gram tubes, Distributed by: Akorn Operating Company LLC, Gurnee, IL 60031. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0786-2023

Code Information:

All Lots

Product Description:

Azelastine Hydrochloride Nasal Spray, 0.15%, 105.5 mcg per spray, Rx Only, For Intranasal Use Only, Manufactured by: Hi-Tech Pharmacal Co., INC., Amityville, NY 11701. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0787-2023

Code Information:

All Lots

Product Description:

AK-POLY-BAC (bacitracin Zinc and Polymyxin B Sulfate) Ophthalmic Ointment, 3.5g, Sterile, Rx Only, For Ophthalmic Use Only, Manufactured by: Akorn, Inc., Lake Forest, IL 60045. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0788-2023

Code Information:

All Lots

Product Description:

Calcipotriene Topical Solution, 0.005% (Scalp Solution), 60 mL bottles, Rx Only, Distributed by: Akorn Operating Company, LLC., Gurnee, IL 60031. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0789-2023

Code Information:

All Lots

Product Description:

Calcitriol Injection 1 mcg/mL, 1 mL ampules Rx Only, Distributed by: Akorn Operating Company, LLC., Gurnee, IL 60031. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0790-2023

Code Information:

All Lots

Product Description:

Cetrorelix Acetate for Injection, 0.25 mg, , One carton contains one packaged tray which contains: 1 vial with lyophilized powder for reconstitution, 1 pre-filled syringe with diluent, 1 20-gauge needle, 1 27-gauge needle, Sterile - For subcutaneous use only, Rx Only, Manufactured by: GP Pharm S.A. Barcelona, Spain (ESP) -08777, Distributed by: Akorn Operating Company, LLC., Gurnee, IL 60031. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0791-2023

Code Information:

All Lots

Product Description:

Ciclopirox Topical Solution 8% (Nail Lacquer), 6.6 mL bottles, Rx Only, Distributed by: Akorn Operating Company, LLC., Gurnee, IL 60031. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0792-2023

Code Information:

All Lots

Product Description:

Cimetidine HCl Oral Solution 300mg/5mL, 237 mL bottles, Rx Only, Distributed by: Akorn Operating Company, LLC., Gurnee, IL 60031. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0793-2023

Code Information:

All Lots

Product Description:

Clobetasol Propionate Cream, USP, 0.05%, packaged in a) 15g tubes, b) 30g tubes, and c) 60g tubes, Rx Only, Distributed by: Akorn Operating Company, LLC., Gurnee, IL 60031. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0794-2023

Code Information:

All Lots

Product Description:

Clobetasol Propionate Ointment, USP, 0.05%, 15 g tubes, Rx Only, Distributed by: Akorn Operating Company, LLC., Gurnee, IL 60031. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0795-2023

Code Information:

All Lots

Product Description:

Clobetasol Propionate Shampoo, 0.05%, 4oz (118 mL) bottles, Rx Only, Distributed by: Akorn Operating Company, LLC., Gurnee, IL 60031. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0796-2023

Code Information:

All Lots

Product Description:

Cromolyn Sodium Ophthalmic Solution, USP, 4%, 10 mL bottles, Rx Only, Manufactured by: Akorn Inc., Lake Forest, IL 60045. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0797-2023

Code Information:

All Lots

Product Description:

DetomiSed (detomidine hydrochloride) packaged in a) 5mL and b)20mL vials, Rx Only, Distributed by: Akorn Operating Company, LLC., Gurnee, IL 60031. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0798-2023

Code Information:

All Lots

Product Description:

Dicyclomine Hydrochloride Injection USP, 20 mg/2 mL (10 mg/mL) ampules, 2 mL ampules, Rx Only, Distributed by: Akorn Operating Company, LLC., Gurnee, IL 60031. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0799-2023

Code Information:

All Lots

Product Description:

Diuril (chlorothiazide sodium) Injection, 500mg/vial, Single-Dose Vial, Rx Only, Distributed by: Akorn Operating Company, LLC., Gurnee, IL 60031. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0800-2023

Code Information:

All Lots

Product Description:

DOCU LIQUID (docusate sodium, 50 mg/5 mL), packaged in 473mL bottles and b)10mL Unit Dose cups, Distributed by: Akorn Operating Company, LLC., Gurnee, IL 60031. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0801-2023

Code Information:

All Lots

Product Description:

