Enforcement Report - Week of August 7, 2019

Class II Drugs Event

Event ID:
83284

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/02/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/30/2019

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Kaitlib Fe norethindrone and ethinyl estradiol chewable tablets (0.8 mg/0.025 mg) and Ferrous Fumarate, Chewable Tablets, Rx Only, Distributed by: Lupin Pharmaceuticals, Inc. Baltimore, MD - 21202 Manufactured by: Lupin Limited Pathampur -454775 India. NDC 68180-903-11 (wallet of 28 tablets) NDC 68180-903-13 (carton of 3 wallets)

Product Quantity:
12938 units

Reason for Recall:
Failed Impurities/Degradation Specifications: Kaitlib Fe Tablets has an out of specification result observed in long term stability study.

Recall Number:
D-1565-2019

Code Information:
Lot L800050

Class II Drugs Event

Event ID:
83315

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/10/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/06/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
LNK International, Inc.
55 Arkay Dr
Hauppauge NY United States

Distribution Pattern:
USA Nationwide

Associated Products

Product Description:
Equate Night-time Sleep Aide (Diphenhydramine HCl), 50 mg, Alcohol Free, Berry Flavor, 12 Fl. Oz. (354 mL), OTC, Distributed by: Walmart Stores, Inc., Bentonville, AR 72716, NDC 49035-330-02, UPC 6 8113117595 1

Product Quantity:
P300456, P300475 and P300489 (Total - 13,500 liters) and P300482 - 3,600 liter

Reason for Recall:
Microbial contamination of non-sterile product

Recall Number:
D-1630-2019

Code Information:
Lot #: P300456, P300475,P300482, P300489, Exp 09/30/2020

Class II Drugs Event

Event ID:
83339

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/12/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/31/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
H J Harkins Company Inc dba Pharma Pac
1400 W Grand Ave Ste F
Grover Beach CA United States

Distribution Pattern:
Distributed in California

Associated Products

Product Description:
Neomycin 3.5 mg/g / Polymyxin B10000 USP Units/g / Dexamethasone 1 mg/g Ophthalmic Ointment, 3.5 g tube, Rx only, Manufactured for H.J. Harkins Company, Inc. dba Pharma Pac by Perrigo Co, Allegan, MI 49010, NDC 52959-0407-01

Product Quantity:
97 boxes

Reason for Recall:
CGMPs Deviations: Insufficient Quality Assurance controls over critical systems in the manufacturing facility.

Recall Number:
D-1580-2019

Code Information:
Lot #: NPD10RP, Exp 08/19; NPD11RP, Exp 09/19; NPD12RP, Exp 11/19; NPD13RP, Exp 02/20; NPD14RP, Exp 02/20; NPD15RP, Exp 05/20; NPD16RP, Exp 06/20; NPD17RP, Exp 01/21; NPD18RP, Exp 02/21

Class II Drugs Event

Event ID:
83353

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/17/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/31/2019

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

Recalling Firm:
ImprimisRx NJ
1705 Us Highway 46 Ste 4
Ledgewood NJ United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Timolol-Latanoprost P-F (0.5/0.005%) ophthalmic drops, packaged in 5mL bottles, Rx only, ImprimisRX NJ 1705 Route 46 West, Suite 4, Ledgewood, NJ 07852 (844) 446-6979

Product Quantity:
405 bottles

Reason for Recall:
Subpotent Drug

Recall Number:
D-1578-2019

Code Information:
Lot #:01252019@1, Exp. 07/21/2019; 03182019@7, Exp. 09/7/2019; 05092019@2, Exp. 11/2/2019

Product Description:
Timolol- Dorzolamide- Latanoprost P-F (0.5/2.0/0.005%) ophthalmic drops, packaged in 5mL bottles, Rx only, ImprimisRx NJ 1705 Route 46 West, Suite 4, Ledgewood, NJ 07852 (844) 446-6979

Product Quantity:
246 bottles

Reason for Recall:
Subpotent Drug

Recall Number:
D-1579-2019

Code Information:
Lot #: 03132019@2, Exp. 09/17/2019; 05102019@2, Exp. 11/02/2019

Class II Drugs Event

Event ID:
83397

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/22/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/31/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Wise Pharmacy
6179 S Balsam Way Ste 150
Littleton CO United States

Distribution Pattern:
CO, TX, WY

Associated Products

Product Description:
Acetylcysteine 2% Otic Drop, 15 mL bottle, Rx only, Refrigerate, Compounded by Wise Pharmacy, Littleton, CO 80123.

