Enforcement Report - Week of August 15, 2018

Class II Drugs Event

Event ID:
77850

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/25/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
08/09/2018

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
U.S. Nationwide

Associated Products

Product Description:
Dymista (azelastine hydrochloride and fluticasone propionate) Nasal Spray, 137 mcg / 50 mcg per spray, packaged in a 23 g net fill weight, Rx only, Manufactured by: Cipla Ltd., Goa, India, M.L.,, NDC 0037-0245-23

Product Quantity:
20,780 bottles

Reason for Recall:
Presence of foreign substance: Potential for glass in the neck area of the glass bottles.

Recall Number:
D-1075-2018

Code Information:
Lot #: GA70246, GA70254, Exp 02/2019

Class II Drugs Event

Event ID:
80118

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/17/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
08/08/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Guardian Pharmacy Services
7920 Elmbrook Dr Ste 108
Dallas TX United States

Distribution Pattern:
Texas

Associated Products

Product Description:
Morphine Sulfate 1 mg/mL CADD 25 mL . RX only. Packaged in a CADD 25 ml. Compounded Guardian Pharmacy Services, 7920 Elmbrook Dr. St e. 108C Dallas TX 75247

Product Quantity:
20 25-ml CADD

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1051-2018

Code Information:
Lots: 58440:42 Use By: 05/23/2018; 58624:42 Use By: 06/11/2018; 58962:42 Use By: 07/11/2018

Product Description:
Ascorbic Acid 500 mg/mL 100 mL vial. Rx Only. Packaged in a 100 ml vial. Compounded Guardian Pharmacy Services, 7920 Elmbrook Dr. Ste. 108 C Dallas TX 75247

Product Quantity:
4900 100-ml vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1052-2018

Code Information:
Lots: 58495:42 Use By: 05/22/2018; 58703/58733 Use By: 06/10/2018; 58852:42 Use By: 06/22/2018; 59006:42 Use By: 07/10/2018;

Product Description:
Ascorbic Acid 500 mg/mL 500 mL TPN. Rx Only. Packaged in 500 ml bag. Compounded Guardian Pharmacy Services, 7920 Elmbrook Dr. Ste. 108 C Dallas TX 75247

Product Quantity:
5000 500-ml bags

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1053-2018

Code Information:
Lots: 58555:42, 58567:42, 58563:42, 58547:42, 58565:42, Use By: 05/25/2018

Product Description:
B-Complex Rx only. packaged in a) 100 mL bag b) 100 ml MDV vial. Compounded Guardian Pharmacy Services, 7920 Elmbrook Dr. Ste. 108C Dall as TX 75247

Product Quantity:
2600 100 ml bags/vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1054-2018

Code Information:
Lots: a) 58572:42 Use By: 05/29/2018 b) 58768:42 Use By: 06/20/2018;

Product Description:
EDTA Disodium 30 mg/mL PF. Rx Only. Packaged in 1 mL pre filled syringe. Compounded Guardian Pharmacy Services, 7920 Elmbrook Dr. Ste. 10 8C Dallas TX 75247

Product Quantity:
1 1-ml syringe

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1055-2018

Code Information:
Lot: 58897:42 Use By: 07/04/2018

Product Description:
Glutathione 200 mg/mL 100ml. Rx Only. Packaged in 100 mL MDV vials. Compounded Guardian Pharmacy Services, 7920 Elmbrook Dr. Ste. 108C Dallas TX 75247

Product Quantity:
2400 100-ml vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1056-2018

Code Information:
Lots: 58436:42 Use By: 05/22/2018; 58653:42 Use By: 06/12/2018; 58773:42, 58766:42, Use By: 06/21/2018; 58766:42 Use By: 06/20/2018;

Product Description:
Glycopyrrolate 0.2 mg/mL 2ml. Rx Only. Packaged in 2 mL syringes. Compounded Guardian Pharmacy Services, 7920 Elmbrook Dr. Ste. 108C Dallas TX 75247

Product Quantity:
100 2-ml syringes

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1057-2018

Code Information:
Lot: 58811:93 Use By: 06/18/2018

Product Description:
Hyaluronidase 150 units/mL 1ml. Rx Only. Packaged in 1 mL vials. Compounded Guardian Pharmacy Services, 7920 Elmbrook Dr. Ste. 108C Dallas TX 75247

Product Quantity:
2 1-ml vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1058-2018

