

Enforcement Report - Week of June 21, 2023

Class I Drugs Event

Event ID:

92457

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

03/27/2023

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

06/14/2023

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Jarman's Midwest Cleaning Systems, Inc.
824 N Grant St
Canton SD United States

Distribution Pattern:

Nationwide in the USA

Associated Products

Product Description:

Alcohol Antiseptic 80%, Topical Solution, Hand Sanitizer, Non-sterile Solution, Volume: 3.785 L, plastic gallon bottle, MCS Midwest Cleaning Solutions, 404 Noid Rd., Canton, SD 57013.

Product Quantity:

2365 gallons

Reason for Recall:

Chemical Contamination: FDA testing found Presence of methanol

Recall Number:

D-0873-2023

Code Information:

All batches labelled with Date of Manufacture (DOM): DOM 26MAR2020; DOM 01APR2020; DOM 02APR2020; DOM 27APR2020; DOM 04MAY2020; DOM 13MAY2020; DOM 04AUG2020.

Product Description:

SOFT HANDS Alcohol Antiseptic 80%, Topical Solution, HAND SANITIZER, NON-STERILE SOLUTION, cleanpro SUPPLY, 1 US gallon / 3785.41ml, plastic gallon bottle, MCS Midwest Cleaning Solutions, 404 Noid Rd., Canton, SD 57013.

Product Quantity:

7303 gallons

Reason for Recall:

Chemical Contamination: FDA testing found Presence of methanol

Recall Number:

D-0874-2023

Code Information:

All product labelled with Date of Manufacture (DOM): DOM 26MAR2020; DOM 01APR2020; DOM 02APR2020; DOM 04APR2020; DOM 27APR2020; DOM 04MAY2020; DOM 07MAY2020; DOM 13MAY2020; DOM 04AUG2020.

Class II Drugs Event

Event ID:

92368

Product Type:

Drugs

Status:**Date Terminated:**

Ongoing

Recall Initiation Date:

05/30/2023

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

06/15/2023

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Amneal Pharmaceuticals of New York, LLC
50 Horseblock Rd
Brookhaven NY United States

Distribution Pattern:

LA, PA and OH.

Associated Products

Product Description:

Extended Phenytoin Sodium Capsules, USP, 100 mg, Rx Only, 100 capsules per bottle, Distributed by: Amneal Pharmaceuticals LLC., Bridgewater, NJ 08807, NDC 65162-212-10.

Product Quantity:

9,056 bottles

Reason for Recall:

Failed Dissolution Specifications: Out-of-specification results for dissolution (above specification)

Recall Number:

D-0876-2023

Code Information:

Lot # HL00721A, Exp. 12/2023

Class II Drugs Event

Event ID:

92457

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

03/27/2023

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

06/14/2023

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Jarman's Midwest Cleaning Systems, Inc.
824 N Grant St
Canton SD United States

Distribution Pattern:

Nationwide in the USA

Associated Products

Product Description:

Isopropyl Alcohol Antiseptic 75%, Topical Solution, Hand Sanitizer Non-sterile Solution, Volume: 3.785 L, plastic gallon bottle, MCS Midwest Cleaning Solutions, 404 Noid Rd., Canton, SD 57013. NDC: 74663-002-01

Product Quantity:

1276 gallons

Reason for Recall:

CGMP deficiencies: Product manufactured at the same site where FDA testing found Presence of methanol in other products.

Recall Number:

D-0872-2023

Code Information:

All batches labelled with Date of Manufacture (DOM): DOM 24MAR2020; DOM 12DEC2020.

Class III Drugs Event

Event ID:

92458

Status:

Ongoing

Recall Initiation Date:

06/12/2023

Center Classification Date:

06/14/2023

Recalling Firm:Amring Pharmaceuticals Inc
1205 Westlakes Dr Ste 275
Berwyn PA United States**Distribution Pattern:**

Nationwide in the USA.

Product Type:

Drugs

Date Terminated:**Voluntary / Mandated:**

Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:

Letter

Associated Products

Product Description:

Lysteda (tranexamic acid) USP Tablets, 650 mg, 30 tablets per bottle, Rx Only, Manufactured for: Amring Pharmaceuticals Inc. Berwyn, PA 19312, NDC 69918-301-30

Product Quantity:

48,989 bottles

Reason for Recall:

Failed Impurities/Degradation Specifications: Out of specification results obtained for conductivity.

Recall Number:

D-0871-2023

Code Information:

Lots: X220317A and X220318A, exp. date 09/25

Class III Drugs Event

Event ID:

92535

Status:

Ongoing

Recall Initiation Date:

06/13/2023

Center Classification Date:

06/15/2023

Recalling Firm:AVKARE LLC
615 N 1st St
Pulaski TN United States**Distribution Pattern:**

Nationwide in the USA.

Product Type:

Drugs

Date Terminated:**Voluntary / Mandated:**

Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:

Letter

Associated Products

Product Description:

Tranexamic Acid USP Tablets, 650 mg, 30 tablets (3X10) Unit Dose, Rx Only, Manufactured for: AvKARE Pulaski, TN 38478, NDC 50268-772-13

Product Quantity:

592 cartons

Reason for Recall:

Failed Impurities/Degradation Specifications: Out of specification results obtained for conductivity.

Recall Number:

D-0875-2023

Code Information:

Lot: 44286 Exp. 02/2025