Product Quantity:
1 bottle

Reason for Recall:
Lack of Processing Controls

Recall Number:
D-1567-2019

Code Information:
Lot #: 7131N, Exp 7/11/19

Product Description:
Alprostadil 100 mcg/mL Injectable, 2.5 mL vial, Rx only, Compounded by Wise Pharmacy, Littleton, CO 80123.

Product Quantity:
4 vials

Reason for Recall:
Lack of Processing Controls

Recall Number:
D-1568-2019

Code Information:
Lot #: 6981N, Exp 10/17/2019

Product Description:
Dexamethasone Sodium Phosphate PF 24 mg/mL Injection, Refrigerate, Single Use Vial, 1 mL vial, Rx only, Compounded by Wise Pharmacy, Littleton, CO 80123.

Product Quantity:
27 vials

Reason for Recall:
Lack of Processing Controls

Recall Number:
D-1569-2019

Code Information:
Lots #: 5506N, Exp 9/21/2019; 7180N, Exp 12/29/2019

Product Description:
Gentamicin (GU) Irrigation 240 mg/500 mL Solution, 250 mL Container, Shake well and Refrigerate, Rx only, Compounded by Wise Pharmacy, Littleton, CO 80123.

Product Quantity:
1 container

Reason for Recall:
Lack of Processing Controls

Recall Number:
D-1570-2019

Code Information:
Lot #: 7179N, Exp 7/16/2019

Product Description:
Tobramycin Irrigation 80 mg/1000 mL Solution, 1000 mL Container, Refrigerate, Nasal,, Rx only, Compounded by Wise Pharmacy, Littleton, CO 80123.

Product Quantity:
1 container

Reason for Recall:
Lack of Processing Controls

Recall Number:
D-1571-2019

Code Information:
Lot #: 7270N, Exp 7/22/2019

Product Description:
Papaverine/Phentolamine 30 mg/1 mg/mL Injectable, 2.5 mL Vial, Rx only, Compounded by Wise Pharmacy, Littleton, CO 80123.

Product Quantity:
8 vials

Reason for Recall:
Lack of Processing Controls

Recall Number:
D-1572-2019

Code Information:
Lot #: 5978N, Exp 8/20/2019; 7266N, Exp 11/5/2019

Product Description:
Papaverine/Phentolamine/Alprostadil 30 mg/0.2 mg/10 mcg/mL Injectable, 2.5 mL Vial, Rx only, Compounded by Wise Pharmacy, Littleton, CO 80123.

Product Quantity:
84 vials

Reason for Recall:
Lack of Processing Controls

Recall Number:
D-1573-2019

Code Information:
Lot #: 6054N; 4796N, Exp 7/16/2019; 7049N, Exp 11/24/2019

Product Description:
Papaverine/Phentolamine/Alprostadil - 30 mg/1 mg/10 mcg/mL Injectable, 2.5 mL Vial, Rx only, Compounded by Wise Pharmacy, Littleton, CO 80123.

Product Quantity:
44 vials

Reason for Recall:
Lack of Processing Controls

Recall Number:
D-1574-2019

Code Information:
Lot #: 5333N, Exp 7/12/2019; 7000N, Exp 10/18/2019

Product Description:
Papaverine/Phentolamine/Alprostadil 30 mg/2 mg/30 mcg/mL Injectable, 2.5 mL Vial, Rx only, Compounded by Wise Pharmacy, Littleton, CO 80123.

Product Quantity:
97 vials

Reason for Recall:
Lack of Processing Controls

Recall Number:
D-1575-2019

Code Information:
Lot #: 5620N, Exp 7/16/2019; 6221N, Exp 8/31/2019; 6952N, Exp 10/16/2019

Product Description:
Papaverine/Phentolamine/Alprostadil 30 mg/2 mg/50 mcg/mL Injectable, 2.5 mL Vial, Rx only, Compounded by Wise Pharmacy, Littleton, CO 80123.

