Class II Drugs Event

Event ID:
76912
Product Type:
Drugs
Status:
Ongoing
Date Terminated:
Recall Initiation Date:
04/18/2017
Voluntary / Mandated:
Voluntary: Firm Initiated
Center Classification Date:
05/17/2017
Initial Firm Notification of Consignee or Public:
Letter
Recalling Firm:
Key Pharmacy and Compounding Center
530 S 336th St
Federal Way WA United States
Distribution Pattern:
Distributed nationwide in U.S.A., Australia and Canada.

Associated Products

Product Description:
5-MTHF *10ML* MDV 5MG/ML INJ, Injection, 5mg/mL, Rx only, 10mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy
Product Quantity:
100 vials
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0707-2017
Code Information:
Lot # t11-21-2016@112, Exp 5/21/2017; 12-15-2016@73, Exp 6/13/2017; 01-13-2017@67, Exp 7/12/2017; t02-14-2017@97, Exp 8/14/2017

Product Description:
5-MTHF 10ML MDV (CALIF) 5MG/ML INJ, Injection, 5mg/mL, Rx only, 10mLGlass/Multiple Dose vial, Prepared by Key Compounding Pharmacy
Product Quantity:
6 vials
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0708-2017
Code Information:
Lot # t11-17-2016@86, Exp 5/17/2017; t12-22-2016@103, Exp 7/4/2017; t01-09-2017@111, Ex

p 7/9/2017; t01-11-2017@118, Exp 7/11/2017; t01-18-2017@89, Exp 7/18/2017; t01-20-2017@83, Exp 7/23/2017.

Product Description:
5-MTHF 10ML SDV (CALIF) 5MG/ML INJ, Injection 5mg/mL, Rx only, 10mL Glass /Single Dose vial, Prepared by Key Compounding Pharmacy
Product Quantity:
3 vials
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0709-2017
Code Information:
Lot # t12-28-2016@113, Exp 6/27/2017.

Product Description:
5-MTHF SDV 5MG/ML INJ, Injection, 5mg/mL, Rx only, packaged in 1 mL, 2 mL, 5 mL, and 10 mL Glass/Single Dose vials, Prepared by Key Compounding Pharmacy
Product Quantity:
63 vials total (29/1 mL vials; 30/2 mL vials; 3/5 mL vials, and 1/10 mL vial)
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0710-2017
Code Information:
Lot # t12-05-2016@116, Exp 6/4/2017; t12-15-2016@84, Exp 6/14/2017; t12-23-2016@67, Exp 6/25/2017; t12-28-2016@105, Exp 6/27/2017; t01-30-2017@88, Exp 7/30/2017; t02-06-2017@109, Exp 8/6/2017; t02-14-2017@92, Exp 8/14/2017; t02-20-2017@79, Exp 8/20/2017

Product Description:
ATROPINE SULFATE 0.01% OPHTH, Ophthalmic, 0.01%, Rx only, 15 mL Glass /Multiple Dose vial, Prepared by Key Compounding Pharmacy
Product Quantity:
60 mL total
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0711-2017
Code Information:
Lot # 01-20-2017@17, Exp 4/20/2017; 01-23-2017@48, Exp 4/23/2017; 01-27-2017@17, Exp 4/27/2017; 01-31-2017@42, Exp 5/1/2017; 02-01-2017@35, Exp 5/2/2017; t02-07-2017@67, Exp 5/9/2017.

Product Description:
ATROPINE SULFATE 0.5% OPHTH, Ophthalmic 0.50%, Rx only, 15mlLGlass /Multiple Dose vial, Prepared by Key Compounding Pharmacy
Product Quantity:
9 mL

Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0712-2017
Code Information:
Lot # t01-26-2017@93, Exp 4/27/2017

Product Description:
CO-Q-10 OIL 20ML MDV (CALIF) 25MG/ML INJ, Injection, 25mg/mL, Rx only, 20mL Glass /Multiple Dose vial, Prepared by Key Compounding Pharmacy
Product Quantity:
1 vial
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0713-2017
Code Information:
Lot # t02-01-2017@119, Exp 5/3/2017.

Product Description:
DMPS ACID *5ML* SDV 50MG/ML INJ, Injection, 50mg/ml, Rx only, 5 mL glass/ Single Dose vial, Prepared by Key Compounding Pharmacy
Product Quantity:
214 vials
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0714-2017
Code Information:
Lot # t12-16-2016@73, Exp 4/18/2017; t12-27-2016@93, Exp 4/27/2017; t01-09-2017@102, Exp 5/10/2017; t01-10-2017@120, Exp 5/11/2017; 02-01-2017@78, Exp 6/1/2017; t02-08-2017@96, Exp 6/9/2017; t02-20-2017@80, Exp 6/21/2017; t02-21-2017@122, Exp 6/23/2017; t02-23-2017@68, Exp 6/24/2017.

