Enforcement Report - Week of August 22, 2018

Class II Drugs Event

Event ID:
80633

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/25/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
08/15/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Ranier's Compounding Laboratory
1107 Lowry Ave
Jeannette PA United States

Distribution Pattern:
Product was distributed within the state of Pennsylvania.

Associated Products

Product Description:
Atropine 0.01% Opth Solution, 5 mL droptainer, Rx only, Ranier's Rx Laboratory, 1107 Lowry Avenue Suite A, Jeannette, PA 15644.

Product Quantity:
5 droptainers

Reason for Recall:
Lack of Assurance of Sterility: Practices at firm may call into question the sterility of products intended to be sterile.

Recall Number:
D-1080-2018

Code Information:
All lots within expiry

Product Description:
DMSO 6.25% Opth Sol, 10 mL droptainer, Rx only, Ranier's Rx Laboratory, 1107 Lowry Avenue Suite A, Jeannette, PA 15644.

Product Quantity:
1 droptainer

Reason for Recall:
Lack of Assurance of Sterility: Practices at firm may call into question the sterility of products intended to be sterile.

Recall Number:
D-1081-2018

Code Information:
All lots within expiry

Product Description:
Avastin 1.25 mg/0.05 mL prefilled syringe, Rx only, Ranier's Rx Laboratory, 1107 Lowry Avenue Suite A, Jeannette, PA 15644.

Product Quantity:
213 prefilled syringes

Reason for Recall:
Lack of Assurance of Sterility: Practices at firm may call into question the sterility of products intended to be sterile.

Recall Number:
D-1082-2018

Code Information:
All lots within expiry

Product Description:
Triple P (Prostaglandin/Papaverine/Phentolamine) Injection, 0.008/22.5/0.83 mg/mL, packaged in a) 5 mL and b) 10 mL vials, Rx only, Ranier's Rx Laboratory, 1107 Lowry Avenue Suite A, Jeannette, PA 15644.

Product Quantity:
a) 1 vial; b) 1 vial

Reason for Recall:
Lack of Assurance of Sterility: Practices at firm may call into question the sterility of products intended to be sterile.

Recall Number:
D-1083-2018

Code Information:
All lots within expiry

Product Description:
PR/PA/PH (Prostaglandin/Papaverine/Phentolamine) Injection, 10mcg/30/1mg/mL, 10 mL vial, Rx only, Ranier's Rx Laboratory, 1107 Lowry Av enue Suite A, Jeannette, PA 15644.

Product Quantity:
1 vial

Reason for Recall:
Lack of Assurance of Sterility: Practices at firm may call into question the sterility of products intended to be sterile.

Recall Number:
D-1084-2018

Code Information:
All lots within expiry

Product Description:
Morphine Sulf inhalation, 5mg/3cc, 3cc per vial, Rx only, Ranier's Rx Laboratory, 1107 Lowry Avenue Suite A, Jeannette, PA 15644.

Product Quantity:
60 vials

Reason for Recall:
Lack of Assurance of Sterility: Practices at firm may call into question the sterility of products intended to be sterile.

Recall Number:
D-1085-2018

Code Information:
All lots within expiry

Product Description:
Dehydrated Alcohol Solution, packaged in a) 1 mL and b) 3 mL vials, Rx only, Ranier's Rx Laboratory, 1107 Lowry Avenue Suite A, Jeannette, PA 15644.

Product Quantity:
a) 2 vials; b) 1 vial

Reason for Recall:
Lack of Assurance of Sterility: Practices at firm may call into question the sterility of products intended to be sterile.

Recall Number:
D-1086-2018

Code Information:
All lots within expiry

Product Description:
Vitamin D3 Injection, 50,000 IU/mL, 4 mL vial, Rx only, Ranier's Rx Laboratory, 1107 Lowry Avenue Suite A, Jeannette, PA 15644.

Product Quantity:
2 vials

Reason for Recall:
Lack of Assurance of Sterility: Practices at firm may call into question the sterility of products intended to be sterile.

