Enforcement Report - Week of March 7, 2018

Class I Drugs Event

Event ID:
78541

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/09/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
02/28/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Kareway Product Inc
2550 S Dominguez Hills Dr
Compton CA United States

Distribution Pattern:
Product was shipped to one customer (Geri-Care Pharmaceuticals Corp.) who further distributed the product U.S.A. nationwide.

Associated Products

Product Description:
GERICARE Eyewash, sterile eye irrigating solution, packaged in a 4 fl oz (118 mL) bottle, OTC, Distributed by Geri-Care Pharmaceuticals Corp., Brooklyn, NY 11204, NDC 57896-0186-04

Product Quantity:
60,000 bottles

Reason for Recall:
Non-sterility: confirmed microbial contamination with Achromobacter xylosoxidans

Recall Number:
D-0551-2018

Code Information:
Lot #: 86041601, Exp 09/19

Class II Drugs Event

Event ID:
78755

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/13/2017

Center Classification Date:
02/23/2018

Recalling Firm:
ALLERGAN
1 Giralda Farms
Madison NJ United States

Distribution Pattern:
Product was distributed nationwide in the USA.

Voluntary / Mandated:
Voluntary: Firm Initiated

Initial Firm Notification of Consignee or Public:
Letter

Associated Products

Product Description:
INFeD (Iron Dextran Injection USP) 100 mg elemental iron/2 ml (50 mg/mL), Rx Only, packaged in a) single dose vials, (NDC 52544-931-07), b) carton of 10 x 2 ml Single Dose Vials (NDC 52544-931-02) Distributed by: Actavis Pharma, Inc. Parsippany, NJ 07054, Manufactured by: Patheon Italia S.p.A. Ferentino, Italy 03013.

Product Quantity:
163,694 cartons

Reason for Recall:
Failed Stability Specifications: Product stability testing results did not meet specifications for iron content.

Recall Number:
D-0545-2018

Code Information:
Lot# 15W05A, Exp.FEB-2018; 16W02A, Exp. DEC 2018; 16W05A, Exp. JAN-2019; 16W13A, Exp. APR-2019; 16W15A, 16W16A, 16W17A, Exp. MAY 2019; 16W18A, Exp. JUN 2019; 16W20A, 16W22A, Exp. SEP 2019; 17W01A, 17W02A, Exp. DEC-2019; 17W04A, 17W05A, Exp. JAN 2020; 17W09A, Exp. MAR-2020; 17W11A, 17W13A, Exp. MAY 2020; 17W14A, 17W15A, Exp. JUN 2020

Class II Drugs Event

Event ID:
79194

Status:
Ongoing

Recall Initiation Date:
02/09/2018

Center Classification Date:
02/23/2018

Recalling Firm:
Apace KY LLC
12954 Fountain Run Rd
Fountain Run KY United States

Product Type:
Drugs

Date Terminated:

Voluntary / Mandated:
Voluntary: Firm Initiated

Initial Firm Notification of Consignee or Public:
Letter

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Acyclovir Tablets, USP, 400 mg, 50 Tablets (5 x 10) unit dose blisters [NDC 50268-061-11] per carton [NDC 50268-061-15], Rx Only, Manufactured for: AvKARE, Inc., Pulaski, TN 38478

Product Quantity:
630 cartons

Reason for Recall:
Presence of Foreign Tablet/Capsule; cartons labeled to contain Acyclovir tablets may contain Torsemide tablets in some of the blister cavities.

Recall Number:
D-0544-2018

Code Information:
Lot: 19900, exp 05/2019

Class II Drugs Event

Event ID:
79253

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/14/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
02/27/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Fagron, Inc
2400 Pilot Knob Rd
Saint Paul MN United States

Distribution Pattern:
Nationwide, USA

Associated Products

Product Description:
SyrSpend SF Suspending Base, a) 500 mL (NDC 51552-1079-5) and b) 4 L (NDC 51552-1079-9), Rx Only, Manufactured by Fagron Inc. St. Paul, MN 55120

Product Quantity:
a) 1007 bottles (500 mL) and b) 738 bottles (4 L)

Reason for Recall:
Microbial contamination of Non-Sterile Product; product contamination with yeast and mold (Paecilomyces saturatus and Aspergillus fumigatus).

Recall Number:
D-0547-2018

Code Information:
a) 17I28-U80-039976, exp. 10/02/2020; b) 17I28-U80-039977, exp. 10/02/2020

Class II Drugs Event

Event ID:
79267

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/15/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
02/26/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Medline Industries Inc
Three Lakes Drive
Northfield IL United States

Distribution Pattern:
Nationwide in the USA and Curacao

Associated Products

Product Description:
PVP Scrub Solution, Povidone Iodine, 7.5% (equivalent to 0.75% available iodine), 4 FL OZ bottle, Manufactured in USA by Medline Industries, Inc., Northfield, IL 60093; Product Number MDS093945; NDC 53329-938-04

Product Quantity:
67,104 bottles

Reason for Recall:
Subpotent Drug: product not meeting the iodine assay level requirements through the labeled expiry.

Recall Number:
D-0546-2018

Code Information:
Lot #: 16EJ0023, Exp 04/18

Class II Drugs Event

Event ID:
79348

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/16/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
02/27/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
B. Braun Medical Inc
2525 McGaw Ave
Irvine CA United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
0.9% Sodium Chloride Irrigation USP, 1000 mL Plastic Irrigation Container (PIC), Rx only, B. Braun Medical Inc., Irvine, CA 92614, Catalog # R5200-01, NDC 0264-2201-00.

Product Quantity:
17,360 plastic irrigation containers

Reason for Recall:
Presence of Particulate Matter: Customer complaint of particulate matter which has been identified as polyethylene, which is consistent with the material used to manufacture the container cap was received.

Recall Number:
D-0549-2018

Code Information:
Batch # J7N912, Exp 10/31/20

Class III Drugs Event

Event ID:
79240

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/14/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
02/28/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
LEADIANT BIOSCIENCES, INC

9841 Washingtonian Blvd Ste 500
Gaithersburg MD United States

Distribution Pattern:
Product was distributed to one specialty pharmacy distributor in the US Walgreens Specialty Pharmacy 16287, 130 Enterprise Drive Pittsburgh, PA 15275 Foreign Account: Italy

Associated Products

Product Description:
Cystaran (cysteamine ophthalmic solution) 0.44%, 15 mL bottle, Rx only, Manufactured by Hi-Tech Pharmacal Co. Inc., Amityville, NY 11701 for Leadiant Biosciences, Inc., Gaithersburg, MD 20878, NDC 54482-020-01

Product Quantity:
1,705 bottles

Reason for Recall:
Subpotent Drug: Out of specification for an active ingredient cysteamine hydrochloride.

Recall Number:
D-0550-2018

Code Information:
Lot #: 356075, Exp 2/28/18