Product Quantity:
32 vials

Reason for Recall:
Lack of Processing Controls

Recall Number:
D-1576-2019

Code Information:
Lot #: 6176N, Exp 8/30/2019; 7162N, Exp 10/20/2019

Product Description:
Papaverine/Phentolamine/Alprostadil/Atropine 30 mg/2 mg/50 mcg/0.15 mg/mL Injectable, 2.5 mL Vial, Rx only, Compounded by Wise Pharmacy, Littleton, CO 80123.

Product Quantity:
14 vials

Reason for Recall:
Lack of Processing Controls

Recall Number:
D-1577-2019

Code Information:
Lot #: 6153N, Exp8/29/2019

Class II Drugs Event

Event ID:
83460

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/24/2019

Voluntary / Mandated:

Center Classification Date:
08/01/2019

Initial Firm Notification of Consignee or Public:

Recalling Firm:
MAJOR PHARMACEUTICALS
17177 N Laurel Park Dr
Livonia MI United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
DIVALPROEX SODIUM EXTENDED-RELEASE TABLETS, USP Tablets, 250 mg, 100 count-unit dose carton, RX only, Manufactured by Dr. Reddy's Laboratories Ltd. Bachupally - 500 090 India. Distributed by: Major Pharmaceuticals 17177 N Laurel Park Dr., Suite 233 Livonia, MI 48152. NDC # 0904-6363-61.

Product Quantity:
828 100-count unit dose cartons

Reason for Recall:
cGMP deviations: Product was exposed above 50% relative humidity levels during packaging operations.

Recall Number:
D-1583-2019

Code Information:
Lot# M02250 EXP 10/2020.

Class II Drugs Event

Event ID:
83466

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/01/2018

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/31/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
American Health Packaging
2550 John Glenn Ave Ste A
Columbus OH United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Doxycycline Hyclate Tablets, USP, 100 mg, 30 Tablets per carton (3 x 10 Unit Dose Blisters), Rx Only, Distributed by: American Health Packaging, Columbus, Ohio, 43217, NDC Carton: 62584-693-21; NDC Unit Dose: 62584-693-11

Product Quantity:
6,579 cartons

Reason for Recall:
Failed Dissolution Specifications: Out of specification result for the dissolution test.

Recall Number:
D-1582-2019

Code Information:
Lot 172569, Exp 7/31/2019

Class III Drugs Event

Event ID:
83018

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/01/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/27/2019

Initial Firm Notification of Consignee or Public:
Telephone

Recalling Firm:
NingBo Huize Commodity Co.,Ltd.
14 Lizhou Road
Yuyao China

Distribution Pattern:
Foreign manufacturer located in China and distributed to seven consignees located in China.

Associated Products

Product Description:
Accent Care of New York Home Care Nursing Personal Care Hand Sanitizer (Ethyl Alcohol 62%), 0.33 oz/10 mL, OTC, Made in China

Product Quantity:
35,500

Reason for Recall:
CGMP deviations: Stability testing was not conducted on manufactured sunscreen and hand sanitizer OTC products.

Recall Number:
D-1529-2019

Code Information:
Lot #: 20170619, Exp 6/18/2019; 20170620, Exp 6/19/2019; 20170621, Exp 6/20/2019

Product Description:
Good to Go Hand Sanitizer (Ethyl Alcohol 62%), 1 FL OZ (30 mL), OTC, Made in China for Cashco Distributors Inc. 6430 N. E. Columbia Blvd Portland OR 97218

Product Quantity:
52,160

Reason for Recall:
CGMP deviations: Stability testing was not conducted on manufactured sunscreen and hand sanitizer OTC products.

Recall Number:
D-1530-2019

Code Information:
Lot #: 20180601 Exp 5/31/2020, 20180604 Exp 6/3/2020, 20180820 Exp 8/19/2020, 20180821 Exp 8/20/2020, 20180822 Exp 8/21/2020

Product Description:
Tootsie Roll POP GRAPE SCENTED ANTIBACTERIAL HAND GEL (Ethyl Alcohol 62%), 1.35 fl oz / 40 mL, OTC, Distributed By: JFL Enterprises, Inc. Cleveland, Ohio 44102, Made in China

Product Quantity:
5112

Reason for Recall:
CGMP deviations: Stability testing was not conducted on manufactured sunscreen and hand sanitizer OTC products.