Product Description:
DMSO 6.25% OPHTH., 6.25%, Rx only, 15 mL plastic/Multiple Dose bottle, Prepared by Key Compounding Pharmacy
Product Quantity:
10 mL total
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0715-2017
Code Information:
Lot # 02-23-2017@36, Exp 5/24/2017

Product Description:
FERR GLUC/PROCAINE 10ML MDV 60/10MG/ML INJ, Injection, 60mg/10mg/mL, Rx only, 10 mL glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy
Product Quantity:
1 vial
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0716-2017
Code Information:
Lot # t01-23-2017@83, Exp 5/24/2017

Product Description:
FOLIC ACID 1ML SDV 10MG/ML INJ, Injection, 10mg/mL, Rx only, 1 mL glass/Single Dose vial, Prepared by Key Compounding Pharmacy
Product Quantity:
20 vials
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0717-2017
Code Information:
Lot # t01-20-2017@80, Exp 4/23/2017

Product Description:
FOLINIC ACID MDV (CALIF) 5MG/ML INJ, Injection, 5mg/mL, Rx only, packaged in 5 mL and10 mL glass/ Multiple Dose vial, Prepared by Key Compounding Pharmacy
Product Quantity:
3 vials total
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0718-2017
Code Information:
Lot # t02-09-2017@74, Exp 5/15/2017; t02-17-2017@89, Exp 5/21/2017; t02-20-2017@72, Exp 5/22/2017.

Product Description:
FOLINIC ACID MDV INJ, Injection, 10 mg/mL, Rx only, packaged in 2mL and 10 mL glass/Multiple Dose vials, Prepared by Key Compounding Pharmacy
Product Quantity:
12 vials total (3/2mL vials and 9/10mL vias)
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0719-2017

Code Information:
Lot # t01-31-2017@128, Exp 5/2/2017; 01-31-2017@118, Exp 5/1/2017.

Product Description:
HCG *10ML* MDV 500U/ML INJ, Injection, 500u/mL, Rx only, 10 mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy
Product Quantity:
72 vials
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0720-2017
Code Information:
Lot # 01-20-2017@74, Exp 4/20/2017; t02-01-2017@123, Exp 5/3/2017; t02-03-2017@47, Exp 5/7/2017; t02-07-2017@70, Exp 5/10/2017; t02-13-2017@100, Exp 5/15/2017.

Product Description:
HYDROXO-B12 *1ML* SDV 1MG/ML INJ, Injection, 1mg/mL, Rx only, 1 mL Glass/Single Dose vial, Prepared by Key Compounding Pharmacy
Product Quantity:
50 vials
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0721-2017
Code Information:
Lot # t01-16-2017@91, Exp 4/17/2017; t02-08-2017@93, Exp 4/30/2017.

Product Description:
HYDROXO-B12 1ML SDV 10MG/ML INJ, Injection, 10mg/mL, Rx only, 1 mL glass/ Single Dose vial, Prepared by Key Compounding Pharmacy HYDROXO-B12 2ML SDV 10MG/ML INJ, Injection, 10mg/mL, RX only, 2 mL glass/ Single Dose vial.
Product Quantity:
50 vials total (10/1mL vials and 40/2mL vials)
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0722-2017
Code Information:
Lot # t01-17-2017@103, Exp 4/18/2017; t01-23-2017@80, Exp 4/24/2017; t02-10-2017@120, Exp 4/30/2017.

Product Description:
HYDROXO-B12 INH PF GV 5MG/ML SOLN, Inhalation Solution, 5mg/mL, Rx only, 5 mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy
Product Quantity:
240 mL

Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0723-2017
Code Information:
Lot # 02-01-2017@38, Exp 4/30/2017

Product Description:
HYDROXO-B12 10ML PBF MDV 5MG/ML INJ, 5mg/mL, Rx only, 10 mL Glass/ Multiple Dose vial, Prepared by Key Compounding Pharmacy HYDROXO-B12 30ML PBF MDV 5MG/ML INJ, 5mg/mL, RX only, 30 mL Glass/ Multiple Dose vial.
Product Quantity:
8 vials total (6/10mL vials and 2/30 mL vials)
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0724-2017
Code Information:
Lot # t01-20-2017@87, Exp 4/23/2017; t02-08-2017@99, Exp 4/30/2017; t02-21-2017@113, Exp 4/30/2017.

