Enforcement Report - Week of October 31, 2018

Class II Drugs Event

Event ID:
80838

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/10/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
10/24/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Westlab Pharmacy, Inc. dba Westlab Pharmacy
4410 W Newberry Rd Ste A5
Gainesville FL United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Alprostadil 500 mcg/mL Injectable, Vials, Westlab Pharmacy, Inc., Gainesville, FL 32607 NDC 10002-7335-00

Product Quantity:
80 syringes

Reason for Recall:
Incorrect Product Formulation

Recall Number:
D-0089-2019

Code Information:
Lot: 03192018@42 Discard after 9/15/2018

Product Description:
ADAA Cataract Drops, (Lido 1.47%, Phenyleph 0.294% Cyclopentolate 0.147%, Tropicamide 0.0735%, Moxiflox 0.0294%, Ketorolac 0.0147%) 1x 1cc syringe, Westlab Pharmacy, Inc., Gainesville, FL 32607 --- NDC 10002-2579-05

Product Quantity:
222 syringes

Reason for Recall:
Lack of Process Controls

Recall Number:
D-0090-2019

Code Information:
Lot: 06182018@30 Exp. 08/28/2018

Product Description:
Cyclosporine 1% Human Eye Drops, Westlab Pharmacy, Inc., Gainesville, FL 32607 NDC 10002-2776-92

Product Quantity:
7 droptainers

Reason for Recall:
Lack of Process Controls

Recall Number:
D-0091-2019

Code Information:
Lot: 07262018@7 Exp. 08/25/2018

Class II Drugs Event

Event ID:
81004

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/24/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
10/22/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Valeant Pharmaceuticals North America LLC
400 Somerset Corporate Blvd
Bridgewater NJ United States

Distribution Pattern:
Product was distributed throughout the United States

Associated Products

Product Description:
Cortaid Intensive Therapy Cooling Spray (1% hydrocortisone), 2 FL OZ (59 mL) spray bottle, OTC, Distributed by: Valeant Pharmaceuticals North America LLC, Bridgewater, NJ 08807, UPC code 301875518028

Product Quantity:
18,408 bottles

Reason for Recall:
CGMP deviations: Notice received from supplier of a voluntary recall of all their nasal products and baby oral gels due to the possibility of microbial contamination. No positive results for the firm's products. were obtained. After the firm review, cGMP deviations ere evident.

Recall Number:
D-0084-2019

Code Information:
Lot #: 171205E, 171951E, Exp 5/19; 173365K, Exp 10/19

Product Description:
Cortaid Maximum Strength Cream (1% hydrocortisone), 1 OZ (28 g) tube, OTC, Distributed by: Valeant Pharmaceuticals North America LLC, Bridgewater, NJ 08807, UPC code 301875521011

Product Quantity:
119,594 tubes

Reason for Recall:
CGMP deviations: Notice received from supplier of a voluntary recall of all their nasal products and baby oral gels due to the possibility of microbial contamination. No positive results for the firm's products. were obtained. After the firm review, cGMP deviations ere evident.

Recall Number:
D-0085-2019

Code Information:
Lot #: 170843B, Exp 2/19; 171484D, Exp 4/19; 171791E, 171848E, Exp 5/19; 172359J, 172360J, 173184J, Exp 9/19; 173512P, Exp 12/19; 180180B, Exp 2/20; 181098C, Exp 3/20

Product Description:
Cortaid 12-Hour Advanced Anti-itch Cream (1% hydrocortisone), NET WT 1.5 oz. (42 g) tube, OTC, Distributed by: Valeant Pharmaceuticals North America LLC, Bridgewater, NJ 08807, UPC code 301875519155

Product Quantity:
5,016 tubes

Reason for Recall:
CGMP deviations: Notice received from supplier of a voluntary recall of all their nasal products and baby oral gels due to the possibility of microbial contamination. No positive results for the firm's products. were obtained. After the firm review, cGMP deviations ere evident.

