# Enforcement Report - Week of November 21, 2018

## Class I Drugs Event

**Event ID:**
81512

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**

**Recall Initiation Date:**
11/05/2018

**Voluntary / Mandated:**
Voluntary: Firm Initiated

**Center Classification Date:**
11/19/2018

**Initial Firm Notification of Consignee or Public:**
E-Mail

**Recalling Firm:**
Kadesh International
9618 Garden Grove Blvd Ste 201
Garden Grove CA United States

**Distribution Pattern:**
Product was distributed via online stores and retail distributors Nationwide in the USA, Uruguay, Canada, China, Dominican Republic, Korea, and Vietnam.

### Associated Products

**Product Description:**
puriton EYE RELIEF DROPS, 0.5 oz (15 ml) bottle, Kadesh Inc., NDC#7079600115, UPC 7 36972 16799 0.

**Product Quantity:**
18,521 bottles

**Reason for Recall:**
Non-Sterility: Product manufactured under non-sterile production conditions.

**Recall Number:**
D-0250-2019

**Code Information:**
All lots, no expiration dates are on the bottles.

## Class II Drugs Event

**Event ID:**
81120

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**

**Recall Initiation Date:**
09/27/2018

**Voluntary / Mandated:**
Voluntary: Firm Initiated

**Center Classification Date:**
11/14/2018

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

**Recalling Firm:**
Teva Pharmaceuticals USA
1090 Horsham Rd
North Wales PA United States

**Distribution Pattern:**
Product was distributed throughout the United States, including Hawaii and Puerto Rico.

### Associated Products

**Product Description:**
Alprostadil Injection USP 500 micrograms/mL 1 mL single use vial, 5 vials per carton, Rx only, TEVA Pharmaceuticals USA, Inc., North Wales, PA --- NDC 0703-1501-02

**Product Quantity:**
1,362 vials

**Reason for Recall:**
Failed Impurities/Degradation Specifications; out-of-specification results for impurities obtained during routine stability testing

**Recall Number:**
D-0244-2019

**Code Information:**
Lot # 31323147B, exp. date 01/2019

## Class II Drugs Event

**Event ID:**
81436

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**

**Recall Initiation Date:**
10/15/2018

**Voluntary / Mandated:**
Voluntary: Firm Initiated

**Center Classification Date:**
11/15/2018

**Initial Firm Notification of Consignee or Public:**
Press Release

**Recalling Firm:**
Zero Xtreme USA
20533 Biscayne Blvd # 825
Aventura FL United States

**Distribution Pattern:**
Nationwide within the USA.

## Associated Products

**Product Description:**
Zero Xtreme Dietary Supplement 30-count capsules. By:Zero Xtreme Registro Sanitario No SD2014-0002208 LLC-USA

**Product Quantity:**
16 bottles

**Reason for Recall:**
Marketed Without an Approved NDA/ANDA: Undeclared Sibutramine

**Recall Number:**
D-0246-2019

**Code Information:**
Lot: 1220062085 Exp. 03/2020

## Class II Drugs Event

**Event ID:**
81457

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**

**Recall Initiation Date:**
11/02/2018

**Voluntary / Mandated:**
Voluntary: Firm Initiated

**Center Classification Date:**
11/20/2018

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

**Recalling Firm:**
Sandoz Inc
100 College Rd W
Princeton NJ United States

**Distribution Pattern:**
Nationwide within the United States

## Associated Products

**Product Description:**
Isosorbide Dinitrate Tablets, USP 20 mg, 100-count bottles, Rx Only NDC 0781-1695-01 Distributed by: Sandoz Inc. Princeton, NJ 08540; NDC 0781-1695-01

**Product Quantity:**
18,832 bottles

**Reason for Recall:**
Cross Contamination with Other Products

**Recall Number:**
D-0258-2019

**Code Information:**
Lots: a) JA9535 Exp. 05/2021.

**Product Description:**
Isosorbide Dinitrate Tablets, USP 5 mg,100-count bottles, Rx Only Manufactured by: Sandoz Inc., Princeton, NJ 08540 For BluePoint Laboratories, NDC 68001-223-00

**Product Quantity:**
7817 bottles

**Reason for Recall:**
Cross Contamination with Other Products

**Recall Number:**
D-0259-2019

**Code Information:**
Lot #: HZ7896, Exp. 05/2021

**Product Description:**
Isosorbide Dinitrate Tablets, USP 10 mg,100-count bottles, Rx Only Manufactured by: Sandoz Inc., Princeton, NJ 08540 For BluePoint Laboratories, NDC 68001-223-00