Product Description:
HYDROXO-B12 5ML PBF MDV 1MG/ML INJ, Injection, 1mg/ml, Rx only, packaged in 5 mL Glass/ Multiple Dose and 30 mL Glass/ Multiple Dose vials,Prepared by Key Compounding Pharmacy
Product Quantity:
7 vials total (1/5mL vial and 6/30 mL vials)
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0725-2017
Code Information:
Lot # t01-26-2017@98, Exp 4/27/2017; t02-06-2017@108, Exp 4/30/2017.

Product Description:
HYDROXO-B12 30ML PBF MDV (CALIF) 1MG/ML INJ, Injection, 1mg/mL, Rx only, 30 mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy
Product Quantity:
2 vials
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0726-2017
Code Information:
Lot # t02-06-2017@102, Exp 4/30/2017; t02-16-2017@106, Exp 4/30/2017.

Product Description:
HYDROXO-B12 PBF MDV 10MG/ML INJ, Injection, 10mg/mL, Rx only, packaged in a 5 mL and 30 mL Glass/ Multiple Dose vials, Prepared by Key Compounding Pharmacy
Product Quantity:
27 vials total (25/5 mL vials and 2/30mL vials)
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0727-2017
Code Information:
Lot # t01-16-2017@93, Exp 4/17/2017; t01-20-2017@81, Exp 4/23/2017.

Product Description:
HYDROXO-B12 5ML PBF MDV (CALIF) 10MG/ML INJ, Injection, 10mg/mL, RX only, 5mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy
Product Quantity:
1 vial
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0728-2017
Code Information:
Lot # t02-15-2017@111, Exp 4/30/2017.

Product Description:
PAPAVERINE/PHENT 5ML MDV 30/0.5MG/ML INJ, Injection, 30/0.5mg/mL, Rx only, 5mL glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy
Product Quantity:
4 vials
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0729-2017
Code Information:
Lot # t11-28-2016@111, Exp 5/28/2017; 02-10-2017@1, Exp 8/9/2017.

Product Description:
PAPAVERINE/PHENT 5ML MDV 30/1MG/ML INJ, Injection, 30mg/1mg/mL, Rx only, 5mL glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy
Product Quantity:
4 vials
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0730-2017

Code Information:
Lot # t12-21-2016@110, Exp 6/20/2017; t12-27-2016@84, Exp 6/26/2017; t12-30-2016@74, Exp 7/2/2017.

Product Description:
PGE1 MDV 20MCG/ML INJ, Injection, 20mcg/mL, Rx only, packaged in a 5 mL, 10mL, and 15 mL Glass/Multiple Dose vials, Prepared by Key Compounding Pharmacy
Product Quantity:
5 vials total (2/5 mL vials, 1/10mL vial, and 2/15mL vials)
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0731-2017
Code Information:
Lot # t01-05-2017@102, Exp 7/5/2017; t02-02-2017@105, Exp 8/2/2017; t02-10-2017@121, Exp 8/2/2017.

Product Description:
PGE1 5ML MDV INJ, Injection, 40mcg/mL, Rx only, 5mL glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy
Product Quantity:
2 vials
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0732-2017
Code Information:
Lot # t01-06-2017@92, Exp 7/5/2017

Product Description:
PGE1/CPZ 5ML MDV 20MCG/1MG/ML INJ, Injection, 20mcg/1mg/mL, Rx only, 5 mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy
Product Quantity:
2 vials
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0733-2017
Code Information:
Lot # t01-25-2017@112, Exp 7/5/2017

Product Description:
PGE1/PAP 10/30 5ML MDV MCG/MG/ML INJ, Injection, 10mg/30mg/mL, Rx only, 5mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy
Product Quantity:
2 vials

Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0734-2017
Code Information:
Lot # t11-16-2016@90, Exp 4/19/2017

Product Description:
TRI MIX 10/15/1 5ML MDV MCG/MG/MG/ML INJ, Injection, 10mcg/15mg/1mg/mL, Rx only, 5 mL Glass/ Multiple Dose vial, Prepared by Key Compounding Pharmacy
Product Quantity:
2 vials
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0735-2017
Code Information:
Lot # t12-22-2016@102, Exp 6/18/2017

Product Description:
TRI MIX 10/15/2.5 5ML MDV MCG/MG/MG/ML INJ, Injection, 10mcg/15mg/2.5mg/mL, Rx only, 5 mL Glass/ Multiple Dose vial, Prepared by Key Compounding Pharmacy
Product Quantity:
1 vial
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0736-2017
Code Information:
Lot # t12-19-2016@69, Exp 5/22/2017

Product Description:
TRI MIX 10/30/0.5 *5ML* MDV MCG/MG/MG/ML INJ, Injection,10mcg/30mg/0.5mg/mL, Rx only, 5 mL Glass/ Multiple Dose vial, Prepared by Key Compounding Pharmacy
Product Quantity:
200 vials
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0737-2017
Code Information:
Lot # 11-18-2016@70, Exp 4/19/2017; 11-23-2016@84, Exp 5/22/2017; t12-14-2016@99, Exp 5/22/2017; t01-03-2017@94, Exp 6/18/2017; 01-13-2017@71, Exp 7/5/2017; 01-25-2017@103, Exp 7/5/2017; 02-06-2017@94, Exp 7/5/2017; t02-17-2017@87, Exp 8/2/2017.

