Enforcement Report - Week of July 18, 2018

Class II Drugs Event

Event ID:
80309

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/03/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
07/11/2018

Initial Firm Notification of Consignee or Public:

Recalling Firm:
Medgyn Products, Inc.
100 W Industrial Rd
Addison IL United States

Distribution Pattern:
Nationwide in the USA, Barbados, Cayman Islands, Chile, Cyprus, Ecuador, El Salvador, Guatemala, Hong Kong, Kuwait, Lebanon, Malaysia, Maldives, Mexico, Mongolia, Montenegro, Mozambique, Pakistan, Paraguay, Peru, Republic of Georgia, Serbia, South Africa, Tanzania, United Arab Emirates, Venezuela, and Vietnam.

Associated Products

Product Description:
Monsel's Solution (Ferric Subsulfate), 20%, packaged as 12 single application vials and 12 applicators, 8 mL per box, Manufactured For: MedGyn Products, Inc., 100 W. Industrial Rd., Addison, IL 60101 USA; Manufactured By: BioDiagnostics Intl, 555 West Lambert Road Unit-C, Brea, CA 92821, NDC 42721-112-08.

Product Quantity:
2750 boxes

Reason for Recall:
CGMP Deviations: The manufacturer of this product recalled because they were not manufactured under current good manufacturing practices.

Recall Number:
D-0917-2018

Code Information:
Lot #s: all lots within expiry

Class II Drugs Event

Event ID:
80310

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/22/2018

Voluntary / Mandated:
Voluntary: FDA Requested

Center Classification Date:
07/09/2018

Initial Firm Notification of Consignee or Public:

Recalling Firm:
Akorn, Inc.
1222 W Grand Ave
Decatur IL United States

Distribution Pattern:
U.S. Nationwide

Associated Products

Product Description:
Acetylcysteine for Injection 6 g/30 mL (200 mg/mL). Rx Only. Manufactured by Akron Inc., Lake Forest, IL 60045. NDC 17478-660-30.

Product Quantity:
89,507 vials

Reason for Recall:
CGMP Deviations

Recall Number:
D-0916-2018

Code Information:
Lots: 061496A, Exp. 06/2018; 111696A, Exp. 11/2018; 061947A, Exp. 06/2019; 091267A, Exp. 09/2019

Class II Drugs Event

Event ID:
80387

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/05/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
07/16/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Sanofi-Aventis U.S. LLC
55 Corporate Dr
Bridgewater NJ United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Admelog Solostar (insulin lispro injection), 100 units/ mL (U-100) injection, packaged in 3mL prefilled pens, 1 pen per box, Rx only, Physician Sample - Not For Sale, Sanofi-Aventis U.S. LLC, Bridgewater, NJ 08807, NDC 0024-5925-00

Product Quantity:
3214 prefilled pens

Reason for Recall:
Temperature Abuse: Product samples of Admelog may not have been shipped at proper temperature.

Recall Number:
D-0925-2018

Code Information:
Lot #: 7F021B, Exp 6/30/20

Class II Drugs Event

Event ID:
80425

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/29/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
07/12/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
SCA Pharmaceuticals
8821 Knoedl Ct
Little Rock AR United States

Distribution Pattern:
United States

Associated Products

Product Description:
Buffered Lidocaine 1% with Sodium Bicarbonate Injection for Local Anesthetic Use (Concentration=10 mg/mL) 0.25 mL Total Volume, Rx only , SCA Pharmaceuticals, 8821 Knoedl Ct. Little Rock, AR 72205 877-550-5059

Product Quantity:
3984 syringes

Reason for Recall:
Subpotent Drug: Stability data does not support the current expiration dating of 55 days after compounding.

Recall Number:
D-0918-2018

Code Information:
Lot #: 20180507@21, Exp 7/1/2018; 20180511@9, 20180511@24, Exp 7/5/2018; 20180518@24, 20180518@31, 20180518@32, Exp 7/12/2018; 20180531@21, Exp 7/25/2018; 20180601@11, Exp 7/26/2018

Class II Drugs Event

Event ID:
80437

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/05/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
07/06/2018

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Nationwide in the USA and Puerto Rico

Associated Products

Product Description:
Fluocinolone Acetonide Topical Solution, USP, 0.01%, 60 mL bottle, Rx Only, Manufactured by: Actavis Laboratories UT, Inc., Salt Lake City, UT 84108 USA; Distributed by: Actavis Pharmac, Inc., Parsippany, NJ 07054 USA, NDC 0591-2990-60.

Product Quantity:
27,803 bottles

Reason for Recall:
Failed Impurities and Degradation Specifications and Subpotent Drug: out-of-specification (OOS) test results for below assay and above specification for degradants.

