Enforcement Report - Week of June 5, 2019

Class II Drugs Event

Event ID:
82645

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

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

Product Description:
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.

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-1310-2019

Code Information:
Batch #: 6657, 6666, 6671, 6679, 6687, 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

Product Description:
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).

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-1311-2019

Code Information:
Batch #: 6736, 6826

Product Description:
Instant Waterless Hand Sanitizer, Ethyl Alcohol, 62%, packaged as a) DermaGel Instant Waterless Hand Sanitizing Gel with Moisturizers, with Aloe Vera & 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-

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, Hauppague, 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, 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, 7048, 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

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", 5031-403-1B, 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, 8/1000ML. 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, 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, 7054, 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, 7237, 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