

Enforcement Report - Week of June 28, 2017

Class II Drugs Event

Event ID:
77427

Status:
Ongoing

Recall Initiation Date:
06/01/2017

Center Classification Date:
06/16/2017

Recalling Firm:
Lucid Pharma LLC
2 Tower Center Blvd Suite 1101B
East Brunswick NJ United States

Distribution Pattern:
Nationwide in the USA

Product Type:
Drugs

Date Terminated:

Voluntary / Mandated:
Voluntary: Firm Initiated

Initial Firm Notification of Consignee or Public:
Letter

Associated Products

Product Description:
Venlafaxine Hydrochloride Extended-Release Capsules USP, 75 mg, packaged in a) 30-count bottles (NDC 52343-132-30) and b) 90-count bottles (NDC 52343-132-90), Rx only, Distributed by: Lucid Pharma LLC, 2 Tower Center Blvd, Suite-1101-B, East Brunswick, NJ 08816 USA.

Product Quantity:
a) 44168 bottles; b) 24960 bottles

Reason for Recall:
Failed Tablet/Capsules Specifications: pharmacists complaints for bottles containing melted capsules.

Recall Number:
D-0921-2017

Code Information:
Lot #: a) V17516045-A, Exp 08/18; b) V17516047-A 09/18

Class II Drugs Event

Event ID:
77517

Status:
Ongoing

Recall Initiation Date:
06/12/2017

Center Classification Date:
06/21/2017

Recalling Firm:
Vf-Jon, Inc.
1 Swan Dr
Smyrna TN United States

Distribution Pattern:
Nationwide U.S.A.

Product Type:
Drugs

Date Terminated:

Voluntary / Mandated:
Voluntary: Firm Initiated

Initial Firm Notification of Consignee or Public:
Letter

Associated Products

Product Description:
Magnesium Citrate Saline Laxative Cherry Flavored, packaged in a) 10 fl. oz. (296 mL) bottle UPC: 072785104556 (Rexall's label), b) 10 fl. oz. (296 mL) bottle UPC: 041163254138 (Equaline's label), OTC, Distributed by a) Dolgencorp, LL, Goodlettsville, TN 37072 b)Supervalu, Inc. Eden Prairie, MN 55344

Product Quantity:
52,212 bottles

Reason for Recall:
Presence of foreign substance: glass particle

Recall Number:
D-0922-2017

Code Information:
Lot: 0313246