Enforcement Report - Week of March 1, 2017

Class II Drugs Event

Event ID:
76407

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/27/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
02/18/2017

Initial Firm Notification of Consignee or Public:
Telephone

Recalling Firm:
Cherry Hill Sales Co.
1115 Eden Way N
Chesapeake VA United States

Distribution Pattern:
Michigan, Illinois, New York, Florida, Pennsylvania .

Associated Products

Product Description:
MakeSense PHARMA, HEMORRHOIDAL RELIEF CREAM Phenylephrine HCL-0.25% Zinc Oxide-12.50%,1 oz. (28 g) tube, Made in China, Distributed by Cherry Hill Associates, Chesapeake, VA 23320, NDC 69020-205-28

Product Quantity:
3,600 cartons

Reason for Recall:
CGMP Deviations

Recall Number:
D-0483-2017

Code Information:
Lot #103811; Exp. 09/17 Lot #105304; Exp. 04/18 NDC 69020-205-28 UPC 857181005108

Product Description:
MakeSense PHARMA FIRST AID CREAM Lidocaine HCL 0.5%, Phenol 0.5%, 1 oz.. (28 g) tube, Made in China, Distributed by Cherry Hill Associates, Chesapeake, VA 23320, NDC 69020-210-28

Product Quantity:
7,200 cartons

Reason for Recall:
CGMP Deviations

Recall Number:
D-0484-2017

Code Information:
Lot # 103814; Exp. 09/17 Lot # 105306; Exp. 04/18 NDC 69020-210-28 UPC 85718005139

Product Description:
MakeSense PHARMA Medicated ANTI-ITCH CREAM WITH SOOTHING ALOE VERA AND VITAMIN E, Camphor-1% Menthol-1%, 1oz.(28 g) tube, Made in China, Distributed by Cherry Hill Associates, Chesapeake, VA 23320, NDC 69020-201-28

Product Quantity:
4,800 cartons

Reason for Recall:
CGMP Deviations

Recall Number:
D-0485-2017

Code Information:
Lot: 103814; Exp. 08/17 NDC 69020-201-28 UPC 85718005016

Product Description:
MakeSense PHARMA ANTIFUNGAL CREAM 1 oz. Miconazole Nitrate 2%, 1 oz. (28 g) tube, Made in China, Distributed by Cherry Hill Associates, Chesapeake, VA 23320, NDC 69020-208-28

Product Quantity:
2,400 cartons

Reason for Recall:
CGMP Deviations

Recall Number:
D-0486-2017

Code Information:
Lot #103810; Exp. 09/17 Lot #105303; Exp. 04/18 NDC 69020-208-28 UPC 857181005092

Product Description:
MakeSense PHARMA ANTIFUNGAL CREAM Clotrimazole 1%, 1.25 oz. (35 g) tube, Made in China, Distributed by Cherry Hill Associates, Chesapeake, VA 23320, NDC 69020-203-35

Product Quantity:
2,400 cartons

Reason for Recall:
CGMP Deviations

Recall Number:
D-0487-2017

Code Information:
Lot # 103803; Exp. 08/17 NDC 69020-203-35 UPC 857181005023

Class II Drugs Event

Event ID:
76435

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/02/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
02/17/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Sandoz Inc
100 College Rd W
Princeton NJ United States

Distribution Pattern:
Nationwide in the USA and Puerto Rico

Associated Products

Product Description:
Transderm Scop (scopolamine) Transdermal System, 1.5 mg, 1 patch per pouch (NDC 66758-208-58), packaged in 4-count patches per carton (NDC 66758-208-54), Rx Only, Manufactured by ALZA Corporation, Vacaville, CA 95688 for Sandoz Inc., Princeton, NJ 08540.

Product Quantity:
157,922 cartons

Reason for Recall:
Labeling: Incorrect Instructions:outer carton contains the incorrect instructions for Step 2 stating "Do cut the patch" rather than the correct instructions of "Do not cut the patch". The pouch containing the patch is labeled correctly.

Recall Number:
D-0481-2017

Code Information:
Lot #: 6323Q11, 6328Q11, Exp 06/19; 6355Q11, Exp 07/19

Class II Drugs Event

Event ID:
76457

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/07/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
02/18/2017

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 a sold customer in FL.

Associated Products

Product Description:
Glipizide 2.5 mg ER Tablets, Manufactured by Watson Laboratories, Inc., Parsippany, NJ 07054, Repackaged by RemedyRepack, Indiana, PA 15701, NDC 52125-0764-02

Product Quantity:
630 pills (21 bottles x 30 pills per HDPE bottle)

Reason for Recall:
Failed Dissolution Specifications

Recall Number:
D-0482-2017

Code Information:
Lot # B0129373-021916; Exp. 10/17 00591-0900-30 Original NDC 52125-0764-02 RemedyRepack NDC

Class II Drugs Event

Event ID:
76460

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/10/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
02/17/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Hospira Inc., A Pfizer Company
275 N Field Dr
Lake Forest IL United States

Distribution Pattern:
Nationwide and Puerto Rico

Associated Products

Product Description:
METRONIDazole Injection, USP 500 mg (5 mg/mL) in 100 mL Single Dose Flexible Container, Rx only, For IV Use, Hospira Inc., Lake Forest, IL --- NDC 0409-7811-24