Recall Number:
D-1087-2018

Code Information:
All lots within expiry

Product Description:
Medroxprogesterone 1% Ophthalmic Solution, 10 mL droptainer, Rx only, Ranier's Rx Laboratory, 1107 Lowry Avenue Suite A, Jeannette, PA 1 5644.

Product Quantity:
1 droptainer

Reason for Recall:
Lack of Assurance of Sterility: Practices at firm may call into question the sterility of products intended to be sterile.

Recall Number:
D-1088-2018

Code Information:
All lots within expiry

Product Description:
Acetylcysteine 10% Oph Solution, 10 mL droptainer, Rx only, Ranier's Rx Laboratory, 1107 Lowry Avenue Suite A, Jeannette, PA 15644.

Product Quantity:
1 droptainer

Reason for Recall:
Lack of Assurance of Sterility: Practices at firm may call into question the sterility of products intended to be sterile.

Recall Number:
D-1089-2018

Code Information:
All lots with expiry

Product Description:
P/P/P (Prostaglandin/Papaverine/Phentolamine) Injection, 0.02/30/2 mg/mL, 5 mL vial, Rx only, Ranier's Rx Laboratory, 1107 Lowry Avenue Su ite A, Jeannette, PA 15644.

Product Quantity:
2 vials

Reason for Recall:
Lack of Assurance of Sterility: Practices at firm may call into question the sterility of products intended to be sterile.

Recall Number:
D-1090-2018

Code Information:
All lots within expiry

Product Description:
PRASH 12.2mcg/1.22m/19.29 (Prostaglandin/Phentolamine/Papaverine) Injection, 10 mL vial, Rx only, Ranier's Rx Laboratory, 1107 Lowry Av enue Suite A, Jeannette, PA 15644.

Product Quantity:
1 vial

Reason for Recall:
Lack of Assurance of Sterility: Practices at firm may call into question the sterility of products intended to be sterile.

Recall Number:
D-1091-2018

Code Information:
All lots within expiry

Product Description:
PRO/PA/PH/AT 18mcg/1.8mg/ (Prostaglandin//Papaverine/Phentolamine/Atropine) Injection, 18mcg/1.8 mg/0.2 mg/0.02 mg/mL, 10 mL vial, Rx only, Ranier's Rx Laboratory, 1107 Lowry Avenue Suite A, Jeannette, PA 15644.

Product Quantity:
1 vial

Reason for Recall:
Lack of Assurance of Sterility: Practices at firm may call into question the sterility of products intended to be sterile.

Recall Number:
D-1092-2018

Code Information:
All lots within expiry

Product Description:
P/P/P 0.02/40/2mg/mL(Prostaglandin//Papaverine/Phentolamine) Injection, 0.02/40/2 mg/mL, 1 mL vial, Rx only, Ranier's Rx Laboratory, 1107 Lowry Avenue Suite A, Jeannette, PA 15644.

Product Quantity:
1 vial

Reason for Recall:
Lack of Assurance of Sterility: Practices at firm may call into question the sterility of products intended to be sterile.

Recall Number:
D-1093-2018

Code Information:
All lots within expiry

Product Description:
Papav 300/Phent 5mg/10mL (Papaverine/Phentolamine) Injection,300 mg/5 mg/10 mL, 10 mL vial, Rx only, Ranier's Rx Laboratory, 1107 Lowry Avenue Suite A, Jeannette, PA 15644.

Product Quantity:
2 vials

Reason for Recall:
Lack of Assurance of Sterility: Practices at firm may call into question the sterility of products intended to be sterile.

Recall Number:
D-1094-2018

Code Information:
All lots within expiry

Class II Drugs Event

Event ID:
80648

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/25/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
08/14/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
The Hain Celestial Group, Inc. - Worldwide HQ
1111 Marcus Ave
New Hyde Park NY United States

Distribution Pattern:
Product was distributed to one distributor in California who may have distributed the product further within the US.