Recall Number:
D-0086-2019

Code Information:
Lot #: 172185F, Exp 6/19

Class II Drugs Event

Event ID:
81168

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/05/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
10/24/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
LUPIN SOMERSET
400 Campus Dr
Somerset NJ United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Fluocinolone Acetonide Topical Solution, USP 0.01%, 60ml Bottle, Manufactured for: Lupin Pharmaceutical, Inc. Baltimore, MD 21202 Manufactured by: Novel Laboratories, Inc. Somerset, NJ 08873. NDC 43386-069-60

Product Quantity:
2712 60-ml bottles

Reason for Recall:
Failed Impurities/Degradation Specifications:Out of specification result noticed for total impurities observed during stability analysis

Recall Number:
D-0092-2019

Code Information:
Lot# M16666, EXP 12/2018

Class II Drugs Event

Event ID:
81225

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/11/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
10/19/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Lannett Company, Inc.
9000 State Rd
Philadelphia PA United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
HydrOXYzine HYDROCHLORIDE SYRUP (HydrOXYzine Hydrochloride Oral Solution, USP), 10 mg per 5 mL, Rx only, Distributed by Lannett Company, Inc., Philadelphia, PA 19154, NDC 54838-502-80.

Product Quantity:
8,324 bottles

Reason for Recall:
CGMP Deviations: cleaning procedures during manufacturing caused out of specification results for unknown impurities.

Recall Number:
D-0083-2019

Code Information:
Lot #: 1097, Exp 10/18

Class II Drugs Event

Event ID:
81276

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/15/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
10/24/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Heritage Pharmaceuticals, Inc.
1 Tower Center Blvd Ste 1700
East Brunswick NJ United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Cidofovir injection 375 mg/mL (75 mg/mL) vial Injection, 5 mL vials, Rx Only, Mfg. By Emcure Pharmaceutical Ltd Hinjawadi, Pune, India, Mfg for: Heritage Pharmaceuticals Inc. UPC 323155216388, NDC 23155-216-31

Product Quantity:
2,789 Units

Reason for Recall:
Lack of Assurance of Sterility: complaints received about dried powder on the outside of the bottle

Recall Number:
D-0094-2019

Code Information:
Lot #: VCIA083, Exp. JUN2020

Class II Drugs Event

Event ID:
81311

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/20/2018

Center Classification Date:
10/24/2018

Recalling Firm:
Pfizer Inc.
235 E 42nd St
New York NY United States

Distribution Pattern:
Nationwide in the US and Puerto Rico

Voluntary / Mandated:
Voluntary: Firm Initiated

Initial Firm Notification of Consignee or Public:
Letter

Associated Products

Product Description:
Meropenem for Injection, USA (I.V.), 1 gram/vial, 25 vials per carton, Sterile, Rx Only, Manufactured for: Hospira, Inc., Lake Forest, IL 60045, USA. NDC carton: 0409-3506-01; NDC vial: 0409-3506-11

Product Quantity:
71,075 vials

Reason for Recall:
Lack of assurance of sterility: loss of container integrity.

Recall Number:
D-0095-2019

Code Information:
Lot: 609G047, EXP 10/2018

Class II Drugs Event

Event ID:
81395

Status:
Terminated

Recall Initiation Date:
08/24/2018

Center Classification Date:
10/24/2018

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

Distribution Pattern:
Product was distributed to a medical facility in South Carolina

Product Type:
Drugs

Date Terminated:
10/29/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Initial Firm Notification of Consignee or Public:
Letter

Associated Products

Product Description:
Amlodipine/Valsartan HCTZ 10 mg/320 mg/25 mg tablets, HDPE 90 cc bottles in cardboard trays Original NDC 13668-0325-30 Repackaged NDC 70518-1220-00

Product Quantity:
2 bottles of 90 tablets (180 tablets)

Reason for Recall:
CGMP Deviations: Detection of trace amounts of NDMA, a possible impurity or contaminant in an active pharmaceutical ingredient.