Recall Number:
D-1531-2019

Code Information:
Lot #: 20181018, Exp 10/17/2020

Product Description:
SPF 30 SUNSCREEN LOTION Active Ingredients Octinoxate 7.5%, Octisalate 2.0%, Oxybenzone 4.0% Titanium Dioxide 2.5% Sunscreen, 53mL/1.8fl.oz., OTC, Distributed by: EVANS, Made in China

Product Quantity:
10, 000

Reason for Recall:
CGMP deviations: Stability testing was not conducted on manufactured sunscreen and hand sanitizer OTC products.

Recall Number:
D-1532-2019

Code Information:
Lot #: 20180709, Exp 07/08/2020; 20180710, Exp 07/09/2020

Product Description:
festpak clearly fun SPF30 sunscreen lotion SPF 30 SUNSCREEN LOTION Active Ingredients Octinoxate 7.5%, Octisalate 2.0%, Oxybenzone 4.0% Titanium Dioxide 2.5% Sunscreen Distributed by: festpak - Austin, TX 78732 Made in China

Product Quantity:
20, 000

Reason for Recall:
CGMP deviations: Stability testing was not conducted on manufactured sunscreen and hand sanitizer OTC products.

Recall Number:
D-1533-2019

Code Information:
Lot #: 20181008, Exp 10/07/2020; 20181009, Exp 10/08/2020

Product Description:
Texas Home Health Home Care Hospice Personal Care Hand Sanitizer (Ethyl Alcohol 62%), 0.33 oz/10 mL, OTC, Made in China

Product Quantity:
50,000

Reason for Recall:
CGMP deviations: Stability testing was not conducted on manufactured sunscreen and hand sanitizer OTC products.

Recall Number:
D-1534-2019

Code Information:
Lot #: 20180410, Exp 4/9/2020; 20180411, Exp 4/10/2020; 20180830, Exp 8/29/2020; 20180831, Exp 8/30/2020

Product Description:
Tootsie Roll POP ORANGE SCENTED ANTIBACTERIAL HAND GEL (Ethyl Alcohol 62%), 1.35 fl oz / 40 mL, OTC, Distributed by: JFL Enterprises, Inc. Cleveland, Ohio 44102.

Product Quantity:
5112

Reason for Recall:
CGMP deviations: Stability testing was not conducted on manufactured sunscreen and hand sanitizer OTC products.

Recall Number:
D-1535-2019

Code Information:
Lot #: 20181015, Exp 10/14/2020

Product Description:
Tootsie Roll POP CHOCOLATE SCENTED ANTIBACTERIAL HAND GEL (Ethyl Alcohol 62%), 1.35 fl oz / 40 mL, OTC, Distributed by: JFL Enterprises, Inc. Cleveland, Ohio 44102.

Product Quantity:
5112

Reason for Recall:
CGMP deviations: Stability testing was not conducted on manufactured sunscreen and hand sanitizer OTC products.

Recall Number:
D-1536-2019

Code Information:
Lot #: 20181016, Exp 10/15/2020

Product Description:
Tootsie Roll POP RASPBERRY SCENTED ANTIBACTERIAL HAND GEL (Ethyl Alcohol 62%), 1.35 fl oz / 40 mL, OTC, Distributed by: JFL Enterprises, Inc. Cleveland, Ohio 44102.

Product Quantity:
5112

Reason for Recall:
CGMP deviations: Stability testing was not conducted on manufactured sunscreen and hand sanitizer OTC products.

Recall Number:
D-1537-2019

Code Information:
Lot #: 20181017, Exp 10/16/2020

Product Description:
DOTS SCENTED ANTIBACTERIAL HAND GEL ORANGE (Ethyl Alcohol 62%), 1.35 fl oz / 40 mL, OTC, Distributed by: JFL Enterprises, Inc. Cleveland, Ohio 44102.

Product Quantity:
3852

Reason for Recall:
CGMP deviations: Stability testing was not conducted on manufactured sunscreen and hand sanitizer OTC products.

Recall Number:
D-1538-2019

Code Information:
Lot #: 20181019, Exp 10/18/2020

Product Description:
DOTS SCENTED ANTIBACTERIAL HAND GEL LIME (Ethyl Alcohol 62%), 1.35 fl oz / 40 mL, OTC, Distributed by: JFL Enterprises, Inc. Cleveland, Ohio 44102.