Code Information:
Lot: 58895:42 Use By: 06/27/2018

Product Description:
Hyaluronidase 150 units/mL 1ml. Rx Only. Packaged in 1 mL syringes. Refridgerate. Compounded Guardian Pharmacy Services, 7920 Elmbrook Dr. Ste. 108C Dallas TX 75247

Product Quantity:
442 1-ml syringes

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1059-2018

Code Information:
Lots: 58895:42 Use By: 06/27/2018; 58856:42 Use By: 06/21/2018;

Product Description:
Magnesium Sulfate 200 mg/mL, 100ml. Rx. Only. Packaged in 100 mL MDV vials. Compounded Guardian Pharmacy Services, 7920 Elmbrook Dr. Ste. 108C Dallas TX 75247

Product Quantity:
1000 100-ml vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1060-2018

Code Information:
Lot: 58212:42 Use By: 06/01/2018

Product Description:
Medroxyprogesterone 150 mg/mL 5ml. Rx Only. Packaged in 5 mL vials. Compounded Guardian Pharmacy Services, 7920 Elmbrook Dr. Ste. 108C Dallas TX 75247

Product Quantity:
60 5-ml vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1061-2018

Code Information:
Lots: 58611:42 Use By: 06/07/2018; 59099:42 Use By: 07/24/2018; 58786:42 Use By: 06/24/2018

Product Description:
Methylene Blue 10 mg/mL 1ml. Packaged in 1 mL syringes. Compounded Guardian Pharmacy Services, 7920 Elmbrook Dr. Ste. 108C Dallas TX 75 247

Product Quantity:
95 1-ml syringes

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1062-2018

Code Information:
Lots: 59185:42 Use By: 07/30/2018; 58471:42 Use By: 05/27/2018; 58745:42 Use By: 06/10/2018;

Product Description:
Fentanyl Citrate 50 mcg/mL 2ml. Rx Only. Packaged in 2 mL syringes. Compounded Guardian Pharmacy Services, 7920 Elmbrook Dr. Ste. 108C D allas TX 75247

Product Quantity:
300 2-ml syringes

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1063-2018

Code Information:
Lots: 58854:42 Use By: 06/28/2018;

Product Description:
Ropivacaine HCl 2 mg/mL 400 mL. Rx Only. Packaged in a ON-Q Pump. Compounded Guardian Pharmacy Services, 7920 Elmbrook Dr. Ste. 108C Dallas TX 75247

Product Quantity:
20 400-ml ON-Q Pump

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1064-2018

Code Information:
Lots: 59088:42 Use By: 05/24/2018; 59159:42 Use By: 05/30/2018

Product Description:
Ropivacaine HCl 2 mg/mL 550 mL. Rx Only. Packaged in a ON-Q Pump. Compounded Guardian Pharmacy Services, 7920 Elmbrook Dr. Ste. 108C Dallas TX 75247

Product Quantity:
25 550-ml ON-Q Pump

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1065-2018

Code Information:
Lots: 59086:42 Use By: 05/24/2018; 59163:42 Use By: 05/30/2018

Product Description:
Ropivacaine HCl 2 mg/mL 750 mL. Rx Only. Packaged in a ON-Q Pump. Compounded Guardian Pharmacy Services, 7920 Elmbrook Dr. Ste. 108C Dallas TX 75247

Product Quantity:
3 750-ml ON-Q Pump

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1066-2018

Code Information:
Lot: 59103:42 Use By: 05/25/2018

Product Description:
Cefazolin 2 Gm/20 mL 20 ml. Rx Only. Packaged in 20 mL syringes. Compounded Guardian Pharmacy Services, 7920 Elmbrook Dr. Ste. 108C Dall as TX 75247

Product Quantity:
60 20-ml syringes

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1067-2018

Code Information:
Lot: 58758; 58760; 58756, 59095:42, 59093:42; 59091:42

Product Description:
Glutathione 200 mg/mL 100 ml. Rx Only. Packaged in 50ml MDV vials. Compounded Guardian Pharmacy Services, 7920 Elmbrook Dr. Ste. 108C D allas TX 75247

Product Quantity:
100 50-ml vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1068-2018

Code Information:
Lot: 58653:42 Use By: 06/12/2018; 58773/58766 Use By: 06/21/2018; 58766:42 Use By: 06/20/2018;

Product Description:
Lidocaine 3% 10 ml. Rx Only. Packaged in 10 mL syringes. Compounded Guardian Pharmacy Services, 7920 Elmbrook Dr. Ste. 108C Dallas TX 75 247

