Enforcement Report - Week of February 22, 2017

Class I Drugs Event

Event ID:
75753

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/30/2016

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
02/13/2017

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
MS Bionic
447 E Gardena Blvd
Gardena CA United States

Distribution Pattern:
CA

Associated Products

Product Description:
MegaJex Herbal Supplement, Maximum Formula for Men, Fast acting, Increase Stamina, 20 capsules, MS Bionics, Gardena, CA

Product Quantity:
100 bottles

Reason for Recall:
Marketed without an Approved NDA/ANDA; product contains sildenafil and tadalafil which are active pharmaceutical ingredients in FDA approved drugs used to treat erectile dysfunction (ED)

Recall Number:
D-0472-2017

Code Information:
All Lots exp. date 12/2019

Class I Drugs Event

Event ID:
75929

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/09/2016

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
02/13/2017

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Jersey Shore Supplements, LLC
705 Brinley Ave
Bradley Beach NJ United States

Distribution Pattern:
New Jersey and Maryland.

Associated Products

Product Description:
SLIMFIT X capsules, packaged in a 60-cont bottle

Product Quantity:
150 bottles

Reason for Recall:
Marketed without an approved NDA/ANDA: Product contains undeclared sibutramine and desmethylsibutramine.

Recall Number:
D-0473-2017

Code Information:
All lots and all expiration dates.

Class II Drugs Event

Event ID:
76105

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/20/2016

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
02/16/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Accord Healthcare, Inc.
1009 Slater Rd Ste 210B
Durham NC United States

Distribution Pattern:
U.S. Nationwide and Puerto Rico

Associated Products

Product Description:
Lisinopril tablets, 5 mg, 1000-count bottle, Rx only, Manufactured for Accord Healthcare, Inc., Durham, NC 27703, NDC 16729-376-17

Product Quantity:
12896 bottles

Reason for Recall:
Failed tablet/capsule specification: missing break line on the 5mg tablet.

Recall Number:
D-0478-2017

Code Information:
Lot # T04483, T04484, Exp 2/18; T06028, Exp 4/18; T08423, Exp 5/18

Class II Drugs Event

Event ID:
76325

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/22/2016

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
02/13/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Aurobindo Pharma USA Inc
666 Plainsboro Rd Ste 210
Plainsboro NJ United States

Distribution Pattern:
Nationwide in the US

Associated Products

Product Description:
Venlafaxine Hydrochloride extended release capsules, 37.5 mg, 30-count bottles, Rx Only, Manufactured for: Aurobindo Pharma USA, Inc. 2400 Route 130 North, Dayton, NJ 08810 Manufactured by: Aurobindo Pharma Limited Hyderabad-500 072 India, NDC 65862-527-30

Product Quantity:
47,040 bottles

Reason for Recall:
Failed Tablet/Capsule Specifications: Some bottles contain punctured, and/or clumped/melted capsules.

Recall Number:
D-0474-2017

Code Information:
Lot #: VI3716010-A, Exp. 04/2018

Class II Drugs Event

Event ID:
76383

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/02/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
02/16/2017

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Nationwide in the United States

Associated Products

Product Description:
Mimvey Lo (estradiol and norethindrone acetate tablets USP), 0.5 mg/0.1 mg, 28 tablets per blister card (NDC 0093-5454-18), packaged in 3 blister cards per carton (NDC 0093-5454-62), Rx only, Manufactured By: Barr Laboratories, Inc., Pomona, NY 10970; Manufactured For: Teva Pharmaceuticals USA, Sellersville, PA 18960.

Product Quantity:
17,473 cartons

Reason for Recall:
Failed Impurities/Degradation Specifications: out of specification test results for the norethindrone impurity.

Recall Number:
D-0479-2017

Code Information:
Lot # 33809881A, Exp 05/17; 33811151A, Exp 08/17

Class II Drugs Event

Event ID:
76406

Product Type:
Drugs