Enforcement Report - Week of June 20, 2018

Class I Drugs Event

Event ID:
80136

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/24/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
06/15/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Allergan, PLC.
5 Giralda Farms
Madison NJ United States

Distribution Pattern:
US Nationwide

Associated Products

Product Description:
Allergan Taytulla Softgel Capsules, 1 mg/20 mcg, 6x28 blister card Physicians's Sample - Not for Sale Distributed by: Allergan USA INC Irvine, CA 92612 NDC 0023-5862-28 (Blister Card) NDC 0023-5862-29 (Blister Carton) NDC 0023-5862-31 (Outer carton) UPC 300235862290

Product Quantity:
168,768 blister cards (4,725,504 softgel capsules)

Reason for Recall:
Contraceptive Tablets Out of Sequence.

Recall Number:
D-0875-2018

Code Information:
Lot# 5620706, Exp. 05/19

Class II Drugs Event

Event ID:
80053

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/07/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
06/08/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
RIJ Pharmaceutical LLC
40 Commercial Ave
Middletown NY United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Preferred Plus Pharmacy Antacid Extra Strength (Aluminum Hydroxide 400mg, Magnesium Hydroxide 400mg, Simethicone 40 mg), packaged in 12 FL. OZ. (355 mL), Manufactured By: RIJ Pharmaceutical Corp.40 Commercial Avenue, Middletown, NY 10941, Distributed by: Kinray Inc. Whitestone, NY 11357 NDC 53807-158-12, UPC 353807158123

Product Quantity:
5043 bottles

Reason for Recall:
CGMP Deviations: Products are being recalled due to an out of specification total aerobic microbial count in a water sample.

Recall Number:
D-0842-2018

Code Information:
Lot #: 707007, Exp. 07/19

Product Description:
Preferred Plus Pharmacy Antacid (Aluminum Hydroxide 200mg, Magnesium Hydroxide 200mg Simethicone 20mg, packaged in 12 FL. OZ. (355 mL) bottles, Manufactured By: RIJ PHARMACEUTICAL CORPORATION 40 Commercial Avenue Middletown, NY 10941, Distributed by: Kinray Inc. Whitestone, NY 11357, NDC 53807-12612, UPC 53807126122

Product Quantity:

Reason for Recall:
CGMP Deviations: Products are being recalled due to an out of specification total aerobic microbial count in a water sample.

Recall Number:
D-0843-2018

Code Information:
Lot #: 707006, Exp. 07/19; 708001, Exp. 08/19

Product Description:
RPC Senna Syrup (Sennosides 8.8mg), packaged in 8 fl oz (237 mL) bottles, RIJ Pharmaceuticals Corporation 40 Commercial Avenue, Middletown, NJ 10941, NDC 5380755608, UPC 353807556080

Product Quantity:
1505 bottles

Reason for Recall:
CGMP Deviations: Products are being recalled due to an out of specification total aerobic microbial count in a water sample.

Recall Number:
D-0844-2018

Code Information:
Lot #: 47070081, Exp 09/18

Product Description:
RPC Children's Non-Aspirin (Acetaminophen 160 mg) Elixir, packaged in 4 FL. OZ. (118 mL), RIJ PHARMACETUICAL CORPORATION, 40 COMMERCIAL AVENUE, MIDDLETOWN, NY 10941, NDC 53807-129-04, UPC 353807129048

Product Quantity:
1272 bottles

Reason for Recall:
CGMP Deviations: Products are being recalled due to an out of specification total aerobic microbial count in a water sample.

Recall Number:
D-0845-2018

Code Information:
Lot #: 47080091, Exp. 08/19

Product Description:
Gericare Liquid Pain Relief Acetaminophen Cherry Flavor 160mg/5mL, packaged in 16 FL OZ (473 mL), Dist. By Gericare Pharmaceuticals 1650 63rd Street Brooklyn, NY 11204, NDC 5789618016, UPC 357896180164

Product Quantity:
13380 bottles

Reason for Recall:
CGMP Deviations: Products are being recalled due to an out of specification total aerobic microbial count in a water sample.