Product Description:
TRI MIX 10/30/1 5ML MDV MCG/MG/MG/ML INJ, Injection, 10mcg/30mg/1mg/mL, Rx only, 5 mL Glass/ Multiple Dose vial, Prepared by Key Compounding Pharmacy
Product Quantity:
6 vials
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0738-2017
Code Information:
Lot # t11-21-2016@125, Exp 4/19/2017; t01-09-2017@105, Exp 6/18/2017; t01-18-2017@90, Exp 7/5/2017.

Product Description:
TRI MIX 11.8/17.6/0.59 5ML MDV MCG/MG/MG/ML INJ, Injection, 11.8mcg/17.6mg/0.59mg/mL, Rx only, 5mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy
Product Quantity:
1 vial
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0739-2017
Code Information:
Lot # t12-12-2016@84, Exp 5/22/2017

Product Description:
TRI MIX 13/30/0.8 5ML MDV MCG/MG/MG/ML INJ, Injection, 13mcg/30mg/0.8mg/mL, RX only, 5 mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy
Product Quantity:
1 vial
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0740-2017
Code Information:
Lot # t01-31-2017@127, Exp 7/5/2017

Product Description:
TRI MIX 16.7/4/0.27 5ML MDV MCG/MG/MG/ML INJ, Injection, 16.7mcg/4mg/0.27mg/ml, Rx only, 5mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy
Product Quantity:
1 vial
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0741-2017

Code Information:
Lot # t01-31-2017@120, Exp 7/5/2017

Product Description:
TRI MIX 20/20/1 5ML MDV MCG/MG/MG/ML INJ, Injection, 20mcg/20mg/1mg/mL, Rx only, 5 mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy
Product Quantity:
25 vials
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0742-2017
Code Information:
Lot # t01-10-2017@115, Exp 7/5/2017.

Product Description:
TRI MIX 20/30/0.5 5ML MDV MCG/MG/MG/ML INJ, Injection, 20mcg/30mg/0.5mg/mL, Rx only, 5 mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy
Product Quantity:
2 vials
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0743-2017
Code Information:
Lot # t11-23-2016@110, Exp 5/22/2017

Product Description:
TRI MIX 20/30/1 5ML MDV MCG/MG/MG/ML INJ, Injection, 20mcg/30mg/1mg/mL, Rx only, 5 mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy
Product Quantity:
3 vials
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0744-2017
Code Information:
Lot # t12-01-2016@93, Exp 5/22/2017; t02-02-2017@100, Exp 8/2/2017.

Product Description:
TRI MIX 20/30/2 5ML MDV MCG/MG/MG/1ML INJ, Injection, 20mcg/30mg/2mg/mL, Rx only, 5 mL Glass/Multiple Dose vial , Prepared by Key Compounding Pharmacy
Product Quantity:
17 vials
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.

Recall Number:
D-0745-2017
Code Information:
Lot # t12-07-2016@97, Exp 5/22/2017; t12-12-2016@88, Exp 5/22/2017; t12-20-2016@109, Exp 5/22/2017; t12-20-2016@119, Exp 6/18/2017; t12-23-2016@63, Exp 6/18/2017; t12-30-2016@84, Exp 6/18/2017; t01-09-2017@97, Exp 6/18/2017; t12-22-2016@120, Exp 6/18/2017; t02-07-2017@72, Exp 8/2/2017

Product Description:
TRI MIX 30/30/1 5ML MDV MCG/MG/MG/ML INJ, Injection, 30mcg/30mg/1mg/mL, Rx only, 5 mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy
Product Quantity:
2 vials
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0746-2017
Code Information:
Lot # t12-13-2016@95, Exp 5/22/2017

Product Description:
TRI MIX 40/30/2 5ML MDV MCG/MG/MG/ML INJ, Injection, 40mcg/30mg/2mg/mL, Rx only, 5 mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy
Product Quantity:
2 vials
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0747-2017
Code Information:
Lot # t02-02-2017@93, Exp 8/2/2017

