

Enforcement Report - Week of April 20, 2022

Class I Drugs Event

Event ID:

89876

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

03/29/2022

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

04/11/2022

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Teva Pharmaceuticals USA Inc
400 Interpace Pkwy Bldg A
Parsippany NJ United States

Distribution Pattern:

Nationwide within the United States

Associated Products

Product Description:

IDArubicin Hydrochloride Injection USP 5gm/5mL (1mg/mL), 5mL Single Dose Vial, Rx Only, Teva Pharmaceuticals, USA, Inc., North Wales, PA 19454, NDC 0703-4154-11.

Product Quantity:

1565 vials

Reason for Recall:

Presence of Particulate Matter: Product was found to contain silica and iron oxide

Recall Number:

D-0765-2022

Code Information:

Lot #: 31329657B, Exp. Date 08/2023

Class II Drugs Event

Event ID:

89918

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

04/04/2022

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

04/14/2022

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Beak & Skiff Cider Mill, Inc.
4472 Cherry Valley Tpke
La Fayette NY United States

Distribution Pattern:

Distributed in NY and sales were made via the internet.

Associated Products

<p>Product Description: BEAK & SKIFF SANITIZER Alcohol Antiseptic 80%, Topical Solution Antiseptic Hand Rub Non-Sterile Solution, Packaged in a) 12OZ/355ML bottles, UPC 48558 94603 6 b) 5 Gallon/18,927ML pail C) 1 Gallon/3,785ML jug; d) 4OZ/118ML spray top bottles; Produced By; Beak & Skiff Farms Apple Farms Inc. Lafayette, NY 13084.</p> <p>Product Quantity: 396/12 oz. bottles, 11/5 gallon pails, 9/1 gallon jugs, 304/4 oz. bottles</p> <p>Reason for Recall: CGMP Deviations: FDA analysis found product to contain acetaldehyde above specification limits.</p> <p>Recall Number:</p> <p>Code Information: Lot # 06090</p>
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Class II Drugs Event

Event ID:

89924

Status:

Ongoing

Recall Initiation Date:

03/23/2022

Center Classification Date:

04/14/2022

Recalling Firm:

Preferred Pharmaceuticals, Inc.
1250 N Lakeview Ave Ste O
Anaheim CA United States

Distribution Pattern:

IL

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

Associated Products

<p>Product Description: Clobetasol Propionate Lotion 0.05%, Generic for Temovate, 118 mL bottle, Rx Only, Mfg: Teligent Pharma, Inc., PREFERRED Pharmaceuticals, Inc., The Physician's Solution, NDC 68788-7768-01</p> <p>Product Quantity: 1568 bottles</p> <p>Reason for Recall: CGMP Deviations: all products within expiry are being recalled because the manufacturing firm, Teligent Pharma, Inc. is discontinuing its stability study program.</p> <p>Recall Number: D-0768-2022</p> <p>Code Information: Lot #: A0721O, A1421Y, A2121G, A2821D, B0421H, B0421I, B0521U, B1121G, B1921C, C0421B, C1821N, L0120F, L2320O, L3020T, Exp.: 4/30/2022; B2521A, C1121S, C2521U, D0121S, D0921B, D1421B, D2921C, E0721A, Exp.: 10/31/2022; D2221A, Exp.: 12/31/2022</p>
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Class II Drugs Event

Event ID:

89943

Status:

Ongoing

Product Type:

Drugs

Date Terminated:

Recall Initiation Date:

03/24/2022

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

04/14/2022

Initial Firm Notification of Consignee or Public:

E-Mail

Recalling Firm:

Preferred Pharmaceuticals, Inc.
1250 N Lakeview Ave Ste O
Anaheim CA United States

Distribution Pattern:

Product distributed in California and Florida.

Associated Products

Product Description:

Econazole Nitrate Cream, 1%, Generic for Spectazole, 30 gm tube, Rx Only, Preferred Pharmaceuticals, Inc., The Physician's Solution, Mfg: Teligent Pharma, Inc., NDC 68788-7406-03

Product Quantity:

41 Tubes

Reason for Recall:

CGMP Deviations: all products within expiry are being recalled because the manufacturing firm, Teligent Pharma, Inc. is discontinuing its stability study program.

Recall Number:

D-0771-2022

Code Information:

Lot #: A1122P, G1421N, Exp. 1/1/2023

Class II Drugs Event

Event ID:

89950

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

03/28/2022

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

04/14/2022

Initial Firm Notification of Consignee or Public:

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

Recalling Firm:

Preferred Pharmaceuticals, Inc.
1250 N Lakeview Ave Ste O
Anaheim CA United States

Distribution Pattern:

Nationwide in the USA and CA.

Associated Products

Product Description:

Preferred Pharmaceuticals, Inc. The Physician's Solution., Lansoprazole Delayed-Release Capsules, 15mg, Generic for Prevacid, 90-Count Bottle, Manufacturer: Dr Reddy's Laboratories Limited, NDC 68788-6390-09

Product Quantity:

791 bottles of 90 - Count

Reason for Recall:

Out of specification results observed in dissolution during long term stability testing.

Recall Number:

D-0769-2022

Code Information:

Lots: H0221R, D3021T, D2221J, D1321X, Exp.12/31/2023.

Class III Drugs Event

Event ID:

89941

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

04/05/2022

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

04/12/2022

Initial Firm Notification of Consignee or Public:**Recalling Firm:**Aurobindo Pharma USA Inc.
279 Princeton Hightstown Rd
East Windsor NJ United States**Distribution Pattern:**

Nationwide in the USA.

Associated Products

Product Description:

Cyanocobalamin Injection, USP, 1,000 mcg per mL, For IM or SC Use Only, 1 mL Vial, Rx Only, Manufactured in India, for Auromedics Pharma LLC, NDC 55150-364-01.

Product Quantity:

433,809 vials

Reason for Recall:

Subpotent Drug: Out of Specification results for Assay

Recall Number:

D-0766-2022

Code Information:

Lots: CCC210004, Exp 09/2022; CCC210005, CCC210006, CCC210007, Exp 11/2022; CCC210010, CCC210011, Exp 04/2023.