Recall Number:
D-0909-2018

Code Information:
Lot #s: 1164898, EXP 10/18; 1164904, 1164909, EXP 11/18; 1211396, EXP 07/19; 1230808, 1231127, EXP 01/20

Class II Drugs Event

Event ID:
80453

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/03/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
07/12/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Medi-Fare Drug and Home Health Center
300 W Pine St
Blacksburg SC United States

Distribution Pattern:
Texas only

Associated Products

Product Description:
Potassium Chloride For Injection Concentrate syringe 40 mEq/20 mL (2 mEq/mL), Rx only, Medi-Fare Drug Pharmaceutical Compounding 300 West Pine St., Blacksburg, SC 29702 800-622-0007

Product Quantity:
1116 syringes

Reason for Recall:
CGMP Deviations: Syringes were filled with 19mL of potassium chloride when the labels displayed a fill of 20mL.

Recall Number:
D-0919-2018

Code Information:
Lot: 20180522@1 Exp.: 08/20/18

Class III Drugs Event

Event ID:
80389

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/25/2018

Voluntary / Mandated:
Voluntary: FDA Requested

Center Classification Date:
07/09/2018

Initial Firm Notification of Consignee or Public:

Recalling Firm:
AMERICAN HEALTH PACKAGING
2550 John Glenn Ave Ste A
Columbus OH United States

Distribution Pattern:
Lot#166023 products distributed from 12/29/16 to 1/19/17 and Lot#168467 distributed from 4/6/17 to 9/11/17. Distributors are the wholesalers who re ceived the product; others are the Corporate Offices for those wholesalers.

Associated Products

Product Description:
Enalapril Maleate Tablets USP, 5 mg, 100 Tablets (10X10) blister cards, 12 cartons in a shipper, Rx, Packaged and Distributed by: American Health

Packaging, Columbus, OH --- NDC 68084-390-01 Carton [68084-390-11 - Unit Dose]

Product Quantity:
1285 cartons (cartons of 100 individual unit doses)

Reason for Recall:
Failed Impurities/Degradation Specification; out-of-specification results for the Enalapril DKT degradant

Recall Number:
D-0915-2018

Code Information:
Lot# 166023 - Exp. 11/30/18 (232 units). Lot# 168467 - Exp. 2/28/19 (1053 units).

Not Yet Classified Drugs Event

Event ID:
80343

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/20/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Gaia Ethnobotanical LLC
2752 Botticelli Dr
Henderson NV United States

Distribution Pattern:
Nationwide.

Associated Products

Product Description:
Gaia Kratom (mitragyna speciosa) powder, Bali Gold, 1oz, 250g 1kg packages, Gaia Ethnobotanical.com

Product Quantity:
unknown

Reason for Recall:
Microbal Contamination of Non-Sterile Product; FDA analysis found salmonella contamination

Recall Number:

Code Information:
Lot # 0102031800

Product Description:
Gaia Kratom (mitragyna speciosa) powder, Elephant, 1oz, 250g, 1kg packages, Gaia Ethnobotanical.com

Product Quantity:
unknown

Reason for Recall:
Microbal Contamination of Non-Sterile Product; FDA analysis found salmonella contamination

Recall Number:

Code Information:
Lot # 0102031800

Product Description:
Gaia Kratom (mitragyna speciosa) powder, Ganesh, 1oz, 250g, 1kg packages, Gaia Ethnobotanical.com

Product Quantity:
unknown

Reason for Recall:
Microbal Contamination of Non-Sterile Product; FDA analysis found salmonella contamination

Recall Number:

Code Information:
Lot # 0102031800

Product Description:
Gaia Kratom (mitragyna speciosa) powder, Green Dragon, 1oz, 250g, 1kg packages, Gaia Ethnobotanical.com

Product Quantity:
unknown

Reason for Recall:
Microbal Contamination of Non-Sterile Product; FDA analysis found salmonella contamination

Recall Number:

Code Information:
Lot # 0102031800

Product Description:
Gaia Kratom (mitragyna speciosa) powder, Green Horn, 1oz, 250g, 1kg packages, Gaia Ethnobotanical.com

Product Quantity:
unknown

Reason for Recall:
Microbal Contamination of Non-Sterile Product; FDA analysis found salmonella contamination

Recall Number:

Code Information:
Lot # 0102031800

Product Description:
Gaia Kratom (mitragyna speciosa) powder, Green Kapuas Hulu, 1oz, 250g, 1kg packages, Gaia Ethnobotanical.com

Product Quantity:
unknown

Reason for Recall:
Microbal Contamination of Non-Sterile Product; FDA analysis found salmonella contamination

Recall Number:

