Enforcement Report - Week of December 13, 2017

Class I Drugs Event

Event ID:
77899

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/07/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
12/01/2017

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
International Laboratories, Inc.
2701 75th St N
St Petersburg FL United States

Distribution Pattern:
U.S.A. nationwide and Puerto Rico

Associated Products

Product Description:
Pravastatin Sodium Tablets, USP, 40 mg, 30-count bottle, Rx only, Packaged for: International Laboratories, LLC. St. Petersburg, FL 33710, NDC 54458-925-16

Product Quantity:
82056 bottles

Reason for Recall:
Labeling: Label mix-up, the product labeled as Pravastatin sodium tablets 40 mg was filled with Bupropion hydrochloride XL Tablets 300 mg.

Recall Number:
D-0102-2018

Code Information:
Lot # 115698A, Exp 02/19

Class I Drugs Event

Event ID:
78151

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/15/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
12/04/2017

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Gadget Island, Inc
5889 Central Ave
Newark CA United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
RHINO 7 Platinum 5000, capsule, Proprietary Material: 750mg, 1-capsule packets, distributed by Fifty Shades Bayside, NY 11361, UPC 617135861224

Product Quantity:
925 1-capsule packets

Reason for Recall:
Marketed without an Approved NDA/ANDA: undeclared Active Pharmaceutical Ingredients sildenafil, desmethyl carbodenafil and tadalafil.

Recall Number:
D-0103-2018

Code Information:
All Lots

Product Description:
PapaZen 3300 capsule, Proprietary Blend 1800mg, 1-capsule packets, distributed by FX Power San Diego, CA 92108, UPC 718122032587

Product Quantity:
89 1-capsule packets

Reason for Recall:
Marketed without an Approved NDA/ANDA: undeclared Active Pharmaceutical Ingredients sildenafil, desmethyl carbodenafil and tadalafil.

Recall Number:
D-0104-2018

Code Information:
Lot# NSS050888, EXP 05-2018

Product Description:
FIFTY SHADES 6000 capsule, Proprietary Raw Material 4550, 1-capsule packets, distributed by Express Pac Trading, UPC 4026666146056

Product Quantity:
273 1-capsule packets

Reason for Recall:
Marketed without an Approved NDA/ANDA: undeclared Active Pharmaceutical Ingredients sildenafil, desmethyl carbodenafil and tadalafil.

Recall Number:
D-0105-2018

Code Information:
All Lots

Product Description:
grande X 5800 capsule, (Maca Root 120 mg, Horny Goat Weed 120 mg, Guarana Seed 80 mg, Ginko Leaf 60 mg, Saw Palmetto 100 mg, Damiana Leaf 100 mg, Ginseng Root 80 mg, Tribulus Terrestris 90 mg, Tongkat Alo 100 mg, Rhodiola Rosea 60 mg, L-Arginine 90 mg), 1-capsule packets, distributed by Grande X Ontario, CA 91745, UPC 640793555440

Product Quantity:
198 1-capsule packets

Reason for Recall:
Marketed without an Approved NDA/ANDA: undeclared Active Pharmaceutical Ingredients sildenafil, desmethyl carbodenafil and tadalafil.

Recall Number:
D-0106-2018

Code Information:
All Lots

Class III Drugs Event

Event ID:
78502

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/13/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
12/05/2017

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Elite Laboratories Inc.
165 Ludlow Ave
Northvale NJ United States

Distribution Pattern:
NY only

Associated Products

Product Description:
Isradapine Capsules USP 2.5 mg, 100-count bottles, Rx only, Manufactured by: Elite Laboratories, Inc. Northvale, NJ 07647, NDC 42806-263-01, UPC 342806263013

Product Quantity:
1264 bottles

Reason for Recall:
Failed Impurities/Degradation Specifications

Recall Number:
D-0107-2018

Code Information:
Lot #: P0910-017, Exp. 05/2019