Recall Number:
D-0846-2018

Code Information:
Lot #: 47080081, 47080093, Exp. 08/19

Product Description:
RPC APAP Elixir (Acetaminophen 160mg), Packaged in 16 FL. OZ. (473 mL) bottles, RIJ PHARMACEUTICAL CORPORATION, 40 COMMERCIAL AVENUE, MIDDLETOWN, NY, NDC 53807-129-16, UPC 353807129161

Product Quantity:
228 bottles

Reason for Recall:
CGMP Deviations: Products are being recalled due to an out of specification total aerobic microbial count in a water sample.

Recall Number:
D-0847-2018

Code Information:
Lot #: 47080092, Exp 08/19

Product Description:
GeriCare Senna Syrup (Sennosides 8.8 mg), 8 fl oz (237 mL) bottles, Dist, by Gericare Pharmaceuticals 1650 63rd Street Brooklyn, NY 11204, NDC 57696-452-08, UPC 357896452087

Product Quantity:
21213 bottles

Reason for Recall:
CGMP Deviations: Products are being recalled due to an out of specification total aerobic microbial count in a water sample.

Recall Number:
D-0848-2018

Code Information:
Lot #: 47070082, 47070043, 47070011, Exp. 09/18

Product Description:
Ritussin DM Dextromethorphan Hydrobormide (Dextromethorphan HBr, USP 10 mg, Guaifenesin, USP 100mg), packaged in 4 FL.OZ. (118 mL), RIJ PHARMACEUTICAL CORPORATION 40 COMMERCIAL AVENUE, MIDDLETOWN, NY 10941, NDC 5380740904, UPC 35380740941

Product Quantity:
9240 bottles

Reason for Recall:
CGMP Deviations: Products are being recalled due to an out of specification total aerobic microbial count in a water sample.

Recall Number:
D-0849-2018

Code Information:
Lot #: 47070021, Exp. 07/19

Product Description:
Geritrex Senna Syrup (sennosides 8.8mg), packaged in 8 FL OZ. (236 mL) bottle, Distributed by Geritrex, LLC 144 Kingsbridge Rd East Mt Vernon, NY 10550, 1-800-736-3437, NDC 54162-007-08, UPC 354162007088

Product Quantity:
31411 bottles

Reason for Recall:
CGMP Deviations: Products are being recalled due to an out of specification total aerobic microbial count in a water sample.

Recall Number:
D-0850-2018

Code Information:
Lot #: 47060011, 47070031, 47070041, Exp. 09/18; 47080031, Exp.10/18

Product Description:
SDA Senna Syrup (Sennosides 8.8mg), packaged in 8 FL. OZ. (236 mL) bottles, Distributed by SDA Laboratories 280 Railroad Avenue, Greenwich CT 06830, NDC 66424-562-08, UPC 366424562082

Product Quantity:
3537 bottles

Reason for Recall:
CGMP Deviations: Products are being recalled due to an out of specification total aerobic microbial count in a water sample.

Recall Number:
D-0851-2018

Code Information:
Lot #: 47070042, Exp. 09/18

Product Description:
Gericare Diocto Liquid (Docusate Sodium 50mg), 50 mg/5 mL, packaged in 16 FL OZ (473 mL) bottles, Dist by: Gericare Pharmaceuticals Corp. 1650 63rd Street, Brooklyn, NY 11204, NDC 57896-403-16, UPC 357896-403164,

Product Quantity:
12756 bottles

Reason for Recall:
CGMP Deviations: Products are being recalled due to an out of specification total aerobic microbial count in a water sample.

Recall Number:
D-0852-2018

Code Information:
Lot #: 47080041, 47080051, Exp. 08/19

Product Description:
Gericare Iron Supplement Elixir Ferrous Sulfate 220 mg, packaged in 16 fl oz. (473 mL) bottles, Dist by: Gericare Pharmaceuticals Corp. 1650 63rd Street Brooklyn, NY 11204, NDC 57896-709-16, UPC 57896709167

Product Quantity:
8124 bottles

Reason for Recall:
CGMP Deviations: Products are being recalled due to an out of specification total aerobic microbial count in a water sample.

