Enforcement Report - Week of January 24, 2018

Class II Drugs Event

Event ID:
77960

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/16/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
01/17/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Pharmatech LLC
4131 SW 47th Ave Ste 1403
Davie FL United States

Distribution Pattern:
MI

Associated Products

Product Description:
Rugby Diocto Liquid, Docusate Sodium 50 mg/ 5 mL, Stool Softener Laxative, One Pint (473 mL) plastic bottles, Dist. by: Rugby Laboratories, 17177 N. Laurel Park Dr., Suite 233, Livonia, MI 48152 --- NDC: 0536-0590-85, Manufactured by PharmaTech LLC, Davie, FL

Product Quantity:
Unknown

Reason for Recall:
Microbial Contamination of Non Sterile Product; presence of yeast and potential B. cepacia contamination

Recall Number:
D-0224-2018

Code Information:
All lots remaining within expiry.

Product Description:
Rugby Diocto Syrup, Docusate Sodium 60 mg/15 mL, Stool Softener Laxative, One Pint (473 mL) plastic bottles, Dist. by: Rugby Laboratories, 17177 N. Laurel Park Drive, Suite 233, Livonia, MI 48152. NDC: 0536-1001-85, Manufactured by PharmaTech LLC, Davie, FL

Product Quantity:
Unknown

Reason for Recall:
Microbial Contamination of Non Sterile Product; presence of yeast and potential B. cepacia contamination

Recall Number:
D-0225-2018

Code Information:
All lots remaining within expiry.

Product Description:
Rugby Senexon Liquid Natural Vegetable Stimulant,(Sennosides) 8.8 mg, 8 fl oz (237 mL) plastic bottles, Distributed by: Rugby Laboratories, 17177 N Laurel Park Drive, Suite 233, Livonia, MI 48152 --- NDC 0536-1000-59 ; ALSO LABELED AS Major Senna Syrup Natural Vegetable Laxative, Sennoside 8.8 mg, 8 fl. oz. (237 mL) plastic bottles, Dist. by: Major Pharmaceuticals, 17177 N Laurel Park Drive, Suite 233, Livonia, MI 48152 USA. NDC: 00904-6289-09; Manufactured by PharmaTech LLC, Davie, FL

Product Quantity:
Unknown

Reason for Recall:
Microbial Contamination of Non Sterile Product; presence of yeast and potential B. cepacia contamination

Recall Number:
D-0226-2018

Code Information:
All lots remaining within expiry.

Product Description:
Rugby Aller-chlor (Chlorpheniramine Maleate Syrup, USP), 2 mg, 4 fl. oz. (120 mL) plastic bottles, Distributed by: Rugby Laboratories 17177 N. Laurel Park Drive, Suite 233, Livonia, MI 48152 USA --- NDC: 0536-1025-47, Manufactured by PharmaTech LLC, Davie FL

Product Quantity:
Unknown

Reason for Recall:
Microbial Contamination of Non Sterile Product; presence of yeast and potential B. cepacia contamination

Recall Number:
D-0227-2018

Code Information:
All lots remaining within expiry.

Class II Drugs Event

Event ID:
78683

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/30/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
01/12/2018

Initial Firm Notification of Consignee or Public:
Telephone

Recalling Firm:
Pharmedium Services, LLC
150 N Field Dr Ste 350
Lake Forest IL United States

Distribution Pattern:
Nationwide within the US

Associated Products

Product Description:
ePHEDrine Sulfate In 0.9% Sodium Chloride, 5 mg per mL (50 mg per 10 mL), 10 mL Total Volume pre-filled syringes, packaged in a) 5-count cartons, NDC 71030-0003-10 and NDC 71030-0003-20, and b) 25-count cartons, NDC 71030-0003-21 and NDC 71030-0003-12, Rx Only, PharMEDium Services, LLC, 913 N. Davis Ave, Cleveland, MS, Code 2R3304.

