Enforcement Report - Week of January 31, 2018

Class II Drugs Event

Event ID:
78822

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/09/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
01/24/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Marksans Pharma Inc.
Suite # 401, 4th Floor Room No. 430, 150 Motor Parkway
Hauppauge NY United States

Distribution Pattern:
Distributed to repackaging firms in NY who then distributed Nationwide in the USA.

Associated Products

Product Description:
Ibuprofen Tablets, USP 200 mg, 6 x 6500 Caplets (Capsule-Shaped Tablets) bulk packed in double polybag shipper packs for further packaging, Rx only, Manufactured by: Marksans Pharma Ltd., Plot No. L-82, L-83, Verna Indl. Estate, Verna, Goa - 403 722, India, NDC 25000-117-30.

Product Quantity:
2,853,500 Caplets

Reason for Recall:
CGMP Deviations: Various strengths of ibuprofen tablets/caplets are being recalled due to complaints of odor related to CGMP deficiencies.

Recall Number:
D-0235-2018

Code Information:
Lot #: HH6001, HH6002, Exp 04/18

Product Description:
Ibuprofen Tablets, USP 200 mg, 6 x 6500 Tablets bulk packed in double polybag shipper packs for further packaging, Rx only, Manufactured by: Marksans Pharma Ltd., Plot No. L-82, L-83, Verna Indl. Estate, Verna, Goa - 403 722, India, NDC 25000-136-20.

Product Quantity:
4,127,500 tablets

Reason for Recall:
CGMP Deviations: Various strengths of ibuprofen tablets/caplets are being recalled due to complaints of odor related to CGMP deficiencies.

Recall Number:
D-0236-2018

Code Information:
Lot #: HI6001, HI6002, HI6003, Exp 02/18

Product Description:
Ibuprofen Tablets, USP 200 mg, 6 x 6500 Tablets bulk packed in double polybag shipper packs for further packaging, Rx only, Manufactured by: Marksans Pharma Ltd., Plot No. L-82, L-83, Verna Indl. Estate, Verna, Goa - 403 722, India, NDC 25000-114-30.

Product Quantity:
205,088,000 tablets

Reason for Recall:
CGMP Deviations: Various strengths of ibuprofen tablets/caplets are being recalled due to complaints of odor related to CGMP deficiencies.

Recall Number:
D-0237-2018

Code Information:
Lot #: HJ6080, HJ6081, HJ6082, HJ6083, HJ6084, HJ6085, HJ6086, HJ6087, HJ6088, HJ6089, HJ6090, HJ6091, HJ6092, HJ6093, HJ6094, HJ6095, HJ6096, HJ6097, HJ6098, HJ6099, HJ6100, HJ6101, HJ6102, HJ6103, HJ6104, HJ6105, HJ6106, HJ6107, HJ6108, HJ6109, HJ6110, HJ6111, HJ6112, Exp 02/18; HJ6113, HJ6114, HJ6115, HJ6116, HJ6117, HJ6118, HJ6119, HJ6120, HJ6121, HJ6122, HJ6123, HJ6124, HJ6125, HJ6126, HJ6127, HJ6128, HJ6129, HJ6130, HJ6131, HJ6132, HJ6133, HJ6134, HJ6135, HJ6136, Exp 03/18; HJ6137, HJ6138, HJ6139, HJ6140, HJ6141, HJ6142, HJ6143, HJ6144, HJ6145, HJ6146, HJ6147, HJ6148, HJ6149, HJ6150, HJ6151, HJ6152, HJ6143, HJ6154, HJ6155, HJ6156, HJ6157, HJ6158, HJ6159, HJ6160, HJ6161, HJ6162, HJ6163, HJ6164, HJ6165, HJ6166, HJ6167, HJ6168, HJ6169, HJ6180, HJ6171, HJ6172, HJ6173, HJ6174, HJ6175, Exp 04/18; HJ6176, HJ6177, HJ6178, HJ6179, HJ6180, HJ6181, HJ6182, HJ6183, HJ6184, HJ6185, HJ6186, HJ6187, HJ6188, HJ6189, HJ6190, HJ6191, HJ6192, HJ6193, HJ6194, HJ6195, HJ6196, HJ6197, HJ6198, HJ6199, HJ6200, HJ6201, HJ6202, HJ6203, Exp 05/18; HJ6204, HJ6025, HJ6206, HJ6207, HJ6208, HJ6209, HJ6210, HJ6211, HJ6212, HJ6213, HJ6214, HJ6215, Exp 06/18; HJ6216, HJ6217, HJ6218, HJ6219, HJ6220, Exp 08/18

Product Description:
Ibuprofen Tablets, USP 400 mg, 6 x 3500 Tablets bulk packed in double polybag shipper packs for further packaging, Rx only, Manufactured by:

Product Quantity:
21,584,100 tablets

Marksans Pharma Ltd., Plot No. L-82, L-83, Verna Indl. Estate, Verna, Goa - 403 722, India, NDC 25000-121-29.

