

Enforcement Report - Week of June 29, 2022

Class II Drugs Event

Event ID:

90340

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

06/03/2022

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

06/22/2022

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

SUN PHARMACEUTICAL INDUSTRIES INC

2 Independence Way

Princeton NJ United States

Distribution Pattern:

nationwide within the United States

Associated Products

Product Description:

Clonazepam Orally Disintegrating Tablets, USP, 0.125mg, Rx Only, 60 Tablets, Mfd. by: Sun Pharmaceutical Industries Ltd. Mumbai, India, Dist. by: Sun Pharmaceutical Industries In., Cranbury, NJ 08512, NDC 57664-783-68, packaged in bottles.

Product Quantity:

4608 bottles

Reason for Recall:

Failed Tablet/Capsule Specification; oversized tablet found in a bottle

Recall Number:

D-1155-2022

Code Information:

Lot #: MHC1430A, Exp. Date 09/2023

Class II Drugs Event

Event ID:

90361

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

06/03/2022

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

06/21/2022

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

SUN PHARMACEUTICAL INDUSTRIES INC

2 Independence Way

Princeton NJ United States

Distribution Pattern:

Nationwide in the USA and Puerto Rico

Associated Products

Product Description:

Testosterone Cypionate Injection, USP, 200 mg/mL, 1 mL Single-dose vial per carton, Rx only, Distributed by: Sun Pharmaceutical Industries, Inc., Cranbury, NJ 08512; Manufactured by: Sun Pharmaceutical Industries Ltd., Halol-Baroda Highway, Halol-389 350, Gujarat, India, NDC 62756-015-40.

Product Quantity:

97,450 vials

Reason for Recall:

CGMP Deviations: lots made with same active pharmaceutical ingredient (API) as lots that were rejected due to manufacturing issues that could cause the product to be out of specification for impurities.

Recall Number:

D-1153-2022

Code Information:

HAC1974A, HAC1978A, Exp 06/2023

Class II Drugs Event

Event ID:

90391

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

06/10/2022

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

06/22/2022

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

SUN PHARMACEUTICAL INDUSTRIES INC

2 Independence Way

Princeton NJ United States

Distribution Pattern:

Nationwide within the United States

Associated Products

Product Description:

Testosterone Cypionate Injection, USP, 200 mg/mL, 1 mL Single-dose vial per carton, Rx only, Distributed by: Sun Pharmaceutical Industries, Inc., Cranbury, NJ 08512; Manufactured by: Sun Pharmaceutical Industries Ltd., Halol-Baroda Highway, Halol-389 350, Gujarat, India, NDC 62756-015-40.

Product Quantity:

47,500 vials

Reason for Recall:

Lack of Assurance of Sterility: Manufacturing deviation which was reported due to a microbial excursion

Recall Number:

D-1154-2022

Code Information:

Lot: HAC3427A, EXP Date: 08/2023

Class II Drugs Event

Event ID:

90406

Product Type:

Drugs

Status:

Ongoing

Date Terminated:

Recall Initiation Date:

06/09/2022

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

06/21/2022

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Mayne Pharma Inc
1240 Sugg Pkwy
Greenville NC United States

Distribution Pattern:

Nationwide in the US Market

Associated Products

Product Description:

Clonidine Transdermal System, USP 0.3 mg/day, 4 Patches (NDC 51862-455-01) per Carton (51862-455-04), Rx only, Manufactured for: Mayne Pharma Greenville, NC 27834

Product Quantity:

1440 cartons

Reason for Recall:

Defective Delivery System: Out of specification for release liner removal force results at the 3-month CRT stability timepoint.

Recall Number:

D-1152-2022

Code Information:

Lot: 41179A Exp. Jan 2023

Class II Drugs Event

Event ID:

90430

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

06/14/2022

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

06/23/2022

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 in the U.S.

Associated Products

Product Description:

Tretinoin Capsules, 10 mg, Rx Only, 100 capsules per bottle, Teva Pharmaceuticals USA Inc., North Wales, PA, 19454, NDC 0555-0808-02.

Product Quantity:

4941 bottles

Reason for Recall:

Failed Dissolution Specifications; Low Out of Specification (OOS) results for dissolution.

Recall Number:

D-1156-2022

Code Information: Lot #s: 100022971, Exp. 08/2022; 100022972, Exp. 05/2023; 100028920, Exp. 09/2023

Class II Drugs Event

Event ID: 90453	Product Type: Drugs
Status: Ongoing	Date Terminated:
Recall Initiation Date: 06/15/2022	Voluntary / Mandated: Voluntary: Firm initiated
Center Classification Date: 06/21/2022	Initial Firm Notification of Consignee or Public: Letter
Recalling Firm: Vi-Jon, LLC 1 Swan Dr Smyrna TN United States	
Distribution Pattern: Nationwide in the USA	

Associated Products

Product Description: 70% ISOPROPYL ALCOHOL First aid antiseptic, 4 FL OZ (118 mL) bottle, Made in US with US and foreign components for Medline Industries, Inc., Mundelein, IL 60060 USA, NDC: 53329-798-04, UPC (01) 10888277362291.
Product Quantity: 3,157,620 bottles
Reason for Recall: Defective Container: Product may leak when squeezed or when not in an upright position determined to be due to defects in the bottle neck finish and insufficient tightening.
Recall Number: D-1151-2022
Code Information: Lots #s: 0517418, Exp. 12/2022; 0506632, 0519195, 0522494, Exp. 01/2023; 0525627, 0525629, 0526051, 0526052, 0527664, 0527665, Exp. 03/2023; 0531133, 0531134, Exp. 04/2023; 0533153, 0534050, Exp. 05/2023; 0534585, 0534587, 0536089, Exp. 06/2023; 0538694, 0541334, Exp. 07/2023; 0539877, 0542355, Exp. 08/2023; 0545225, 0547054, 0547055, 0547131, Exp. 09/2023; 0547130, 0551014, 0551015, 0552608, Exp. 10/2023; 0552609, 0552610, 0553905, Exp. 11/2023; 0556144, 0557513, Exp. 12/2023; 0559594, 0559602, 0559603, Exp. 01/2024; 0551013, 0559596, 0559604, 0559605, 0561393, 0561395, Exp. 02/2024; 0556143, 0561396, 0561549, Exp. 03/2024; 0565877, Exp. 04/2024