Product Quantity:
5002 syringes

Reason for Recall:
Subpotent Drug

Recall Number:
D-0220-2018

Code Information:
Lot #: 172950036M, Exp. 1/21/2018; 172940003M, Exp. 1/20/2018; 172880044M, Exp. 1/14/2018; 172840176M, Exp. 1/11/2018; 172920115M, Exp. 1/18/2018; 172840015D, Exp. 1/10/2018; 172930139M, Exp. 1/19/2018.

Class II Drugs Event

Event ID:
78695

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/26/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
01/12/2018

Initial Firm Notification of Consignee or Public:
Telephone

Recalling Firm:
Pharmedium Services, LLC
150 N Field Dr Ste 350
Lake Forest IL United States

Distribution Pattern:
Nationwide within the US

Associated Products

Product Description:
Phenylephrine HCL 100 mcg per mL (1 mg/10 mL) in 0.9% Sodium Chloride 10 mL syringes, PharMEDium Services, LLC 913 N Davis Ave Cleveland, MS, NDC 71019-263-20

Product Quantity:
2390 syringes

Reason for Recall:
Superpotent Drug

Recall Number:
D-0221-2018

Code Information:
Lot #: 172560019M, Exp. 12/13/2017

Class II Drugs Event

Event ID:
78786

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/19/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
01/17/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Unichem Pharmaceuticals Usa Inc
777 Terrace Ave Suite 102
Hasbrouck Heights NJ United States

Distribution Pattern:
Product was distributed nationwide in the USA.

Associated Products

Product Description:
Divalproex Sodium Delayed Release Tablets USP, 500 mg, 100-count bottle, RX Only, Manufactured by: Unichem Laboratories Ltd. Ind. Area, Meerut Road, Ghaziabad-201 003, India. Marketed By: Unichem Pharmaceuticals (USA), Inc. Hasbrouck Heights, NJ 07604. NDC 29300-140-01

Product Quantity:
96,876 Bottles of 30's

Reason for Recall:
Cross Contamination With Other Products: metronidazole powder was found in one bottle of Divalproex Sodium.

Recall Number:
D-0228-2018

Code Information:
Lot: ZDPH17040

Class II Drugs Event

Event ID:
78791

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/14/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
01/12/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
SHISEIDO AMERICA INC.
366 Princeton Hightstown Rd
East Windsor NJ United States

Distribution Pattern:
Product was distributed nationwide.

Associated Products

Product Description:
bareMinerals Broad Spectrum SPF 50 Daily Prep Lotion (zinc oxide 23.8%, titanium dioxide 4.1%), 40 mL/1.35 fl. oz. bottle, Dist. by Bare Escentuals Beauty, Inc. SF, CA 94105 USA, NDC 98132-761-01

Product Quantity:
248,661 bottle and /tubes

Reason for Recall:
GMP Deviations: manufacturing of API material did not meet GMP and quality requirements.

Recall Number:
D-0214-2018

Code Information:
SKU#: BE8047201

Product Description:
Shiseido Future Solution LX Universal Defense SPF 50+ (octinoxate 4.9%, octocrylebe 3.0%, oxybenzone 1.0% and zinc oxide 15.4%), packaged in a) 2mL, b) 15 mL and c) 50 mL tubes, Shiseido Americas Corporation Dist. New York, NY 10022. NDC 58411-256-60

Product Quantity:

Reason for Recall:
GMP Deviations: manufacturing of API material did not meet GMP and quality requirements.

Recall Number:
D-0215-2018

Code Information:
SKU#: a) 8C52541, b) 8B41841, c) 1155840, 1155841, 1155842, 1155851, 0710341, 0710342

Product Description:
Shiseido Future Solution LX Discovery Set contains SPF 50+ (octinoxate 4.9%, octocrylebe 3.0%, oxybenzone 1.0% and zinc oxide 15.4%), packaged in 15 mL tubes, Shiseido Americas Corporation Dist. New York, NY 10022,

Product Quantity:

Reason for Recall:
GMP Deviations: manufacturing of API material did not meet GMP and quality requirements.