Associated Products

Product Description:
alba BOTANICA Sensitive Sheer Shield Sunscreen Fragrance Free spf 50+ , 85 g 3 oz tube. Manufactured by: The Haine Celestial Group, Inc. Lake Success, NY, UPC 7 24742 00438 5

Product Quantity:
1,098 tubes

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

Recall Number:
D-1078-2018

Code Information:
Lot code 8041

Class II Drugs Event

Event ID:
80703

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/18/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
08/15/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Northwind Pharmaceuticals LLC
9402 Uptown Dr Ste 1100
Indianapolis IN United States

Distribution Pattern:
Indiana

Associated Products

Product Description:
Valsartan, 160 mg, 30 tablets per bottle, Rx Only, Repackaged By: Northwind Pharmaceuticals, Indianapolis, IN 46256. NDC: 51655-460-52

Product Quantity:
68 bottles

Reason for Recall:
CGMP Deviations: Carcinogen impurity detected in API used to manufacture drug product.

Recall Number:
D-1095-2018

Code Information:
Lot: UT48320002, exp 07/31/2018; Lot UT48320003, exp 05/31/2019

Product Description:
Valsartan HCTZ, 160/12.5mg, 30 tablets per bottle, Rx Only, Repackaged By: Northwind Pharmaceuticals, Indianapolis, IN 46256. NDC: 51655-950-52

Product Quantity:
43 bottles

Reason for Recall:
CGMP Deviations: Carcinogen impurity detected in API used to manufacture drug product.

Recall Number:
D-1096-2018

Code Information:
Lot: UTB23790003, exp 02/28/2019

Product Description:
Valsartan, 80mg, 30 tablets per bottle, Rx Only, Repackaged By: Northwind Pharmaceuticals, Indianapolis, IN 46256. NDC: 51655-0652-52

Product Quantity:
2 bottles

Reason for Recall:
CGMP Deviations: Carcinogen impurity detected in API used to manufacture drug product.

Recall Number:
D-1097-2018

Code Information:
Lot: UT48310002, exp 10/31/2018

Product Description:
Valsartan, 320mg, 30 tablets per bottle, Rx Only, Repackaged By: Northwind Pharmaceuticals, Indianapolis, IN 46256. NDC: 51655-0654-52

Product Quantity:
14 bottles

Reason for Recall:
CGMP Deviations: Carcinogen impurity detected in API used to manufacture drug product.

Recall Number:
D-1098-2018

Code Information:
Lot: UT48100001, exp 9/30/2019

Class II Drugs Event

Event ID:
80789

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/13/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
08/13/2018

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:
Product was distributed to distributors, mail order pharmacy and supermarkets throughout the United States.

Associated Products

Product Description:
Lisinopril Tablets USP, 10mg, 1000-count bottles, Rx only, Manufactured for: Lupin Pharmaceuticals Inc. Baltimore, Maryland 21202, NDC 68180-980-03

Product Quantity:
11,706 bottles

Reason for Recall:
Presence of Foreign Substance: Product complaint was received of metal contaminant observed in one tablet.

Recall Number:
D-1077-2018

Code Information:
Lot #: H800414, Exp. 12/2019

Class II Drugs Event

Event ID:
80827

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/10/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
08/16/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
RemedyRepack Inc.
625 Kolter Dr Ste 4
Indiana PA United States

Distribution Pattern:
Product was distributed to three customers in FL and VA.

Associated Products

Product Description:
Valsartan 80 mg Tablet,s HDPE 90 cc bottles in cardboard trays, Rx Only, RemedyRepack, Inc., 625 Kolter Drive, Suite 4, Indiana, PA 15701, NDC 61786-0791-19

Product Quantity:
9 bottles of 90 = 810 tablets

Reason for Recall:
CGMP Deviations: Carcinogen impurity detected in API used to manufacture drug product.

