## Class II Drugs Event

**Event ID:** 82645  
**Product Type:** Drugs  
**Status:** Ongoing  

**Recall Initiation Date:** 04/22/2019  
**Voluntary / Mandated:** Voluntary: Firm Initiated  

**Center Classification Date:** 05/29/2019  
**Initial Firm Notification of Consignee or Public:** Letter  

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

**Distribution Pattern:** Nationwide in the USA  

### Associated Products

<table>
<thead>
<tr>
<th>Product Description</th>
<th>Reason for Recall</th>
<th>Recall Number</th>
<th>Code Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANTIBACTERIAL Foaming Hand Wash With Moisturizers labeled as Antibacterial Foaming Soap, ACTIVE: P.C.M.X, packaged in a) 18 oz bottles, 12/18 oz bottles per case, 5063-432-02; b) 1 gallon bottles, 4/1 gallon bottles per case, 5063-420-03; c) Options Systems Antibacterial Foaming Hand Wash with .3% PCMX, packaged in 1000mL pouches, 6/1000ML pouches per case, 5063-OS1000; d) INOFOAM Antibacterial Foaming Hand Wash with .3% PCMX, packaged in 1000mL pouches, 6-1000ml pouches per case, 5063-FL1000, Inopak LTD., 24 Executive Parkway, Ringwood, NJ 07456.</td>
<td>CGMP Deviations: hand sanitizers and soaps were not produced under current good manufacturing practices.</td>
<td>D-1310-2019</td>
<td>Batch #: 6657, 6666, 6671, 6679, 6695, 6702, 6718, 6730, 6744, 6754, 6760, 6772, 6773, 6784, 6793, 6804, 6812, 6819, 6838, 6846, 6856, 6862, 6877, 6890, 6896, 6902, 6910, 6919, 6938, 6944, 6953, 6971, 6985, 6990, 6998, 7005, 7012, 7018, 7028, 7033, 7039, 7043, 7053, 7060, 7068, 7080, 7092, 7101, 7110, 7116, 7126, 7143, 7153, 7161, 7167, 7175, 7188, 7204, 7208, 7213, 7221, 7232, 7242, 7248, 7267, 7275, 7284, 7287, 7295, 7308, 7314, 7324, 7329, 7336, 7348, 7357, 7363, 7372, 7382, 7389, 7397, 7403, and 7411</td>
</tr>
<tr>
<td>AQUACIL instant foaming hand sanitizer, alcohol free formula, benzalkonium chloride 0.1% (w/w), packaged in a) 18 FL OZ (532 mL) bottles, 12/18OZ bottles per case, Product Code BIO-5075-432-02; b) 1000 ML pouches, 6/1000 ML pouches per case, Product Code BIO575-OS1000, Biocentris Pharmaceuticals (Division of Inopak).</td>
<td>CGMP Deviations: hand sanitizers and soaps were not produced under current good manufacturing practices.</td>
<td>D-1311-2019</td>
<td>Batch #: 6736, 6826</td>
</tr>
<tr>
<td>Instant Waterless Hand Sanitizer, Ethyl Alcohol, 62%, packaged as a) DermaGel Instant Waterless Hand Sanitizing Gel with Moisturizers, with Aloe Vera &amp; Vitamin E, packaged in a) 1000 ml Disc Pump pouches (NDC 58575-340), 8 x 1000 ml Disc Pump pouches per case, Product Code 5025-</td>
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</tr>
</tbody>
</table>

https://www.accessdata.fda.gov/scripts/ires/index.cfm?action=print.getPrintData&ts=562019123612

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L1000; b) 2 fl. oz. bottles, 80/2 oz bottles per case, 5025-480-02; c) 18 fl. oz. bottles (NDC 58575-340), 16/18 oz bottles per case, 5025-430-02; d) 8 fl OZ. bottle, 24/8 oz bottle per case, 5025-440-03; e) 4 fl. oz. bottles, 24 x 4oz. Bottles per case, 5025-450-03; f) 800 ml pouches, 12 x 800 ml Universal Valve pouches per case, 5025-404-NB; g) 1 Gallon bottles, 4/1 gallon bottles per case, 5025-4202-02; Inopak LTD., Ringwood, NJ 07456. SaniTyze Hand Sanitizer with Aloe Vera, Vitamin E & Keratin, packaged as h) 8 fl oz (237 ml) bottles, 24/ 8 Oz. bottles per case; Manufactured for Crosstex International, Inc., 10 Rarick Road, Hauppauge, NY 11788-4209.

**Product Quantity:**
17,850 pounds per batch

**Reason for Recall:**
CGMP Deviations: hand sanitizers and soaps were not produced under current good manufacturing practices.

