Enforcement Report - Week of May 30, 2018

Class I Drugs Event

Event ID:
79852

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/13/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
05/18/2018

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
AMA Wholesale
4195 Chino Hills Pkwy #609
Chino Hills CA United States

Distribution Pattern:
Nationwide within the US

Associated Products

Product Description:
Rhino 69 Extreme 50000 packaged in 1 capsule per blister pack, Distributed by AMA Wholesale Inc. Chino Hills, CA, 91709-2618, UPC Code: 718122071128

Product Quantity:
unknown

Reason for Recall:
Marketed Without An Approved NDA/ANDA: FDA analysis found the product to contain undeclared tadalafil. The presence of tadalafil makes Rhino Extreme 50000 an unapproved drug for which safety and efficacy have not been established and, therefore, subject to recall.

Recall Number:
D-0821-2018

Code Information:
All Lots

Class II Drugs Event

Event ID:
79501

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/13/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
05/22/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Fresenius Medical Care Renal Therapies Group, LLC
920 Winter St
Waltham MA United States

Distribution Pattern:
Product was distributed throughout the United States.

Associated Products

Product Description:
0.9% Sodium Chloride Injection, USP, 1000 mL, Rx Only, Fresenius Medical Care North America, Waltham, MA 02451, NDC 49230-0300-10.

Product Quantity:
25,356 1 liter bags

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0827-2018

Code Information:
Lot # 17LU05005; Exp. 09/18 Part Number 060-10109

Class II Drugs Event

Event ID:
79955

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/24/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
05/22/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Mylan Pharmaceuticals Inc.
781 Chestnut Ridge Rd
Morgantown WV United States

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

Associated Products

Product Description:
Loxapine Capsules, USP 25 mg, Rx Only, 100-count bottles, NDC 0378-7025-01

Product Quantity:
8,679 bottles

Reason for Recall:
CGMP Deviations

Recall Number:
D-0824-2018

Code Information:
NDC # 0378-7025-01 Lot Numbers: 3083756, Exp. 3/31/19 3083757, Exp. 3/31/19 3083758, Exp. 3/31/19 3083759, Exp. 3/31/19 3083760, Exp. 3/31/19 3083761, Exp. 3/31/19

Product Description:
Loxapine Capsules, USP 50 mg, Rx Only, 100-count bottles, NDC 0378-7050-01

Product Quantity:
11,650 bottles

Reason for Recall:
CGMP Deviations

Recall Number:
D-0825-2018

Code Information:
NDC 0378-7050-01 Lot Numbers: 3079386, Exp. 10/31/18 3079387, Exp. 10/31/18 3079388, Exp. 10/31/18 3083762, Exp. 3/31/19 3083763, Exp. 3/31/19 3083764, Exp. 3/31/19 3083765, Exp. 3/31/19 3083766, Exp. 3/31/19 3083767, Exp. 3/31/19

Class II Drugs Event

Event ID:
79967

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/16/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
05/24/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Ideaz Llc
400 Sproul St
Mc Kees Rocks PA United States

Distribution Pattern:
Nationwide in the U.S.A.

Associated Products

Product Description:
screamin' hot (capsaicin) Pain Relieving Gel, 0.03%, packaged in a) 2 OZ (57g) tubes, UPC 7 50263 80072 4; b) 5 oz. (141g) tubes, UPC 7 50263 80007 6; and c) 16 oz. (454g) bottles, UPC 7 50263 80076 2; MFD FOR: Toast Products, 400 Sproul Street, Pittsburgh, PA 15136; NDC 52099-8005.

Product Quantity:
820.125 pounds

Reason for Recall:
CGMP Deviations: Products manufactured with an ingredient that exceed the benzene levels allowed in drug products.

Recall Number:
D-0834-2018

Code Information:
Lot #: 116002, Exp 01/19; 217003, Exp 02/20; 1217017, Exp 12/20

Product Description:
screamin' menthol (menthol) Pain Relieving Gel, 4%, packaged in a) 2 OZ (57g) tubes, UPC 7 50263 80062 5; b) 5 oz. (141g) tubes, UPC 7 50263 80006 9; and c) 16 oz. (454g) bottles, UPC 7 50263 80066 3; MFD FOR: Toast Products, 400 Sproul Street, Pittsburgh, PA 15136; NDC 52099-8010.

