Enforcement Report - Week of May 10, 2023

Class II Drugs Event

Event ID:
92081

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/06/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/01/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
PD-Rx Pharmaceuticals, Inc.
727 N Ann Arbor Ave
Oklahoma City OK United States

Distribution Pattern:
Nationwide in the US.

Associated Products

Product Description:
Montelukast Sodium USP, 10 mg, 30 count-bottles, Rx only, Intas Pharm, Limited Ahmedabad 380 054 India Pkg By: PD-Rx Pharmaceuticals Incorporated Oklahoma City, OK 73127, NDC 43063-0762-30

Product Quantity:
352 bottles

Reason for Recall:
CGMP deviations.

Recall Number:
D-0557-2023

Code Information:
Lots: L22C80, I22D93, K21C72 Exp. 11/30/23; A23A90, B23A09 Exp. 07/31/24; K22C33 Exp. 05/31/24; G22E88, G22F66, I22E27, C22B27, D22B94, E22C71 Exp. 02/28/24; I21E36 Exp. 09/30/23

Product Description:
Simvastatin USP, 10 mg, Rx only, Intas Pharm, Limited Ahmedabad 380 054 India Pkg By: PD-Rx Pharmaceuticals Incorporated Oklahoma City, OK 73127 a) 30 count-bottle (NDC 43063-0727-30) b) 90 count-bottle (NDC 43063-0727-90)

Product Quantity:
37 bottles

Reason for Recall:
CGMP deviations.

Recall Number:
D-0558-2023

Code Information:
Lots: a) K22E32 Exp. 10/31/23; b) H22C33 Exp. 09/30/23; H22C81, J22C83, K22E36 Exp. 10/31/23

Product Description:
Glimepiride USP, 4 mg, 90 count-bottles, Rx only, Intas Pharm. Limited Pkg By: PD-Rx Pharmaceuticals Incorporated Oklahoma City, OK 73127, NDC 43063-0587-90

Product Quantity:
186 bottles

Reason for Recall:

CGMP deviations.

Recall Number:
D-0559-2023

Code Information:
Lots: A22B45 Exp. 01/31/24; C22A73, E22E41, C22D28, F22B68, G22A29, H22B97, K22A36 Exp. 03/31/24; K22B99, A23D07, B23B25 Exp. 10/31/24; B23B55 Exp. 06/30/25

Product Description:
Simvastatin USP 20 mg, Rx only, Intas Pharm. Limited Ahmedabad 380 054 India Pkg By: PD-Rx Pharmaceuticals Incorporated Oklahoma City, OK 73127 a) 30 count-bottles (NDC 43063-008-30), b) 90 count-bottles (NDC: 43063-0008-90)

Product Quantity:
520 bottles

Reason for Recall:
CGMP deviations.

Recall Number:
D-0560-2023

Code Information:
Lots: a) G22B32, D22B92, D22F82, Exp. 06/30/23; G22F41, J22F25, L22C14, Exp. 01/31/24; D22B92, D22F82 Exp. 06/30/23; B22A12, Exp. 03/31/23 b) H22A32, I22E83, J22E94, K22E34 Exp. 01/31/24; C22F31, D22G16, E22D75, F22E06, Exp. 06/30/23; L21E09, B22C61, Exp. 01/31/23.

Product Description:
Simvastatin USP 40 mg, Rx only, Intas Pharm. Limited Ahmedabad 380 054 India Pkg By: PD-Rx Pharmaceuticals Incorporated Oklahoma City, OK 73127 a) 30 count-bottle (NDC 43063-0726-30) b) 90 count-bottle (NDC 43063-0726-90)

Product Quantity:
393 bottles

Reason for Recall:
CGMP deviations.

Recall Number:
D-0561-2023

Code Information:
Lots: a) A22A17, D22C21 Exp. 07/31/23; K22D89, L22B26, L22D14 Exp. 03/31/24; L22D96 Exp. 04/30/24; b) L21E06 Exp. 05/31/23; B22C05, D22B91, E22C82 Exp. 07/31/23; G22B03 G22B79, H22A30, J22B81 Exp. 08/31/23; J22F27, K22B37, K22B88 Exp. 10/31/23; L22D32 Exp. 03/31/24; B23E07 Exp. 04/30/24

Class II Drugs Event

Event ID:
92164

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/19/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/03/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Seatex LLC
445 Highway 36 N
Rosenberg TX United States

Distribution Pattern:
FL, GA, TX

Associated Products

Product Description:
Seatex Alcohol Antiseptic 80% Topical Solution Hand Sanitizer Non-Sterile Solution Net Contents: 3.785 L (1 Gallon) Container, UPC 6 12592 01480 0 Seatex, LLC. 445 TX Hwy 36 Rosenberg, TX 77471.

Product Quantity:
2880 containers

Reason for Recall:
Subpotent Drug: Ethanol sup-potency and Impurities out of specification for allowable limit.

