Enforcement Report - Week of May 16, 2018

Class II Drugs Event

Event ID:
79748

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/03/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
05/10/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Kroger Specialty Pharmacy, Inc.
100 Pear Orchard Dr Ste A
Vicksburg MS United States

Distribution Pattern:
MS, LA, AR, IL, FL

Associated Products

Product Description:
Humira Pen Sub-q Kit a.) 40 mg/0.8 mL (NDC 00074-4339-02); Humira Pen Psor Kit b.) 40 mg/0.8 mL (NDC 00074-4339-07) 28 day supply, Rx Only,

Product Quantity:
Unknown

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0734-2018

Code Information:
All lots remaining within expiry dispensed 12/01/2017 through 02/12/2018

Product Description:
Albuterol 0.083% Inh Sol. 30 days supply, Rx Only, 39183, NDC 76204-0200-60, 30

Product Quantity:
Unknown

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0735-2018

Code Information:
All lots remaining within expiry dispensed 12/01/2017 through 02/12/2018

Product Description:
Kalydeco 150 mg tablet blister, 28 days supply, Rx Only, 39183, NDC 51167-0200-01

Product Quantity:
Unknown

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0736-2018

Code Information:
All lots remaining within expiry dispensed 12/01/2017 through 02/12/2018

Product Description:
Pediasure Liq. Vanilla G+G (CAN) #24 24 days supply, NDC 70074-0558-98

Product Quantity:
Unknown

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0737-2018

Code Information:
All lots remaining within expiry dispensed 12/01/2017 through 02/12/2018

Product Description:
Polyethylene Glycol 3350, powder, for solution 527g BRE, Rx Only, 28 days supply, NDC 51991-0457-57

Product Quantity:
Unknown

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0738-2018

Code Information:
All lots remaining within expiry dispensed 12/01/2017 through 02/12/2018

Product Description:
Pulmicort Respules 0.5 mg/2mL s, 30 days supply, NDC 00186-1989-04

Product Quantity:
Unknown

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0739-2018

Code Information:
All lots remaining within expiry dispensed 12/01/2017 through 02/12/2018

Product Description:
Otezla 30 mg tablet NDC 59572-0631-06 30 days supply;

Product Quantity:
Unknown

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0740-2018

Code Information:
All lots remaining within expiry dispensed 12/01/2017 through 02/12/2018

Product Description:
Taltz 80 mg/mL Pen 1-pk NDC 00002-1445-11 28 days supply

Product Quantity:
Unknown

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0741-2018

Code Information:
All lots remaining within expiry dispensed 12/01/2017 through 02/12/2018

Product Description:
Cosentyx 150 mg/mL PFS 300 mg Dose NDC 00078-0639-98, 28 days supply

Product Quantity:
Unknown

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0742-2018

Code Information:
All lots remaining within expiry dispensed 12/01/2017 through 02/12/2018

Product Description:
Altera Handset NDC 83490-0678-05 56 days supply

Product Quantity:
Unknown

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0743-2018

Code Information:
All lots remaining within expiry dispensed 12/01/2017 through 02/12/2018

Product Description:
Cayston 75 mg Inh. Soln. SDV NDC 61958-0901-01 56 days supply

Product Quantity:
Unknown

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0744-2018

Code Information:
All lots remaining within expiry dispensed 12/01/2017 through 02/12/2018

Product Description:
Repatha 140 mg/mL Sureclick AI 2-pk NDC 55513-0760-02 28 days supply

Product Quantity:
Unknown

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0745-2018

Code Information:
All lots remaining within expiry dispensed 12/01/2017 through 02/12/2018

Product Description:
Enbrel PFS 50 mg/mL Inj #4 NDC 58406-0435-04 28 days supply;

Product Quantity:
Unknown

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0746-2018

Code Information:
All lots remaining within expiry dispensed 12/01/2017 through 02/12/2018

Product Description:
Botox 100 Units Vial NDC 00023-1145-01 90 days supply.

Product Quantity:
Unknown

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0747-2018

Code Information:
All lots remaining within expiry dispensed 12/01/2017 through 02/12/2018

Product Description:
Prolia 60 mg/1 mL PF syringe NDC 55513-0710-01 180 days supply.