Product Quantity:
3852

Reason for Recall:
CGMP deviations: Stability testing was not conducted on manufactured sunscreen and hand sanitizer OTC products.

Recall Number:
D-1539-2019

Code Information:
Lot #: 20181022, Exp 10/21/2020

Product Description:
DOTS SCENTED ANTIBACTERIAL HAND GEL STRAWBRRY (Ethyl Alcohol 62%), 1.35 fl oz / 40 mL, OTC, Distributed by: JFL Enterprises, Inc. Cleveland, Ohio 44102.

Product Quantity:
3852

Reason for Recall:
CGMP deviations: Stability testing was not conducted on manufactured sunscreen and hand sanitizer OTC products.

Recall Number:
D-1540-2019

Code Information:
Lot #: 20181023, Exp 10/22/2020

Product Description:
DOTS SCENTED ANTIBACTERIAL HAND GEL LEMON (Ethyl Alcohol 62%), 1.35 fl oz / 40 mL, OTC, Distributed by: JFL Enterprises, Inc. Cleveland, Ohio 44102.

Product Quantity:
3852

Reason for Recall:
CGMP deviations: Stability testing was not conducted on manufactured sunscreen and hand sanitizer OTC products.

Recall Number:
D-1541-2019

Code Information:
Lot #: 20181024, Exp 10/23/2020

Product Description:
CHARMS BLOW POP CHERRY SCENTED ANTIBACTERIAL HAND GEL (Ethyl Alcohol 62%), 1.35 fl oz / 40 mL, OTC, Distributed by: JFL Enterprises, Inc. Cleveland, Ohio 44102.

Product Quantity:
18036

Reason for Recall:
CGMP deviations: Stability testing was not conducted on manufactured sunscreen and hand sanitizer OTC products.

Recall Number:
D-1542-2019

Code Information:
Lot #: 20181025, Exp 10/24/2020; 20181026, Exp 10/25/2020

Product Description:
CHARMS BLOW POP WATERMELON SCENTED ANTIBACTERIAL HAND GEL (Ethyl Alcohol 62%), 1.35 fl oz / 40 mL, OTC, Distributed by: JFL Enterprises, Inc. Cleveland, Ohio 44102.

Product Quantity:
18036

Reason for Recall:
CGMP deviations: Stability testing was not conducted on manufactured sunscreen and hand sanitizer OTC products.

Recall Number:
D-1543-2019

Code Information:
Lot #: 20181029, Exp 10/28/2020; 20181030, Exp 10/29/2020

Product Description:
CHARMS BLOW POP BLUE RAZZ BERRY SCENTED ANTIBACTERIAL HAND GEL (Ethyl Alcohol 62%), 1.35 fl oz / 40 mL, OTC, Distributed by: JFL Enterprises, Inc. Cleveland, Ohio 44102.

Product Quantity:
18036

Reason for Recall:
CGMP deviations: Stability testing was not conducted on manufactured sunscreen and hand sanitizer OTC products.

Recall Number:
D-1544-2019

Code Information:
Lot #: 20181031, Exp 10/28/2020; 20181101, Exp 10/31/2020

Product Description:
CHARMS BLOW POP SOUR APPLE SCENTED ANTIBACTERIAL HAND GEL (Ethyl Alcohol 62%), 1.35 fl oz / 40 mL, OTC, Distributed by: JFL Enterprises, Inc. Cleveland, Ohio 44102.

Product Quantity:
18036

Reason for Recall:
CGMP deviations: Stability testing was not conducted on manufactured sunscreen and hand sanitizer OTC products.

Recall Number:
D-1545-2019

Code Information:
Lot #: 20181102, Exp 11/1/2020; 20181105, Exp 11/4/2020

Product Description:
AMERICA'S ORIGINAL DUBBLE BUBBLE SCENTED ANTIBACTERIAL HAND GEL (Ethyl Alcohol 62%), 1.35 fl oz / 40 mL, OTC, Distributed by: JFL Enterprises, Inc. Cleveland, Ohio 44102.

Product Quantity:
20160

Reason for Recall:
CGMP deviations: Stability testing was not conducted on manufactured sunscreen and hand sanitizer OTC products.