Recall Number:
D-0562-2023

Code Information:
Lot: 220888, Exp. 05/20/2023

Class II Drugs Event

Event ID:
92248

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/31/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/04/2023

Initial Firm Notification of Consignee or Public:
Two or more of the following: Email, Fax, Letter, Press Release, Telephone, Visit

Recalling Firm:
Family Dollar Stores, Llc.
500 Volvo Pkwy
Chesapeake VA United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Advil Ibuprofen Tablets, 200 mg Pain Reliever/Fever Reducer (NSAID) packaged in a) 100-count bottles, b) 50-count bottles, and c) 3 (2 count) packets.

Product Quantity:
Pending.

Reason for Recall:
CGMP deviation: product outside labeled storage temperature requirements.

Recall Number:
D-0563-2023

Code Information:
SKUs a) 0901458; b) 0913023; c) 0999259 stored and distributed from DCs 07/28/2022 through 03/31/2023.

Product Description:
Advil Ibuprofen Tablets, 200 mg Pain Reliever/Fever Reducer (NSAID) 24-count Caplets

Product Quantity:
Pending

Reason for Recall:
CGMP deviation: product outside labeled storage temperature requirements.

Recall Number:
D-0564-2023

Code Information:
SKU 0901839 stored and distributed from DCs 07/28/2022 through 03/31/2023.

Product Description:
Advil Dual Action with Acetaminophen Acetaminophen 250 mg and Ibuprofen (NSAID) 125 mg Tablets Pain Reliever, 36 Caplets bottles

Product Quantity:

Reason for Recall:
CGMP deviation: product outside labeled storage temperature requirements.

Recall Number:
D-0565-2023

Code Information:
SKUs 0902867 stored and distributed from DCs 07/28/2022 through 03/31/2023.

Product Description:
Advil Liqui-Gels Solubilized Ibuprofen Capsules, 200 mg Pain Reliever/Fever Reducer (NSAID) a) 20-count Liquid Filled Capsule bottles; b) 40-count Liquid Filled Capsule bottles.

Product Quantity:
Pending

Reason for Recall:
CGMP deviation: product outside labeled storage temperature requirements.

Recall Number:
D-0566-2023

Code Information:
SKUs a) 0999841; b) 0916071 stored and distributed from DCs 07/28/2022 through 03/31/2023.

Class III Drugs Event

Event ID:
92161

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/20/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
04/28/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Bryant Ranch Prepack, Inc.
1919 N Victory Pl
Burbank CA United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Lidocaine Patch 5%, 1 patch (63629-8755-20) packaged in 30-count patches per carton (63629-8755-1), Rx only, each patch contains: 700 mg (50mg per gram adhesive) in an aqueous base, Manufactured by: Actavis Laboratories UT, Inc., Relabeled by: Bryant Ranch Prepack, Inc. Burbank, CA 91504 USA

Product Quantity:
403 boxes

Reason for Recall:
Labeling: Typographical error on the upper left-hand side of the box and individual patch label that has the incorrect dosage form stating, each tablet contains instead of each adhesive patch contains.

Recall Number:
D-0556-2023

Code Information:
Lot: 204603, Exp: 09/30/2024; Lots:208608, 208749, 208445, 209101, 208609, 208295, 209106, 209102, 209212, 208975, 209211, 209706, 209779, 209624, 209839, 209548, Exp: 12/31/2024; Lots: 204604, 204601, 204550, 204599, 204871, 204555, 205616, Exp: 11/30/2024; Lots: 205612, 204832, 205127, 204996, 205615, 205324, 205494, 205611, 206232, Exp: 10/31/2024.

Not Yet Classified Drugs Event

Event ID:
92203

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/26/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Gadget Island, Inc
1275 Halyard Dr Ste 175
West Sacramento CA United States

Distribution Pattern:
Nationwide in the USA.

Associated Products

Product Description:
Pro Power Knight Plus capsule, 2550mg, 1-count blister card, Distributed by Beyond Health and youth Inc, Seattle, WA 98110, UPC 4 94922 90522 0.

Product Quantity:
628 blister cards

Reason for Recall:
Marketed without an Approved NDA/ANDA: FDA analysis found product to be tainted with undeclared sildenafil and tadalafil, ingredients found in FDA approved products for the treatment of male sexual enhancement, making this an unapproved drug.

Recall Number:

Code Information:
No lot number, Exp: 06/2026

Product Description:
NUX Male Enhancement capsule, 1-count blister card, distributed by SX Power CO., Chicago, Il 60612, UPC 6 01577 51236 3.

Product Quantity:
18 blister cards

Reason for Recall:
Marketed without an Approved NDA/ANDA: FDA analysis found product to be tainted with undeclared sildenafil and tadalafil, ingredients found in FDA approved products for the treatment of male sexual enhancement, making this an unapproved drug.

Recall Number:

Code Information:
Lot#: RO 927996, Exp: 12/25/2024

Product Description:
DYNAMITE SUPER capsule, 58,000 MG, 1-count blister card, Made in America, UPC 6 75799 37602 7.

Product Quantity:
140 blister packs

Reason for Recall:
Marketed without an Approved NDA/ANDA: FDA analysis found product to be tainted with undeclared sildenafil and tadalafil, ingredients found in FDA approved products for the treatment of male sexual enhancement, making this an unapproved drug.

Recall Number:

Code Information:
Lot/Item#: OMS760-B, Exp: 12/2025