Product Quantity:
Unknown

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0748-2018

Code Information:
All lots remaining within expiry dispensed 12/01/2017 through 02/12/2018

Product Description:
Kitabis Pak 300 mg/5 mL Soln PARI #56 NDC 24492-0850-56 56 days supply

Product Quantity:
Unknown

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0749-2018

Code Information:
All lots remaining within expiry dispensed 12/01/2017 through 02/12/2018

Product Description:
Orkambi 200 mg/125 mg Tablets #112 NDC 51167-0809-01 28 days supply.

Product Quantity:
Unknown

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0750-2018

Code Information:
All lots remaining within expiry dispensed 12/01/2017 through 02/12/2018

Product Description:
Orkambi 100 mg/125 mg Tablets #112 NDC 51167-0700-02 28 days supply.

Product Quantity:
Unknown

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0751-2018

Code Information:
All lots remaining within expiry dispensed 12/01/2017 through 02/12/2018

Product Description:
Bethkis 300 mg/4 mL Ampule #56 NDC 10122-0820-56 56 days supply

Product Quantity:
Unknown

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0752-2018

Code Information:
All lots remaining within expiry dispensed 12/01/2017 through 02/12/2018

Product Description:
Pulmozyme 1 mg/mL Inh. Soln. #30 NDC 50242-0100-40 30 days supply.

Product Quantity:
Unknown

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0753-2018

Code Information:
All lots remaining within expiry dispensed 12/01/2017 through 02/12/2018

Product Description:
Azithromycin 250 mg tablet #18 TEV NDC 50111-0787-66 28 days supply

Product Quantity:
Unknown

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0754-2018

Code Information:
All lots remaining within expiry dispensed 12/01/2017 through 02/12/2018

Product Description:
Creon DR 24,000 Units Capsule #250 NDC 00032-1224-07 30 days supply

Product Quantity:
Unknown

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0755-2018

Code Information:
All lots remaining within expiry dispensed 12/01/2017 through 02/12/2018

Product Description:
MVW Complete Softgels NDC 58204-0004-00 30 days supply; MVW Complete Chew Vitamin Grape NDC 58204-0004-15 30 days supply.

Product Quantity:

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0756-2018

Code Information:
All lots remaining within expiry dispensed 12/01/2017 through 02/12/2018

Product Description:
Sodium Chloride 3% Inh. 4 mL NEP #30 NDC 00487-9003-60 30 days supply.

Product Quantity:
Unknown

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0757-2018

Code Information:
All lots remaining within expiry dispensed 12/01/2017 through 02/12/2018

Product Description:
Xolair 150 mg SDV NDC 50242-0040-62 28 days

Product Quantity:
Unknown

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0758-2018

Code Information:
All lots remaining within expiry dispensed 12/01/2017 through 02/12/2018

Product Description:
Vosevi 400/100/100 mg Tablets #28 NDC 61958-2401-01 28 days supply.

Product Quantity:
Unknown

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0759-2018

Code Information:
All lots remaining within expiry dispensed 12/01/2017 through 02/12/2018

Product Description:
Dupixent 300 mg/2 mL PFS #2 w/ NS NDC 00024-5914-01 28 days supply

Product Quantity:
Unknown

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0760-2018

Code Information:
All lots remaining within expiry dispensed 12/01/2017 through 02/12/2018

Product Description:
Boost VHC Oral Liquid VAN #27 NDC 43900-0182-15 27 days supply

Product Quantity:
Unknown

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0761-2018

Code Information:
All lots remaining within expiry dispensed 12/01/2017 through 02/12/2018

Product Description:
Stelara 90 mg/MI PFS NDC 57894-0061-03 84 days supply

Product Quantity:
Unknown

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0762-2018

Code Information:
All lots remaining within expiry dispensed 12/01/2017 through 02/12/2018

Product Description:
Cimzia 200 mg/mL PFS Kit #2 NDC 50474-0710-79 28 days supply.

Product Quantity:
Unknown

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0763-2018

Code Information:
All lots remaining within expiry dispensed 12/01/2017 through 02/12/2018

Product Description:
Praluent 75 mg Pen (2 pens/Pkg) NDC 00024-5901-02 28 days supply

Product Quantity:
Unknown

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0764-2018

Code Information:
All lots remaining within expiry dispensed 12/01/2017 through 02/12/2018

Product Description:
Copaxone 40 mg Injection (12) NDC 68546-0325-12 28 days supply.

Product Quantity:
Unknown

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0765-2018

Code Information:
All lots remaining within expiry dispensed 12/01/2017 through 02/12/2018

Product Description:
Copaxone 20 mg Injection PFS (30) NDC 68546-0317-30 30 days supply.