Recall Number:
D-0853-2018

Code Information:
Lot #: 4780111, Exp. 08/19

Class II Drugs Event

Event ID:
80119

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/15/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
06/14/2018

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
MBi Distributing Inc. dba MBi Nutraceuticals
211 N 1800 W
Lindon UT United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Teething Drops, Homeopathic Drops for Temporary Relief of Pain Caused by Teething, 1 Fl Ounce glass amber bottle with glass dropper, MBi Nutraceuticals, Lindon, UT 84042. Bar Code: 3 58301 04011 0

Product Quantity:
121 bottles

Reason for Recall:
Lack of Processing Controls: Firm is voluntarily recalling all lots of homeopathic Teething Drops, Nausea Drops, Intestinal Colic Drops, Stomach Calm, Expectorant Cough Syrup, Silver-Zinc Throat Spray, and Argentum Elixir, within expiry, due to lack of adequate controls during manufacturing.

Recall Number:
D-0867-2018

Code Information:
Lot: 15041402, No EXP date

Product Description:
Nausea Drops, Homeopathic Drops for Temporary Relief of Motion Sickness, Morning Sickness, and General Nausea, 1 Fl. Ounce amber glass bottle with glass dropper. MBi Nutraceuticals Lindon, UT 84042. Bar Code: 1 58301 04711 4

Product Quantity:
48 bottles

Reason for Recall:
Lack of Processing Controls: Firm is voluntarily recalling all lots of homeopathic Teething Drops, Nausea Drops, Intestinal Colic Drops, Stomach Calm, Expectorant Cough Syrup, Silver-Zinc Throat Spray, and Argentum Elixir, within expiry, due to lack of adequate controls during manufacturing.

Recall Number:
D-0868-2018

Code Information:
Lot: 17011201, No EXP Date

Product Description:
Intestinal Colic Drops, Homeopathic Drops for Temporary Relief of Flatulent Colic, 1 ounce amber glass bottle with glass dropper, liquid, Meteorism, and Porphyrinuria. MBi Nutraceuticals Lindon, UT 84042

Product Quantity:
78 bottles

Reason for Recall:
Lack of Processing Controls: Firm is voluntarily recalling all lots of homeopathic Teething Drops, Nausea Drops, Intestinal Colic Drops, Stomach Calm, Expectorant Cough Syrup, Silver-Zinc Throat Spray, and Argentum Elixir, within expiry, due to lack of adequate controls during manufacturing.

Recall Number:
D-0869-2018

Code Information:
Lot: 8040802, EXP 04/2021.

Product Description:
Stomach Calm, Calms Upset Stomach and Aids in Treatment of Simple Diarrhea, 8 fl. oz., liquid 8 ounce amber PET bottle with Black CRC Cap, MBi Nutraceuticals Lindon, UT 84042. Bar Code: 3 58301 38414 2

Product Quantity:
343 bottles

Reason for Recall:
Lack of Processing Controls: Firm is voluntarily recalling all lots of homeopathic Teething Drops, Nausea Drops, Intestinal Colic Drops, Stomach Calm, Expectorant Cough Syrup, Silver-Zinc Throat Spray, and Argentum Elixir, within expiry, due to lack of adequate controls during manufacturing.

Recall Number:
D-0870-2018

Code Information:
Lot: 14093001, EXP 09/2020

Product Description:
Expectorant Cough Syrup, Homeopathic Syrup for Temporary Relief of Cough & Bronchitis. 8 Fl Ounces amber PET bottle with black cap. MBi Nutraceuticals 211 N 1800 W, Lindon, UT 84042. Bar Code: 3 58301 08214 1

Product Quantity:
1,971 bottles

Reason for Recall:
Lack of Processing Controls: Firm is voluntarily recalling all lots of homeopathic Teething Drops, Nausea Drops, Intestinal Colic Drops, Stomach Calm, Expectorant Cough Syrup, Silver-Zinc Throat Spray, and Argentum Elixir, within expiry, due to lack of adequate controls during manufacturing.