Recall Number:
D-0216-2018

Code Information:
SKU#: 95167

Product Description:
Shiseido Future Solution LX Luxurious Eye & Lip Collection contains SPF 50+ (octinoxate 4.9%, octocrylebe 3.0%, oxybenzone 1.0% and zinc oxide 15.4%), packaged in 15 mL tubes, Shiseido Americas Corporation Dist. New York, NY 10022

Product Quantity:

Reason for Recall:
GMP Deviations: manufacturing of API material did not meet GMP and quality requirements.

Recall Number:
D-0217-2018

Code Information:
SKU#: 95393

Product Description:
Shiseido Future Solutions LX Triple Points Bonus contains SPF 50+ (octinoxate 4.9%, octocrylebe 3.0%, oxybenzone 1.0% and zinc oxide 15.4%), packaged in 15 mL tubes, Shiseido Americas Corporation Dist. New York, NY 10022, NDC 58411-256-60

Product Quantity:

Reason for Recall:
GMP Deviations: manufacturing of API material did not meet GMP and quality requirements.

Recall Number:
D-0218-2018

Code Information:
SKU#: 95284

Class II Drugs Event

Event ID:
78867

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/03/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
01/12/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
AVKARE Inc.
615 N 1st St
Pulaski TN United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Lovastatin Tablets USP, 40 mg, 50 Tablets (5x10) Unit Dose carton, Rx only, Manufactured for AvKARE, Inc. Pulaski, TN 38478, NDC 50268-512-

Product Quantity:
237 cartons

15.

Reason for Recall:
Failed Dissolution Specifications: Low out of specification results for dissolution during annual stability testing.

Recall Number:
D-0222-2018

Code Information:
Lot: 15270, Exp. 01/18

Class III Drugs Event

Event ID:
78821

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/22/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
01/16/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Hetero Labs, Ltd. - Unit III
Plot 22-110, Part Ii, Ida Rangareddy, Jeedimetla
Hyderabad India

Distribution Pattern:
U.S.A. nationwide

Associated Products

Product Description:
Simvastatin Tablets, USP, 40 mg, 1000-count bottle, Rx only, Manufactured for: Camber Pharmaceuticals, Inc., Piscataway, NJ 08854, Manufactured by: Hetero (trademark), Hetero Labs Limited, Jeedimetla, Hyderabad - 500 055, India, NDC 31722-513-10

Product Quantity:

Reason for Recall:
Presence of foreign substance: metallic razor blade was found in one bottle.

Recall Number:
D-0223-2018

Code Information:
Lot #: E171280, Exp 06/19

Class III Drugs Event

Event ID:
78851

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/24/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
01/12/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Shionogi Inc.
5770 Shiloh Rd
Alpharetta GA United States

Distribution Pattern:
U.S.A. Nationwide

Associated Products

Product Description:
Mefenamic Acid Capsules, USP, 250 mg, 30-count bottle, Rx only, Distributed by Prasco Laboratories, Mason, OH 45040, Manufactured by Halo Pharmaceutical Inc., Whippany, NJ 07981, NDC 66993-070-30

Product Quantity:
968 bottles

Reason for Recall:
Presence of foreign substance: The recall was initiated due to black particles being observed while performing routine post-release stability testing on Mefenamic acid capsules

Recall Number:
D-0219-2018

Code Information:
Lot#: 7H66200103G, Exp 12/19

Not Yet Classified Drugs Event

Event ID:
78928

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/11/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Premier Pharmacy Labs Inc
8265 Commercial Way
Weeki Wachee FL United States

Distribution Pattern:
Nationwide.

Associated Products

Product Description:
Mitomycin 40 mg/mL Preservative Free Irrigation Volume: 10 mL SDV , Compounded by: Premier Pharmacy Labs 8265 Commercial Way, Weeki Wachee, FL 34613, NDC: 69623-160-35.

Product Quantity:
Unknown

Reason for Recall:
Labeling: Not Elsewhere Classified: Mitomycin 40 mg/10 mL labeled incorrectly as Mitomycin 40 mg/mL.

Recall Number:

Code Information:
Lot: MIT100217SVDS BUD: 03/01/2018