**Product Quantity:**
5100 bottles

**Reason for Recall:**
Cross Contamination with Other Products

**Recall Number:**
D-0260-2019

**Code Information:**
Lot #: JA3077, Exp. 05/2021

**Product Description:**
Isosorbide Dinitrate Tablets, USP 20 mg,100-count bottles, Rx Only Manufactured by: Sandoz Inc., Princeton, NJ 08540 For BluePoint Laboratories, NDC 68001-223-00

**Product Quantity:**
1550 bottles

**Reason for Recall:**
Cross Contamination with Other Products

**Recall Number:**
D-0261-2019

**Code Information:**
Lot #: JA9534, Exp. 05/2021

## Class II Drugs Event

**Event ID:**
81483

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**

**Recall Initiation Date:**
10/19/2018

**Voluntary / Mandated:**
Voluntary: Firm Initiated

**Center Classification Date:**
11/20/2018

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

**Recalling Firm:**
Taro Pharmaceuticals U.S.A., Inc.
3 Skyline Dr
Hawthorne NY United States

**Distribution Pattern:**
Nationwide in the USA

## Associated Products

**Product Description:**
Children's 24 Hour Allergy (cetirizine hydrochloride) Oral Solution 1 mg/mL, Bubble Gum Flavor, Sugar Free/Dye Free, 4 FL OZ (120 mL) bottle, Dist. by Meijer Distribution, Inc., Grand Rapids, MI 40644, NDC 41250-106-08, UPC 7 13733 88578 2.

**Product Quantity:**
12,432 bottles

**Reason for Recall:**
Failed Impurities/Degradation Specifications: unknown impurity higher than the specified limit was detected during routine stability testing.

**Recall Number:**
D-0276-2019

**Code Information:**
Lot # 313342, Exp 12/18

**Product Description:**
children's allergy (cetirizine hydrochloride) Oral Solution, 1 mg/mL, ANTIHISTAMINE, Dye-Free, Sugar-Free, 4 FL OZ (120 mL) bottle, Distributed by Publix Super Markets, Inc., 3300 Publix Corporate Parkway, Lakeland, FL 33811, NDC 56062-106-08, UPC 0 41415 43573 5.

**Product Quantity:**
8328 bottles

**Reason for Recall:**
Failed Impurities/Degradation Specifications: unknown impurity higher than the specified limit was detected during routine stability testing.

**Recall Number:**
D-0277-2019

**Code Information:**
Lot # 313345, Exp 12/18

**Product Description:**
children's allergy relief (cetirizine hydrochloride) oral solution, 1 mg/mL, Dye Free, Sugar Free, Alcohol Free, 4 FL OZ (120 mL) bottle, Distributed by Rite-Aid, 30 Hunter Lane, Camp Hill, PA 17011, Made in Israel, UPC 0 11822 57363 4.

**Product Quantity:**

**Reason for Recall:**
Failed Impurities/Degradation Specifications: unknown impurity higher than the specified limit was detected during routine stability testing.

**Recall Number:**
D-0278-2019

**Code Information:**
Lot # 313344, Exp 12/18

## Class III Drugs Event

**Event ID:**
81198

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**

**Recall Initiation Date:**
09/25/2018

**Voluntary / Mandated:**
Voluntary: Firm Initiated

**Center Classification Date:**
11/14/2018

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

**Recalling Firm:**
Right Value Drug Stores, Inc.
122 Grapevine Hwy
Hurst TX United States

**Distribution Pattern:**
Distributed in California

## Associated Products

**Product Description:**
Progesterone SR 100 mg Capsules, packed in 8,13, 20, 30, 40 or 60 dram screw top pill bottle, Carie Boyd's Prescription Shop 122 Grapevine Hwy. Hurst, TX 76054 817-282-9376. NDC 99999-0104-55

**Product Quantity:**
6580 capsules

**Reason for Recall:**
Labeling Not Elsewhere Classified: Misbranding.

**Recall Number:**
D-0240-2019

**Code Information:**
Lots: 03272018@10 Exp. 09/11/2018; 03282018@8 Exp. 09/24/2018; 03282018@18 Exp. 09/24/2018; 04232018@3 Exp. 09/24/2018; 05302018@4 Exp. 10/22/2018; 06072018@6 Exp. 10/22/2018; 06212018@1 Exp. 10/22/2018; 06252018@7 Exp. 10/22/2018; 07192018@8 Exp. 10/22/2018; 07192018@10 Exp. 01/15/2019; 08282018@6 Exp. 2/23/2019; 08282018@7 Exp. 2/23/2019; 09142018@1 Exp. 02/23/2018; 09182018@10 Exp. 2/23/2019