Recall Number:
D-1546-2019

Code Information:
Lot #: 20181106, Exp 11/5/2020; 20181107, Exp 11/6/2020

Product Description:
AMERICA'S ORIGINAL DUBBLE BUBBLE Pink Lemonade SCENTED ANTIBACTERIAL HAND GEL (Ethyl Alcohol 62%), 1.35 fl oz / 40 mL, OTC, Distributed by: JFL Enterprises, Inc. Cleveland, Ohio 44102.

Product Quantity:
20,160

Reason for Recall:
CGMP deviations: Stability testing was not conducted on manufactured sunscreen and hand sanitizer OTC products.

Recall Number:
D-1547-2019

Code Information:
Lot #: 20181108, Exp 11/7/2020; 20181109, Exp 11/8/2020

Product Description:
TOOTSIE ROLL FRUIT CHEWS LEMON SCENTED ANTIBACTERIAL HAND GEL (Ethyl Alcohol 62%), 1.35 fl oz / 40 mL, OTC, Distributed by: JFL Enterprises, Inc. Cleveland, Ohio 44102.

Product Quantity:
8,856

Reason for Recall:
CGMP deviations: Stability testing was not conducted on manufactured sunscreen and hand sanitizer OTC products.

Recall Number:
D-1548-2019

Code Information:
Lot #: 20181112, Exp 11/11/2020

Product Description:
TOOTSIE ROLL FRUIT CHEWS VANILLA SCENTED ANTIBACTERIAL HAND GEL (Ethyl Alcohol 62%), 1.35 fl oz / 40 mL, OTC, Distributed by: JFL Enterprises, Inc. Cleveland, Ohio 44102.

Product Quantity:
8,856

Reason for Recall:
CGMP deviations: Stability testing was not conducted on manufactured sunscreen and hand sanitizer OTC products.

Recall Number:
D-1549-2019

Code Information:
Lot #: 20181113, Exp 11/12/2020

Product Description:
TOOTSIE ROLL FRUIT CHEWS LIME SCENTED ANTIBACTERIAL HAND GEL (Ethyl Alcohol 62%), 1.35 fl oz / 40 mL, OTC, Distributed by: JFL Enterprises, Inc. Cleveland, Ohio 44102.

Product Quantity:
8,856

Reason for Recall:
CGMP deviations: Stability testing was not conducted on manufactured sunscreen and hand sanitizer OTC products.

Recall Number:
D-1550-2019

Code Information:
Lot #: 20181114, Exp 11/13/2020

Product Description:
TOOTSIE ROLL SCENTED ANTIBACTERIAL HAND GEL (Ethyl Alcohol 62%), 1.35 fl oz / 40 mL, OTC, Distributed by: JFL Enterprises, Inc. Cleveland, Ohio 44102.

Product Quantity:
8,856

Reason for Recall:
CGMP deviations: Stability testing was not conducted on manufactured sunscreen and hand sanitizer OTC products.

Recall Number:
D-1551-2019

Code Information:
Lot #: 20181115, Exp 11/14/2020

Product Description:
AIR HEADS STRAWBERRY SCENTED ANTIBACTERIAL HAND GEL (Ethyl Alcohol 62%), 1.35 fl oz / 40 mL, OTC, Distributed by: JFL Enterprises, Inc. Cleveland, Ohio 44102.

Product Quantity:
13,068

Reason for Recall:
CGMP deviations: Stability testing was not conducted on manufactured sunscreen and hand sanitizer OTC products.

Recall Number:
D-1552-2019

Code Information:
Lot #: 20181116, Exp 11/15/2020; 20181119, Exp 11/18/2020

Product Description:
AIR HEADS BLUE RASPBERRY SCENTED ANTIBACTERIAL HAND GEL (Ethyl Alcohol 62%), 1.35 fl oz / 40 mL, OTC, Distributed by: JFL Enterprises, Inc. Cleveland, Ohio 44102.

Product Quantity:
13,068

Reason for Recall:
CGMP deviations: Stability testing was not conducted on manufactured sunscreen and hand sanitizer OTC products.

