Enforcement Report - Week of December 6, 2017

Class II Drugs Event

Event ID:
78304

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/06/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
11/25/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
NEW RELIANCE TRADING, INC.
5563 59th St
Maspeth NY United States

Distribution Pattern:
NY

Associated Products

Product Description:
No.1 Faiza Beauty Cream Manufactured by: Poonia Brothers (Pak), Gujranwala, Distributed by NEW RELIANCE TRADING, INC., 5563 59th St., Maspeth, New York, 11378-2358, UPC 8993138993349, 5842109854239.

Product Quantity:
513 foil packets

Reason for Recall:
Marketed Without an Approved NDA/ANDA

Recall Number:
D-0095-2018

Code Information:
UPC 8993138993349, 5842109854239

Class II Drugs Event

Event ID:
78544

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/09/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
11/29/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Mayne Pharma Inc
1240 Sugg Pkwy
Greenville NC United States

Distribution Pattern:
Nationwide within USA

Associated Products

Product Description:
Liothyronine Sodium Tablets, USP 25 mcg ,100-count bottles, Rx Only, Distributed by Perrigo Minneapolis, MN 55427, NDC 0574-0222-01

Product Quantity:
11,364 bottles

Reason for Recall:
Failed Dissolution Specifications.

Recall Number:
D-0098-2018

Code Information:
Lot: #:16F649, Exp: May 2018

Class II Drugs Event

Event ID:
78552

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/09/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
11/27/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Teva Pharmaceuticals USA
1090 Horsham Rd
North Wales PA United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Clozapine Tablets USP, 100 mg, 500 count bottles, Rx only, Manufactured in Israel by: TEVA PHARMACEUTICALS IND, LTD, Jerusalem Israel, Manufactured For: TEVA PHARMACEUTICALS USA, North Wales, PA

Product Quantity:
3,870 bottles

Reason for Recall:
Failed Tablet/Capsule Specifications; potential presence of broken tablets.

Recall Number:
D-0096-2018

Code Information:
Lot # 39C192, exp 06/2019

Class II Drugs Event

Event ID:
78595

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/28/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
11/30/2017

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
EAI-JR286 INC
20100 S Vermont Ave
Torrance CA United States

Distribution Pattern:
Nationwide in the USA and Puerto Rico.

Associated Products

Product Description:
Vertra Elemental Resistance (Octyl Methoxycinnamate 6%, Oxybenzone 5%, Titanium Dioxide 6.3%, Zinc Oxide 9.9%) Sun Protection Cream, SPF 50+, Net. Wt. 2.8 oz (80 g) tube in a carton, Distributed by Vertra/EAI-JR286, 20100 S Vermont Ave, Torrance, CA 90502, Made In Australia, UPC 8 94140 00103 0.

Product Quantity:
5,355 tubes

Reason for Recall:
CGMP Deviations: products manufactured in a manner that may impact product quality that includes but is not limited to failed viscosity.

Recall Number:
D-0100-2018

Code Information:
Lot #: 609124, Exp 03/18 Manufacturing batches were mfg at Delta Laboratories under Batch Number 511103 11/16/2015 Batch Number 609124 09/21/2016

Class II Drugs Event

Event ID:
78612

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/20/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
11/30/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Zydus Pharmaceuticals USA Inc
73 Route 31 N
Pennington NJ United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Paroxetine Tablets USP, 30 mg, a) 30 count (NDC 68382-099-06), b) 500 count (NDC 68382-099-05), and c) 1000 count (NDC 68382-099-10) count bottles, Rx Only, Manufactured by: Cadila Healthcare Ltd, Ahmedabad, India Distributed by: Zydus Pharmaceuticals USA, Inc., Pennington, NJ 08534

Product Quantity:
19812 bottles

Reason for Recall:
Presence of Foreign Tablets/Capsules: Risperidone Tablets were found in bottle of Paroxetine Tablets

Recall Number:
D-0101-2018

Code Information:
a) Z701308, b) Z701309, c) Z701310 exp April 2019

Class III Drugs Event

Event ID:
78596

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/21/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
11/28/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Lupin Pharmaceuticals Inc.
111 S Calvert St Fl 21ST
Baltimore MD United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Duloxetine Delayed-Release Capsules USP, 30 mg, 30-count bottles, Rx Only, Manufactured for: Lupin Pharmaceuticals, Inc. Baltimore, Maryland 21202 United States, Manufactured by: Lupin Limited Goa 403 722 India, NDC 68180-295-06, UPC 368180295068

Product Quantity:
111,648 units

Reason for Recall:
Failed Dissolution Specification

Recall Number:
D-0097-2018

Code Information:
Lot #: G602051, Exp. 12/2017