Recall Number:
D-0871-2018

Code Information:
Lot numbers: 16081901, EXP: 08/2018: 17031604, EXP: 03/2019; 17110901, EXP: 11/2019

Product Description:
Argentum Elixir Colloidal Silver, 50 PPM Homeopathic Infection Fighter, 8 fl oz. amber PET bottle with white sprayer. MBi nutraceuticals Lindon UT, 84042. Bar COde: 3 58301 18114 1

Product Quantity:
1,688 bottles

Reason for Recall:
Lack of Processing Controls: Firm is voluntarily recalling all lots of homeopathic Teething Drops, Nausea Drops, Intestinal Colic Drops, Stomach Calm, Expectorant Cough Syrup, Silver-Zinc Throat Spray, and Argentum Elixir, within expiry, due to lack of adequate controls during manufacturing.

Recall Number:
D-0872-2018

Code Information:
Lot numbers 15060201, EXP: 06/2019, 16081704, EXP: 08/2020

Product Description:
Silver-Zinc Throat Spray, HOMEOPATHIC IMMUNE DEFENSE, 50PPM, 4oz/50 ppm/ 120ml,amber PET bottle with white sprayer. MBi Nutraceuticals Lindon, Utah 84042 USA. Bar Code: 3 58301 18118 9

Product Quantity:
134 bottles

Reason for Recall:
Lack of Processing Controls: Firm is voluntarily recalling all lots of homeopathic Teething Drops, Nausea Drops, Intestinal Colic Drops, Stomach Calm, Expectorant Cough Syrup, Silver-Zinc Throat Spray, and Argentum Elixir, within expiry, due to lack of adequate controls during manufacturing.

Recall Number:
D-0873-2018

Code Information:
Lot: 15050801, EXP 05/2018

Class II Drugs Event

Event ID:
80184

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/25/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
06/12/2018

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Shadow Holdings DBA Bocchi Labs
26421 Ruether Ave
Santa Clarita CA United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
X-Jow (menthol USP) Pain Gel, 1.25%, packaged in a) 4 oz. (113g) bottles (UPC 850547 00502 6) and b) 8 oz. (226g) bottles (UPC 8 50547 00503 3, Distributed by Herb-X Solutions, Inc., 3838 West Burbank Blvd., Burbank CA 91505.

Product Quantity:
12,252 bottles

Reason for Recall:
CGMP Deviations: products may be contaminated with bacteria.

Recall Number:
D-0858-2018

Code Information:
All lots

Product Description:
Acne Shave Post-Shave Moisturizer (salicylic acid), 0.5%, 3.3 FL OZ (98 mL) tube, Distributed by: United Exchange Corp., 17211 Valley View Blvd., Cerritos, CA 90703 USA, UPC 7 80707 73112 3.

Product Quantity:
15,216 tubes

Reason for Recall:
CGMP Deviations: products may be contaminated with bacteria.

Recall Number:
D-0859-2018

Code Information:
All lots

Product Description:
Acne Shave (salicylic acid) Shave Cream Acne Shield, 0.5%, 5.1 FL OZ (150 mL) tube, Distributed by: United Exchange Corp., 17311 Valley View Blvd, Cerritos, CA 90703 USA, UPC 7 80707 73111 6.

Product Quantity:
8,208 tubes

Reason for Recall:
CGMP Deviations: products may be contaminated with bacteria.

Recall Number:
D-0860-2018

Code Information:
All lots

Product Description:
Acne Shave 3 Step Shaving System, contains one tube Acne Shave (salicylic acid) Shave Cream Acne Shield, one tube Acne Shave Post-Shave Moisturizer (salicylic acid), 0.5% tube, and one Power Shaver per box, Distributed by: United Exchange Corp., 17311 Valley View Blvd, Cerritos CA 90703 USA, UPC 7 80707 73114 7.