**Product Description:**
Progesterone SR 200 mg Capsules, packed in 8,13, 20, 30, 40 or 60 dram screw top pill bottle, Carie Boyd's Prescription Shop 122 Grapevine Hwy. Hurst, TX 76054 817-282-9376. NDC 99999-0018-74

**Product Quantity:**
8240 capsules

**Reason for Recall:**
Labeling Not Elsewhere Classified: Misbranding.

**Recall Number:**
D-0241-2019

**Code Information:**
Lots: 04052018@16 Exp. 9/11/2018; 04242018@2 Exp. 10/21/2018; 05072018@8 Exp. 10/21/2018; 05302018@3 Exp. 10/22/2018; 06192018@9 Exp. 10/22/2018; 06192018@10 Exp. 12/15/2018; 06202018@12 Exp. 12/15/2018; 07022018@15 Exp. 12/15/2018; 07242018@2 Exp. 1/13/2018; 08312018@3 Exp. 2/6/2018

**Product Description:**
Tadalafil SR 7 mg Capsules packed in 8,13, 20, 30, 40 or 60 dram screw top pill bottle, Carie Boyd's Prescription Shop 122 Grapevine Hwy. Hurst, TX 76054. NDC 99999-9970-88

**Product Quantity:**
660 capsules

**Reason for Recall:**
Labeling Not Elsewhere Classified: Misbranding.

**Recall Number:**
D-0242-2019

**Code Information:**
Lots: 04242018@16 Exp. 10/21/2018; 05042018@17 Exp. 10/31/2018; 07232018@13 Exp. 01/19/2019; 08032018@2 Exp. 01/30/2019

**Product Description:**
Tadalafil SR 12 mg Capsules packed in 8,13, 20, 30, 40 or 60 dram screw top pill bottle, Carie Boyd's Prescription Shop 122 Grapevine Hwy. Hurst, TX 76054 817-282-9376 NDC 99999-9969-51

**Product Quantity:**
180 capsules

**Reason for Recall:**
Labeling Not Elsewhere Classified: Misbranding.

**Recall Number:**
D-0243-2019

**Code Information:**
Lots: 07232018@15 Exp. 1/19/2019; 08102018@10 Exp. 2/6/2019

## Class III Drugs Event

**Event ID:**
81457

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**

**Recall Initiation Date:**
11/02/2018

**Voluntary / Mandated:**
Voluntary: Firm Initiated

**Center Classification Date:**
11/20/2018

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

**Recalling Firm:**
Sandoz Inc
100 College Rd W
Princeton NJ United States

**Distribution Pattern:**
Nationwide within the United States

## Associated Products

**Product Description:**
Nitrofurantoin Capsules, USP (Monohydrate/Macrocrystals) 100 mg, packaged in a) 100-capsule bottles (NDC 0185-0122-01); and b) 1000-capsule bottles, (NDC 0185-0122-10); Rx Only, Distributed by Sandoz Inc. Princeton, NJ 08540

**Product Quantity:**
14366 bottles

**Reason for Recall:**
Cross Contamination with Other Products

**Recall Number:**
D-0257-2019

**Code Information:**
Lots: a) JB4952, JA7322 Exp. 03/2020; b) JA7324, Exp.03/2020

**Product Description:**
Nitrofurantoin Capsules, USP (Monohydrate/Macrocrystals) 100 mg, 100-count bottoles, Rx Only, Manufactured for: Northstar Rx LLC Memphis, TN 38141 Manufactured by: Sandoz Inc. Princeton, NJ 08540,NDC 16714-439-01

**Product Quantity:**
23053 bottles

**Reason for Recall:**
Cross Contamination with Other Products

**Recall Number:**
D-0262-2019

**Code Information:**
Lot #: JA7319, JA 7320, JA7321, Exp. 03/2020

## Class III Drugs Event

**Event ID:**
81511

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**

**Recall Initiation Date:**
11/08/2018

**Voluntary / Mandated:**
Voluntary: Firm Initiated

**Center Classification Date:**
11/15/2018

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

**Recalling Firm:**
Eli Lilly
1400 W Raymond St
Indianapolis IN United States

**Distribution Pattern:**
AL, AZ, CA, KS, LA, MS, OH, OR, TN, TX and Puerto Rico

## Associated Products

**Product Description:**
ERBITUX CETUXIMAB Injection, 200 mg/100 mL (2 mg/mL), 100 mL per single-use vial, Rx only, Manufactured by: ImClone LLC, a wholly-owned subsidiary of Eli Lilly and Company, Branchburg, NJ 08876 USA. NDC: 66733-958-23