Product Quantity:
800 pounds

Reason for Recall:
CGMP Deviations: Products manufactured with an ingredient that exceed the benzene levels allowed in drug products.

Recall Number:
D-0835-2018

Code Information:
Lot #: 1015019, Exp 10/18; 1116011, Exp 11/19

Class II Drugs Event

Event ID:
79969

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/20/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
05/22/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Exela Pharma Sciences LLC
1245 Blowing Rock Blvd
Lenoir NC United States

Distribution Pattern:
Nationwide in the USA and Puerto Rico

Associated Products

Product Description:
Diclofenac Sodium and Misoprostol Delayed Release Tablets 75 mg/0.2 mg, 60-count bottle, Rx Only, Manufactured by: Cipla Ltd., India; For: EAGLE PHARMACEUTICALS, INC., Woodcliff Lake, NJ 07677 USA, NDC 42367-111-06.

Product Quantity:
5256 bottles

Reason for Recall:
Labeling: Label Mix-Up: bottle labeled as Diclofenac Sodium and Misoprostol 75 mg/0.2 mg contained Diclofenac Sodium and Misoprostol 50 mg/0.2 mg tablets.

Recall Number:
D-0826-2018

Code Information:
Lot: GH70154, Exp 12/18

Class II Drugs Event

Event ID:
79977

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/01/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
05/22/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Mylan Institutional, Inc. (d.b.a. UDL Laboratories)
1718 Northrock Ct
Rockford IL United States

Distribution Pattern:
Nationwide in the U.S.

Associated Products

Product Description:
Loxapine Capsules, USP 25 mg, packaged in 100 Unit Dose Capsules, Rx only, Manufactured by Mylan Pharmaceuticals Inc. Morgantown, WV 26505 U.S.A. NDC 51079-902-20

Product Quantity:
1,065 blister cards of 100 capsules each

Reason for Recall:
GMP Deviations: a recent FDA inspection of the manufacturing site revealed multiple cGMP violations that would place Loxapine at risk for cross contamination

Recall Number:
D-0822-2018

Code Information:
Lot #: 3090454, Exp. 03/2019

Product Description:
Loxapine Capsules, USP 50 mg, packaged in 100 Unit Dose capsules, Rx only, Manufactured by Mylan Pharmaceuticals Inc. Morgantown, WV 26505 U.S.A. NDC 51079-903-20.

Product Quantity:

Reason for Recall:
GMP Deviations: a recent FDA inspection of the manufacturing site revealed multiple cGMP violations that would place Loxapine at risk for cross contamination

Recall Number:
D-0823-2018

Code Information:
Lot #: 3092310, Exp. 03/2019

Class II Drugs Event

Event ID:
80006

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/30/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
05/22/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Mylan Pharmaceuticals Inc.
781 Chestnut Ridge Rd
Morgantown WV United States

Distribution Pattern:
Recalling firm distributed product to wholesalers throughout the United States, including Puerto Rico.

Associated Products

Product Description:
PrednisoLONE Sodium Phosphate Orally Disintegrating Tablets 10 mg, Rx Only, 48-count bottle

Product Quantity:
7,334 48-count bottles

Reason for Recall:
CGMP Deviations

Recall Number:
D-0829-2018

Code Information:
Lot #: 3081542, Exp. 08/18 3081543, Exp. 08/18 3081544, Exp. 08/18 3082235, Exp. 08/18 3085903, Exp. 12/18 3088974, Exp. 06/19 3090445, Exp. 06/19

Product Description:
PrednisoLONE Sodium Phosphate Orally Disintegrating Tablets 15 mg, Rx Only, 48-count bottle

Product Quantity:
9,906 48-count bottles

Reason for Recall:
CGMP Deviations

Recall Number:
D-0830-2018

Code Information:
Lot #: 3082509; Exp. 08/18 3085901; Exp. 12/18

Product Description:
PrednisoLONE Sodium Phosphate Orally Disintegrating Tablets, 30 mg, Rx Only, 48-count bottle

