

# Enforcement Report - Week of April 18, 2018

## Class II Drugs Event

**Event ID:**

79606

**Product Type:**

Drugs

**Status:**

Ongoing

**Date Terminated:**
**Recall Initiation Date:**

03/28/2018

**Voluntary / Mandated:**

Voluntary: Firm Initiated

**Center Classification Date:**

04/06/2018

**Initial Firm Notification of Consignee or Public:**

Letter

**Recalling Firm:**

Elroselabs Inc.  
3875 Saint Johns Pkwy  
Sanford FL United States

**Distribution Pattern:**

Nationwide.

## Associated Products

**Product Description:**

Conzerol zero molluscum contagiosum, Topical Cream, Net weight 0.78 (22g), Elrose Labs, Sanford FI 32771 USA --- NDC 70223-001-06

**Product Quantity:**

Unknown

**Reason for Recall:**

cGMP Deviations

**Recall Number:**

D-0621-2018

**Code Information:**

All product within expiry

**Product Description:**

Molleave, 2 oz bottle, OTC, Manufactured for Elrose Labs, Inc.

**Product Quantity:**

Unknown

**Reason for Recall:**

cGMP Deviations

**Recall Number:**

D-0622-2018

**Code Information:**

All product within expiry

**Product Description:**

Conzerol (antipoxin) H2O2 Gel, Hydrogen Peroxide Gel 3%, 1.5 oz. tube, OTC, Manufactured for Elrose Labs, Inc., Sanford, FL

**Product Quantity:**

Unknown

**Reason for Recall:**

cGMP Deviations

**Recall Number:**

D-0623-2018

**Code Information:**

All product within expiry

**Class II Drugs Event****Event ID:**

79693

**Product Type:**

Drugs

**Status:**

Ongoing

**Date Terminated:****Recall Initiation Date:**

03/29/2018

**Voluntary / Mandated:**

Voluntary: Firm Initiated

**Center Classification Date:**

04/10/2018

**Initial Firm Notification of Consignee or Public:**

Letter

**Recalling Firm:**

United Pacific Co Ltd  
11030 Weaver Ave  
South El Monte CA United States

**Distribution Pattern:**

Nationwide within US

**Associated Products****Product Description:**

Zhong Hua Jiu (menthol 1%) Patch, Distributed by United Pacific Company, UPC 6 924938 100226, NDC 53614-001-02

**Product Quantity:**

15,190 boxes

**Reason for Recall:**

CGMP Deviations: the product was produced with substandard GMP manufacturing processes.

**Recall Number:**

D-0624-2018

**Code Information:**

Lot #:14122921, Exp.12/30/20119, 15091512, Exp. 9/15/2020, 6032321, Exp. 3/23/2021, 17030921, Exp. 3/09/2022

**Class III Drugs Event****Event ID:**

79640

**Product Type:**

Drugs

**Status:**

Ongoing

**Date Terminated:****Recall Initiation Date:**

03/19/2018

**Voluntary / Mandated:**

Voluntary: Firm Initiated

**Center Classification Date:**

04/11/2018

**Initial Firm Notification of Consignee or Public:**

Telephone

**Recalling Firm:**

Lake Erie Medical & Surgical Supply Inc  
6920 Hall St  
Holland OH United States

**Distribution Pattern:**

FL, VA

**Associated Products****Product Description:**

Tramadol Hydrochloride 50 mg tablets, 120-count, Rx Only; Distributed by Quality Care Products, Temperance, MI 48182 Mfr. CSPC Ouyi Pharm

Co., Ltd. Shijazhuang, Hebei, China; NDC 55700-0412-01

**Product Quantity:**

16 paper cartons

**Reason for Recall:**

Labeling: Incorrect or Missing Lot and/or Exp Date

**Recall Number:**

D-0626-2018

**Code Information:**

Lot # 116289, Exp. 09/20

## Not Yet Classified Drugs Event

**Event ID:**

79729

**Status:**

Ongoing

**Recall Initiation Date:**

03/05/2018

**Center Classification Date:****Product Type:**

Drugs

**Date Terminated:****Voluntary / Mandated:**

Voluntary: Firm Initiated

**Initial Firm Notification of Consignee or Public:**

Two or more of the following: Email, Fax, Letter, Press Release, Telephone, Visit

**Recalling Firm:**

InvaGen Pharmaceuticals, Inc.  
550 S Research Pl  
Central Islip NY United States

**Distribution Pattern:**

US only

## Associated Products

**Product Description:**

Decitabine for Injection, 50mg per vial, Rx only, Manufactured by: Cipla Ltd., Verna Goa, India, Manufactured for: Cipla USA, Inc., 1560 Sawgrass Corporate Parkway, Suite 130, Sunrise, FL 33323, NDC 69097-285-37

**Product Quantity:**

3222 Vvials

**Reason for Recall:**

Failed impurities/degradation specifications: Failure to water content and impurity

**Recall Number:****Code Information:**

Lot #: GE70493, GE70502, GE70512, Exp 8/2019