**Product Quantity:**
9,380 vials

**Reason for Recall:**
Labeling: Missing label; potential for missing primary container label on the vial.

**Recall Number:**
D-0248-2019

**Code Information:**
Lot number: C1700167, exp 9/2020

## Class III Drugs Event

**Event ID:**
81523

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**

**Recall Initiation Date:**
11/06/2018

**Voluntary / Mandated:**
Voluntary: Firm Initiated

**Center Classification Date:**
11/20/2018

**Initial Firm Notification of Consignee or Public:**
E-Mail

**Recalling Firm:**
Breckenridge Pharmaceutical, Inc.

6111 Broken Sound Pkwy NW Ste 170
Boca Raton FL United States

**Distribution Pattern:**
Nationwide within the United States

## Associated Products

**Product Description:**
Megestrol Acetate Oral Suspension, USP 625 mg/5mL, 150 mL bottle, Rx only, Distributed by: Breckenridge Pharmaceutical, Inc. Boca Raton, FL 33487, Manufactured by: Pharmaceutics International Inc. Hunt Valley, MD 21031

**Product Quantity:**
9,193 bottles

**Reason for Recall:**
Failed Stability Specifications: Out-of-Specification results obtained for particle size distribution during stability testing.

**Recall Number:**
D-0279-2019

**Code Information:**
Lot #: 5599.008A, 5599.009A, 5599.010A, Exp. 04/2019; 5599.012A, 5599.013A, Exp. 11/2019; 5599.014A, Exp. 01/2020

## Class III Drugs Event

**Event ID:**
81554

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**

**Recall Initiation Date:**
10/26/2018

**Voluntary / Mandated:**
Voluntary: Firm Initiated

**Center Classification Date:**
11/14/2018

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

**Recalling Firm:**
RemedyRepack Inc.
625 Kolter Dr Ste 4
Indiana PA United States

**Distribution Pattern:**
1 vial was distributed to a medical facility in Mayville, NY.

## Associated Products

**Product Description:**
Metoprolol Tartrate Injection, USP 5mg/5mL, vials, Rx only, MFG: Claris Lifesciences Inc., North Brunswick, NJ 08902, NDC# 70518-0868-00

**Product Quantity:**
1 vial

**Reason for Recall:**
Failed pH Specifications: High Out-of-Specification results for pH were obtained during stability testing.

**Recall Number:**
D-0245-2019

**Code Information:**
Lot #: A0A0253, Exp. 02/2019; Lot #: B0369427-112717, Exp. 08/2019

## Not Yet Classified Drugs Event

**Event ID:**
79842

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**

**Recall Initiation Date:**
04/16/2018

**Voluntary / Mandated:**
Voluntary: Firm Initiated

**Center Classification Date:**

**Initial Firm Notification of Consignee or Public:**
Press Release

**Recalling Firm:**
Epic Products, LLC
11730 W 135th St #224
Overland Park KS United States

**Distribution Pattern:**
Nationwide in the USA

## Associated Products

**Product Description:**
Euphoric Premium Male Performance Enhancer capsules, packaged in a)1-count blister cards, UPC 6 96859 28646 9, b) 3-count bottle, UPC 6 96859 28647 6 and c) 12-count bottle, UPC 6 96859 28648 3.

**Product Quantity:**
a) 106,329 cards; b) 109,725 bottles; c) 28,644 bottles

**Reason for Recall:**
Marketed Without An Approved NDA/ANDA: product contains undeclared sildenafil, tadalafil, and oxytetracycline, FDA approved drug products making Euphoric an unapproved drug.

**Recall Number:**

**Code Information:**
All lots

## Not Yet Classified Drugs Event

**Event ID:**
81518

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**

**Recall Initiation Date:**
11/06/2018

**Voluntary / Mandated:**
Voluntary: Firm Initiated

**Center Classification Date:**

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

**Recalling Firm:**
Takeda Development Center Americas, Inc.
1 Takeda Pkwy 4034BB1
Deerfield IL United States

**Distribution Pattern:**
Product was distributed to 32 distributors throughout the United States.

## Associated Products

**Product Description:**
AMITIZA (lubiprostone) capsules 8 mcg. 60-count bottle, Rx Only. Marketed by: Sucampo Pharma Americas, LLC, Rockville MD 20850 and Takeda Pharmaceuticals America, Inc. Deerfield, IL 60015. Active Ingredient made in Japan, encapsulated in the United States. NDC 64764-080-60

**Product Quantity:**
69,075 60-count bottles (4,144,500 capsules)

**Reason for Recall:**
Failed Impurities/Degradation Specifications:Elevated levels of a known impurity in the 20-month stability sample testing.

**Recall Number:**

**Code Information:**
Lot # 3098628-61, exp. date 02/28/2021