Enforcement Report - Week of May 23, 2018

Class II Drugs Event

Event ID:
79802

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/10/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
05/15/2018

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
US Nationwide

Associated Products

Product Description:
Kit for the Preparation of Technetium TC-99M Mebrofenin, 45 mg in 10 mL (5 count), NDC 45567-0455-1 and (30 count), NDC 45567-0455-2 . Manufactured by: Pharmalucence, Inc., Billerica, MA 01821.

Product Quantity:
157 units (5 count) and 464 units (30 count)

Reason for Recall:
Failed Stability Specifications

Recall Number:
D-0815-2018

Code Information:
Part Number MEM05 and MEB30 both with expiry date 12/2018

Class II Drugs Event

Event ID:
79909

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/19/2018

Voluntary / Mandated:
Voluntary: FDA Requested

Center Classification Date:
05/11/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Sun Pharmaceutical Industries, Inc.
270 Prospect Plains Rd
Cranbury NJ United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Sulfamethoxazole and Trimethoprim Tablets USP, 800 mg/160 mg, Rx Only, 500-count bottle, Mfg. by: Frontida BioPharm, Inc., 1100 Orthodox St., Philadelphia, PA 19124, Dist, by: Sun Pharmaceutical Industries, Inc., Cranbury, NJ 08512. NDC 53489-146-05

Product Quantity:
1,908 500-count bottles

Reason for Recall:
Presence of Foreign Substance:Sun Pharma is recalling one (1) lot of Sulfamethoxazole and Trimethoprim Tablets USP, 800 mg/160 mg (500 ct.) because a foreign matter identified as polyethylene was detected in two (2) tablets.

Recall Number:
D-0802-2018

Code Information:
Lot 6848501, EXP 04/2020

Class II Drugs Event

Event ID:
79957

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/24/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
05/17/2018

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 United States

Associated Products

Product Description:
Amlodipine and Benazapril HCL Capsules, USP, 5 mg/10 mg, 100 count bottles, Mylan Pharmaceuticals, Inc., Morgantown, WV --- NDC 0378-6896-01

Product Quantity:
25,488 bottles

Reason for Recall:
cGMP Deviations; cleaning process for equipment used to manufacture the specified batches was not followed according to procedure

Recall Number:
D-0819-2018

Code Information:
Lot Numbers# 3083005, 3083006, 3086121, and 3086122, exp Jan 2019

Product Description:
Amlodipine and Benazapril HCL Capsules, USP, 5 mg/40 mg, 100 count bottles, Mylan Pharmaceuticals, Inc., Morgantown, WV --- NDC 0378-6899-01

Product Quantity:
12,924 bottles

Reason for Recall:
cGMP Deviations; cleaning processes for equipment used to manufacture the specified batches was not followed according to procedure

Recall Number:
D-0820-2018

Code Information:
Lot Numbers# 3083008 and 3086124, exp Jan 2019

Class II Drugs Event

Event ID:
79961

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/24/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
05/14/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Prescript Pharmaceuticals, Inc.
39 California Ave Ste 104
Pleasanton CA United States

Distribution Pattern:
California.

Associated Products

Product Description:
Clindamycin 150 mg capsules, USP, 30-count M-Pak container. Mnfct by: Lannett Co. Inc., Philadelphia, PA. Mnfct for: Lannett Co. Inc., Philadelphia, PA. Pckgd by PreScript Pharm. Inc. Pleasanton, CA 94566. NC 00527-1382-01, Bar Code 0639-30-176

Product Quantity:
50 30-count containers

Reason for Recall:
Labeling: Not Elsewhere Classified: due to a labeled declaration of; Store at 15¿C to 30¿C (59¿F to 86¿F) which differs from the original manufacturer declaration of; Store at 20¿C to 25¿C (68¿F to 77¿F).

