Enforcement Report - Week of May 25, 2016

Biologics | Cosmetics | Devices | Drugs | Food | Tobacco | Veterinary

Class II Drugs Event

Event ID:
73571
Product Type:
Drugs

Status:
Ongoing
Recalling Firm:
TMIG Inc
3535 Roswell Rd Ste 21
Marietta GA United States
Recall Initiation Date:
03/23/2016
Center Classification Date:
05/17/2016
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
Distribution Pattern:
Nationwide

Associated Products

Product Description:
Renovo Patch (Capsaicin, 0.0375%, Menthol, USP 5.00%), 3-count patches per carton, Rx only, Distributed By: TMIG Inc, Marietta , GA 30062, Manufactured By: Pocono Coated Products LLC., Cherryville, NC 28021
NDC: 69176-025-03
Product Quantity:
unknown
Code Information:
All lots

Reason for Recall:
Marketed Without An Approved NDA/ANDA: product is an unapproved drug and additionally 3 lots were found to be subpotent.

Recall Number:
D-0855-2016

Class II Drugs Event

Event ID:
73895
Product Type:
Drugs

Status:
Completed
Recalling Firm:
Keystone Laboratories Inc
1103 Kansas St
Memphis TN United States
Recall Initiation Date:
04/04/2016
Center Classification Date:
05/16/2016
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
Distribution Pattern:
U.S. Including: MD and NJ

Associated Products

Product Description:
BETTER BRAIDS UN-BRAID (salicylic acid), Le Demelant, Packaged in 12 FL. OZ. (355 ml) Bottles, Over the Counter Only. Distributed by KEYSTONE LABORATORIES, UPC 07059600430.
Product Quantity:
7 Cases of 12 Bottles
Code Information:
Lot #: 10AN5

Reason for Recall:
Microbial Contamination of Non-Sterile Products: Failed S.aureus test.

Recall Number:
D-0853-2016

Class III Drugs Event

Event ID:
73569
Product Type:
Drugs

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

Status:
Ongoing
Recalling Firm:
Allegiant Health
75 N Industry Ct
Deer Park NY United States
Recall Initiation Date:
02/29/2016
Center Classification Date:
05/17/2016
Date Terminated:

Distribution Pattern:
Nationwide

Associated Products

Product Description:
col-rite (docusate sodium) stool softener softgels, 50 mg, packaged in a) 30-count, item 351104, UPC 0 11822 51104 9; and b) 60-count, item 357392, UPC 0 11822 57392 4; DISTRIBUTED BY: RITE AID, 30 HUNTER LANE, CAMP HILL , PA 17011.
Product Quantity:
a) 9816 bottles; b) 9648 bottles
Code Information:
Lot #: 5C344105, Exp 02/17

Reason for Recall:
Superpotent Drug: High out of specification results for assay at the 6 month time point interval.

Recall Number:
D-0856-2016

Class III Drugs Event

Event ID:
73681
Product Type:
Drugs

Status:
Ongoing

Recalling Firm:
Hospira Inc.
275 N Field Dr
Lake Forest IL United States

Voluntary / Mandated:
Voluntary: Firm Initiated
Initial Firm Notification of Consignee or Public:
Letter
Distribution Pattern:
Nationwide, Puerto Rico, United Arab Emirates, Israel, Kuwait, Bahrain, and Trinidad & Tobago

Recall Initiation Date:
03/23/2016
Center Classification Date:
05/16/2016
Date Terminated:

Associated Products

Product Description:
Magnesium Sulfate Inj., USP 50%, 10 g/20 mL (0.5 g/mL), (4 mEq Magnesium/mL, 20 mL Single-dose vial, packaged in 25 vials per box, Rx Only, Hospira, Inc., Lake Forest, IL 60045, NDC 0409-2168-02, barcode (01) 2 030409 216802 5.

Reason for Recall:
Failed pH Specifications: Confirmed high out of specification (OOS) results for pH.

Product Quantity:
715,200 vials

Recall Number:
D-0854-2016

Code Information:
Lot #: 42-335-DK, Exp 1JUN2016; 48-128-DK, 48-129-DK, 48-261-DK, 48-262-DK, 48-351-DK, Exp 1DEC2016; 52-361-DK, Exp 1APR2017; note that the lot number may be followed by numbers from 01 to 99.