Ephedrine Sulfate Injection, USP, 50 mg/mL, 1mL Single Dose Ampules, For Intravenous Use, Rx Only, Distributed by: Akorn Operating Company LLC, Gurnee, IL 60031. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0802-2023

Code Information:

All Lots

Product Description:

Ferrous Sulfate Iron Supplement Drops, packaged in 50 mL bottles, Distributed by: Akorn Operating Company LLC, Gurnee, IL 60031. ALL NDCs

Product Quantity:

Reason for Recall:

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0803-2023

Code Information:

All Lots

Product Description:

Fluticasone Propionate Nasal Spray, 50mcg, 16 g bottles, Manufactured by: HI-TECH PHARMACAL CO., INC., Amiy. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0804-2023

Code Information:

All Lots

Product Description:

Gonak Hypromellose Ophthalmic Solution 25mg/mL, 15 mL bottles, Rx Only, Manufactured by: Akorn, Inc., Lake Forest, IL 60045. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0805-2023

Code Information:

All Lots

Product Description:

Granisetrone HCl Injection, USP, 1 mg/mL, packaged in a) 1mL and b) 4 mL vials, Rx Only, For Intravenous Use Only, Manufactured by: Akorn, Inc., Lake Forest, IL 60045. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0806-2023

Code Information:

All Lots

Product Description:

Guaifenesin AC Sugar-Free, Each teaspoonful (5 mL) contains: Guaifenesin (100 mg), Codeine Phosphate (10 mg), Alcohol (3.5% v/v), a) packaged in a) 118 mL bottles, b) 473 mL bottles and c) 100 unit dose cups, Rx Only, Distributed by: Akorn, Inc., Lake Forest, IL 60045. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0807-2023

Code Information:

All Lots

Product Description:

Guaifenesin Oral Solution, 300 mg/ 15 mL, Sugar Free/Alcohol Free, Rx Only, For Institutional Use Only, Hi-Tech Pharmacal Co., Inc., Amityville, NY 11701. ALL NDCs

Product Quantity:

Reason for Recall:

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0808-2023

Code Information:

All Lots

Product Description:

HydrALAZINE HCl Injection, USP, 20 mg/mL, 1 mL Single Dose vials, For Intramuscular or Intravenous Use, Rx Only, Manufactured by: Akorn, Inc., Lake Forest, IL 60045. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0809-2023

Code Information:

All Lots

Product Description:

Hydrocortisone and Acetic Acid Otic Solution, USP, 10 mL bottles, Rx Only, Distributed by: Akorn, Inc., Gurnee, IL 60031. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0810-2023

Code Information:

All Lots

Product Description:

Hydromorphone Hydrochloride Injection, USP, 50mg/5mL (10 mg/mL) packaged in a) 1 mL ampules, b) 5 mL ampules, c) 50 mL vials, Rx Only, Sterile, Manufactured by: Akorn, Inc., Lake Forest, IL 60045. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0811-2023

Code Information:

All Lots

Product Description:

IC-Green (indocyanine green for injection, USP) 25 mg/10 mL Kit, Rx Only, Sterile, Manufactured by: Akorn, Inc., Lake Forest, IL 60045. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0812-2023

Code Information:

All Lots

Product Description:

Ketorolac Tromethamine Ophthalmic Solution, 0.5%, Sterile, packaged in a) 3mL bottles, b bottles) 5 mL, and c)10 mL bottles, Rx Only, Manufactured by: Akorn, Inc., Lake Forest, IL 60045. ALL NDCs

Product Quantity:

Reason for Recall:

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0813-2023

Code Information:

All Lots

Product Description:

Lactulose Solution, USP (Oral), 10g/15 mL, packaged in a) 15mL bottles, b) 30 mL bottles, c) 473 mL bottles, and d) 946 mL bottles, Rx Only, Distributed by: Akorn, Inc., Gurnee, IL 60031. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0814-2023

Code Information:

All Lots

Product Description:

Lactulose Solution, USP (For oral or rectal administration), 30 mL Unit Dose Cups, Rx Only, Distributed by: Akorn, Inc., Gurnee, IL 60031. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0815-2023

Code Information:

All Lots

Product Description:

Levetiracetam Oral Solution 100 mg/mL (100 mg/mL), 473 mL, Rx Only, Distributed by: Akorn, Inc., Gurnee, IL 60031. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0816-2023

Code Information:

All Lots

Product Description:

Levocarnitine Oral Solution, USP, 118 mL bottles, Rx Only, Distributed by: Akorn, Inc., Gurnee, IL 60031. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0817-2023