Product Description:
TRI MIX 40/30/4 5ML MDV MCG/MG/MG/ML INJ, Injection, 40mcg/30mg/4mg/mL, Rx only, 5 mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy
Product Quantity:
5 vials
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0748-2017
Code Information:
Lot # t12-30-2016@73, Exp 6/18/2017

Product Description:
TRI MIX 45.45/27.27/0.45 5ML MDV MCG/MG/MG/ML INJ, Injection, 45.45mcg/27.27mg/0.45mg/mL, Rx only, 5 mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy

Product Quantity:
1 vial
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0749-2017
Code Information:
Lot # t12-12-2016@87, Exp 5/22/2017

Product Description:
TRI MIX 5.88/17.65/0.588 5ML MDV MCG/MG/MG/ML INJ, , Injection, 5.88mcg/17.65mg/0.588mg/mL, Rx only, 5 mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy
Product Quantity:
3 vials
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0750-2017
Code Information:
Lot # t12-02-2016@100, Exp 5/22/2017; t12-28-2016@104, Exp 6/18/2017.

Product Description:
TRI MIX 5.95/17.8572/0.6 5ML MDV MCG/MG/MG/ML INJ, Injection, 5.95mcg/17.85mg/0.6mg/mL, Rx only, 5 mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy
Product Quantity:
4 vials
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0751-2017
Code Information:
Lot # t12-12-2016@93, Exp 5/22/2017; t02-22-2017@93, Exp 8/2/2017

Product Description:
TRI MIX 5/30/0.5 5ML MDV MCG/MG/MG/ML INJ, Injection, 5mcg/30mg/0.5mg/mL, Rx only, 5 mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy
Product Quantity:
2 vials
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0752-2017
Code Information:
Lot # t02-01-2017@127, Exp 7/5/2017

Product Description:
TRI MIX 6/18/0.6 5ML MDV MCG/MG/MG/ML INJ, Injection, 6mcg/18mg/0.6mg/mL, Rx only, 5 mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy
Product Quantity:
2 vials
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0753-2017
Code Information:
Lot # t12-13-2016@98, Exp 5/22/2017

Product Description:
QUAD MIX 1/30/0.5/0.1 5ML MDV MCG/MG/MG/MG/ML INJ, Injection, 1mcg/30mg/0.5mg/0.15mg/mL, Rx only, 5 mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy
Product Quantity:
2 vials
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0754-2017
Code Information:
Lot # t01-05-2017@110, Exp 6/17/2017

Product Description:
QUAD MIX 50/30/1/0.2 5ML MDV (CALIF) MCG/MG/MG/MG/ML INJ, Injection, 50mcg/30mg/1mg/0.2mg/mL, Rx only, 5 mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy
Product Quantity:
1 vial
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0755-2017
Code Information:
Lot # t02-02-2017@102, Exp 7/26/2017

Product Description:
PGE1/PROCAINE 5ML MDV 20MCG/ML/0.1% INJ, Injection, 20mcg/ml 0.1%, Rx only, 5 mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy
Product Quantity:
3 vials
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0756-2017

Code Information:
Lot # t12-12-2016@92, Exp 5/22/2017; t02-14-2017@103, Exp 8/2/2017

Product Description:
PGE1/PROCAINE 5ML MDV 40MCG/ML/0.1% INJ, Injection, 40mcg/mL, 0.1%, Rx only, 5 mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy
Product Quantity:
4 vials
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0757-2017
Code Information:
Lot # t11-28-2016@86, Exp 5/22/2017; t12-19-2016@73, Exp 5/22/2017

Product Description:
ALPHA LIPOIC ACID 25ML MDV 25MG/ML INJ, Injection, 25mg/mL, Rx only, 25 mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy
Product Quantity:
1 vial
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0758-2017
Code Information:
Lot # t02-22-2017@96, Exp 5/24/2017

Product Description:
VIT C/GSH 1.25%-1.25% OPHTH, Ophthalmic, 1.25%, Rx only, 15 mL Plastic/ Multiple Dose bottle, Prepared by Key Compounding Pharmacy
Product Quantity:
10 mL
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0759-2017
Code Information:
Lot # 02-23-2017@35, Exp 4/24/2017

Product Description:
CHOL/IN/ME(L)/B6 10ML MDV 50/50/25/0.1MG/ML INJ, Injection, 50mg/50mg/25mg/0.1mg/mL, Rx only, 10mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy
Product Quantity:
1 vial
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.