Recall Number:
D-0093-2019

Code Information:
Lot # B0438903-052118 70518-1220-00

Class III Drugs Event

Event ID:
81213

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/09/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
10/23/2018

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 within the United States

Associated Products

Product Description:
Testosterone Topical Solution, 30mg/1.5mL, 110mL bottles, Rx only, Manufactured for: Lupin Pharmaceuticals Inc. Baltimore, Maryland 21202 United States, Manufactured by: Lupin Limited Pithampur (M.P.) 454 775 INDIA, NDC 68180-943-11

Product Quantity:
6,752 bottles

Reason for Recall:
Defective Container: Repetitive complaints received indicating pump not working.

Recall Number:
D-0087-2019

Code Information:
Lot #: K700085, K700087, Exp. November 2019

Not Yet Classified Drugs Event

Event ID:
81174

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/19/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Upsher Smith Laboratories, Inc.
6701 Evenstad Dr N
Maple Grove MN United States

Distribution Pattern:
Nationwide USA, Puerto Rico and Guam

Associated Products

Product Description:
Bumetanide Tablets, USP, 1 mg, 100-count bottle, Rx only, Manufactured by: Upser-Smith Laboratories, LLC, Maple Grove, MN 55369, NDC 0832-0541-11

Product Quantity:
44,764 bottles

Reason for Recall:
Product is Out of Specification for an unspecified degradation product.

Recall Number:

Code Information:
Lot#: 375716, Exp 4/30/2020; 372957, 372958, 372959, Exp 3/31/2020; 374541, 375717, 376688, Exp 5/31/2020

Product Description:
Bumetanide Tablets, USP, 2 mg, 100-count bottle, Rx only, Manufactured by: Upser-Smith Laboratories, LLC, Maple Grove, MN 55369, NDC 0832-0542-11

Product Quantity:
29,080 bottles

Reason for Recall:
Product is Out of Specification for an unspecified degradation product.

Recall Number:

Code Information:
Lot#: 372461, 372952, 372954, 372955, 373624, 374539, Exp 3/31/2020; 375719, 375721, 376684, Exp 5/31/2020

Not Yet Classified Drugs Event

Event ID:
81316

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/25/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
RXQ Compounding LLC
340 W State St Unit 9
Athens OH United States

Distribution Pattern:
U.S.A. nationwide

Associated Products

Product Description:
Lidocaine 1% + Epinephrine 1:100,000 (MDV) INJ SOL, 50 mL per glass vial, Rx only, 340 West State Street, Unit 9, Athens, OH 45701. NDC: 7073197450

Product Quantity:
395 vials

Reason for Recall:
Subpotent product.

Recall Number:

Code Information:
Lot# 04042018:58, Exp 10/17/18

Not Yet Classified Drugs Event

Event ID:
81326

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/19/2018

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 to distributors, wholesalers and retail chains throughout the United States, including Puerto Rico.

Associated Products

Product Description:
Metoprolol Succinate Extended Release Tablets, USP 50 mg, 100-count bottle, Rx only, Manufactured by: Actavis Laboratories FL, Inc., Fort Lauderdale, FL 33314, Distributed by: Actavis Pharma, Inc., Parsippany, NJ 07054, NDC 62037-831-01

Product Quantity:
53,451 bottles

Reason for Recall:
Out-of-Specification dissolution test result obtained during routine stability testing.

Recall Number:

Code Information:
Lot # 1220211M, Exp 02/2019

Not Yet Classified Drugs Event

Event ID:
81351

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/18/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Promise Pharmacy LLC
31818 US Highway 19 N
Palm Harbor FL United States

Distribution Pattern:

Associated Products

Product Description:
Prednisolone and Gatifloxacin Ophthalmic Solution, 1%/0.5%, 3 mL vials, Rx Only, 31818 US Hwy 19N, Palm Harbor, FL 34684

Product Quantity:

Reason for Recall:
Presence of Particulate Matter

Recall Number:

Code Information:
Lot#: 04092018@2, Exp 12/03/2018