Recall Number:
D-0805-2018

Code Information:
Lot # 0130126

Product Description:
Acetaminophen 300 mg with Codeine Phosphate 30 mg tablets, USP, 20-count M-Pak containers, Rx Only. Mnfct for: Aurobindo Pharma USA, Inc., Dayton, NJ 08810. Mnfct by: Aurolife Pharma LLC, Dayton, NJ 08810. Pckgd by PreScript Pharm Inc. Pleasanton, CA 94566. NDC: 13107-059-99 Bar Code 0078-20-2033

Product Quantity:
1 20-count containers

Reason for Recall:
Labeling: Not Elsewhere Classified: due to a labeled declaration of; Store at 15¿C to 30¿C (59¿F to 86¿F) which differs from the original manufacturer declaration of; Store at 20¿C to 25¿C (68¿F to 77¿F).

Recall Number:
D-0806-2018

Code Information:
Lot # 0130131, EXP 8/31/20

Product Description:
Chlorhexidine 0.12% liquid, 473 MILLILITERS. Rx Only. Mnfct for: XTTRUM Laboratories, Chicago, IL 60609. Mnfct by: pharmaceutical Assoiates, Inc., Greenville, SC 29605. Distrib by: PreScript Pharm. INC., Pleasanton, CA 94588. NDC: 00116-2001-16, Bar Code 1385-38-482

Product Quantity:
24 473-ml bottles

Reason for Recall:
Labeling: Not Elsewhere Classified: due to a labeled declaration of; Store at 15¿C to 30¿C (59¿F to 86¿F) which differs from the original manufacturer declaration of; Store at 20¿C to 25¿C (68¿F to 77¿F).

Recall Number:
D-0807-2018

Code Information:
Lot # 130128, EXP 08/31/20

Product Description:
Clindamycin 300 mg capsules, USP, 28-count M-Pak containers, Rx Only. Mnfct for: Lannett Co. Inc., Philadelphia, PA 19136. Mnfct. by: Lannett Co. Inc., Philadelphia, PA 19136. Pckgd by PreScript Pharm. Inc., Pleasanton, CA 94566. NDC: 00527-1383-01, Bar Code 0784-28-11

Product Quantity:
5 28-count containers

Reason for Recall:
Labeling: Not Elsewhere Classified: due to a labeled declaration of; Store at 15¿C to 30¿C (59¿F to 86¿F) which differs from the original manufacturer declaration of; Store at 20¿C to 25¿C (68¿F to 77¿F).

Recall Number:
D-0808-2018

Code Information:
Lot # 0130132, EXP 3/31/19

Product Description:
Acetaminophen 300 mg with Codeine Phosphate 30 mg tablets, USP, 20-count M-Pak containers, Rx Only. Mnfct for: Mallinckrodt Inc. Hazelwood, MO 63042. Mnfct by:Mallinckrodt Inc. Hazelwood, MO 63042. Pckgd by PreScript Pharm Inc. Pleasanton, CA 94566 NDC: 00406-0484-10 Bar Code 0078-20-1834

Product Quantity:
199 tablets in 20-count containers

Reason for Recall:
Labeling: Not Elsewhere Classified: due to a labeled declaration of; Store at 15¿C to 30¿C (59¿F to 86¿F) which differs from the original manufacturer declaration of; Store at 20¿C to 25¿C (68¿F to 77¿F).

Recall Number:
D-0809-2018

Code Information:
Lot # 0130130 EXP 12/31/20

Class II Drugs Event

Event ID:
80041

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/11/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
05/15/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
L. Perrigo Company
515 Eastern Ave
Allegan MI United States

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

Associated Products

Product Description:
Scopolamine Transdermal Therapeutic System, 1 mg/3 days, a) 4-count (NDC 45802-580-84); b) 10-count (NDC 45802-580-46); c) 24-count (NDC 45802-580-62), Rx only, Mfd. by: Aveva Drug Delivery Systems, A Nitto Denko Company, Miramar, FL 33025 Distributed by Perrigo, Allegan, MI 49010

Product Quantity:
569,520 cartons

Reason for Recall:
Defective delivery system

Recall Number:
D-0816-2018

Code Information:
Lot #: a) 46397, 46457 Exp 03/19; 46621, Exp 04/19; 46894, 46904, 46905, Exp 06/19; 47133, Exp 07/19; 47153, Exp 08/19; 47154, 47213, 47214, Exp 09/19; b) 46695, Exp 04/19; 46994, 47012, Exp 07/19; 47322 10/19; c) 46822, Exp 05/19 ; 47155, 47212, Exp 09/19