Recall Number:
D-0760-2017
Code Information:
Lot # t02-06-2017@107, Exp 4/30/2017 Lot t02-06-2017@107, Expiry date 4/30/2017

Product Description:
CYANOCOBALAMIN 10ML MDV 1MG/ML INJ, Injection, 1mg/mL, Rx only, 10mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy
Product Quantity:
2 vials
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0761-2017
Code Information:
Lot # t02-13-2017@99, Exp 5/15/2017

Product Description:
CYCLOSPORIN (VET) *CORN OIL* 1% OPHTH, Ophthalmic, 1%, Rx only, 15mL Plastic/Multiple Dose vial, Prepared by Key Compounding Pharmacy
Product Quantity:
9 mL
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0762-2017
Code Information:
Lot # 01-30-2017@2, Exp 4/30/2017

Product Description:
FERR GLUC MDV 60MG/ML INJ, Injection, 60mg/mL, Rx only, Packaged in 5mL and 10mL Glass /Multiple Dose vial, Prepared by Key Compounding Pharmacy
Product Quantity:
3 vials total (2/5mL vials and 1/10mL)
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0763-2017
Code Information:
Lot # t02-13-2017@98, Exp 5/15/2017; t02-14-2017@98, Exp 5/16/2017; t02-15-2017@120, Ex p 5/17/2017

Product Description:
IRON SPECIAL 5ML MDV 60/10MG/5MCG/ML INJ, Injection, 60mg/1mg/5mcg/mL, Rx only, 5mL Glass /Multiple Dose vial, Prepared by Key Compounding Pharmacy
Product Quantity:
2 vials

Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0764-2017
Code Information:
Lot # t02-16-2017@108, Exp 5/18/2017

Product Description:
GLUTATHIONE INH *PV* 200MG/ML SOLN, Inhalation Solution, 200mg/mL, Rx only, 4mL Plastic/Multiple Dose vial, Prepared by Key Compounding Pharmacy
Product Quantity:
240 mL
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0765-2017
Code Information:
Lot # 02-20-2017@8, Exp 4/21/2017.

Product Description:
GSH/NAC INH 2ML PV 60/100MG/ML SOLN, Inhalation Solution, 60mg/100mg/mL, Rx only, 5mL Plastic/Single Dose vial, Prepared by Key Compounding Pharmacy
Product Quantity:
50 mL
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0766-2017
Code Information:
Lot # t02-20-2017@75, Exp 4/22/2017.

Product Description:
GSH/NAC INH PV 150/50MG/ML SOLN, Inhalation Solution, 150mg/50mg/mL, Rx only, 4mL Plastic/Multiple Dose vial, Prepared by Key Compounding Pharmacy
Product Quantity:
180mL
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0767-2017
Code Information:
Lot # t02-21-2017@111, Exp 4/23/2017

Product Description:
MAGNESIUM SO4 10ML MDV 50% INJ, Injection, 50%, Rx only, 10 mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy

Product Quantity:
3 vials
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0768-2017
Code Information:
Lot # t02-06-2017@106, Exp 5/8/2017; 02-13-2017@75, Exp 5/14/2017

Product Description:
METHYL-B12 5ML MDV (CALIF) 1MG/ML INJ, Injection, 1mg/mL, Rx only, 5 mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy
Product Quantity:
26 vials
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0769-2017
Code Information:
Lot # t02-17-2017@101, Exp 4/21/2017; t02-17-2017@88, Exp 4/21/2017.

Product Description:
METHYL-B12 *10ML* MDV 5MG/ML INJ, Injection, 5mg/mL, Rx only, 10 mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy
Product Quantity:
25 vials
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0770-2017
Code Information:
Lot # t02-17-2017@86, Exp 4/21/2017

Product Description:
PROCAINE HCL 50ML MDV (CALIF) 1% INJ, Injection, 1%, Rx only, 50mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy
Product Quantity:
2 vials
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0771-2017
Code Information:
Lot # t01-18-2017@94, Exp 4/19/2017; t01-25-2017@115, Exp 4/26/2017

Product Description:
PROCAINE HCL *5ML* SDV SULFITE FREE 1% INJ, Injection, 1%, RXxonly, 5mL Glass/Single Dose vials, Prepared by Key Compounding Pharmacy
Product Quantity:
40 vials
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0772-2017
Code Information:
Lot # t01-13-2017@84, Exp 4/18/2017; 02-02-2017@97, Exp 5/3/2017

Product Description:
PROCAINE HCL SDV 1% INJ, Injection, 1%, Rx only, packaged in 5mL and 50 mL Glass/Single Dose vials, Prepared by Key Compounding Pharmacy
Product Quantity:
86 vials total (78/5mL vials and 8/50mL vials)
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0773-2017
Code Information:
Lot # t11-21-2016@115, Exp 5/21/2017; t11-23-2016@109, Exp 5/27/2017; t12-13-2016@94, Exp 6/12/2017; t01-19-2017@85, Exp 7/22/2017; 02/01/2017@116, Exp 7/31/2017

