Enforcement Report - Week of March 8, 2017

Class I Drugs Event

Event ID:
75092

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/02/2016

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
02/27/2017

Initial Firm Notification of Consignee or Public:
Telephone

Recalling Firm:
United Exchange Corporation
17211 Valley View Ave
Cerritos CA United States

Distribution Pattern:
Nationwide, Puerto Rico and Guyana

Associated Products

Product Description:
EYE WASH, 4 fl oz. (118 mL) bottle, OTC, Distributed by: Major Pharmaceutical, 31778 Enterprise Drive, Livonia, MI 48150, Made in Korea, NDC 0904-6491-20

Product Quantity:
46,080 bottles

Reason for Recall:
Non-Sterility: Direct evidence of contamination for 2 lots based on FDA samples.

Recall Number:
D-0496-2017

Code Information:
Lot # G15905, G15907, Exp 10/2018

Class I Drugs Event

Event ID:
75741

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/23/2016

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
02/27/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Jeffreys Drug Store
1 N Central Ave
Canonsburg PA United States

Distribution Pattern:
PA

Associated Products

Product Description:
Domperidone capsules 10 mg, compounded, dispensed in 60, 90, and 360 count bottles, Jeffreys Drug Store 1 North Central Ave. Canonsburg, PA

Product Quantity:
9

Reason for Recall:
Marketed without an approved NDA/ANDA for which safety and efficacy has not been established.

Recall Number:
D-0494-2017

Code Information:
Lot #: 071116-103323, Exp. Date 1/7/2017

Class I Drugs Event

Event ID:
76109

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/13/2016

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
03/01/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Pacific Medical Solutions
13967 Campo Rd Ste 102
Jamul CA United States

Distribution Pattern:
Nationwide in the United States and Mexico

Associated Products

Product Description:
Nano PNC Water, packaged in amber glass bottles, Rx only, ICRPstudy.com, Immune Cellular Restoration Program.

Product Quantity:

Reason for Recall:
Marketed without an Approved NDA/ANDA and non-sterility: NANO PNC Water by nebulizer was sampled and found to contain variovorax paradoxus.

Recall Number:
D-0505-2017

Code Information:
None

Class II Drugs Event

Event ID:
75092

Status:
Ongoing

Recall Initiation Date:
09/02/2016

Center Classification Date:
02/27/2017

Recalling Firm:
United Exchange Corporation
17211 Valley View Ave
Cerritos CA United States

Distribution Pattern:
Nationwide, Puerto Rico and Guyana

Product Type:
Drugs

Date Terminated:

Voluntary / Mandated:
Voluntary: Firm Initiated

Initial Firm Notification of Consignee or Public:
Telephone

Associated Products

Product Description:
Eye Irrigating Solution, 4 fl oz (118 mL) bottle, OTC, Distributed by: Rugby Laboratories, 31778 Enterprise Drive, Livonia, MI 48150, Made in Korea, NDC 0536-1083-97

Product Quantity:
112,320 bottles

Reason for Recall:
Lack of assurance of sterility

Recall Number:
D-0497-2017

Code Information:
Lot # G15908, Exp 10/2018; G15909, Exp 01/2018; G16904, Exp 01/2019; G16908, Exp 02/2019; G16912, G16913, Exp 03/2019

Product Description:
Eye Wash, 4 fl oz (118 mL) bottle, OTC, Distributed by: United Exchange Corp., 17211 Valley View Ave., Cerritos, CA 90703, Made in Korea, UPC Code: 780707005828

Product Quantity:
77,184 bottles

Reason for Recall:
Lack of assurance of sterility

Recall Number:
D-0498-2017

Code Information:
Lot # G15901, G15902, G15903, G15904, Exp 07/31/2018; G16909, Exp 05/30/2019

Product Description:
EYE WASH, 4 fl oz. (118 mL) bottle, OTC, Distributed by: Major Pharmaceutical, 31778 Enterprise Drive, Livonia, MI 48150, Made in Korea, NDC 0904-6491-20

Product Quantity:
190,710 bottles

Reason for Recall:
Lack of assurance of sterility

Recall Number:
D-0499-2017

Code Information:
Lot # G15906, Exp 10/2018; G15910, G15911, G15912, Exp 11/2018; G16901, G16902, G16903, Exp 01/2019; G16905, G16906, G16907, Exp 02/2019; G16910, G16911, Exp 03/2019

