

Enforcement Report - Week of March 13, 2024

Class II Drugs Event

Event ID:

94075

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

02/20/2024

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

03/04/2024

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Eugia US LLC

279 Princeton Hightstown Rd

East Windsor NJ United States

Distribution Pattern:

OH, TN, LA, MS

Associated Products

Product Description:

Methylprednisolone acetate Injectable Suspension, USP, 400mg per 5mL (80mg/mL, 5mL Multiple-Dose Vial, Rx only, Mfd. in India for: Eugia US LLC, E. Windsor, NJ 08520, NDC 55150-314-01

Product Quantity:

10,080 vials

Reason for Recall:

Failed Dissolution Specifications

Recall Number:

D-0366-2024

Code Information:

Lot #: 3MA23001, 3MA23002, 3MA23003, Exp 3/31/2025

Class III Drugs Event

Event ID:

93960

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

02/09/2024

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

03/06/2024

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Stason Pharmaceuticals, Inc.

11 Morgan

Irvine CA United States

Distribution Pattern:

USA Nationwide

Associated Products

Product Description:

Mercaptopurine Tablets, USP 50 mg, packaged in: a) 25-count bottle (NDC 69076-913-02), b) 250-count bottle (NDC 69076-913-25), Rx only, Manufactured for: Quinn Pharmaceuticals, Boca Raton, FL, www.quinnrx.com

Product Quantity:

54, 131 bottles

Reason for Recall:

Failed Dissolution Specifications: results slightly under spec at at 9-months.

Recall Number:

D-0367-2024

Code Information:

Lot #: a)22K012, 22K013A, Exp: 04/30/2024; 23A001, 23A002A, Exp: 07/31/2024; 23D006, 23D007A, 23D007C, Exp:10/31/2024; b)22K013B, Exp: 04/30/2024; 23A002B, Exp:07/31/2024; 23D007B, Exp: 10/31/2024.

Class III Drugs Event

Event ID:

94066

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

02/20/2024

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

03/01/2024

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Contract Pharmaceuticals Limited Canada
7600 East Danbro Cres
Mississauga Canada

Distribution Pattern:

Nationwide in the U.S. and Puerto Rico

Associated Products

Product Description:

Clindamycin Phosphate, Topical Solution USP, 1%, 60 mL, Rx Only, Manufactured for and Distributed by: Marlex Pharmaceuticals, Inc., New Castle, DE 19720, NDC 10135-0691-61

Product Quantity:

45,875 bottles

Reason for Recall:

Defective Container: Out of specification for weight due to a slow leakage at the 12-month stability timepoint.

Recall Number:

D-0364-2024

Code Information:

Lot #: 119466, 119467 Exp 04/2025; 120351 Exp 08/2025; 121712 Exp 11/2025

Product Description:

Clindamycin Phosphate Topical Solution USP, 1%, 60 mL bottle, Manufactured for: Glasshouse Pharmaceuticals Limited Canada, Mississauga, Ontario, Canada, L5N 6R8, NDC 71428-0003-60

Product Quantity:

11,750 bottles

Reason for Recall:

Defective Container: Out of specification for weight due to a slow leakage at the 12-month stability timepoint.

Recall Number:

D-0365-2024

Code Information:

Lot #: 119874; Exp 06/30/2025