Code Information:

All Lots

Product Description:

Levofloxacin Injection 500mg/20 mL (25 mg/mL), For Intravenous Infusion, packaged in a) 20mL vials and b) 30 mL vials, Rx Only, Manufactured by: Akorn, Inc., Lake Forest, IL 60045. ALL NDCs

Product Quantity:

Reason for Recall:

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0818-2023

Code Information:

All Lots

Product Description:

Levofloxacin Oral Solution, 25 mg/mL, packaged in a) 100 mL bottles, b) 200 mL bottles, and c) 480 mL bottles, Rx Only, Distributed by: Akorn, Inc., Gurnee, IL 60031. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0819-2023

Code Information:

All Lots

Product Description:

Levofloxacin Ophthalmic Solution, 0.5%, 5 mL bottles, Rx Only, Manufactured by: Akorn, Inc., Lake Forest, IL 60045. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0820-2023

Code Information:

All Lots

Product Description:

Lidocaine 2.5% & Prilocaine 2.5% Cream, 30 gram tubes, Rx Only, Manufactured by: HI-TECH PHARMACAL CO., INC., Amityville, NY 11701. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0821-2023

Code Information:

All Lots

Product Description:

Lidocaine Ointment USP, 5%, 1 1/4 oz tubes, Rx Only, Manufactured for: HI-TECH PHARMACAL CO., INC., Amityville, NY 11701. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0822-2023

Code Information:

All Lots

Product Description:

Lidocaine HCl Jelly USP, 2%, 5mL tubes, Rx Only, Manufactured by: Akorn, Inc., Lake Forest, IL 60045. ALL NDCs

Product Quantity:

Reason for Recall:

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0823-2023

Code Information:

All Lots

Product Description:

Lidocaine Hydrochloride Oral Topical Solution, USP (Viscous) 2%, 100mL tubes, Rx Only, Distributed by: Akorn Operating Company LLC, Gurnee, IL 60031. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0824-2023

Code Information:

All Lots

Product Description:

Lorazepam Injection, USP 2 mg/mL vial, 1 mL vials, Rx Only, Sterile, Manufactured by: Akorn, Inc., Lake Forest, IL 60045. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0825-2023

Code Information:

All Lots

Product Description:

Lorazepam Oral Concentrate, USP, 2mg per mL, 30 mL bottles, Rx Only, Sterile, Distributed by: Akorn Operating Company, LLC., Gurnee, IL 60031. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0826-2023

Code Information:

All Lots

Product Description:

Megestrol Acetate Oral Suspension, USP 40 mg/mL, 240 mL bottles, Rx Only, Distributed by: Akorn Operating Company, LLC., Gurnee, IL 60031. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0827-2023

Code Information:

All Lots

Product Description:

Midazolam Injection, USP 2mg/2mL (1 mg/mL) For Intramuscular or Intravenous Use Only, 2mL vials, Rx Only, Manufactured by: Akorn, Inc., Lake Forest, IL 60045. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0828-2023

Code Information:

All Lots

Product Description:

Moxifloxacin HCl Ophthalmic Solution, USP, 0.5%, 3 mL bottles, Rx Only, Manufactured by: Akorn, Inc., Lake Forest, IL 60045. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0829-2023

Code Information:

All Lots

Product Description:

Naloxone Injection, USP 0.4 mg/mL, For Intravenous, Intramuscular or Subcutaneous Use, 1 mL vials, Rx only, Manufactured by: Akorn, Inc., Lake Forest, IL 60045. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0830-2023

Code Information:

All Lots

Product Description:

Neomycin & Polymyxin B Sulfates, and Bacitracin Zinc Ophthalmic Ointment, 3.5 g tubes, Rx Only, Manufactured by: Akorn, Inc., Lake Forest, IL 60045. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0831-2023

Code Information:

All Lots

Product Description:

Olopatadine HCl Nasal Spray, 665 mcg, 30.5 g bottles, Rx Only, Manufactured by: Akorn, Operating Company LLC, Gurnee, IL 60031. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0832-2023

Code Information:

All Lots

Product Description:

Olopatadine HCl Ophthalmic Solution, USP, 0.1%, 5 mL bottles, Rx Only, Manufactured by: Akorn, Inc., Lake Forest, IL 60045. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0833-2023

Code Information:

All Lots

Product Description:

Oxcarbazepine Oral Suspension, USP, 300 mg/5 mL, 250 mL bottles, Rx Only, Distributed by: Akorn Operating Company LLC, Gurnee, IL 60031. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0834-2023