Class II Drugs Event

Event ID:
76199

Status:
Completed

Recall Initiation Date:
01/13/2017

Center Classification Date:
02/27/2017

Recalling Firm:
AbbVie Inc.
1 N Waukegan Rd
North Chicago IL United States

Product Type:
Drugs

Date Terminated:

Voluntary / Mandated:
Voluntary: Firm Initiated

Initial Firm Notification of Consignee or Public:
E-Mail

Distribution Pattern:
TN and IL

Associated Products

Product Description:
Duopa (carbidopa and levodopa enteral suspension), 4.63 mg/20 mg per mL, 100 mL cassette, 7 cassettes per carton, Rx Only, AbbVie Inc., North Chicago, IL 60064 --- NDC 0074-3012-07

Product Quantity:
4021 cartons, 7 100-mL cassettes each

Reason for Recall:
Failed Stability Specifications: confirmed out of specification results obtained during refrigerated material stability testing indicating that drug may settle within drug cassettes nearing the end of their refrigerated shelf-life

Recall Number:
D-0495-2017

Code Information:
Lots: 1055692, Expiration Date (Frozen) 06/01/2018 1057881, Expiration Date (Frozen) 06/02/2018 1060138, Expiration Date (Frozen) 06/13/2018 1060140, Expiration Date (Frozen) 06/15/2018 1061258, Expiration Date (Frozen) 06/17/2018 1061262, Expiration Date (Frozen) 06/30/2018 1063033, Expiration Date (Frozen) 07/14/2018

Class II Drugs Event

Event ID:
76291

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/19/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
02/24/2017

Initial Firm Notification of Consignee or Public:
E-Mail

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

Distribution Pattern:
Nationwide

Associated Products

Product Description:
glipiZIDE Extended-Release Tablets, 5 mg, 1000 count bottles, Rx only, Mylan Pharmaceuticals Inc., Morgantown, WV --- NDC 0378-0342-10

Product Quantity:
1338 bottles

Reason for Recall:
Presence of Foreign Tablets/Capsules; bottles of Glipizide 5 mg tablets may contain Glipizide 10 mg tablets

Recall Number:
D-0491-2017

Code Information:
Batch # 3074621, June 2018

Class II Drugs Event

Event ID:
76430

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/07/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
03/01/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
G & W Laboratories, Inc.
111 Coolidge St
South Plainfield NJ United States

Distribution Pattern:
Within United States

Associated Products

Product Description:
Indocin (Indomethacin) suppositories, USP, 50 mg, laminate strips packed in boxes of 30, Rx only, Manufactured by: G&W Laboratories Inc. South Plainfield, NJ 07080, Distributed by Iroko Pharmaceuticals, LLC Philadelphia, PA 19112, NDC 42211-0102-43

Product Quantity:
3456 boxes

Reason for Recall:
Failed Impurities/Degradation Specifications: Out of specification (OOS) for total impurity and out of trend for known impurity results encountered during stability testing.

Recall Number:
D-0501-2017

Code Information:
Lot #: 017600011, Exp. Jan 2018, 0176000014, Exp. Aug 2018, 017600015, Exp. Sep 2018

Class II Drugs Event

Event ID:
76484

Status:
Ongoing

Recall Initiation Date:
02/08/2017

Center Classification Date:
02/24/2017

Recalling Firm:
Amerisource Health Services
2550 John Glenn Ave Ste A
Columbus OH United States

Distribution Pattern:
Nationwide

Product Type:
Drugs

Date Terminated:

Voluntary / Mandated:
Voluntary: Firm Initiated

Initial Firm Notification of Consignee or Public:
Letter

Associated Products

Product Description:
CycloSPORINE Capsules, USP, 100 mg, 30 count (5x6) blister cartons, Rx only, Distributed by American Health Packaging, Columbus, OH--- NDC 68084-921-25

Product Quantity:
454 cartons

Reason for Recall:
Failed Impurities/Degradations Specifications; out of specification results for Maximum Unknown Impurities and Total Impurities