Product Description:
PROCAINE HCL SDV 2% INJ, Injection, 2%, Rx only, packaged in 10mL and 50 mL Glass/Single Dose vials, Prepared by Key Compounding Pharmacy
Product Quantity:
9 vials total (3/10mL vials and 6/50mL vials)
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0774-2017
Code Information:
Lot # t01-25-2017@122, Exp 4/26/2017; t12-12-2016@98, Exp 6/11/2017; t01-10-2017@119, Exp 7/10/2017

Product Description:
PROGESTERONE SESAME OIL 10ML MDV 100MG/ML INJ, Injection, 100mg/mL, Rx only, 10mL Glass; Multiple Dose vial, Prepared by Key Compounding Pharmacy
Product Quantity:
1 vial
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0775-2017

Code Information:
Lot t# 02-14-2017@102, Exp 5/1/2017

Product Description:
PYRIDOXAL-5-PHOS 10ML MDV 100MG/ML INJ, Injection, 100mg/mL, Rx only, 10mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy
Product Quantity:
1 vial
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0776-2017
Code Information:
Lot # t01-31-2017@132, Exp 5/2/2017

Product Description:
PYRIDOXAL-5-PHOS 5ML MDV 50MG/ML INJ, 50mg/mL, Rx only, 5mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy
Product Quantity:
3 vials
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0777-2017
Code Information:
Lot # t02-20-2017@74, Exp 5/22/2017

Product Description:
SODIUM BICARB 50ML MDV 8.4% (2 MOSMOL/ML) INJ, Injection, 8.40%, Rx only, 5mL Glass/Multiple Dose via, Prepared by Key Compounding Pharmacy
Product Quantity:
2 vials
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0778-2017
Code Information:
Lot # t01-26-2017@94, Exp 4/27/2017

Product Description:
SODIUM CARBOXYM-CELL PF 0.5% OPHTH, opthalmic, 0.50%, Rx only, 10mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy
Product Quantity:
30 mL
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.

Recall Number:
D-0779-2017
Code Information:
Lot # t02-17-2017@85, Exp 5/21/2017

Product Description:
SODIUM CHLORIDE INH PF GV 0.9% SOLN, Inhalation Solution, 0.90%, Rx only, 5mL Glass/Single Dose vial, Prepared by Key Compounding Pharmacy
Product Quantity:
75 mL
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0780-2017
Code Information:
Lot # 11-29-2016@27, Exp 5/20/2017; 01-25-2017@25, Exp 7/24/2017

Product Description:
SOD PHENYLBUTYRATE SDV 30ML (CALIF or NEZ-CALIF) 200MG/ML INJ, Injection, 200mg/mL, Rx only, 30 mL Glass/Single Dose vial, Prepared by Key Compounding Pharmacy
Product Quantity:
91 vials
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0781-2017
Code Information:
Lot # t12-19-2016@76, Exp 4/27/2017; t11-28-2016@114, Exp 5/28/2017; t11-29-2016@102, Exp 5/29/2017; t12-06-2016@98, Exp 6/6/2017; t12-22-2016@118, Exp 6/21/2017; t12-22-2016@119, Exp 6/21/2017; t02-06-2017@98, Exp 8/6/2017; t02-07-2017@60, Exp 8/7/2017; t02-21-2017@109, Exp 08/21/2017

Product Description:
TESTOST CYP SESAME OIL 5ML MDV 100MG/ML INJ, Injection, 100mg/mL, Rx only, 5 mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy
Product Quantity:
2 vials
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0782-2017
Code Information:
Lot # t01-16-2017@9, Exp 4/17/2017; t01-19-2017@89, Exp 4/20/2017.

Product Description:
TESTOST AQ MDV 50MG/ML INJ, Injection, 50mg/mL, Rx only, packaged in 5mL and 10mL Glass/Multiple Dose vial, Prepared by Key Compounding Pharmacy

Product Quantity:
6 vials total (5/5mL vials and 1/10mL vial)
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0783-2017
Code Information:
Lot # t02-09-2017@79, Exp 5/14/2017; t02-22-2017@91, Exp 5/24/2017

Product Description:
VITAMIN B COMPLEX 1ML SDV NA INJ, Injection, 100mg/2mg/2mg/2mg/100mg/mL, Rx only, 1mL Glass; Single Dose, Prepared by Key Compounding Pharmacy
Product Quantity:
3 vials
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0784-2017
Code Information:
Lot # t02-03-2017@37, Exp 5/7/2017

