Enforcement Report - Week of February 14, 2018

Class I Drugs Event

Event ID:
78696

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/04/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
02/08/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
AuroMedics Pharma LLC
279 Princeton Hightstown Rd
East Windsor NJ United States

Distribution Pattern:
Product was distributed nationwide in the USA

Associated Products

Product Description:
Pantoprazole Sodium for Injection, 40 mg per vial, single dose vial, Rx only, Manufactured in India for: AuroMedics Pharma LLC, 6 Wheeling ROad, Dayton, NJ 08810. NDC 55150-202-00

Product Quantity:
66,100 vials

Reason for Recall:
Presence of Particulate Matter: One vial from a lot of Pantoprazole Sodium for Injection (40 mg) contained a piece of glass

Recall Number:
D-0340-2018

Code Information:
Lot # CPO170035

Class I Drugs Event

Event ID:
78800

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/20/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
02/08/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
AuroMedics Pharma LLC
279 Princeton Hightstown Rd
East Windsor NJ United States

Distribution Pattern:
Product was distributed throughout United States.

Associated Products

Product Description:
Linezolid Injection 600 mg/300 mL (2 mg/mL), 300 mL Single-use, ready-to-use flexible plastic infusion bags in a foil laminate overwrap, Rx only, Mfd in India for: AuroMedics Pharma LLC, Dayton, NJ --- NDC 55150-242-51

Product Quantity:
9,050 bags

Reason for Recall:
Presence of Particulate Matter; white particulate matter identified as mold was found in one bag

Recall Number:
D-0337-2018

Code Information:
Lot # CLZ160007, Exp August 2018

Class I Drugs Event

Event ID:
78847

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/02/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
02/08/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Aurobindo Pharma Ltd.
Unit Xii, Lactam Formulation Plant Survey No. 314, Bachupally, Quthbullapur
Hyderabad India

Distribution Pattern:
distributed nationwide in the USA

Associated Products

Product Description:
Ampicillian and Sulbactam for Injection 1.5 g vial, sterile Dry Powder for injection, 10 vials per carton, Distributed by AuroMedics Pharma LLC. 279 Princeton-Highstown Rd. E. Windsor, NJ 08520, NDC 55150-116-20

Product Quantity:
53,040 vials

Reason for Recall:
Presence of Particulate Matter: A confirmed customer report was received for the presence of visible particulate matter, confirmed as glass, within a single vial.

Recall Number:
D-0339-2018

Code Information:
Lot Number AF0117001-A

Class II Drugs Event

Event ID:
78669

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/30/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
02/04/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Intrathecal Compounding Specialist, LLC
206 Jacobs Run
Scott LA United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
All sterile drug preparations remaining within expiry prepared from Fentanyl Citrate Base Solution dispensed between October 16, 2017 and November 17, 2017 Compounded by Intrathecal Compounding Specialists, Scott, LA 70583.

Product Quantity:
Unknown.

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0320-2018

Code Information:
All lots remaining within expiry (BUDs between November 15, 2017 and December 16, 2017)

Product Description:
All sterile drug preparations remaining within expiry prepared from Hydromorphone Base Solution dispensed between October 16, 2017 and November 17, 2017, Compounded by Intrathecal Compounding Specialists, Scott, LA 70583.

Product Quantity:
Unknown

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0321-2018

Code Information:
All lots remaining within expiry (BUDs between November 15, 2017 and December 16, 2017).

Product Description:
All sterile drug preparations remaining within expiry prepared from Morphine Sulfate PF Base Solution dispensed between October 16, 2017 and November 17, 2017, Compounded by Intrathecal Compounding Specialists, Scott, LA 70583.

Product Quantity:
Unknown

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0322-2018

Code Information:
All lots remaining within expiry (BUD between November 15, 2017 and December 16, 2017).

Product Description:
All sterile drug preparations remaining within expiry prepared from Sufentanil Citrate Base Solution dispensed between October 16, 2017 and November 17, 2017, Compounded by Intrathecal Compounding Specialists, Scott, LA 70583.

Product Quantity:
Unknown

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0323-2018

Code Information:
All lots remaining within expiry (BUDs between November 15, 2017 and December 16, 2017).

Class II Drugs Event

Event ID:
78991

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/19/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
02/05/2018

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Flawless Beauty LLC
1215 Main St
Asbury Park NJ United States

Distribution Pattern:
Product was distributed U.S.A. nationwide.

Associated Products

Product Description:
Relumins Advanced Glutathione kits, 900 mg vials, 1500 mg vials and 3000 mg vials

Product Quantity:

Reason for Recall:
Marketed Without An Approved NDA/ANDA: Flawless Beauty, LLC is voluntarily recalling all lots of different products sold individually or as part of multi-unit kits in accordance with Consent Decree of Permanent Injunction ordered by the United States District Court due to misbranding and unapproved new drugs pursuant to the FD&C Act.