Class II Drugs Event

Event ID:
80042

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/04/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
05/15/2018

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Within the United States and Puerto Rico

Associated Products

Product Description:
B Prox 10 Anti-blemish Wash, (Benzoyl peroxide 10%), 200 mL bottles, Dermatologic Cosmetic Laboratories, East Haven, CT 06512 USA

Product Quantity:
3,477 plastic bottles

Reason for Recall:
Microbial Contamination of Non-sterile Product

Recall Number:
D-0811-2018

Code Information:
Lot: # ET507-0, Exp. 5/27/2019; GU894-8, Exp. 7/20/2010

Product Description:
Solar Defense Sheer Sunscreen Broad Spectrum SPF50 (Octinoxate 7.5%, Zinc Oxide 10.5%), 2.5 FL OZ. 74 mL, Distributed by: BeautyRx LLC, NY, NY 10128

Product Quantity:
2,156 tubes

Reason for Recall:
GMP Deviations

Recall Number:
D-0812-2018

Code Information:
Lot #: KU455-2, Exp. 11/09/2020; KU455-6, Exp.11/26/2020

Product Description:
Naturmetic SPF 50 Sunscreen (Octinoxate 7.5%, Zinc Oxide 10.5%), 2.0 fl oz/60mL bottles, Fortis BioPharma, Magnolia, TX 77354.

Product Quantity:
4,815 tubes

Reason for Recall:
GMP Deviations

Recall Number:
D-0813-2018

Code Information:
Lot #: KU455-4, Exp.10/30/2020

Product Description:
MD Complete Clarifying Cleanser (Salicylic Acid 2.0%), 3 fl oz, (88.7mL), MD Professional LLC, Minneapolis, MN

Product Quantity:
14,491 tubes

Reason for Recall:
GMP Deviations

Recall Number:
D-0814-2018

Code Information:
Lot #: KU503-6, KU393-6, Exp. 12/28/2020

Class II Drugs Event

Event ID:
80049

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/07/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
05/16/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Perrigo New York
1700 Bathgate Ave
Bronx NY United States

Distribution Pattern:
US Nationwide including Puerto Rico.

Associated Products

Product Description:
Hydrocortisone Ointment, USP 2.5%, Net Wt. 20g, Rx Only, Manufactured By Perrigo, Bronx, NY 10457, Distributed by Perrigo, Allegan MI 49010, NDC 45802-014-02

Product Quantity:
571,632 tubes

Reason for Recall:
Failed Stability Specifications

Recall Number:
D-0817-2018

Code Information:
Lot Numbers: 7AT0283V, exp. 11/18 7AT0284V, exp. 11/18 7AT0285V, exp. 11/18 7FT0460, exp. 05/19 7FT0461, exp. 05/19 7GT0465, exp. 06/19 7GT0466, exp. 06/19 7JT0390, exp. 08/19 7JT0392, exp. 08/19 7KT0588, exp. 09/19 7KT0589, exp. 09/19

Class III Drugs Event

Event ID:
79835

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/10/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
05/15/2018

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Aidarex Pharmaceuticals LLC
595 N Smith Ave
Corona CA United States

Distribution Pattern:
Product was distributed to Florida

Associated Products

Product Description:
Ferrous Sulfate 325 MG tablet

Product Quantity:
450 bottles

Reason for Recall:
Presence of Foreign Tablets/Capsules

Recall Number:
D-0810-2018

Code Information:
Batch ID: 57909-1, exp. date 04/30/2019 57909-2, exp. date 06/30/2019

Class III Drugs Event

Event ID:
79846

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/13/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
05/11/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Boiron Inc.
6 Campus Blvd
Newtown Square PA United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Calendula Cream, calendula officinalis 1X HUS-10%, 2.5 oz. tubes, Distributed by Boiron Inc., Newtown Square, PA

Product Quantity:
52,810 tubes

Reason for Recall:
Labeling: Labeling Error on Declared Strength; The outer carton (secondary packaging) statement of ingredients misstates the concentration of active ingredient at 7%. The primary packaging (tube) correctly states the active ingredient at 10%.

