Enforcement Report - Week of December 5, 2018

Class II Drugs Event

Event ID:
81535

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/08/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
11/23/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
ALLERGAN
1 Giralda Farms
Madison NJ United States

Distribution Pattern:
Product was distributed throughout the United States.

Associated Products

Product Description:
INFed (Iron Dextran Injection USP) 100 mg elemental iron/2 mL (50 mg/mL), Rx only, packaged in 2 mL Sterile Single Dose Vial, Mfd by Patheon Italia S.p.A. Ferentino, Italy NDC 52544-931-07

Product Quantity:
111,132 cartons/10 vials per carton

Reason for Recall:
Failed Stability Specification: out of specification for iron content.

Recall Number:
D-0282-2019

Code Information:
Lot Numbers: 16W06A, 16W07A, 16W08A, exp. date 02/2019; 16W09A, 16W10A, exp. date 03/2019; 16W11A, 16W14A, exp. date 04/2019; 16W21A, exp. date 09/2019; 16W23A, exp. date 11/2019; 17W10A, exp. date 04/2020; 17W12A, exp. date 05/2020; 17W16A, 17W18A, exp. date 06/2020; 17W22A, exp. date 08/2020

Class II Drugs Event

Event ID:
81568

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/14/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
11/28/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Ascend Laboratories LLC
339 Jefferson Rd Ste 101
Parsippany NJ United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Quetiapine Tablets USP 400 mg, 100 tablet bottles, Rx Only, Manufactured by: Alkem Laboratories Ltd., Mumbai - 400 013, India. Distributed by: Ascend Laboratories, LLC Parsippany, NJ 07054 --- NDC 67877-248-01, UPC code: 3 67877-248-01 1

Product Quantity:

Reason for Recall:
Presence of Foreign Substance; metal shard found in tablet

Recall Number:
D-0287-2019

Code Information:
Lot 7143908, exp Nov 2020

Class II Drugs Event

Event ID:
81603

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/20/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
11/28/2018

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
WA only

Associated Products

Product Description:
Germ Bloc Health Hand Sanitizer Foam (benzalkonium chloride 0.13%) 7.5fl.oz./222mL refill bags, AvKARE, Inc. Pulaski, TN 38478 www.avkare.com, NDC 5026835427, UPC 3 50268 35408

Product Quantity:
1602 bags

Reason for Recall:
Microbial Contamination of Non-Sterile Product: Presence of Pseudomonas aeruginosa in product

Recall Number:
D-0285-2019

Code Information:
Lot #: 13417 Exp. 05/2020

Class III Drugs Event

Event ID:
81638

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/07/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
11/27/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
RemedyRepack Inc.
625 Kolter Dr Ste 4
Indiana PA United States

Distribution Pattern:
Product was distributed to two medical facilities in Pennsylvania.

Associated Products

Product Description:
Nitrofurantoin Monohydrate/Macrocrystals capsules,100 mg, packaged in HDPE 60 cc bottles, Rx only, MFG: Sandoz Inc., Princeton, NJ, Repackaged by: RemedyRepack, Indiana, PA, Original NDC 00185-0122-01Repackaged NDC 70518-1087-00, 14 capsules in HDPE 60 cc bottles in cardboard trays & HDPE 60 cc bottles in plastic bags, Repackaged NDC 70518-1087-01, 10 capsules in HDPE 60 cc bottles in cardboard trays.

Product Quantity:
3,148 capsules

Reason for Recall:
Cross contamination with other products: Product is being recalled due to the potential presence of unrelated ingredients (Benazepril, Haloperidol and Perphenazine).

Recall Number:
D-0284-2019

Code Information:
Lot #: B0484872-081718, B0481339-081018, Exp 08/2019; B0506246-092718, Exp 09/2019; B0509938-100418, Exp 10/2019

Not Yet Classified Drugs Event

Event ID:
81426

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/29/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Nationwide USA and Puerto Rico

Associated Products

Product Description:
Clindamycin Phosphate Topical Solution USP, 1% (10 mg/mL clindamycin), 60 pledget applicators per jar, Rx only. Manufactured by Ei LLC 2865 N. Cannon Blvd. Kannapolis, NC 18083. NDC# 61748-0201-60

Product Quantity:
58,393 jars

Reason for Recall:
Failed Impurities/Degradation Specifications; out of specification results observed for other individual impurities

Recall Number:

Code Information:
Lot# 2530200, Expiration date: 1/31/2019. Lot# 2530300, Expiration date: 1/31/2019. Lot# 2530400, Expiration date: 1/31/2019. Lot# 2607300,

Expiration date: 1/31/2019. Lot# 2607400, Expiration date: 1/31/2019. Lot# 2607500, Expiration date: 1/31/2019. Lot# 2607600, Expiration date: 1/31/2019. Lot# 2615800, Expiration date: 1/31/2019. Lot# 2630200, Expiration date: 2/28/2019. Lot# 2630300, Expiration date: 2/28/2019.

Not Yet Classified Drugs Event

Event ID:
81485

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/01/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Sandoz, Inc
506 Carnegie Ctr Ste 400
Princeton NJ United States

Distribution Pattern:
OH, PR

Associated Products

Product Description:
Sandoz Losartan Potassium Hydrochlorothiazide Tablets, USP Rx Only 1000 Tablets Lek Pharmaceuticals d.d. SI-1526 Ljubljana,Sovenia for Sandoz Inc., Princeton, NJ 08540 NDC 0781-5207-10

Product Quantity:
170 units

Reason for Recall:
Losartan Potassium Hydrochlorothiazide Tablets USP 100mg/25mg has NDEA impurity which is above the typically established limits.

Recall Number:

Code Information:
JB8912