Reason for Recall:
CGMP Deviations: Various strengths of ibuprofen tablets/caplets are being recalled due to complaints of odor related to CGMP deficiencies.

Recall Number:
D-0238-2018

Code Information:
Lot #: HK6001, HK6002, HK6003, HK6004, HK6005, HK6006, HK6007, HK6008, HK6009, HK6010, HK6011, HK6012, HK6013, HK6014, HK6015, Exp 09/18

Product Description:
Ibuprofen Tablets, USP 600 mg, 6 x 2500 Tablets bulk packed in double polybag shipper packs for further packaging, Rx only, Manufactured by: Marksans Pharma Ltd., Plot No. L-82, L-83, Verna Indl. Estate, Verna, Goa - 403 722, India, NDC 25000-122-28.

Product Quantity:
23,088,900 tablets

Reason for Recall:
CGMP Deviations: Various strengths of ibuprofen tablets/caplets are being recalled due to complaints of odor related to CGMP deficiencies.

Recall Number:
D-0239-2018

Code Information:
Lot #: HN6004, HN6005, HN6006, HN6007, HN6008, HN6009, HN6010, HN6011, HN6012, HN6013, HN6014, Exp 03/18; HN6015, HN6016, HN6017, HN6018, HN6019, HN6020, HN6021, HN6022, HN6023, Exp 04/18; HN6024, Exp 07/18; HN6025, HN6026, HN6027, Exp 09/18

Product Description:
Ibuprofen Tablets, USP 800 mg, 6 x 1900 Tablets bulk packed in double polybag shipper packs for further packaging, Rx only, Manufactured by: Marksans Pharma Ltd., Plot No. L-82, L-83, Verna Indl. Estate, Verna, Goa - 403 722, India, NDC 25000-123-27.

Product Quantity:
52,549,000 tablets

Reason for Recall:
CGMP Deviations: Various strengths of ibuprofen tablets/caplets are being recalled due to complaints of odor related to CGMP deficiencies.

Recall Number:
D-0240-2018

Code Information:
Lot #: Lot #: HM6067, HM6068, HM6069, HM6070, HM6072, HM6072, HM6073, HM6074, HM6075, HM6076, HM6077, HM6078, HM6079, HM6080, HM6081, HM6082, HM6083, HM6084, HM6085, HM6086, HM6087, HM6088, HM6089, HM6090, HM6091, HM6092, HM6093, HM6094, HM6095, HM6096, Exp 02/18; HM6097, HM6098, HM6099, Exp 03/18; HM6100, HM6101, HM6102, HM6103, HM6104, HM6105, HM6106, HM6107, HM6108, HM6109, HM6110, HM6111, HM6112, HM6113, HM6114, HM6115, HM6116, HM6117, HM6118, HM6119, HM6120, HM6121, HM6122, HM6123, HM6124, HM6125, HM6126, HM6127, HM6128, HM6129, HM6130, HM6131, HM6132, Exp 08/18; HM6133, HM6134, HM6135, HM6136, HM6137, HM6128, HM6139; Exp 09/18

Class II Drugs Event

Event ID:
78841

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/28/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
01/25/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
DLC Laboratories, Inc
7008 Marcelle St
Paramount CA United States

Distribution Pattern:
Product was distributed nationwide.

Associated Products

Product Description:
Earth's Care Eczema Lotion (2% Colloidal Oatmeal) Skin Protectant with Aloe and Almond Oil, 8 fl. oz. (237 mL) HPDE bottle, Distributed by: Earth's Care Natural Products, Inc. Long Beach, California 90805, NDC 24286-1569-08, UPC 85730700307.

Product Quantity:
4,081 HDPE bottles

Reason for Recall:
Microbial Contamination of Non-Sterile Products.

Recall Number:
D-0241-2018

Code Information:
Batch # 4317; Exp. 02/19 Batch # 4393; Exp. 05/19 Batch # 4437; Exp. 07/19

Class II Drugs Event

Event ID:
78887

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/20/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
01/24/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Odan Laboratories Ltd
325 Stillview Ave
Pointe-Claire Canada

Distribution Pattern:
distributed nationwide in the USA

Associated Products

Product Description:
Day Cream SPF15 Cr¿me de jour FPS 15, { Avobenzone 2%, Octinoxate 7%, Oxybenzone 5%} 15 ml / 0.5 fl. oz jar. Made in Canada, Kamins Dermatologics Inc. Montreal, Quebec H9R 2Y6. Distributed by Kamins Dermatologics Montreal, Quebec H9R 2Y6 Made in Fabrique au Canada. UPC code 6 26354 10955 0

Product Quantity:
21 jars

Reason for Recall:
Failed Stability Specifications:stability failure at 12 months, long term RT conditions.