Code Information:
Lot # 0102031800

Product Description:
Gaia Kratom (mitragyna speciosa) powder, Green Malay, 1oz, 250g, 1kg packages, Gaia Ethnobotanical.com

Product Quantity:
unknown

Reason for Recall:
Microbal Contamination of Non-Sterile Product; FDA analysis found salmonella contamination

Recall Number:

Code Information:
Lot # 0102031800, exp

Product Description:
Gaia Kratom (mitragyna speciosa) powder, Green MD, 1oz, 250g, 1kg packages, Gaia Ethnobotanical.com

Product Quantity:

Reason for Recall:
Microbal Contamination of Non-Sterile Product; FDA analysis found salmonella contamination

Recall Number:

Code Information:
Lot # 0102031800, exp

Product Description:
Gaia Kratom (mitragyna speciosa) powder, Green Thai, 1oz, 250g, 1kg packages, Gaia Ethnobotanical.com

Product Quantity:
unknown

Reason for Recall:
Microbal Contamination of Non-Sterile Product; FDA analysis found salmonella contamination

Recall Number:

Code Information:
Lot # 0102031800

Product Description:
Gaia Kratom (mitragyna speciosa) powder, Plantation Red MD, 1oz, 250g, 1kg packages, Gaia Ethnobotanical.com

Product Quantity:
unknown

Reason for Recall:
Microbal Contamination of Non-Sterile Product; FDA analysis found salmonella contamination

Recall Number:

Code Information:
Lot # 0102031800

Product Description:
Gaia Kratom (mitragyna speciosa) powder, Plantation White MD, 1oz, 250g, 1kg packages, Gaia Ethnobotanical.com

Product Quantity:

Reason for Recall:
Microbal Contamination of Non-Sterile Product; FDA analysis found salmonella contamination

Recall Number:

Code Information:
Lot # 0102031800

Product Description:
Gaia Kratom (mitragyna speciosa) powder, Purple 8-1, 1oz, 250g, 1kg packages, Gaia Ethnobotanical.com

Product Quantity:
unknown

Reason for Recall:
Microbal Contamination of Non-Sterile Product; FDA analysis found salmonella contamination

Recall Number:

Code Information:
Lot # 0102031800

Product Description:
Gaia Kratom (mitragyna speciosa) powder, Red Bali, 1oz, 250g, 1kg packages, Gaia Ethnobotanical.com Gaia Ethnobotanical Red Borneo, 1oz, 250g, kg Gaia Ethnobotanical Red Dragon, 1oz, 250g, 1kg Gaia Ethnobotanical Red Horn, 1oz, 250g, 1kg Gaia Ethnobotanical Red Kapuas Hulu 1oz, 250g, 1kg Gaia Ethnobotanical Red MD, 1oz, 250g, 1kg Gaia Ethnobotanical Red Thai, 1oz, 250g,. 1kg Gaia Ethnobotanical Super Green Malay 1oz, 250g, 1kg Gaia Ethnobotanical White Borneo 1oz, 250g, 1kg Gaia Ethnobotanical White Horn, 1 oz, 250g, 1kg Gaia Ethnobotanical White MD, 1 oz, 250 g, 1 kg Gaia Ethnobotanical White Thai, 1oz, 250 g, 1 kg Gaia Ethnobotanical Yellow Thai, 1oz, 250 g, 1kg Gaia Ethnobotanical Yellow Vietnam 1oz, 250g, 1kg

Product Quantity:
unknown

Reason for Recall:
Microbal Contamination of Non-Sterile Product; FDA analysis found salmonella contamination

Recall Number:

Code Information:
Lot # 0102031800

Product Description:
Gaia Kratom (mitragyna speciosa) powder, Red Borneo, 1oz, 250g, 1kg packages, Gaia Ethnobotanical.com

Product Quantity:
unknown

Reason for Recall:
Microbal Contamination of Non-Sterile Product; FDA analysis found salmonella contamination

Recall Number:

Code Information:
Lot # 0102031800

Product Description:
Gaia Kratom (mitragyna speciosa) powder, Red Dragon, 1oz, 250g, 1kg packages, Gaia Ethnobotanical.com

Product Quantity:
unknown

Reason for Recall:
Microbal Contamination of Non-Sterile Product; FDA analysis found salmonella contamination

Recall Number:

Code Information:
Lot # 0102031800

Product Description:
Gaia Kratom (mitragyna speciosa) powder, Red Horn, 1oz, 250g, 1kg packages, Gaia Ethnobotanical.com

Product Quantity:
unknown

Reason for Recall:
Microbal Contamination of Non-Sterile Product; FDA analysis found salmonella contamination

Recall Number:

Code Information:
Lot # 0102031800

Product Description:
Gaia Kratom (mitragyna speciosa) powder, Red Kapuas Hulu , 1oz, 250g, 1kg packages, Gaia Ethnobotanical.com