Recall Number:
D-0803-2018

Code Information:
Lot Numbers: M7090711, M7090712, M7090713, M7090709, M7090807, Exp: 09/2019 and M7110589, Exp: 11/2019

Class III Drugs Event

Event ID:
79979

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/26/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
05/16/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Sun Pharmaceutical Industries, Inc.
270 Prospect Plains Rd
Cranbury NJ United States

Distribution Pattern:
US Nationwide in the USA

Associated Products

Product Description:
Riomet (metformin hydrochloride oral solution), 500 mg/5 mL (16 fl. oz.), 473 mL plastic bottle, Manufactured by: Mikart, Inc., Atlanta, GA 30318, Distributed by: Sun Pharmaceutical Industries, Inc., Cranbury, NJ 08512. NDC 10631-206-02

Product Quantity:
19,758 473 mL bottles

Reason for Recall:
Labeling: Not Elsewhere Classified: Sun Pharma has decided to initiate this recall in response to identified labeling discrepancies in the patient literature.

Recall Number:
D-0818-2018

Code Information:
Lot Numbers: E170210A, EXP 06/09/2019; F170214A, 07/05/2019; F170223A, EXP 07/06/2019; F170224A EXP 07/10/2019; F170231A , EXP 07/12/2019; F170232A EXP 07/13/2019.

Not Yet Classified Drugs Event

Event ID:
79995

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/01/2018

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:
CA, MI, MS, OH and TX

Associated Products

Product Description:
Piperacillin and Tazobactam for Injection, USP 3.375 grams per vial, For Intravenous Use Only, Single-Dose vial, Rx Only, Manufactured for: AuroMedics Pharma LLC, 6 Wheeling Road, Dayton, NJ 05610. NDC 55150-120-30

Product Quantity:
77,400 vials

Reason for Recall:
Presence of Particulate Matter: confirmed customer report for presence of visible particulate matter, confirmed as glass

Recall Number:

Code Information:
Lot #s: PP0317061-A, PP0317049-A; EXP August 2019

Not Yet Classified Drugs Event

Event ID:
80010

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/04/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
IN Only

Associated Products

Product Description:
Piperacillin and Tazobactam for Injection, USP 3.375 grams/vial, Rx only, Mfg. by Hospira Healthcare India Pvt. Ltd., Irungattukottai - 602 105, India, Mfg. for Apotex Corp. Weston, FL 33326, NDC 60505-0687-4

Product Quantity:
1,236,820 vials

Reason for Recall:
Subpotent Drug

Recall Number:

Code Information:
Lot #: 501G014, Exp 05/2018; 501G015, Exp 09/2018; 501G016, 501G017, 501G018, 501G019, 501G020, 501G021, 501G022, 501G023, Exp 10/2018; 501G024, 501G025, 501G026, 501G027, 501G028, 501G029, 501G030, Exp 11/2018; 501H001, 501H002, 501H003, 501H004, 501H006, 501H007, 501H008, Exp 12/2018; 501H009, Exp 04/2019; 501H012, 501H013, Exp 06/2019; 501H018, 501H019, Exp 09/2019.

Product Description:
Piperacillin and Tazobactam for Injection, USP 4.5 grams/vial, Rx only, Mfg. by Hospira Healthcare India Pvt. Ltd., Irungattukottai - 602 105, India, Mfg. for Apotex Corp. Weston, FL 33326, NDC 60505-0688-4

Product Quantity:
564,580 vials

Reason for Recall:
Subpotent Drug

Recall Number:

Code Information:
Lot #: 502H001, Exp 01/2019; 502H003, 502H004, 502H005, Exp 04/2019; 502H006, 502H007, 502H008, 502H009, 502H010, 502H011, 502H012, 502H013, 502H017, Exp 05/2019; 502H022, 502H023, Exp 06/2019; 502H024, 502H026, 502H027, 502H028, Exp 07/2019.