Product Quantity:
250 10-ml syringes

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1069-2018

Code Information:
Lots: 58641:42 Use By: 06/04/2018; 58775:42 Use By: 06/16/2018; 59077:42 Use By: 07/17/2018

Product Description:
Glutathione 200 mg/mL 50 ml MDV. Rx Only. Packaged in 50 mL vials. Compounded Guardian Pharmacy Services, 7920 Elmbrook Dr. Ste. 108C D allas TX 75247

Product Quantity:
100 50-ml vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1070-2018

Code Information:
Lot: 59097:42 Use By: 07/23/2018

Product Description:
Methylcobalamin 1000 mcg/mL 100 mL. RX Only. Packaged in 100ml MDV vials. Compounded Guardian Pharmacy Services, 7920 Elmbrook Dr. St e. 108C Dallas TX 75247

Product Quantity:
2000 100-ml vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1071-2018

Code Information:
Lots: 58409:42, Use By: 05/21/2018; 58899:42, Use By: 07/04/2018; 59215:42 Use By: 08/01/2018

Product Description:
MIC "B" COMBO LIPOTROPIC 50 ml. Packaged in a 50ml MDV vial. Compounded Guardian Pharmacy Services, 7920 Elmbrook Dr. Ste. 108C Dal las TX 75247

Product Quantity:
250 50-ml vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1072-2018

Code Information:
Lots: 58618:42 UB, Use By: 06/10/2018

Product Description:
Phenol 6% with Glycerin Inj 10 ml. Packaged in 10 ml vials. Compounded Guardian Pharmacy Services, 7920 Elmbrook Dr. Ste. 108C Dallas TX 75 247

Product Quantity:
40 10-ml vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-1073-2018

Code Information:
Lots: 58913:42 Use By: 06/05/2018

Class II Drugs Event

Event ID:
80386

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/24/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
08/03/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Morton Grove Pharmaceuticals, Inc.
6451 Main St
Morton Grove IL United States

Distribution Pattern:
U.S. Nationwide

Associated Products

Product Description:
Prednisolone Sodium Phosphate Oral Solution, 15 mg/5 mL, 8 fl oz (237 mL) Bottle, Rx only, Manufactured By: Morton Grove Pharmaceuticals, Inc., Morton Grove, IL 60053, NDC 60432-212-08.

Product Quantity:
38,280 bottles

Reason for Recall:
Defective Container: Tamper Evident foil seal not completely intact.

Recall Number:
D-1042-2018

Code Information:
Lot US1259

Class II Drugs Event

Event ID:
80428

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/06/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
08/03/2018

Initial Firm Notification of Consignee or Public:
Telephone

Recalling Firm:
Pharmalucence, Inc.
29 Dunham Rd
Billerica MA United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Kit for the Preparation of Technetium Tc99m Medronate, 20mg in 10 mL vial, packaged in a) 5-count box (NDC 45567-0040-1), b) 30-count box, NDC 45567-0040-2 , Rx only, Manufactured by: Pharmalucence, Inc., Billerica, MA 01821.

Product Quantity:
95 kits

Reason for Recall:
Lack of assurance of sterility: Technetium TC-99M Medronate Kit has a reported breach of sterility.

Recall Number:
D-1040-2018

Code Information:
Lot 4223

Class II Drugs Event

Event ID:
80550

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/16/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
08/08/2018

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

Associated Products

Product Description:
Omega-3-Acid Ethyl Esters Capsules USP, 1 gram* 120-count bottle Rx Only. Manufactured by: Banner Pharmacaps, Inc. High Point, NC 27265. Manufactured for: Teva Pharmaceuticals USA Inc. North Wales, PA 19454 NDC 0093-5401-89

Product Quantity:
13,715 120-count bottles

Reason for Recall:
API material used in the manufacturing of the product did not receive regulatory approval prior to release.

Recall Number:
D-1074-2018

Code Information:
Lot # 150001420A, EXP 2/2019

Class II Drugs Event

Event ID:
80629

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/01/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
08/07/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Akorn, Inc.

1925 W Field Ct Ste 300
Lake Forest IL United States

Distribution Pattern:
Nationwide within the USA

Associated Products

Product Description:
Lidocaine 2.5% and Prilocaine Cream, 2.5%. 30g tube, Rx only, Manufactured by: Hi-Tech Pharmacal Co., Inc., Amityville, NY 11701, NDC 50383-667-30

Product Quantity:
22,605 tubes

Reason for Recall:
Failed Impurities/Degredation Specifications: Out of Specification results for an unknown impurity was found during routine stability testing at 12 months.