Product Quantity:
unknown

Reason for Recall:
Microbal Contamination of Non-Sterile Product; FDA analysis found salmonella contamination

Recall Number:

Code Information:
Lot # 0102031800

Product Description:
Gaia Kratom (mitragyna speciosa) powder, Red MD, 1oz, 250g, 1kg packages, Gaia Ethnobotanical.com

Product Quantity:
unknown

Reason for Recall:
Microbal Contamination of Non-Sterile Product; FDA analysis found salmonella contamination

Recall Number:

Code Information:
Lot # 0102031800

Product Description:
Gaia Kratom (mitragyna speciosa) powder, White Borneo, 1oz, 250g, 1kg packages, Gaia Ethnobotanical.com

Product Quantity:
unknown

Reason for Recall:
Microbal Contamination of Non-Sterile Product; FDA analysis found salmonella contamination

Recall Number:

Code Information:
Lot # 0102031800

Product Description:
Gaia Kratom (mitragyna speciosa) powder, White Horn, 1oz, 250g, 1kg packages, Gaia Ethnobotanical.com

Product Quantity:
unknown

Reason for Recall:
Microbal Contamination of Non-Sterile Product; FDA analysis found salmonella contamination

Recall Number:

Code Information:
Lot # 0102031800

Product Description:
Gaia Kratom (mitragyna speciosa) powder, White MD, 1oz, 250g, 1kg packages, Gaia Ethnobotanical.com

Product Quantity:
unknown

Reason for Recall:
Microbal Contamination of Non-Sterile Product; FDA analysis found salmonella contamination

Recall Number:

Code Information:
Lot # 0102031800

Product Description:
Gaia Kratom (mitragyna speciosa) powder, White Thai, 1oz, 250g, 1kg packages, Gaia Ethnobotanical.com

Product Quantity:
unknown

Reason for Recall:
Microbal Contamination of Non-Sterile Product; FDA analysis found salmonella contamination

Recall Number:

Code Information:
Lot # 0102031800

Product Description:
Gaia Kratom (mitragyna speciosa) powder, Yellow Thai, 1oz, 250g, 1kg packages, Gaia Ethnobotanical.com

Product Quantity:
unknown

Reason for Recall:
Microbal Contamination of Non-Sterile Product; FDA analysis found salmonella contamination

Recall Number:

Code Information:
Lot # 0102031800

Product Description:
Gaia Kratom (mitragyna speciosa) powder, Yellow Vietnam, 1oz, 250g, 1kg packages, Gaia Ethnobotanical.com

Product Quantity:
unknown

Reason for Recall:
Microbal Contamination of Non-Sterile Product; FDA analysis found salmonella contamination

Recall Number:

Code Information:
Lot # 0102031800

Not Yet Classified Drugs Event

Event ID:
80377

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/28/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
nationwide within the US

Associated Products

Product Description:
Nitrofurantoin Oral Suspension USP, 25mg/5mL, 230 mL Bottle, Rx Only, Manufactured by: Novel Laboratories, Inc. Somerset, NJ 08873, Manufactured for: Lupin Pharmaceuticals, Inc. Baltimore, MD 21202, UPC 343386-450-114, NDC 43386-450-11

Product Quantity:
3456 cartons

Reason for Recall:
Subpotent Drug

Recall Number:

Code Information:
Lot#: S700065, Exp. 02/2019; 700619, Exp. 08/2019

Not Yet Classified Drugs Event

Event ID:
80390

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/02/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
AuroMedics Pharma LLC
279 Princeton Hightstown Rd
East Windsor NJ United States

Distribution Pattern:
Nationwide US

Associated Products

Product Description:
Auromedics Piperacillin and Tazobactam for Injection 3.375 grams per vial For Intravenous Use Only Single-Dose Vial Rx Only Manufactured for: Auromedics Pharma LLC 6 Wheeling Road Dayton NJ 08810 Made in India NDC 55150-120-30 UPC 355150120307

Product Quantity:
73620 single-dose vials

Reason for Recall:
Presence of Particulate Matter

Recall Number:

Code Information:
PP0317059-A; Expiry February 2019 PP0317012-A; Expiry August 2019

Not Yet Classified Drugs Event

Event ID:
80454

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/09/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Nationwide.

Associated Products

Product Description:
Triamterene and Hydrochlorothiazide Tablets, USP 37.5 mg/25 mg 100-count bottle, Rx only, Mylan Pharmaceuticals, Inc. Morgantown, WV 26505, NDC 0378-1352-01

Product Quantity:
28,436 bottles

Reason for Recall:
Out of specification for stability.

Recall Number:

Code Information:
Lot: 2007979 Exp. Nov. 2020