

# Enforcement Report - Week of October 11, 2017

## Class II Drugs Event

**Event ID:**  
78098

**Status:**  
Ongoing

**Recall Initiation Date:**  
08/23/2017

**Center Classification Date:**  
10/04/2017

**Recalling Firm:**  
Inopak Ltd  
24 Executive Pkwy  
Ringwood NJ United States

**Distribution Pattern:**  
nationwide

**Product Type:**  
Drugs

**Date Terminated:**

**Voluntary / Mandated:**  
Voluntary: Firm Initiated

**Initial Firm Notification of Consignee or Public:**  
Letter

## Associated Products

**Product Description:**  
Option Systems Antibacterial Foaming Hand Wash, 0.3% P.C.M.X., 8 fl oz and 18 fl oz. bottles and 500, mL 800 mL, and 1000 mL pouches, ALSO labeled as STYLE Antibacterial Hand Soap, Inopak Ltd Ringwood, NJ --- NDC 5031-431-02

**Product Quantity:**

**Reason for Recall:**  
GMP Deviations; potential bacterial contamination may have been introduced to products through a contaminated diaphragm pump

**Recall Number:**  
D-0002-2018

**Code Information:**  
Batch Numbers || 6718, 6730, 6744, 6754, 6760, 6773, 6784, 6793, 6804, 6812, 6819, 6838, 6846, 6862, 6877, 6890, 6902, 6910, 6919, 6838, 6846, 6862, 6877, 6890, 6902, 6910, 6919, 6938, 6944, Style Batch Numbers || 6725, 6732, 6735, 6742, 6756, 6762, 6766, 6770, 6777, 6792, 6798, 6807, 6813, 6816, 6829, 6839, 6868, 6872, 6875, 6891, 6904, 6906, 6914, 6916, 6923, 6932, 6939, 6820

**Product Description:**  
Mild Healthcare Antibacterial Hand Soap, 6% P.C.M.X., 1000 mL and 2000 mL Disc Pump, 800 mL Universal Valve, and 1 gallon bottles, Inopak. Ltd, Ringwood, NJ 07456

**Product Quantity:**

**Reason for Recall:**  
GMP Deviations; potential bacterial contamination may have been introduced to products through a contaminated diaphragm pump.

**Recall Number:**  
D-0003-2018

**Code Information:**  
Batch Numbers || 6749, 6909

**Product Description:**  
Choice Antibacterial Hand Soap, (ethyl alcohol 61%) 800 ml/ 27 fl oz, Universal Valve, Inopak LTD, Ringwood, NJ

**Product Quantity:**

**Reason for Recall:**  
GMP Deviations; potential bacterial contamination may have been introduced to products through a contaminated diaphragm pump.

**Recall Number:**  
D-0004-2018

**Code Information:**  
All lots within expiry

## Class III Drugs Event

**Event ID:**  
77731

**Status:**  
Ongoing

**Recall Initiation Date:**  
07/12/2017

**Center Classification Date:**  
10/03/2017

**Recalling Firm:**  
Pfizer Inc.  
235 E 42nd St  
New York NY United States

**Distribution Pattern:**  
Nationwide

**Product Type:**  
Drugs

**Date Terminated:**

**Voluntary / Mandated:**  
Voluntary: Firm Initiated

**Initial Firm Notification of Consignee or Public:**  
Letter

## Associated Products

**Product Description:**  
Deferoxamine Mesylate for injection, USP, Single-use Vial, 500 mg/vial, 10 mL vial. Intravenous, Intramuscular, Subcutaneous Use, Rx Only, Hospira, Inc., Lake Forest IL USA, NDC 0406-2336-10.

**Product Quantity:**  
32,276 10 mL vials

**Reason for Recall:**  
CGMP Deviations: Firm failed to control impurity for color change at the API stage.

**Recall Number:**  
D-0001-2018

**Code Information:**  
Lot: 51275DD; Exp. 09/01/17

## Class III Drugs Event

**Event ID:**  
78099

**Status:**  
Ongoing

**Recall Initiation Date:**  
09/13/2017

**Center Classification Date:**  
10/05/2017

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

**Distribution Pattern:**  
United States and Canada

**Product Type:**  
Drugs

**Date Terminated:**

**Voluntary / Mandated:**  
Voluntary: Firm Initiated

**Initial Firm Notification of Consignee or Public:**  
Letter

### Associated Products

<p><b>Product Description:</b> Magnesium Citrate Oral Solution Lemon Flavor, 1.745g per fl oz, packaged in 10 fl. oz. (296 mL) bottles, Labeled as a) CVS Health, Distributed by: CVS Pharmacy, Inc. One CVS Drive, Woonsocket, RI 02895; NDC 59779-667-38, UPC 05042842790; b) Swan Citroma, Distributed by: Vi-Jon One Swan Drive Smyrna, TN 37167, NDC 0869066738, UPC 308690667382; c) GoodSense, Distributed By: Geiss, Destin &amp; Dunn, Inc. Peachtree City, GA 30269, NDC 50804-667-38, UPC 846036007374; d) Leader, Distributed By: Cardinal Health, Dublin, Ohio, 43017, NDC 3720511038, UPC 096295382433; e) Signature Care, Distributed By: Better Living Brands, LLC. P.O. Box 99, Pleasanton, CA 94566-0009, NDC 21130-667-38, UPC 321130779155; f) Discount Drug Mart Food Fair, Distributed By: Drug Mart-Food Fair Medina, Ohio 44256, NDC 5394301077, UPC 093351100383; g) Sunmark, Distributed By McKesson One Post Street San Francisco, CA 94104, NDC 4934869649, UPC 010939112330, h) Major, Distributed By: Major Pharmaceuticals 31778 Enterprise Drive Livonia, MI 48150 USA, NDC 0904630477, UPC 309046304777</p> <p><b>Product Quantity:</b> 348,384 bottles</p> <p><b>Reason for Recall:</b> Failed Impurities/Degradation Specifications.</p> <p><b>Recall Number:</b> D-0005-2018</p> <p><b>Code Information:</b> Lot #: a) 0326166 Exp. 07/2018; b) 0326164, Exp. 07/2018; 0326730, Exp. 08/2018; c) 0326183, Exp. 07/2018; 0326730 Exp. 08/2018; d) 0326183, Exp. 07/2018, e) 0326183, Exp. 07/2018, f) 0326730 Exp. 08/2018, g) 0326736, Exp. 08/2018, 0341351 Exp. 11/2018, h) 0326736, Exp. 08/2018.</p>
<p><b>Product Description:</b> Magnesium Citrate Oral Solution Cherry Flavor, 1.745 g per fl oz, packaged in 10 fl. oz ( 296 mL) bottles, Labeled as a) CVS Health, Distributed by: CVS Pharmacy, Inc. One CVS Drive, Woonsocket, RI 02895; NDC 6984238038, UPC 050428418321, b) Meijer, Dist. By Meijer Distribution, Inc. Grand Rapids, MI 49544, NDC 4125038038, UPC 708820824294, c) Life Brand, Manufactured for: Shoppers Drug Mark/Pharmaprix Toronto, UPC 057800856405</p> <p><b>Product Quantity:</b> 87,972 bottles</p> <p><b>Reason for Recall:</b> Failed Impurities/Degradation Specifications.</p> <p><b>Recall Number:</b> D-0006-2018</p> <p><b>Code Information:</b> Lot #: 0323439 Exp. 07/2018</p>