Product Description:
VITAMIN D3 IN OLIVE OIL SDV 100,000U/ML INJ, Injection, 100,000u/mL, Rx only, packaged in 1 mL Glass/Single Dose vial, Prepared by Key Compounding Pharmacy
Product Quantity:
6/1mL vials
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0785-2017
Code Information:
Lot # t02-10-2017@122, Exp 5/14/2017

Product Description:
VITAMIN D3 IN OLIVE OIL SDV 100,000U/ML INJ, Injection, 150,000u/mL, Rx only, packaged in 2mL Glass/Single Dose vial, Prepared by Key Compounding Pharmacy
Product Quantity:
5/2 mL vials
Reason for Recall:
Lack of Assurance of Sterility: The firm is recalling sterile compounded drugs within expiry due to lack of assurance of sterility.
Recall Number:
D-0786-2017
Code Information:
Lot # t01-31-2017@119, Exp 5/2/2017; t02-01-2017@130, Exp 5/4/2017

Class II Drugs Event

Event ID:
77247
Product Type:
Drugs
Status:
Ongoing
Date Terminated:
Recall Initiation Date:
05/15/2017
Voluntary / Mandated:
Voluntary: Firm Initiated
Center Classification Date:
05/18/2017
Initial Firm Notification of Consignee or Public:
Recalling Firm:
Baxter Healthcare Corporation
1 Baxter Pkwy
Deerfield IL United States
Distribution Pattern:
US and foreign countries: United Arab Emirates, Colombia, and Canada

Associated Products

Product Description:
Fluconazole Injection, USP, 200 mg/100 mL (2mg/mL), 100 mL Single-Dose Intravia Container bag, Rx only, Baxter Healthcare Corporation, Deerfield, IL 60015 USA, Product Code 2J1446, NDC 0338-6046-48
Product Quantity:
113,590 bags
Reason for Recall:
Lack of assurance of sterility: customer complaints received for the presence of leaks.
Recall Number:
D-0788-2017
Code Information:
Lot #: P344028/P344028A, Exp 12/31/17; P352377, Exp 8/31/18; P348136, Exp 4/30/18

Product Description:
Milrinone Lactate in 5% Dextrose Injection, 20 mg/100 mL, 100 mL Single-Dose Intravia Container bag, Rx only, Baxter Healthcare Corporation, Deerfield, IL 60015, NDC 0338-6010-48
Product Quantity:
90,450 bags
Reason for Recall:
Lack of assurance of sterility: customer complaints received for the presence of leaks.
Recall Number:
D-0789-2017
Code Information:
Lot #: P342485, Exp 11/30/17; P344408, Exp 12/31/17

Class III Drugs Event

Event ID:
76837
Product Type:
Drugs
Status:
Ongoing
Date Terminated:
Recall Initiation Date:
03/17/2017
Voluntary / Mandated:
Voluntary: Firm Initiated
Center Classification Date:
05/18/2017
Initial Firm Notification of Consignee or Public:
Letter
Recalling Firm:
Taro Pharmaceuticals U.S.A., Inc.
3 Skyline Dr
Hawthorne NY United States
Distribution Pattern:
U.S. Nationwide

Associated Products

Product Description:
Fluocinonide Cream UPS, 0.05% (Emulsified Base), packaged in 60 g tube, Rx only, Mfd. by: Taro Pharmaceuticals Inc., Brampton, Ontario, Canada, Dist. by Taro Pharmaceuticals U.S.A., Inc., Hawthorne, NY 10532, NDC 51672-1254-3
Product Quantity:
7,776 tubes
Reason for Recall:
Cross contamination with other products: Certain lots of Fluocinonide Cream were found to be contaminated with a small quantity of hydrocortisone-17-valerate.
Recall Number:
D-0790-2017
Code Information:
Lot #: D301311473, D301411473, Exp 3/2017

Class III Drugs Event

Event ID:
77061
Product Type:
Drugs
Status:
Ongoing
Date Terminated:
Recall Initiation Date:
04/07/2017

Voluntary / Mandated:
Voluntary: Firm Initiated
Center Classification Date:
05/18/2017
Initial Firm Notification of Consignee or Public:
Letter
Recalling Firm:
Teligent, Inc.
105 Lincoln Avenue
Buena NJ United States
Distribution Pattern:
TN

Associated Products

Product Description:
Desoximetasone Ointment USP, 0.25%, 15 g tubes, Rx Only, Teligent Pharma, Inc. Buena. New Jersey 08310 NDC 52565-030-15
Product Quantity:
3600 tubes
Reason for Recall:
Superpotent Drug
Recall Number:
D-0787-2017
Code Information:
Lot #: 5760, Exp. 5/31/2018