Code Information:

All Lots

Product Description:

Pilocarpine Hydrochloride Ophthalmic Solution, USP 1%, 15 mL bottles, Rx Only, Sterile, Distributed by: Akorn Operating Company LLC, Gurnee, IL 60031. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0835-2023

Code Information:

All Lots

Product Description:

Prednisolone Oral Solution, USP, 15 mg/5 mL, packaged in a) 240 mL and b) 480 mL bottles, Rx Only, Distributed by: Akorn Operating Company LLC, Gurnee, IL 60031. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0836-2023

Code Information:

All Lots

Product Description:

Promethazine HCl & Codeine Phosphate Oral Solution, USP, 6.25mg/10mg per 5 mL, Rx Only, Distributed by: Akorn Operating Company LLC, Gurnee, IL 60031. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0837-2023

Code Information:

All Lots

Product Description:

Promethazine HCl Oral Solution, USP, 6.25 mg/5mL, 473 mL bottles, Rx Only, Distributed by: Akorn Operating Company LLC, Gurnee, IL 60031. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0838-2023

Code Information:

All Lots

Product Description:

Proparacaine HCl Ophthalmic Solution, USP 0.5%, 15 mL bottles, Rx Only, Distributed by: Akorn Operating Company LLC, Gurnee, IL 60031. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0839-2023

Code Information:

All Lots

Product Description:

Rifampin Capsules USP, 150 mg, 30-count bottles, Rx Only, Sterile, Distributed by: Akorn Operating Company LLC, Gurnee, IL 60031. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0840-2023

Code Information:

All Lots

Product Description:

Rifampin Capsules USP, 300 mg, packaged in a) 30 count bottles and b) 60 count bottles, Rx Only, Distributed by: Akorn Operating Company LLC, Gurnee, IL 60031. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0841-2023

Code Information:

All Lots

Product Description:

Ropivacaine Hydrochloride Injection USP, 0.5%, 150mg/30 mL (5 mg/mL), 30 mL Single-dose Vial, Rx Only, Manufactured by: Akorn Inc., Lake Forest, IL 60045. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0842-2023

Code Information:

All Lots

Product Description:

Fentanyl Citrate Injection, USP 100 mcg/2mL (50 mcg/mL), Rx Only, Manufactured by: Akorn Inc., Lake Forest, IL 60045. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0843-2023

Code Information:

All Lots

Product Description:

Sodium Chloride Ophthalmic Ointment, USP, 5%, 3.5g tubes, Manufactured by: Akorn Inc., Lake Forest, IL 60045. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0844-2023

Code Information:

All Lots

Product Description:

Sodium Chloride Ophthalmic Solution, USP, 5%, 50mg/mL, 15 mL bottles, Distributed by: Akorn Operating Company LLC, Gurnee, IL 60031. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0845-2023

Code Information:

All Lots

Product Description:

Sodium DIURIL (chlorothiazide sodium), 0.5g/vial, Single-dose vial Rx only, Distributed by: Akorn Operating Company LLC, Gurnee, IL 60031. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0846-2023

Code Information:

All Lots

Product Description:

Sufenta (Sufentanil Citrate Injection, USP) 50 mcg/mL, packaged in a) 1 mL ampules, b) 2mL ampules, c) 5mL ampules, For Intravenous and Epidural Use, Rx only, Manufactured by: Akorn Inc., Lake Forest, IL 60045. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0847-2023

Code Information:

All Lots

Product Description:

Sulfamethoxazole & Trimethoprim Oral Suspension USP, 200mg/40mg per 5mL, 473 mL bottles, Cherry Flavor, Rx only, Manufactured by: Akorn Operating Company LLC, Gurnee, IL 60031. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0848-2023

Code Information:

All Lots

Product Description:

Timolol Maleate Ophthalmic Solution, USP 0.5%, packaged in a) 2.5mL bottles, b) 5mL bottles, c) 10 mL bottles, and d)15mL bottles, Rx only, Manufactured by: Akorn , Inc, Lake Forest, IL 60045. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0849-2023

Code Information:

All Lots

Product Description:

Tobramycin Inhalation Solution USP, 300 mg/5 mL, 4 single-dose ampules, Rx only, Manufactured by: Akorn, Inc, Lake Forest, IL 60045. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0850-2023

Code Information:

All Lots

Product Description:

