

Enforcement Report - Week of April 26, 2017

Class II Drugs Event

Event ID:
76954

Status:
Ongoing

Recall Initiation Date:
03/28/2017

Center Classification Date:
04/20/2017

Recalling Firm:
Taro Pharmaceuticals U.S.A., Inc.
3 Skyline Dr
Hawthorne NY United States

Distribution Pattern:
Nationwide 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:

Nystatin and Triamcinolone Acetonide Cream, USP, 100,000 USP nystatin units and 1 mg triamcinolone acetonide, distributed in a) 15 grams (NDC 51672-1263-1), b) 30 grams (NDC 51672-1263-2) and c) 60 grams (NDC 51672-1263-3) tubes, Rx only, TARO label; Mfd. by: Taro Pharmaceuticals Inc. Brampton, Ontario, Canada L6T 1C1 -- Dist. by: Taro Pharmaceuticals U.S.A. Inc., Hawthorne, NY 10532

Product Quantity:
278,304 tubes

Reason for Recall:
Failed Content Uniformity Specifications; out-of-specification (OOS) results 18-month stability

Recall Number:
D-0676-2017

Code Information:

a) 15 g: Lot B505118501, exp. date January 2018; b) 30 g: Lot B504918500, exp. date January 2018; c) 60 g: Lots: I416616979, exp. date August 2017, I416716979, exp. date August 2017 and D504519119, exp. date March 2018

Class III Drugs Event

Event ID:
76743

Status:
Ongoing

Recall Initiation Date:
03/20/2017

Center Classification Date:
04/17/2017

Recalling Firm:
Valeant Pharmaceuticals North America LLC
400 Somerset Corporate Blvd
Bridgewater NJ 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:

CLENZIderm M.D. Pore Therapy Salicylic Acid 2% Acne Treatment 5 fl. oz. (148 mL), Valeant Pharmaceuticals North America LLC Distributed by OMP, Inc Long Beach, CA 90806 Made in USA. Product SKU 301876102042, NDC 0187-6102-04

Product Quantity:
38,767 units

Reason for Recall:
Discoloration.

Recall Number:
D-0672-2017

Code Information:
Lot #: 15J1277, Exp. 04/2017

Product Description:

CLENZIderm M.D. Acne Treatment System, kit has 3 bottles a) Therapeutic Lotion (benzoyl peroxide 5% Acne Treatment) 47mL bottle, b) Daily Care Foaming Cleanser (Salicylic Acid 2% Acne Treatment) 118 mL bottle, c) Salicylic Acid 2% Acne Treatment 148mL, Valeant Pharmaceuticals North America LLC Distributed by OMP, Inc Long Beach, CA 90806 Made in USA, Product SKU 301876103018, NDC 0187-6103-01

Product Quantity:
5,647 units

Reason for Recall:
Discoloration.

Recall Number:
D-0673-2017

Code Information:
Lot #: a) 15I1234, Exp. 09/18, b) 15E1221, Exp. 09/18, c) 15G1235 and 15I1236, Exp. 09/18.

Class III Drugs Event

Event ID:
76933

Status:
Ongoing

Recall Initiation Date:
01/05/2017

Center Classification Date:
04/19/2017

Recalling Firm:
InnovaGel
14193 Sw 119th Ave
Miami FL United States

Distribution Pattern:
NY only

Product Type:
Drugs

Date Terminated:

Voluntary / Mandated:
Voluntary: Firm Initiated

Initial Firm Notification of Consignee or Public:
Telephone

Associated Products

Product Description:
Diphenhydramine HCl 25 mg, Softgel Gelatin Capsule, 15,000-count bulk drums, aenova/Swiss Caps USA, Inc., 14193 S.W. 119th Avenue, Miami, FL 33186, Product Code MSU0048P, NDC 6897080284

Product Quantity:
Approximately 7,920,177 capsules

Reason for Recall:
Subpotent

Recall Number:
D-0674-2017

Code Information:
Batch #: 1404811, 1409802, 1502817, 1504808, 1509810, 1511802, 1603801, Exp. 12/12/2018.

Product Description:
Dye Free Allergy Softgel Gelatin Capsule, 15,000-count bulk drums, aenova/Swiss Caps USA, Inc., 14193 S.W. 119th Avenue, Miami, FL 33186, Product Code MSU0067P, NDC 6897080284

Product Quantity:
9,992,768 softgels

Reason for Recall:
Subpotent

Recall Number:
D-0675-2017

Code Information:
Batch #: 1508803,1602801, 1602802, 1604801, 1604802, 1606801, 1606802, 1606803, 1606804, Exp. 08/03/2018.