**Recall Number:**
D-1312-2019

**Code Information:**
Batch #: 7069, 6648, 6649, 6652, 6654, 6667, 6669, 6675, 6677, 6684, 6686, 6692, 6694, 6703, 6704, 6710, 6717, 6719, 6726, 6727, 6731, 6733, 6739, 6743, 6748, 6751, 6752, 6759, 6763, 6767, 6769, 6771, 6775, 6776, 6780, 6782, 6787, 6788, 6801, 6805, 6808, 6811, 6814, 6815, 6821, 6824, 6825, 6830, 6831, 6836, 6843, 6845, 6852, 6859, 6860, 6874, 6878, 6880, 6881, 6884, 6889, 6897, 6900, 6903, 6905, 6906, 6912, 6920, 6922, 6926, 6928, 6931, 6940, 6945, 6948, 6951, 6954, 6962, 6967, 6969, 6972, 6975, 6980, 6986, 6989, 6995, 7002, 7015, 7023, 7029, 7030, 7035, 7044, 7047, 7051, 7059, 7062, 7066, 7072, 7073, 7079, 7081, 7084, 7085, 7088, 7090, 7095, 7096, 7099, 7102, 7105, 7112, 7113, 7115, 7124, 7125, and 7128.

**Product Description:**
INODERM Antiseptic Hand Soap (E-2), .6% (incorrectly labeled on bags as 75%) PCMX, 800ml/27fl.oz.pouches (NDC 058575-110), 12 x 800 Bag-N-Box pouches per case (NDC 058575-110-80), 5014-404-NB; INOPAK, 24 Executive PKWY, Ringwood, NJ 07456.

**Product Quantity:**
17,850 pounds per batch

**Reason for Recall:**
CGMP Deviations: hand sanitizers and soaps were not produced under current good manufacturing practices.

**Recall Number:**
D-1313-2019

**Code Information:**
Batch #: 7074

**Product Description:**
INOFOAM Foaming E-2 Food Handling Wash with .6% PCMX, 1000mL pouch (NDC 058575-110-11), 6/1000 ML pouches per case (NDC 058575-110-80), 5064-FL1000, Inopak, LTD.

**Product Quantity:**
17,850 pounds per batch

**Reason for Recall:**
CGMP Deviations: hand sanitizers and soaps were not produced under current good manufacturing practices.

**Recall Number:**
D-1314-2019

**Code Information:**
Batch #: 7304, 7180, 6707, 7065

**Product Description:**
Antibacterial Hand Soap, Healthcare 2000, labeled as a) DERMA System CARE SaniClenz Antimicrobial Skin Cleanser (Chlorhexidine Gluconate), 4 x (1 gallon containers), Reorder/REF #JSCG; Manufactured for Crosstex International, Inc.; b) MEDI-WASH CHG Anti-Microbial Hand Wash with Chlorhexidine Gluconate; 1000ML pouches, 8/1000ML pouches per case, Walter G. Legge Co Inc, 444 Central AVE, Peekskill, NY 10566.

**Product Quantity:**
17,850 pounds per batch

**Reason for Recall:**
CGMP Deviations: hand sanitizers and soaps were not produced under current good manufacturing practices.

**Recall Number:**
D-1315-2019

**Code Information:**
Batch #: 6802, 6803, 6909, 6655

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Product Description:
Mild Health Care Antibacterial Hand Soap, .6% P.C.M.X., packaged in a) 1000 ml Disc Pump pouches, 8 x 1000 ml Disc Pump pouches per case, 5013-L1000, b) 2000 ml. Disc Pump pouches, 4 x 2000 ml Disc Pump pouches per case, 5013-XL2000, c) 800 ml Universal Valve pouches, 12 x 800 ml Universal Valve pouches per case, 5013-404, d) 1 gallon bottles, 4/1 gallon bottles per case, 5013-420-02, INOPAK, LTD., 24 Executive Parkway, Ringwood, NJ 07456.

Product Quantity:
17,850 pounds per batch

Reason for Recall:
CGMP Deviations: hand sanitizers and soaps were not produced under current good manufacturing practices.

Recall Number:
D-1316-2019

Code Information:
Batch #: 6656, 6959, 7008

Product Description:
Sani-Guard-SF Waterless Foam Hand Sanitizer, Ethyl Alcohol 70%, packaged in a) 6/1000 ml pouches per case, 5068-FL1000, b) 1000 ml cartridge pouch, 6/1000 ml .8ml Option Cartridge pouches per case, 5068-OS1000, Inopak LTD.

Product Quantity:
17,850 pounds per batch

Reason for Recall:
CGMP Deviations: hand sanitizers and soaps were not produced under current good manufacturing practices.