Tobramycin Ophthalmic Solution, USP 0.3%, 5mL bottles, Rx only, Manufactured by: Akorn , Inc, Lake Forest, IL 60045. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0851-2023

Code Information:

All Lots

Product Description:

Trihexyphenidyl Hydrochloride Oral Solution, USP, 2mg/5mL, 473 mL bottles, Rx only, Distributed by: VersaPharm, Inc. - An Akorn Company- Lake Forest, IL 60045. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0852-2023

Code Information:

All Lots

Product Description:

Tropicamide Ophthalmic Solution, USP 0.5%, 15 mL bottles, Rx only, Distributed by: Akorn Operating Company LLC, Gurnee, IL 60031. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0853-2023

Code Information:

All Lots

Product Description:

Valproic Acid Oral Solution, USP, 250mg/5mL, 473 mL bottles, Rx only, Distributed by: Akorn Operating Company LLC, Gurnee, IL 60031. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0854-2023

Code Information:

All Lots

Product Description:

Vitamin D Supplement Drops, 400 IU, Cherry Flavored 50mL bottle, Distributed by: Akorn Operating Company LLC, Gurnee, IL 60031. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0855-2023

Code Information:

All Lots

Product Description:

XOPENEX (levalbuterol HCl) Inhalation Solution Concentrate, 1.25mg/3mL, 0.5 mL unit-dose vials, Rx only, Distributed by: Akorn, Inc., Lake Forest, IL 60045. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0856-2023

Code Information:

All Lots

Product Description:

Amantadine Hydrochloride Oral Solution USP, 50mg/5mL, 473mL bottles, Rx only, Distributed by: Akorn Operating Company LLC, Gurnee, IL 60031. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0857-2023

Code Information:

All Lots

Product Description:

Calcitriol Injection 2 mcg/mL, 1 mL ampules Rx Only, Distributed by: Akorn Operating Company, LLC., Gurnee, IL 60031. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0858-2023

Code Information:

All Lots

Product Description:

Midazolam Injection, USP, 50 mg/10mL (5mg/mL), For Intramuscular or Intravenous Use Only, 10 mL vials, Rx Only, Manufactured by: Akorn, Inc., Lake Forest, IL 60045. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0859-2023

Code Information:

All Lots

Product Description:

Olopatadine HCl Ophthalmic Solution, USP, 0.2%, 5mL bottles, Rx Only, Sterile, Manufactured by: Akorn, Inc., Lake Forest, IL 60045. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0860-2023

Code Information:

All Lots

Product Description:

Pilocarpine Hydrochloride Ophthalmic Solution, USP 2%, 15 mL bottles, Rx Only, Sterile, Distributed by: Akorn Operating Company LLC, Gurnee, IL 60031. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0861-2023

Code Information:

All Lots

Product Description:

Pilocarpine Hydrochloride Ophthalmic Solution, USP 4%, 15 mL bottles, Rx Only, Sterile, Distributed by: Akorn Operating Company LLC, Gurnee, IL 60031. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0862-2023

Code Information:

All Lots

Product Description:

Ropivacaine Hydrochloride Injection USP, 0.2%, 200mg/100 mL (2 mg/mL), 100 mL Vial, Rx Only, Manufactured by: Akorn Inc., Lake Forest, IL 60045. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0863-2023

Code Information:

All Lots

Product Description:

Tropicamide Ophthalmic Solution, USP 0.1%, 15 mL bottles, Rx only, Distributed by: Akorn Operating Company LLC, Gurnee, IL 60031. ALL NDCs

Product Quantity:**Reason for Recall:**

CGMP Deviations: Firm went out of business and could no longer continue stability studies.

Recall Number:

D-0864-2023

Code Information:

All Lots

Class II Drugs Event

Event ID:

92268

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

05/03/2023

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

05/31/2023

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Denison Pharmaceuticals, LLC
1 Powder Hill Rd
Lincoln RI United States

Distribution Pattern:

Product was distributed Nationwide.

Associated Products

Product Description:

Safe tussin DM, DAY TIME Cough Relief, (Dextromethorphan HBr, USP 10mg Guaifenesin, USP 100mg), 4.0 FL OZ (118mL) bottle, Kramer Laboratories , Inc. Bridgewater, NJ 08807.

Product Quantity:

86,616 4 OZ bottles

Reason for Recall:

CGMP Deviations: Use of non-food grade lubricant in mixing vessel.