Recall Number:
D-1046-2018

Code Information:
Lot #: 356309, Exp. 3/2019

Class II Drugs Event

Event ID:
80638

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/24/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
08/03/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
PharMEDium Services, LLC
36 Stults Rd
Dayton NJ United States

Distribution Pattern:
Product was distributed throughout the United States

Associated Products

Product Description:
10 mcg/mL Fentanyl Citrate (Preservative Free) in 0.9% Sodium Chloride 250 mL in 250 mL Intravia Bag and 10 mcg/mL Fentanyl Citrate (Preservative Free) in 0.9% Sodium Chloride 100 mL in 150 mL Intravia Bag, PharMEDium Services, LLC.

Product Quantity:
230 Intravia Bags

Reason for Recall:
CGMP deviations: Product was released while a hood certification discrepancy was being investigated.

Recall Number:
D-1043-2018

Code Information:
Lot 181760013D, 181730007D, Exp 08/09/2018, 09/02/2018

Product Description:
5 mg/mL Ephedrine Sulfate (Preservative Free) in 0.9% Sodium Chloride 5 mL in 5 mL BD Syringe Kit Check Tagged, PharMEDium Services, LLC.

Product Quantity:
450 Syringes

Reason for Recall:
CGMP deviations: Product was released while a hood certification discrepancy was being investigated.

Recall Number:
D-1044-2018

Code Information:
Lot 181730039D, Exp 09/20/2018

Product Description:
10 mg/mL Rocuronium Bromide (Preservative Free) 5 mL BD Syringe, PharMEDium Services, LLC.

Product Quantity:
575 Syringes

Reason for Recall:
CGMP deviations: Product was released while a hood certification discrepancy was being investigated.

Recall Number:
D-1045-2018

Code Information:
Lot 181780003D

Class II Drugs Event

Event ID:
80701

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/30/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
08/03/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
NuCare Pharmaceuticals Inc
622 W Katella Ave
Orange CA United States

Distribution Pattern:
Distributed to three customers in Fl and CA

Associated Products

Product Description:
Valsartan/HCTZ 160/12.5 mg Tablets, 90-count jar, Rx Only, Packaged by NuCare Pharmaceuticals, Inc., Orange, CA 92867, NDC 68071-4311-9

Product Quantity:

Reason for Recall:
CGMP Deviations: Carcinogen impurity detected in API used to manufacture drug product.

Recall Number:
D-1037-2018

Code Information:
Lot # U01779; Exp. 04/30/2019

Product Description:
Valsartan/HCTZ 160/25mg Tablets, 30-count jar, Rx Only, Packaged by NuCare Pharmaceuticals, Inc., Orange, CA 92867,

Product Quantity:

Reason for Recall:
CGMP Deviations: Carcinogen impurity detected in API used to manufacture drug product.

Recall Number:
D-1038-2018

Code Information:
Lot # T11443; Exp. 02/28/2019

Product Description:
Valsartan/HCTZ 320/25mg Tablets, 30-count jar, Rx Only, Packaged by NuCare Pharmaceuticals, Inc., Orange, CA 92867, NDC 68071-4183-3

Product Quantity:

Reason for Recall:
CGMP Deviations: Carcinogen impurity detected in API used to manufacture drug product.

Recall Number:
D-1039-2018

Code Information:
Lot # T11577; Exp. 06/30/2019

Class III Drugs Event

Event ID:
80653

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/01/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
08/03/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Baxter Healthcare Corporation
1 Baxter Pkwy
Deerfield IL United States

Distribution Pattern:
Nationwide USA and Puerto Rico

Associated Products

Product Description:
Levofloxacin Injection in 5% Dextrose, 250 mg (5 mg/mL), 250 mg in 50 mL 5% Dextrose, 50 mL Single Use Container bag, Rx only, Manufactured for: Claris Lifesciences Inc., North Brunswick, NJ 08902; By: Claris Injectables Ltd., Gujarat, India, NDC 36000-046-24.

Product Quantity:
191,256 bags

Reason for Recall:
Superpotent Drug: High out of specification results for levofloxacin resulting in increased concentration of solution.

Recall Number:
D-1034-2018

Code Information:
Lot #: A061178, A061183, A061236, Exp 09/18; A0A0937, Exp 08/19; A0A1044, A0A1048, Exp 10/19

Product Description:
Levofloxacin Injection in 5% Dextrose, 500 mg (5 mg/mL), 500 mg in 100 mL 5% Dextrose, 100 mL Single Use Container bag, Rx only, Manufactured for: Claris Lifesciences Inc., North Brunswick, NJ 08902; By: Claris Injectables Ltd., Gujarat, India, NDC 36000-047-24.

