Enforcement Report - Week of August 10, 2022

Class I Drugs Event

Event ID:
90675

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/22/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/09/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Distributor RFR, LLC.
3580 Nw 85th Ct Apt 150
Doral FL United States

Distribution Pattern:
Retail stores in the state of FL, Nationwide in the USA via website sales, and Bolivarian Republic of Venezuela

Associated Products

Product Description:
SANGTER Energy Supplement Capsules, 3000mg x 7 grain, 7-count blister pack within a carton, Distributed by: Distributor RFR, LLC, (800) 519-0204 Miami 33172 FL, USA; UPC 0 705632 523285

Product Quantity:
2000 cartons

Reason for Recall:
Marketed Without An Approved NDA/ANDA: FDA analysis found the product to be tainted with sildenafil.

Recall Number:
D-1333-2022

Code Information:
Lot: 48656, Exp. 01/2025

Class II Drugs Event

Event ID:
90580

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/11/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/01/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Tolmar, Inc.
701 Centre Ave
Fort Collins CO United States

Distribution Pattern:
distributed to 1 consignee in KY.

Associated Products

Product Description:
Naftifine Hydrochloride Gel, USP 1%, packaged in cartons with: a) Net Wt. 90g tube (NDC 0115-1510-48), b) Net Wt. 40g tube (NDC 0115-1510-63), c) Net Wt. 60g tube (NDC 0115-1510-58), Rx only, Manufactured by: Tolmar, Inc., Fort Collins, CO, 80526, Distributed by: Amneal Pharmaceuticals LLC, Bridgewater, NJ 08807

Product Quantity:
1271 tubes

Reason for Recall:
Failed Impurities/ degradation specifications: Out-of-Specification test results obtained for Unspecified Impurity Relative Retention Time

Recall Number:
D-1300-2022

Code Information:
Lot #: a) 12070A, Exp 5/2023; 11801A, Exp 9/2022; b) 12386A, Exp 8/2023; 11800A, Exp 9/2022; c) 11940A, Exp 12/2022

Class II Drugs Event

Event ID:
90635

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/21/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/04/2022

Initial Firm Notification of Consignee or Public:

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

Distribution Pattern:
Nationwide in the USA and Puerto Rico

Associated Products

Product Description:
Matzim LA (Diltiazem Hydrochloride) Extended-Release Tablets, 180 mg, 30-count bottle, Rx Only, Manufactured by: Actavis Laboratories FL, Inc., Fort Lauderdale, FL 33314, USA; Distributed by: Actavis Pharma, Inc., Parsippany, NJ 07054, USA; NDC 52544-691-30.

Product Quantity:
8022 bottles

Reason for Recall:
Failed Dissolution Specifications: below specification limits for dissolution.

Recall Number:
D-1302-2022

Code Information:
Lot 1411593A, Exp 09/22

Product Description:
Matzim LA (Diltiazem Hydrochloride) Extended-Release Tablets, 240 mg, 30-count bottles, Rx Only, Manufactured by: Actavis Laboratories FL, Inc., Fort Lauderdale, FL USA 33314, USA, Distributed by: Actavis Pharma Inc., Parsippany, NJ 07054 USA; NDC 58544-692-30.

Product Quantity:
5677 bottles

Reason for Recall:
Failed Dissolution Specifications: below specification limits for dissolution.

Recall Number:
D-1303-2022

Code Information:
Lot 1411596A, Exp 09/22

Class III Drugs Event

Event ID:
90550

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/11/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/04/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Glenmark Pharmaceuticals Inc., USA
750 Corporate Dr
Mahwah NJ United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Tacrolimus Ointment, 0.1%, For Dermatological Use Only, Not for Ophthalmic Use, Rx Only, a) 30 g tube, NDC 68462-534-35, b) 60 g tube, NDC 68462-534-65, c) 100 g tube, NDC 68462-534-94, Manufactured for: Glenmark Pharmaceuticals Inc., USA, Mahwah, NJ 07430, Product of India.

Product Quantity:
654,756 tubes

Reason for Recall:
Defective Container: Tube split from side seam

Recall Number:
D-1304-2022

Code Information:
Lot #s: a) 15200058, 15200066, 15200067, Exp 06/2022; 15200075, Exp 07/2022; 15200094, Exp 08/2022; 15200119, 15200120, 15200122, Exp 09/2022; 15200131, 15200132, Exp 10/2022; 15200133, 15200134, 15200136, 15200139, Exp 11/2022; 15210033, 15210035, 15210036, 15210038 Exp 01/2023; 15210092, 15210094, 15210097, 15210099, Exp 03/2023; 15210100, 15210101, 15210104, Exp 04/2023; 15210122, Exp 05/2023; 15210148, 15210149, 15210153, 15210155, 15210157, 15210158, Exp 06/2023; 15210173, 15210174, 15210176, 15210177, 15210178, 15210179, Exp 07/2023; 15210184, 15210186, Exp 08/2023; 15210214, Exp 09/2023; 15210225, 15210226, 15210228, 15210230, 15210231, Exp 10/2023; 15220001, 15220002, Exp 12/2023. b) 15200092, Exp 08/2022; 15200114, 15200115, Exp 09/2022; 15200123, 15200124, Exp 10/2022; 15200142, 15200144, Exp 11/2022; 15210014, 15210015, 15210021, Exp 12/2022; 15210031, Exp 01/2023; 15210055, Exp 02/2023; 15210073, 15210075, Exp 03/2023; 15210117, 15210118, Exp 04/2023; 15210144, 15210147, 15210160, 15210162, Exp 06/2023; 15210171, Exp 07/2023; 15210187, 15210190, 15210191, 15210193, Exp 08/2023; 15210212, Exp 09/2023; 15210244, 15210247, Exp 11/2023; 15220007, Exp 12/2023; 15220019, 15220028, Exp 01/2024; 15220032, 15220034, 15220053, Exp 02/2024; 15220062, 15220064, 15220072, Exp 03/2024. c) 15200065, Exp 06/2022; 15200108, 15200109, Exp 09/2022; 15200125, Exp 10/2022; 15200148, 15200149, 15200150, Exp 11/2022; 15210007, 15210009, 15210012, 15210018, Exp 12/2022; 15210049, Exp 02/2023; 15210076, 15210077, 15210089, Exp 03/2023; 15210112, 15210114, Exp 04/2023; 15210124, 15210125, 15210127, Exp 05/2023; 15210169, 15210170, Exp 07/2023; 15210196, 15210199, Exp 08/2023; 15210204, 15210206, 15210207, 15210210, Exp 09/2023; 15210248, Exp 11/2023; 15220004, 15220013, 15220014, 15220015, Exp 12/2023; 15220025, 15220026, Exp 01/2024.

Not Yet Classified Drugs Event

Event ID:
90659

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/21/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Ultra Supplement LLC
1007 N Market St
Wilmington DE United States

Distribution Pattern:
Product was distributed nationwide in the USA via Amazon Marketplace on www.amazon.com.

Associated Products

Product Description:
SUSTANGO (Pendenadril Tytrate Blend) Capsules, 400 mg, 10-count blisters per carton, Formulated by: Male FX Labs, Bangor, ME, ASIN X0024468I9.

Product Quantity:
750 cartons

Reason for Recall:
Marketed Without an Approved NDA/ANDA: Firm was informed by Amazon that analytical testing showed the presence of tadalafil.

Recall Number:

Code Information:
Lot DAP272109, Exp: 4/1/2026