Recall Number:

D-0772-2023

Code Information:

Lot: 8314, Exp: 04/2023, 8753, 8753A, Exp: 10/2023; 8659, Exp: 08-2023

Product Description:

Colic Calm, Colic, Gas & Reflux, Homeopathic Medicine, 2 Fl. Oz (59 ml) bottle. Distributed by Ketomi LLC, 1215 Sarasota Center Blvd., Sarasota FL 34240.

Product Quantity:

54,222 bottles

Reason for Recall:

CGMP Deviations: Use of non-food grade lubricant in mixing vessel.

Recall Number:

D-0773-2023

Code Information:

Lot 8290V, Exp: 10-2023

Product Description:

Pin-Away PYRENTAL PAMOATE (Pyrantel base 50 mg / mL) Pinworm Treatment, 2 FL OZ (60 mL) bottle, Distributed by: Cara Incorporated, 333 Strawberry Field Road, Warwick, RI 05886. NDC 70309-080-02

Product Quantity:

4,812 units

Reason for Recall:

CGMP Deviations: Use of non-food grade lubricant in mixing vessel.

Recall Number:

D-0774-2023

Code Information:

Lot 8640, Exp: 11/2023

Product Description:

Safe tussin PM, NIGHT TIME Cough Relief, (Dextromethorphan HBr, USP 7.5mg, Doxylamine Succinate 3.125mg), 4.0 FL OZ (118mL) bottle, Kramer Laboratories , Inc. Bridgewater, NJ 08807.

Product Quantity:

13,968 bottles

Reason for Recall:

CGMP Deviations: Use of non-food grade lubricant in mixing vessel.

Recall Number:

D-0775-2023

Code Information:

Lot 8639, Exp: 8/2023

Class II Drugs Event

Event ID:

92395

Status:

Ongoing

Recall Initiation Date:

05/09/2023

Center Classification Date:

05/31/2023

Recalling Firm:

SSM Health Care St. Louis DBA SSM St. Clare Health Center

1015 Bowles Ave

Fenton MO United States

Product Type:

Drugs

Date Terminated:**Voluntary / Mandated:**

Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:

Letter

Distribution Pattern:

Product was distributed in Missouri.

Associated Products

Product Description:

HYDROMORPHONE HCl 10 mg in 0.9% Sodium Chloride, 50 mL syringe (0.2 mg/mL), Rx Only, SSM Health Care Corporation Outsourcing Facility, 1015 Bowles Ave, Fenton, MO 63026-2394. NDC: 60652-0600-2

Product Quantity:

3,232 syringes

Reason for Recall:

CGMP Deviations: Discontinuation of the Quality program by manufacturer that would assure product meet the identity, strength, quality, and purity characteristics that they are purported or represented to possess.

Recall Number:

D-0776-2023

Code Information:

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 Drugs Event

Event ID:

92403

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

05/23/2023

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

06/01/2023

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Fresenius Medical Care Holdings, Inc.
920 Winter St Bld 950
Waltham MA United States

Distribution Pattern:

Product was distributed to 32 clinics in SC, NC and VA.

Associated Products

Product Description:

Sodium Chloride 0.9% Injection, USP, 1000 mL bags, 12 bags per carton, Rx only, Fresenius Medical Care North America, Waltham, MA 02451, NDC # 49230-300-10

Product Quantity:

53,424 bags

Reason for Recall:

Lack of assurance of sterility: The product was potentially exposed to below-recommended storage temperatures, which may cause leaks in the packaging.

Recall Number:

D-0777-2023

Code Information:

Lot # 23AU05030, Exp 01/13/2024; 23AU05035, Exp 01/15/2024

Class III Drugs Event

Event ID:

92374

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

05/22/2023

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

06/01/2023

Initial Firm Notification of Consignee or Public:

E-Mail

Recalling Firm:

New England Life Care, Inc. dba Advanced Compounding Solutions
4 Constitution Way Ste L
Woburn MA United States

Distribution Pattern:

Nationwide in the USA.

Associated Products

Product Description:

Phenylephrine HCl 20 mg added to 0.9% Sodium Chloride 250mL Bag, Rx Only, Compounded by: Advanced Compounding Solutions, 4 Constitution Way Ste L Woburn, Massachusetts 01801-1042 United States, NDC 71546-451-25

Product Quantity:

198

Reason for Recall:

Product Mix up; Product was compounded in 250 mL 5% Dextrose instead of 250 mL 0.9% Sodium Chloride

Recall Number:

D-0778-2023

Code Information:

Lot # 20230323-728BF8, exp. 08/20/2023