Recall Number:
D-0324-2018

Code Information:
all lots

Product Description:
Relumins Vitamin C Solvent ampules

Product Quantity:

Reason for Recall:
Marketed Without An Approved NDA/ANDA: Flawless Beauty, LLC is voluntarily recalling all lots of different products sold individually or as part of multi-unit kits in accordance with Consent Decree of Permanent Injunction ordered by the United States District Court due to misbranding and unapproved new drugs pursuant to the FD&C Act.

Recall Number:
D-0325-2018

Code Information:
all lots

Product Description:
Tatiomax Gluatathione Whitening kits, 1400mg vials, Made in Japan

Product Quantity:

Reason for Recall:
Marketed Without An Approved NDA/ANDA: Flawless Beauty, LLC is voluntarily recalling all lots of different products sold individually or as part of multi-unit kits in accordance with Consent Decree of Permanent Injunction ordered by the United States District Court due to misbranding and unapproved new drugs pursuant to the FD&C Act.

Recall Number:
D-0326-2018

Code Information:
all lots

Product Description:
Laroscorbine Platinum Vitamin C 1 gm Collagen 0.35 gm, Roche

Product Quantity:

Reason for Recall:
Marketed Without An Approved NDA/ANDA: Flawless Beauty, LLC is voluntarily recalling all lots of different products sold individually or as part of multi-unit kits in accordance with Consent Decree of Permanent Injunction ordered by the United States District Court due to misbranding and unapproved new drugs pursuant to the FD&C Act.

Recall Number:
D-0327-2018

Code Information:
all lots

Product Description:
Tationil Glutathione, 600 mg/ 4 mL, polvere e solvente per soluzione iniettabile, Teofarma, s.r.l.

Product Quantity:

Reason for Recall:
Marketed Without An Approved NDA/ANDA: Flawless Beauty, LLC is voluntarily recalling all lots of different products sold individually or as part of multi-unit kits in accordance with Consent Decree of Permanent Injunction ordered by the United States District Court due to misbranding and unapproved new drugs pursuant to the FD&C Act.

Recall Number:
D-0328-2018

Code Information:
all lots

Product Description:
Laennec INJ, Placenta extract (human), 2mL vials, Manufactured by: GCJBP Corp, Korea

Product Quantity:

Reason for Recall:
Marketed Without An Approved NDA/ANDA: Flawless Beauty, LLC is voluntarily recalling all lots of different products sold individually or as part of multi-unit kits in accordance with Consent Decree of Permanent Injunction ordered by the United States District Court due to misbranding and unapproved new drugs pursuant to the FD&C Act.

Recall Number:
D-0329-2018

Code Information:
all lots

Product Description:
Reiki Glutathione Whitening kits

Product Quantity:

Reason for Recall:
Marketed Without An Approved NDA/ANDA: Flawless Beauty, LLC is voluntarily recalling all lots of different products sold individually or as part of multi-unit kits in accordance with Consent Decree of Permanent Injunction ordered by the United States District Court due to misbranding and unapproved new drugs pursuant to the FD&C Act.

Recall Number:
D-0330-2018

Code Information:
all lots

Product Description:
TP Drug Laboratories Vitamin C ampules

Product Quantity:

Reason for Recall:
Marketed Without An Approved NDA/ANDA: Flawless Beauty, LLC is voluntarily recalling all lots of different products sold individually or as part of multi-unit kits in accordance with Consent Decree of Permanent Injunction ordered by the United States District Court due to misbranding and unapproved new drugs pursuant to the FD&C Act.

Recall Number:
D-0331-2018

Code Information:
all lots

Product Description:
Sterilized water for injections BP, 50 x 5 mL plastic ampules, Manufactured in India

Product Quantity:

Reason for Recall:
Marketed Without An Approved NDA/ANDA: Flawless Beauty, LLC is voluntarily recalling all lots of different products sold individually or as part of multi-unit kits in accordance with Consent Decree of Permanent Injunction ordered by the United States District Court due to misbranding and unapproved new drugs pursuant to the FD&C Act.

Recall Number:
D-0332-2018

Code Information:
all lots

Product Description:
Ling Zhi capsules

Product Quantity:

Reason for Recall:
Marketed Without An Approved NDA/ANDA: Flawless Beauty, LLC is voluntarily recalling all lots of different products sold individually or as part of multi-unit kits in accordance with Consent Decree of Permanent Injunction ordered by the United States District Court due to misbranding and unapproved new drugs pursuant to the FD&C Act.