Recall Number:
D-1553-2019

Code Information:
Lot #: 20181120, Exp 11/19/2020; 20181121, Exp 11/20/2020

Product Description:
AIR HEADS PINK LEMONADE SCENTED ANTIBACTERIAL HAND GEL (Ethyl Alcohol 62%), 1.35 fl oz / 40 mL, OTC, Distributed by: JFL Enterprises, Inc. Cleveland, Ohio 44102.

Product Quantity:
13,068

Reason for Recall:
CGMP deviations: Stability testing was not conducted on manufactured sunscreen and hand sanitizer OTC products.

Recall Number:
D-1554-2019

Code Information:
Lot #: 20181122, Exp 11/21/2020; 20181123, Exp 11/22/2020

Product Description:
AIR HEADS ORANGE SCENTED ANTIBACTERIAL HAND GEL (Ethyl Alcohol 62%), 1.35 fl oz / 40 mL, OTC, Distributed by: JFL Enterprises, Inc. Cleveland, Ohio 44102.

Product Quantity:
13,068

Reason for Recall:
CGMP deviations: Stability testing was not conducted on manufactured sunscreen and hand sanitizer OTC products.

Recall Number:
D-1555-2019

Code Information:
Lot #: 20181126, Exp 11/25/2020; 20181127, Exp 11/26/2020

Product Description:
ICEE LEMON LIME SCENTED ANTIBACTERIAL HAND GEL (Ethyl Alcohol 62%), 1.35 fl oz / 40 mL, OTC, Distributed by: JFL Enterprises, Inc. Cleveland, Ohio 44102.

Product Quantity:
13,068

Reason for Recall:
CGMP deviations: Stability testing was not conducted on manufactured sunscreen and hand sanitizer OTC products.

Recall Number:
D-1556-2019

Code Information:
Lot #: 20181128, Exp 11/27/2020; 20181129, Exp 11/28/2020

Product Description:
ICEE PEACH SCENTED ANTIBACTERIAL HAND GEL (Ethyl Alcohol 62%), 1.35 fl oz / 40 mL, OTC, Distributed by: JFL Enterprises, Inc. Cleveland, Ohio 44102.

Product Quantity:
13,068

Reason for Recall:
CGMP deviations: Stability testing was not conducted on manufactured sunscreen and hand sanitizer OTC products.

Recall Number:
D-1557-2019

Code Information:
Lot #: 20181130, Exp 11/29/2020; 20181203, Exp 12/2/2020

Product Description:
ICEE CHERRY SCENTED ANTIBACTERIAL HAND GEL (Ethyl Alcohol 62%), 1.35 fl oz / 40 mL, OTC, Distributed by: JFL Enterprises, Inc. Cleveland, Ohio 44102.

Product Quantity:
13,068

Reason for Recall:
CGMP deviations: Stability testing was not conducted on manufactured sunscreen and hand sanitizer OTC products.

Recall Number:
D-1558-2019

Code Information:
Lot #: 20181204, Exp 12/3/2020; 20181205, Exp 12/4/2020

Product Description:
ICEE BLUE RASPBERRY SCENTED ANTIBACTERIAL HAND GEL (Ethyl Alcohol 62%), 1.35 fl oz / 40 mL, OTC, Distributed by: JFL Enterprises, Inc. Cleveland, Ohio 44102.

Product Quantity:
13,068

Reason for Recall:
CGMP deviations: Stability testing was not conducted on manufactured sunscreen and hand sanitizer OTC products.

Recall Number:
D-1559-2019

Code Information:
Lot #: 20181206, Exp 12/5/2020; 20181207, Exp 12/6/2020

Product Description:
DIPPIN' DOTS SCENTED BANANA SPLIT ANTIBACTERIAL HAND GEL (Ethyl Alcohol 62%), 1.35 fl oz / 40 mL, OTC, Distributed by: JFL Enterprises, Inc. Cleveland, Ohio 44102.

Product Quantity:
13,068

Reason for Recall:
CGMP deviations: Stability testing was not conducted on manufactured sunscreen and hand sanitizer OTC products.

Recall Number:
D-1560-2019

Code Information:
Lot #: 20181210, Exp 12/09/2020

Product Description:
DIPPIN' DOTS SCENTED BIRTHDAY CAKE ANTIBACTERIAL HAND GEL (Ethyl Alcohol 62%), 1.35 fl oz / 40 mL, OTC, Distributed by: JFL Enterprises, Inc. Cleveland, Ohio 44102.