Recall Number:
D-0490-2017

Code Information:
Lot 154527, exp 4/30/2017

Class II Drugs Event

Event ID:
76495

Status:
Ongoing

Recall Initiation Date:
02/16/2017

Center Classification Date:
02/28/2017

Recalling Firm:
Allegiant Health
75 N Industry Ct
Deer Park NY United States

Distribution Pattern:
Nationwide

Product Type:
Drugs

Date Terminated:

Voluntary / Mandated:
Voluntary: Firm Initiated

Initial Firm Notification of Consignee or Public:
Two or more of the following: Email, Fax, Letter, Press Release, Telephone, Visit

Associated Products

Product Description:
HealthA2Z CHEWABLE Aspirin (NSAID) 81 mg, Orange Flavor, 36 Chewable Tablets, a) packaged in 36-count bottle [UPC Code 369168288362 (FP0545)], b) bulk product (6K28817), OTC, Manufactured by: Allegiant Health Deer Park, NY 11729

Product Quantity:
70,176 bottles; 9,000,000 tablets (bulk)

Reason for Recall:
cGMP deviations - presence of rubber particles found loose in the bulk product.

Recall Number:
D-0500-2017

Code Information:
Lot # 6K28817, Exp 10/19 (Packaged in bottle), 10/17 (Bulk)

Class II Drugs Event

Event ID:
76543

Status:
Ongoing

Recall Initiation Date:
01/05/2017

Center Classification Date:
03/01/2017

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

Distribution Pattern:
Nationwide in the USA and Puerto Rico.

Product Type:
Drugs

Date Terminated:

Voluntary / Mandated:
Voluntary: Firm Initiated

Initial Firm Notification of Consignee or Public:
Letter

Associated Products

Product Description:
Alfuzosin Hydrochloride Extended-release Tablets, 10 mg, 100-count bottles, Rx only, Distributed by: Sun Pharmaceutical Industries, Inc., Cranbury, NJ 08512; Manufactured by: Sun Pharmaceutical Ind. Ltd., Halol-Baroda Highway, Halol-389, Gujarat, India, NDC 47335-956-88.

Product Quantity:
22,915 bottles

Reason for Recall:
Presence of Foreign Substance: consumer complaint for foreign matter embedded in the tablet identified as a broken piece of wire rope from the manufacturing equipment.

Recall Number:
D-0502-2017

Code Information:
Lot #: JKR5219A, JKR5200A, JKR5220A, JKR5221A, JKR5222A, Exp 03/18

Class III Drugs Event

Event ID:
76357

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/19/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
02/24/2017

Initial Firm Notification of Consignee or Public:
E-Mail

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

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Mirtazapine Tablets, USP 45 mg, a) 30 count, b) 100 count and c) 500 count bottles, Rx only, Mylan Pharmaceuticals Inc., Morgantown, WV

Product Quantity:
37,445 bottles

Reason for Recall:
Presence of Foreign Tablets/Capsules; possibility of Glipizide 10 mg tablet in bottle

Recall Number:
D-0492-2017

Code Information:
a) 3078937 and 3078938 (NDC 0378-3545-93), exp August 2019 b) 3078937 (NDC 0378-3545-01), exp August 2019 c) 3078936 (0378-3545-05), exp August 2019

Class III Drugs Event

Event ID:
76443

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/13/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
03/01/2017

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Nationwide within United States

Associated Products

Product Description:
Salicylic Acid Shampoo, 6%, 177 mL bottle, Rx only, Manufactured By Perrigo Yeruham, Israel, Distributed By Perrigo Allegan, MI 49010, NDC 45802-237-01, UPC 3 45802-237-01 9.

Product Quantity:
10,656 units total for both products

Reason for Recall:
Failed Impurities/Degradation Specifications: The API for these products had an out of specification result for an organic impurity.

Recall Number:
D-0503-2017

Code Information:
Lot #: 099534, Exp. 07/18; 099512 Exp. 06/18.

Product Description:
Salicylic Acid Cream, 6%, 400g bottle, Rx Only, Manufactured By Perrigo Yeruham, Israel 80500, Distributed By Perrigo Allegan, MI 49010, NDC 45802-806-01, UPC 3 45802-806-01 7.

Product Quantity:
10,656 units total for both products

Reason for Recall:
Failed Impurities/Degradation Specifications: The API for these products had an out of specification result for an organic impurity.

Recall Number:
D-0504-2017

Code Information:
Lot #: 098840, 098779, Exp.06/18.