Product Quantity:
4,932 boxes

Reason for Recall:
CGMP Deviations: products may be contaminated with bacteria.

Recall Number:
D-0861-2018

Code Information:
All lots

Class II Drugs Event

Event ID:
80192

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/22/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
06/08/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Medline Industries Inc (Northpoint Services)
1160 S Northpoint Blvd
Waukegan IL United States

Distribution Pattern:
Nationwide in the U.S. and Qatar.

Associated Products

Product Description:
READYFLUSH PROTECT with Dimethicone (3.2%), Flushable Personal Cleaning Cloths, 24-count flexible pack. Manufactured by Medline Industries, Inc. Mundelein, IL 60060 USA. NDC 53329-066-58.

Product Quantity:
19,0800 24-count flexible packs

Reason for Recall:
Microbial Contamination of a Non-Sterile Product.

Recall Number:
D-0855-2018

Code Information:
Lot # 18BE0005, 18BE0006, Exp. 02/2020

Class II Drugs Event

Event ID:
80196

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/16/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
06/13/2018

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Option Systems Antibacterial Foaming Hand Wash with .3% PCMX, 1000 mL pouches, Inopak, LTD, Ringwood, NJ

Product Quantity:
1345 cases

Reason for Recall:
Microbial contamination of NonSterile Product; FDA analysis returned out of specification results for total aerobic microbial counts

Recall Number:
D-0864-2018

Code Information:
7302 01 039, 7302 03 039, 7302 01 040 and 7302 01 043

Class II Drugs Event

Event ID:
80251

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/05/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
06/08/2018

Initial Firm Notification of Consignee or Public:
Telephone

Recalling Firm:
PharMEDium Services, LLC
36 Stults Rd
Dayton NJ United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
HYDROmorphone HCl 0.5 mg per mL in 0.9% Sodium Chloride, 1 mL Total Volume in 3 mL syringe, Rx, PharMEDium Services, LLC, Dayton, NJ

Product Quantity:
2,800 syringes

Reason for Recall:
Superpotent and Subpotent

Recall Number:
D-0854-2018

Code Information:
Lot numbers: 180820005D, exp 6/21/2018; 180990007D, exp 7/8/2018; and 181000020D, exp 7/9/2018

Class II Drugs Event

Event ID:
80277

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/11/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
06/14/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
BioDiagnostic International
555 W Lambert Rd Ste C
Brea CA United States

Distribution Pattern:
Product was distributed to one sole customer in Illinois who further distributed Nationwide in the USA.

Associated Products

Product Description:
Monsel's Solution (Ferric Subsulfate), 20%, packaged as 12 single application vials and 12 applicators, 8 mL per box, Manufactured For: MedGyn

Products, Inc., 100 W. Industrial Rd., Addison, IL 60101 USA; Manufactured By: BioDiagnostics Intl, 555 West Lambert Road Unit-C, Brea, CA 92821, NDC 42721-112-08.

Product Quantity:
1000 boxes

Reason for Recall:
CGMP Deviations: Products not manufactured under current good manufacturing practices.

Recall Number:
D-0874-2018

Code Information:
All lots within expiry

Class III Drugs Event

Event ID:
80261

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/07/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
06/15/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Mylan Pharmaceuticals Inc.
781 Chestnut Ridge Rd
Morgantown WV United States

Distribution Pattern:
Product was distributed throughout the United States

Associated Products

Product Description:
Maxzide-25 (Triamterene and hydrochlorothiazide) tablets, USP, 37.5 mg/ 25 mg, 100-count bottle, Rx only, Mylan Pharmaceuticals Inc., Morgantown, WV 26505, NDC 0378-0464-01

Product Quantity:
1,620 bottles

Reason for Recall:
Superpotent Drug: Composite assay results obtained during routine stability testing were slightly above specification.

Recall Number:
D-0877-2018

Code Information:
Lot #: 3087136, Exp 5/20