Recall Number:
D-1100-2018

Code Information:
Lot # B0335344-081717, exp. date 08/2018 Lot # B0363364-110917, exp. date 11/2018 Lot # B0391225-012218, exp. date 01/2019 Lot # B040 8458-030618, exp. date 03/2019 Lot # B0384871-010318, exp. date 01/2019 Lot # B0436862-051518, exp. date 05/2019

Product Description:
Valsartan 160 mg Tablets, HDPE 90 cc bottles in cardboard trays, Rx Only, RemedyRepack, Inc., 625 Kolter Drive, Suite 4, Indiana, PA 15701, NDC: 61786-0792-19

Product Quantity:
21 bottles of 90 = 1890 tablets

Reason for Recall:
CGMP Deviations: Carcinogen impurity detected in API used to manufacture drug product.

Recall Number:
D-1101-2018

Code Information:
Lot # B0335344-081717, exp. date 08/2018 Lot # B0363364-110917, exp. date 11/2018 Lot # B0391225-012218, exp. date 01/2019 Lot # B040 8458-030618, exp. date 03/2019 Lot # B0384871-010318, exp. date 01/2019 Lot # B0436862-051518, exp. date 05/2019

Product Description:
Valsartan 320 mg Tablets, HDPE 90 cc bottles in cardboard trays, Rx Only, RemedyRepack, Inc., 625 Kolter Drive, Suite 4, Indiana, PA 15701, NDC 61786-0793-19

Product Quantity:
36 bottles of 90 = 3240 tablets

Reason for Recall:
CGMP Deviations: Carcinogen impurity detected in API used to manufacture drug product.

Recall Number:
D-1102-2018

Code Information:
Lot # B0362988-110917, exp. date 10/2018 Lot # B0432265-050318, exp. date 05/2019 Lot # B0450321-061218, exp. date 06/2019 Lot # B04 50322-061218, exp. date 05/2019 Lot # B0408652-030718, exp. date 02/2019

Class III Drugs Event

Event ID:
80675

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/02/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
08/14/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Dr. Reddy's Laboratories, Inc.
107 College Rd E
Princeton NJ United States

Distribution Pattern:
U.S.A. Nationwide

Associated Products

Product Description:
Atorvastatin Calcium tablets, 40 mg, 500-count bottle, Rx only, Mfd By: Dr. Reddy's Laboratories Limited, Srikakulam - 532 409 India, NDC 551 11-123-05

Product Quantity:
2280 bottles

Reason for Recall:
Failed Impurities/Degradation Specifications - OOS was observed for ATV Cyclo FP Impurity and Total Degradation Impurities tested at the 18 month stability time point in Atorvastatin Calcium Tablets 40 mg 500 tablets.

Recall Number:
D-1079-2018

Code Information:
T60045

Class III Drugs Event

Event ID:
80753

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/03/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
08/10/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Huijing (Shanghai) Bio-tech Co., Ltd.
No 811 Gaofeng Rd.
Shanghai China

Distribution Pattern:
Product was distributed to one distributor in VA

Associated Products

Product Description:
Acne Treatment Pads (2% salicylic acid), packaged in a 50-count jar, OTC, Distributed by: Greenbrier International, Inc. 500 Volvo Parkway, Chesapeake, VA 23320, NDC 71537-001-02

Product Quantity:
75,000 pads

Reason for Recall:
Subpotent drug: The product active ingredient level not matching the exact levels indicated on the packaging label.

Recall Number:
D-1076-2018

Code Information:
Lot # 2458067, Exp 11/2019

Class III Drugs Event

Event ID:
80801

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/09/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
08/16/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Orexigen Therapeutics, Inc.
3344 N Torrey Pines Ct Ste 200
La Jolla CA United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Contrave (naltrexone HCl and bupropion HCl) Extended-Release Tablets, 8 mg/90 mg, 120-count bottle, Rx only, Distributed by Orexigen therapeutics, Inc., La Jolla, CA 92037, NDC 51267-890-99.

Product Quantity:
95,296 bottles

Reason for Recall:
Defective Container: Customer complaints of punctures in the bottle.

Recall Number:
D-1099-2018

Code Information:
Lot #: ZCXM, Exp 01NOV2020; ZCXN, Exp 02NOV2020; ZCXP, Exp 09NOV2020; ZCXS, 10NOV2020; ZCXT, Exp 13NOV2020; and ZCXV, Exp 17NOV2020