Recall Number:
D-0231-2018

Code Information:
Lot # J146C, EXP 02-2019.

Product Description:
Dry to Normal Skin Starter Kit, Trousse debutante pour peau seche a normale. Kit includes: (Vegetable Cleanser (60 ml / 2 oz), Night Cream (15 g / 0.5 oz), Day Cream SPF15 {Octinoxate 7%, Avobenzone 2% and Oxybenzone 5%} (15 g / 0.5 oz), Eye Cream (6 g / 0.21 oz).Made in Canada, Kamins Dermatologics Inc. Montreal, Quebec H9R 2Y6. Distributed by Kamins Dermatologics (USA) Inc. 99 Hudson, New York, NY, USA. UPC code 6 06354 61322 4

Product Quantity:
179 kits

Reason for Recall:
Failed Stability Specifications:stability failure at 12 months, long term RT conditions.

Recall Number:
D-0232-2018

Code Information:
Lots # J203, J204, EXP 02-2018; J228, J274, EXP 09-2018

Class II Drugs Event

Event ID:
78939

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/12/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
01/24/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
International Laboratories, Inc.
6950 Bryan Dairy Rd Ste A
Seminole FL United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Pravastatin Sodium Tablets, USP, 10 mg, 30-count bottles, packaged in 12 x 30 tablets for individual patient dispensing per pharmacy dispenser cartons, Rx only, Packaged for: International Laboratories, LLC. St. Petersburg, FL 33710, NDC 54458-927-16.

Product Quantity:
9,052 cartons

Reason for Recall:
Presence of Foreign Tablets/Capsules: bottles could contain both pravastatin sodium 10 mg and 20 mg tablets in the same bottle.

Recall Number:
D-0233-2018

Code Information:
Lot: 117093A, Exp. 06/19

Product Description:
Pravastatin Sodium Tablets, USP, 20 mg, 30-count bottles, packaged in 12 x 30 tablets for individual patient dispensing per pharmacy dispenser carton, Rx only, Packaged for: International Laboratories, LLC. St. Petersburg, FL 33710, NDC 54458-926-16.

Product Quantity:
13,403 cartons

Reason for Recall:
Presence of Foreign Tablets/Capsules: bottles could contain both pravastatin sodium 10 mg and 20 mg tablets in the same bottle.

Recall Number:
D-0234-2018

Code Information:
Lot: 117103A, Exp. 03/19

Class II Drugs Event

Event ID:
78947

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/16/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
01/19/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Sun Pharmaceutical Industries, Inc.
270 Prospect Plains Rd
Cranbury NJ United States

Distribution Pattern:
Product was distributed nationwide in the USA

Associated Products

Product Description:
DOXOrubicin Hydrochloride Liposome Injection, 20 mg/10 ml (2 mg/mL), 10 mL Single Use Vial, Distributed by: Sun Pharmaceutical Industries , Inc. Cranbury, NJ 08512. Manufactured by: Sun Pharmaceutical Ind. Ltd. Halol-Baroda Highway. Halol-389 350, Gujarat, India. NDC 47335-049-40

Product Quantity:
393 vials

Reason for Recall:
Lack Of Assurance Of Sterility

Recall Number:
D-0229-2018

Code Information:
Lot # JKS0403A Exp 02/2019

Class III Drugs Event

Event ID:
78487

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/03/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
01/19/2018

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 nationwide in the USA

Associated Products

Product Description:
bupPROPion HCL Extended-Release Tablets, USP (XL) 300 mg, 500-count bottle, Rx only, Mylan Pharmaceuticals Inc. Morgantown, WV 26505 U.S.A. NDC: 0378-2009-05

Product Quantity:
1,414/500 count bottles

Reason for Recall:
Failed Impurities/Degradation Specifications: Mylan Pharmaceuticals Inc. is conducting a voluntary recall due to related out of specification compound results obtained during routine stability testing.

Recall Number:
D-0230-2018

Code Information:
Lot # 3077281, EXP 06-2018

Not Yet Classified Drugs Event

Event ID:
78889

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/05/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Advanced Pharma Inc.
9265 Kirby Dr
Houston TX United States

Distribution Pattern:
Texas

Associated Products

Product Description:
MAGnesium 2 gm in NS 100 mL Magnesium SULfate (USP) 0.9% Sodium Chloride (USP) in 100 mL Sterile single dose bag, Rx only, Avella of Houston 9265 Katy Dr., Houston, TX ---NDC 42852-907-10

Product Quantity:
25 bags

Reason for Recall:
Subpotent

Recall Number:

Code Information:
Lot: 12/22/17 1422 108-90710P UD: 3/22/2018