Recall Number:
D-0333-2018

Code Information:
all lots

Product Description:
Saluta Glutathione Whitening kits, packaged in 600 mg, 1200 mg and 1800 mg glass vials, Manufactured by: Shandong Luye Pharmaceutical Co, Ltd, Yantai, Shandong. PRC

Product Quantity:

Reason for Recall:
Marketed Without An Approved NDA/ANDA: Flawless Beauty, LLC is voluntarily recalling all lots of different products sold individually or as part of multi-unit kits in accordance with Consent Decree of Permanent Injunction ordered by the United States District Court due to misbranding and unapproved new drugs pursuant to the FD&C Act.

Recall Number:
D-0334-2018

Code Information:
all lots

Product Description:
TAD Glutathione Whitening Kits lyophilized powder for injection, 600 mg vials, 10 vials + 10 amps x 4 mL, Manufactured by: Biomedica Foscama Industria, Ferentino, Italy

Product Quantity:

Reason for Recall:
Marketed Without An Approved NDA/ANDA: Flawless Beauty, LLC is voluntarily recalling all lots of different products sold individually or as part of multi-unit kits in accordance with Consent Decree of Permanent Injunction ordered by the United States District Court due to misbranding and unapproved new drugs pursuant to the FD&C Act.

Recall Number:
D-0335-2018

Code Information:
all lots

Class III Drugs Event

Event ID:
78974

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/19/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
02/02/2018

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

Recalling Firm:
G & W Laboratories, Inc.
200 Helen St
South Plainfield NJ United States

Distribution Pattern:
Nationwide in the USA and Puerto Rico

Associated Products

Product Description:
Ciclopirox Olamine Cream USP, 0.77%, packaged in a) 15 g tubes (NDC 0713-0638-15); b) 30 g tubes (NDC 0713-0638-31); and c) 90 g tubes (NDC 0713-0638-18), Rx Only, Manufactured by: G&W Laboratories, Inc., South Plainfield, NJ 07080.

Product Quantity:
142,236 tubes

Reason for Recall:
Discoloration: Product is supposed to be a white to off white homogenous cream and may have intermittent yellow discoloration.

Recall Number:
D-0250-2018

Code Information:
Lot #: a) 1002896, Exp 09/18; 1005797, Exp 05/19; 1006100, Exp 07/19; b) 1002561, Exp 06/18; 1002897, Exp 09/18; 1005798, Exp 05/19; 1006101, Exp 07/19; c) 1002898, Exp 10/18; 1004283, Exp 12/18; 1005837, Exp 05/19; 1006321, 1006322, Exp 07/19

Class III Drugs Event

Event ID:
79060

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/29/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
02/08/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Mckesson Packaging Services
7101 Weddington Rd Nw
Concord NC United States

Distribution Pattern:
U.S.A. Nationwide

Associated Products

Product Description:
Megestrol Acetate Oral Suspension, USP 400 mg/ 10mL (10 mL UD cups in boxes of 20 cups), Rx Only, Dist. By McKesson Packaging Services a business unit of McKesson Corporation 7101 Weddington Rd. Concord, NC 28027, NDC 63739-549-51

Product Quantity:
24120 cups

Reason for Recall:
Subpotent Drug: Out of specification for assay (stability testing)

Recall Number:
D-0338-2018

Code Information:
Lot #: 0114588, Exp 10/18

Not Yet Classified Drugs Event

Event ID:
78809

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/10/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Hetero Labs, Ltd. - Unit III
Plot 22-110, Part Ii, Ida Rangareddy, Jeedimetla
Hyderabad India

Distribution Pattern:
NJ Only

Associated Products

Product Description:
Aripiprazole Tablets, USP, 10 mg, 30-count bottles, Rx Only, Manufactured for Camber Pharmaceuticals, Inc. Piscataway, NJ 08854, By; Hetero Hetero Labs Limited Unit V Polepallly Jadcheria Mahaboob Nagar - 509 301 India, NDC 31722-827-30

Product Quantity:
3000 bottles

Reason for Recall:
Failed Dissolution Specifications.

Recall Number:

Code Information:
Lot #: ARI17089, ARI17090, Exp. 5/2019

Not Yet Classified Drugs Event

Event ID:
78981

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/22/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Astellas Pharma US Inc
1 Astellas Way
Northbrook IL United States

Distribution Pattern:
Nationwide.

Associated Products

Product Description:
Mycamine (micafungin) for Injection 100 mg/vial Single-Dose Vial Rx only NDC 0469-3211-10 Marketed by: Astellas Pharma US, Inc. Northbrook, IL 60062.

Product Quantity:
63600 vials

Reason for Recall:
Labeling: Label Error on Declared Strength: Primary package vial label for Mycamine 100 mg incorrectly states the strength as 50 mg micafungin on the side of the primary package label

Recall Number:

Code Information:
Lots: F1700164 Exp. 02/2020; A000000220 Exp. 06/2020

Not Yet Classified Drugs Event

Event ID:
79062

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/29/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Teva Pharmaceuticals USA
1090 Horsham Rd
North Wales PA United States

Distribution Pattern:
Distributed nationwide within the United States

Associated Products

Product Description:
Fentanyl Transdermal System. 25 mcg/h, packaged in 5 pouch system cartons (NDC 0591-3198-72), Rx Only, Manufactured by: Actavis Laboratoies UT, Inc. Salt Lake City, UT 84108, Distributed by: Actavis Pharma, Inc. Parsippany, NJ 07054 USA. Individual pouch NDC 0591-3198-54.