Product Quantity:
106,320 bags

Reason for Recall:
Superpotent Drug: High out of specification results for levofloxacin resulting in increased concentration of solution.

Recall Number:
D-1035-2018

Code Information:
Lot#: A0A0954, A0A0958, A0A0970, Exp 09/19

Product Description:
Levofloxacin Injection in 5% Dextrose, 750 mg (5 mg/mL), 750 mg in 150 mL 5% Dextrose, 150 mL Single Use Container bag, Rx only, Manufactured for: Claris Lifesciences Inc., North Brunswick, NJ 08902; By: Claris Injectables Ltd., Gujarat, India, NDC 36000-048-24.

Product Quantity:
711,216 bags

Reason for Recall:
Superpotent Drug: High out of specification results for levofloxacin resulting in increased concentration of solution.

Recall Number:
D-1036-2018

Code Information:
Lot #: A060940, A060948, A060951, A060956, A060958, A060963, Exp 07/18; A061105, A061110, A061113, A061115, A061119, Exp 08/18; A061243, Exp 09/18; A0A0813, Exp 07/19; A0A0899, A0A0904, A0A0907, A0A0914, A0A0916, A0A0921, A0A0925, Exp 08/19; A0A0971, A0A0976, Exp 09/19; A0A0994, A0A0996, A0A0997, A0A0999, A0A1000, A0A1001, A0A1003, A0A1004, Exp 10/19.

Class III Drugs Event

Event ID:
80655

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/26/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
08/07/2018

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Nationwide with the United States

Associated Products

Product Description:
Testosterone 200 mg Pellet, Rx only, Carie Boyd's Prescription Shop 122 Grapevine Hwy., Hurst, TX 76054, 800-930-4361

Product Quantity:
4800 pellets

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date: Incorrect expiration date on label

Recall Number:
D-1047-2018

Code Information:
Lot #: 061918@08, Exp.11/28/2019

Class III Drugs Event

Event ID:
80662

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/10/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
08/03/2018

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:
Nationwide in the USA

Associated Products

Product Description:
Diazepam Rectal Gel, 2.5 mg, TWIN PACK that Contains two pre-filled, unit-dose, rectal delivery systems with lubricating jelly and instructions for use per carton, Rx only, Manufactured for: Oceanside Pharmaceuticals, a division of Valeant Pharmaceuticals North America LLC, Bridgewater, NJ 08807; Manufactured by: DPT Laboratories, Ltd., San Antonio, TX 78215; NDC 68682-650-20.

Product Quantity:
306 cartons

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date: Product distributed without a lot number or expiration date on the outer carton.

Recall Number:
D-1041-2018

Code Information:
Lot #: NBBN, Exp 02/22

Not Yet Classified Drugs Event

Event ID:
80365

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/26/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:

Recalling Firm:
World Organix, LLC
6149 S. Rainbow Blvd #5
Las Vegas NV United States

Distribution Pattern:
Nationwide in the USA.

Associated Products

Product Description:
Red Maeng Da, 100% Mitragyna Speciosa, 50 capsule White Foil Pouches, Dist. by World Organix LLC, Las Vegas, Nevada UPC#7 22589 32355 3

Product Quantity:
789 50-count pouches, total of 39,450 capsules

Reason for Recall:
Microbial Contamination of Non-Sterile Products: The firm is initiating a recall of some of its products due to the potential of high microbial loads.

Recall Number:

Code Information:
Lot Code: 102710. Best by date: 03/2019

Product Description:
Blissful Remedies, 4 Hour Chill, Slow Motion Blend, Herbal Shot. 1.93 Fluid Oz (57ml) UPC#6 02401 88900 3.

Product Quantity:
164 2oz bottles

Reason for Recall:
Microbial Contamination of Non-Sterile Products: The firm is initiating a recall of some of its products due to the potential of high microbial loads.

Recall Number:

Code Information:
Lot Code: 22. Best by date: 06/2019

Product Description:
Red Maeng Da Liquid Kratom Mitragyna Speciosa, 12mL. Distributed by World Organix LLC Las Vegas Nevada. UPC#7 14983 56525 7

Product Quantity:
681 12 mL-bottle

Reason for Recall:
Microbial Contamination of Non-Sterile Products: The firm is initiating a recall of some of its products due to the potential of high microbial loads.

Recall Number:

Code Information:
Lot Code: 2001. Best by date: 03/2019