Product Quantity:
3,844 48-count bottles

Reason for Recall:
CGMP Deviations

Recall Number:
D-0831-2018

Code Information:
Lot #: 3082921; Exp. 12/18 3088975; Exp. 06/19

Class III Drugs Event

Event ID:
80045

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/04/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
05/22/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Milbar Laboratories, Inc.
20 Commerce St
East Haven CT United States

Distribution Pattern:
Product was distributed to physicians and internet sales throughout the United States and Hong Kong, Panama, UK, China, Jordan, Qatar, Kuwait, a nd Central America.

Associated Products

Product Description:
T Shampoo For Hair and Body, Solution Coal Tar 3% (0.6% coal tar), 300 ml/10.1 fl. oz. bottles, Dermatologic Cosmetic Laboratories, East Haven, CT

Product Quantity:
952 bottles

Reason for Recall:
Subpotent

Recall Number:
D-0832-2018

Code Information:
Lot # MT390-8, expiration date 12/01/2020 GU925-4, expiration date 07/05/2020

Product Description:
Zoma Shampoo, Zinc Pyrithione 1.92%, 300 ml/10.01 fl. oz. bottles, Dermatologic Cosmetic Laboratories, East Haven, CT

Product Quantity:
1,348 bottles

Reason for Recall:
Subpotent

Recall Number:
D-0833-2018

Code Information:
Lot # HT659-6, expiration date 08/11/2019 LT168-7, expiration date 11/10/2019

Not Yet Classified Drugs Event

Event ID:
80004

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/30/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:

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

Associated Products

Product Description:
Lidocaine Patch 5%, NDC 0591-3525-30, 30 envelopes containing 1 patch each/ 30 Patches/Carton Carton Lot Number Patch Lot Number:1147020B Patch Lot Number: 1147020 Transdermal Patch description: Lidocaine Patch 5% is comprised of an adhesive material containing 5% lidocaine, which is applied to a white non-woven polyethylene terephthalate (PET) material backing and covered with a transparent PET release liner. The release liner is removed prior to application to the skin. The size of the patch is 10 cm x 14 cm.

Product Quantity:
30,382 patches

Reason for Recall:
Recall is being conducted due to an out of specification (OOS) test result for water content obtained during routine stability testing activities.

Recall Number:

Code Information:
Carton Lot Number Patch Lot Number:1147020B Patch Lot Number: 1147020

Not Yet Classified Drugs Event

Event ID:
80097

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/17/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Lupin Pharmaceuticals Inc.
111 S Calvert St Fl 21ST
Baltimore MD United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
My Way (Levonorgestrel) Tablets TWO PACK, 1.5 mg each, packaged as 2 Treatments (Two 1.5mg Levonorgestrel Tablets) per carton, GAVIS Pharmaceuticals, A Lupin Group Company; Mfg. for Lupin Pharmaceuticals, Inc., Baltimore, MD 21202, UPC 3 43386-622-31 3.

Product Quantity:
43,922 cartons

Reason for Recall:
Marketed Without an Approved NDA/ANDA: 2-pack configuration did not receive appropriate regulatory approval prior to release.

Recall Number:

Code Information:
Lot #: M16317A1, M16317A4, M16317A5, Exp 11/18

Product Description:
My Way (levonorgestrel) Tablets TWO PACK, 1.5 mg each, packaged as 2 Treatments (Two 1.5mg Levonorgestrel Tablets) per carton, Manufactured for: Lupin Pharmaceuticals, Inc., Baltimore, MD 21202; Manufactured by: Lupin Limited, Pithampur (M.P.) - 454 775, INDIA, UPC 3 68180 85212 4.

Product Quantity:
43,640 cartons

Reason for Recall:
Marketed Without an Approved NDA/ANDA: 2-pack configuration did not receive appropriate regulatory approval prior to release.

Recall Number:

Code Information:
Lot #: L700329, Exp 08/19; L700670, Exp 11/19