Product Quantity:
13,068

Reason for Recall:
CGMP deviations: Stability testing was not conducted on manufactured sunscreen and hand sanitizer OTC products.

Recall Number:
D-1561-2019

Code Information:
Lot #: 20181211, Exp 12/10/2020

Product Description:
DIPPIN' DOTS SCENTED COOKIES 'N CREAM ANTIBACTERIAL HAND GEL (Ethyl Alcohol 62%), 1.35 fl oz / 40 mL, OTC, Distributed by: JFL Enterprises, Inc. Cleveland, Ohio 44102.

Product Quantity:
13,068

Reason for Recall:
CGMP deviations: Stability testing was not conducted on manufactured sunscreen and hand sanitizer OTC products.

Recall Number:
D-1562-2019

Code Information:
Lot #: 20181212, Exp 12/11/2020

Product Description:
DIPPIN' DOTS SCENTED COTTON CANDY ANTIBACTERIAL HAND GEL (Ethyl Alcohol 62%), 1.35 fl oz / 40 mL, OTC, Distributed by: JFL Enterprises, Inc. Cleveland, Ohio 44102.

Product Quantity:
13,068

Reason for Recall:
CGMP deviations: Stability testing was not conducted on manufactured sunscreen and hand sanitizer OTC products.

Recall Number:
D-1563-2019

Code Information:
Lot #: 20181213, Exp 12/12/2020

Product Description:
Lemon Hand Sanitizer (Alcohol 62%), 30 mL / 1.0 fl.oz, OTC, Made in China.

Product Quantity:
126,500

Reason for Recall:
CGMP deviations: Stability testing was not conducted on manufactured sunscreen and hand sanitizer OTC products.

Recall Number:
D-1564-2019

Code Information:
Lot #: 20170410, Exp 04/09/2019; 20170515, Exp 05/14/2019; 20170516, Exp 05/15/2019; 20170517, Exp 05/16/2019; 20170518, Exp 05/17/2019; 20170519, Exp 05/18/2019; 20170522, Exp 05/21/2019; 20170523, Exp 05/22/2019: 20170524, Exp 05/23/2019; 20170525, Exp 05/24/2019; 20170526, Exp 05/25/2019; 20180615, Exp 06/14/2020

Not Yet Classified Drugs Event

Event ID:
83280

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/08/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Piramal Critical Care, Inc.

3950 Schelden Cir
Bethlehem PA United States

Distribution Pattern:
US Nationwide

Associated Products

Product Description:
Gablofen (baclofen injection), 50 mcg/mL, Single Use Syringe, Rx only, packaged in a box containing one 1 mL syringe, Distributed by: Primal Critical Care, Inc., 3950 Schelden Circle Bethlehem, PA, 18017, NDC 66794-151-01

Product Quantity:
Lot 2155-111 (1,418 units) and Lot 2155-111A (5,640 units)

Reason for Recall:
Failed Impurities/Degradation Specification -This recall is being initiated as a precaution due to the presence of an unknown impurity observed during shelf life of the product.

Recall Number:

Code Information:
Lot #: 2155-111, 2155-111A, Exp 6/20

Not Yet Classified Drugs Event

Event ID:
83408

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/09/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Jubilant Cadista Pharmaceuticals, Inc.
207 Kiley Dr
Salisbury MD United States

Distribution Pattern:
Recall product was distributed to 3 wholesalers, 6 distributors and 1 retailer in Florida, Louisiana, Mississippi, Ohio, New Jersey, New York, and North Dakota. Distributors and wholesalers may have further distributed the product.

Associated Products

Product Description:
Drospirenone and Ethinyl Estradiol Tablets, USP, 3 mg/0.02 mg, packaged into a carton containing 3 blister cards each blister card contains 28-film coated, biconvex tablets, Rx Only, Manufactured by: Cyndea Pharma, S.L., Olvega (Soria), 42110 Spain, Distributed by: Jubilant Cadista Pharmaceuticals, Inc., Salisbury, MD, 21801 USA, 59746-763-43

Product Quantity:
11,412 cartons/34,236 blister cards/28 pills each card

Reason for Recall:
Failed dissolution results at the 3-month stability time point.

Recall Number:

Code Information:
Lot number 183222,exp. date 11/2020.