Enforcement Report - Week of June 6, 2018

Class III Drugs Event

Event ID:
80187

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/24/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
05/31/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
LUPIN SOMERSET
400 Campus Dr
Somerset NJ United States

Distribution Pattern:
OH

Associated Products

Product Description:
Hydrocodone Bitartrate and Acetaminophen Tablets, USP, 5 mg/325 mg, 1000-count bottle Rx Only, Manufactured by: Novel Laboratories, Inc. Somerset NJ 08873 Manufactured for: Lupin Pharmaceuticals, Inc. Baltimore, MD 212020 NDC 43386-356-10 UPC 343386356102

Product Quantity:
1,672 (1000-count) bottles

Reason for Recall:
Labeling: Missing Label

Recall Number:
D-0836-2018

Code Information:
Lot # S800257; Exp. 01/20

Not Yet Classified Drugs Event

Event ID:
80128

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/17/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Shoreside Enterprises Inc.
6345 Newtown Cir Apt A3 Ste A-3
Tampa FL United States

Distribution Pattern:
Nationwide.

Associated Products

Product Description:
POSEIDON Xtreme PLATINUM 4500,1000mg, packaged in packaged in single packs sold in 24-count boxes, Distributed by: Poseidon Distribution Atlanta, GA, UPC 638632428857

Product Quantity:
Unknown

Reason for Recall:
Marketed Without An Approved NDA/ANDA: FDA analysis found products to contain undeclared sildenafil and tadalafil. The presence of sildenafil and tadalafil makes these products an unapproved drug for which safety and efficacy have not been established and, therefore, subject to recall.

Recall Number:

Code Information:
Lot #: 201117BL, Exp. 01/2020

Product Description:
7K capsules packaged in single packs sold in 24-count boxes, Distributed by SX Power Co. San Diego, CA 92108, UPC 601577513148

Product Quantity:
Unknown

Reason for Recall:
Marketed Without An Approved NDA/ANDA: FDA analysis found products to contain undeclared sildenafil and tadalafil. The presence of sildenafil and tadalafil makes these products an unapproved drug for which safety and efficacy have not been established and, therefore, subject to recall.

Recall Number:

Code Information:
Lot #: RO, Exp. 12/31/2021