Enforcement Report - Week of July 29, 2020

Class I Drugs Event

Event ID:
85957

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/29/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/24/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Transliquid Technologies, LLC
330 Rayford Rd
Spring TX United States

Distribution Pattern:
Distributed Nationwide in the US

Associated Products

Product Description:
Mystic Shield PROTECTION, ALCOHOL ANTISEPTIC 70%, Topical Solution, Antiseptic Hand Rub, Non-sterile Solution, Extra strength Formula*, 8.45 fl. oz. (250 ml) bottle, Labeled with green or blue labels, Manufactured by Mystic Intl S.A. de C.V. UPC barcode: 7 87790 33952 6

Product Quantity:
20,340 bottles

Reason for Recall:
Chemical Contamination: Presence of Undeclared Methanol

Recall Number:
D-1408-2020

Code Information:
Lots: All Lots

Class II Drugs Event

Event ID:
85955

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/03/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/28/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
WALKER EMULSIONS INC
4401 Se Johnson Creek Blvd
Portland OR United States

Distribution Pattern:
US Distribution: Product distributed to sister plant site located in SC, and one donation made to consignee located in OR. Majority of hand sanitizer shipped to Canada (Health Canada has already received consignee information and classified the recall).

Associated Products

Product Description:
Walker Emulsions Hand Sanitizer (60%), Non-Sterile Solution, Alcohol Antiseptic 60%, 1 Gallon, Topical Solution, Walker Emulsions Inc., 4401 SE Johnson Creek Blvd., Portland, OR 97222, NDC 74940-0415-1

Product Quantity:

Reason for Recall:
Incorrect/Undeclared Excipients: Notification received from Health Canada that DA-2I Ethanol is a type not an approved for use in Hand Sanitizer.

Recall Number:
D-1416-2020

Code Information:
Lot # 209638

Product Description:
Walker Hand Sanitizer, Non-Sterile Solution, Alcohol Antiseptic, 70%, 32 oz and 16 oz, Topical Solution, Walker Emulsions Inc., 4401 SE Johnson Creek Blvd., Portland, OR 97222, NDC 74940-0415-1

Product Quantity:

Reason for Recall:
Incorrect/Undeclared Excipients: Notification received from Health Canada that DA-2I Ethanol is a type not an approved for use in Hand Sanitizer.

Recall Number:
D-1417-2020

Code Information:
Lot # 210061

Class II Drugs Event

Event ID:
85960

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/02/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/23/2020

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
U.S.A. Nationwide

Associated Products

Product Description:
Cefdinir for Oral Suspension USP, 250 mg/5mL, packaged in 60 mL bottles, Rx only, Manufactured for: Lupin Pharmaceuticals, Inc., Baltimore, Maryland, Manufactured by: Lupin Limited, Mandideep, India, NDC 68180-723-20

Product Quantity:
35,928 bottles

Reason for Recall:
Superpotent Drug: Out-of-specification (OOS) result observed in an assay test of retention samples.

Recall Number:
D-1406-2020

Code Information:
Lot # F802189, Exp 10/2020, F900240, Exp 1/2021

Class III Drugs Event

Event ID:
85916

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/17/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/21/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
HF Acquisition Co. LLC
11629 49th Pl W
Mukilteo WA United States

Distribution Pattern:
The vials were distributed to one consignee located in CT.

Associated Products

Product Description:
Famotidine Injection, USP, 20 mg/2mL, 2 mL vial, Rx only, Single Dose Vial, For Intravenous Use Only After Dilution, Distributed by HF Acquisition Co, LLC, Mukilteo, WA 98275, NDC 63323-739-12

Product Quantity:

Reason for Recall:
TEMPERATURE ABUSE: Complaint received from customer that product was received in a non-refrigerated state.

Recall Number:
D-1392-2020

Code Information:
Lot #: 6122639, Exp. Date 08/2021