Product Quantity:
1,118,046 (5 pouches/carton)

Reason for Recall:
Failed Impurities/Degradation Specifications: Fentanyl-n-Oxide (FNO) degradant exceeding the specification limits

Recall Number:

Code Information:
Lot #:1103907A, Exp. Mar 2018; 1114170A, Exp. Apr 2018; 1117212A,, Exp. May 2018; 1130863A, 1140570A, Exp. Jul 2018;; 1153178A, Exp. Aug 2018; 1153185A, Exp. Sep 2018; 1171608A, Exp. Nov 2018; 1188715A, Exp. Jan 2019; 1193264A, 1208789A, Exp. Apr 2019; 1212340A, 1225166A, Exp. Jul 2019; 1238442A, Exp. Aug 2019.

Product Description:
Fentanyl Transdermal System, 50 mcg/h, packaged in 5 pouch system cartons (NDC 0591-3212-72), Rx Only, Manufactured by: Actavis Laboratoies UT, Inc. Salt Lake City, UT 84108, Distributed by: Actavis Pharma, Inc. Parsippany, NJ 07054 USA. Individual pouch NDC 0591-3212-54.

Product Quantity:
929,916 (5 pouches/carton)

Reason for Recall:
Failed Impurities/Degradation Specifications: Fentanyl-n-Oxide (FNO) degradant exceeding the specification limits

Recall Number:

Code Information:
Lot #: 1103917A, Exp. Feb 2018; 1114192A, Exp. Apr 2018; 1125605A, Exp. Jun 2018; 1138897A, 1153171A, Exp. Aug 2018; 1156261A, Exp. Oct 2018; 1171595A, Exp. Nov 2018; 1179544A, Exp. Jan 2019; 1189531A, Exp. Mar 2019; 1211389A,Exp. May 2019; 1227468A, Exp. Jun 2019; 1231784A, 1232943A, Exp. Sep 2019.

Product Description:
Fentanyl Transdermal System. 75 mcg/h, packaged in 5 pouch system (NDC 0591-3213-72), Rx Only, Manufactured by: Actavis Laboratoies UT, Inc. Salt Lake City, UT 84108, Distributed by: Actavis Pharma, Inc. Parsippany, NJ 07054 USA. Individual pouch NDC 0591-3213-54.

Product Quantity:
576, 760 (5 pouches/carton)

Reason for Recall:
Failed Impurities/Degradation Specifications: Fentanyl-n-Oxide (FNO) degradant exceeding the specification limits

Recall Number:

Code Information:
Lot #: 1107745A, Exp. Mar 2018;1122452A, 1137109A, Exp. Jun 2018; 1144515A, Exp. Oct 2018; 1189477A, Exp. Mar 2019; 1215224A, Exp. Aug 2019.

Product Description:
Fentanyl Transdermal System, 100 mcg/h, packaged in 5 pouch system (NDC 0591-3214-72), Rx Only, Manufactured by: Actavis Laboratoies UT, Inc. Salt Lake City, UT 84108, Distributed by: Actavis Pharma, Inc. Parsippany, NJ 07054 USA. Individual pouch NDC 0591-3214-54.

Product Quantity:
554, 562 (5 pouches/carton)

Reason for Recall:
Failed Impurities/Degradation Specifications: Fentanyl-n-Oxide (FNO) degradant exceeding the specification limits

Recall Number:

Code Information:
Lot #: 1096857A, Exp. Feb 2018; 1115872A, Exp. Apr 2018; 1123625A, Exp. May 2018; 1148775A. 1157255A, Exp. Aug 2018; 1169928A, Exp. Nov 2018; 1196300A, Exp. Apr 2019; 1213533A, Exp. Jun 2019.

Not Yet Classified Drugs Event

Event ID:
79083

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/30/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Millennium Pharmaceuticals Inc.
40 Landsdowne St
Cambridge MA United States

Distribution Pattern:
Distributed nationwide. They estimate 4% of the product may be recovered.

Associated Products

Product Description:
Velcade (bortezomib) for injection, 3.5 mg/vial White to Off-white powder to a liquid - reconstituted for infusion vials with paper carton

Product Quantity:
154,372 vials

Reason for Recall:
Millennium Pharmaceuticals, Inc. is conducting a voluntary recall due to loose vial crimps.

Recall Number:

Code Information:
Lot Numbers # 224161, 224546 and 224547