Recall Number:
D-1317-2019

Code Information:
Batch #: 6668, 6721

Product Description:
Antibacterial Hand Soap, .3% P.C.M.X, labeled as STYLE Antibacterial Hand Soap with moisturizers, a) 1000 ml pouches, 10/1000 ML. Large Valve pouches per case, 5031-404-LN, b) 1000 ml pouches, 8/1000 ML. Disc Pumps pouches per case, 5031-L1000, c) 800 ML Universal Valve pouches, 12/800 ML Universal Valve pouches per case, 5031-404, d) 800 ml pouches, 12/800 ML Presspak pouches per case, "B", 5031-403-1B, e) 800 ml pouches, 12 x 800ML. KC Valve pouches per case, 5031-404-KC, f) 800 ml pouches, 12/800 ML Universal Valve pouches per case, 5031-404, g) 800 ml pouches, 12/800 ML Presspak pouches per case, "B", 5031-403-18, h) 500 ml pouches, 6/500 ML. KC Valve pouches per case, 5031-404-500-6, i) 500 ml pouches, 18/500 ML. KC Valve pouches per case, 5031-404-500, j) 500 ml pouches, 6/500 ML. KC Valve pouches per case, 5031-404-500-6, k) 8 oz. bottles, 24/8 OZ. bottles with pumps per case, 5031-440-03, l) 18 oz. bottles, 16 x 18 OZ. Bottles with Pumps per case, 5031-430-02, m) 1000 ml pouches, 10/1000 ML. Large Valve pouches per case, 5031-404-LN, n) 1000 ml pouches, 6/1000ML. Disc Pumps pouches per case, 5031-L1000, Choice Antibacterial Hand Soap, packaged as o) 800 ml/27fl.oz. pouches, 12/800 ml Universal Valve pouches per case, 5031-404UV-CH, Manufactured by Inopak LTD., Ringwood, NJ.

Product Quantity:
17,850 pounds per batch

Reason for Recall:
CGMP Deviations: hand sanitizers and soaps were not produced under current good manufacturing practices.

Recall Number:
D-1318-2019

Code Information:
Batch #: 6660, 6664, 6676, 6682, 6685, 6698, 6701, 6725, 6732, 6742, 6744, 6746, 6756, 6762, 6770, 6777, 6792, 6798, 6807, 6808, 6813, 6816, 6820, 6829, 6839, 6868, 6872, 6875, 6891, 6892, 6904, 6906, 6914, 6916, 6923, 6932, 6939, 6952, 6958, 6963, 6970, 6978, 6982, 6987, 6993, 6997, 7004, 7006, 7024, 7038, 7049, 7056, 7058, 7078, 7087, 7098, 7104, 7108, 7111, 7129, 7132, 7134, 7138, 7145, 7152, 7157, 7160, 7164, 7170, 7177, 7184, 7190, 7192, 7203, 7207, 7220, 7224, 7231, 7235, 7243, 7247, 7252, 7258, 7260, 7269, 7281, 7285, 7291, 7296, 7301, 7306, 7311, 7312, 7319, 7322, 7326, 7335, 7338, 7340, 7347, 7351, 7353, 7368, 7377, 7384, 7387, 7394 and 7399

Product Description:
Unison Hand Care Products, WHITE PEARLIZED Anti-Bacterial Hand Cleaner with Triclosan, #4302, with exclusive Bajan fragrance, packaged in 800 ML (27 FL OZ) pouch containers, 12-800 ml containers/12-27 FL. OZ. container pouches per case, National Chemical Laboratories, Inc., 401 North 10th Street, Philadelphia, PA 19123.

Product Quantity:
17,850 pounds per batch
Reason for Recall:
CGMP Deviations: hand sanitizers and soaps were not produced under current good manufacturing practices.

Recall Number:
D-1319-2019

Code Information:
Batch # 6827

Class II Drugs Event

Event ID:
82790

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/03/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
05/29/2019

Initial Firm Notification of Consignee or Public:
Two or more of the following: Email, Fax, Letter, Press Release, Telephone, Visit

Recalling Firm:
Avella of Deer Valley, Inc. Store 38
24416 N 19th Ave
Phoenix AZ United States

Distribution Pattern:
U.S.A. nationwide

Associated Products

Product Description:
Bevacizumab 2.5 mg/0.1 mL, packaged in a Prefilled Syringe, Rx only, AVELLA SPECIALTY PHARMACY 24416 N. 19TH AVENUE PHOENIX, AZ 85085, NDC 42852-001-27

Product Quantity:
730 syringes

Reason for Recall:
Lack of assurance of sterility

Recall Number:
D-1308-2019

Code Information:
Lot #: 138-20191202@64, Exp 05/13/19