Product Quantity:
Unknown

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0766-2018

Code Information:
All lots remaining within expiry dispensed 12/01/2017 through 02/12/2018

Product Description:
Tecfidera 240 mg capsule NDC 64406-0006-02 30 days supply

Product Quantity:
Unknown

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0767-2018

Code Information:
All lots remaining within expiry dispensed 12/01/2017 through 02/12/2018

Product Description:
Pomalyst 3 mg capsule NDC 59572-0503-21 28 days supply

Product Quantity:
Unknown

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0768-2018

Code Information:
All lots remaining within expiry dispensed 12/01/2017 through 02/12/2018

Product Description:
Xtandi 40 mg capsule NDC 00469-0125-99 30 days supply

Product Quantity:
Unknown

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0769-2018

Code Information:
All lots remaining within expiry dispensed 12/01/2017 through 02/12/2018

Product Description:
Promacta 50 mg tablet NDC 00078-0686-15 30 days supply

Product Quantity:
Unknown

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0770-2018

Code Information:
All lots remaining within expiry dispensed 12/01/2017 through 02/12/2018

Product Description:
Revlimid 10 mg oral cap NDC 59572-0410-28 28 days supply

Product Quantity:
Unknown

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0771-2018

Code Information:
All lots remaining within expiry dispensed 12/01/2017 through 02/12/2018

Product Description:
Revlimid 15 mg oral cap NDC 59572-0415-21 28 days supply

Product Quantity:
Unknown

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0772-2018

Code Information:
All lots remaining within expiry dispensed 12/01/2017 through 02/12/2018

Product Description:
Revlimid 20 mg oral cap NDC 59572-0420-21 28 days supply

Product Quantity:
Unknown

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0773-2018

Code Information:
All lots remaining within expiry dispensed 12/01/2017 through 02/12/2018

Product Description:
Revlimid 5 mg oral cap NDC 59572-0405-28 28 days supply

Product Quantity:
Unknown

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0774-2018

Code Information:
All lots remaining within expiry dispensed 12/01/2017 through 02/12/2018

Product Description:
Revlimid 25 mg oral cap NDC 59572-0425-21 28 days supply

Product Quantity:
Unknown

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0775-2018

Code Information:
All lots remaining within expiry dispensed 12/01/2017 through 02/12/2018

Product Description:
Avonex 30 mcg/0.5 mL PFS Kit NDC 59627-0222-05 28 days supply

Product Quantity:
Unknown

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0776-2018

Code Information:
All lots remaining within expiry dispensed 12/01/2017 through 02/12/2018

Product Description:
Ibrance 125 mg cap NDC 00069-0189-21 28 days supply

Product Quantity:
Unknown

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0777-2018

Code Information:
All lots remaining within expiry dispensed 12/01/2017 through 02/12/2018

Product Description:
Glatiramer Acetate 40 mg/mL NDC 00378-6961-12 28 days supply

Product Quantity:
Unknown

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0778-2018

Code Information:
All lots remaining within expiry dispensed 12/01/2017 through 02/12/2018

Product Description:
Xalkori 250 mg cap NDC 00069-8140-20 30 days supply

Product Quantity:
Unknown

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0779-2018

Code Information:
All lots remaining within expiry dispensed 12/01/2017 through 02/12/2018

Product Description:
Temozolomide 20 mg NDC 43975-0253-05 28 days supply

Product Quantity:
Unknown

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0780-2018

Code Information:
All lots remaining within expiry dispensed 12/01/2017 through 02/12/2018

Product Description:
Temozolomide 250 mg NDC 43975-0257-05 28 days supply

Product Quantity:
Unknown

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0781-2018

Code Information:
All lots remaining within expiry dispensed 12/01/2017 through 02/12/2018

Product Description:
Gleevec 100 mg tablet NDC 00078-0401-34 30 days supply

Product Quantity:
Unknown

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0782-2018

Code Information:
All lots remaining within expiry dispensed 12/01/2017 through 02/12/2018

Product Description:
Sprycel 80 mg tablet NDC 00003-0855-22 30 days supply

Product Quantity:
Unknown

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0783-2018

Code Information:
All lots remaining within expiry dispensed 12/01/2017 through 02/12/2018

Product Description:
Sprycel 100 mg tablet NDC 00003-0852-22 30 days supply

Product Quantity:
Unknown

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0784-2018

Code Information:
All lots remaining within expiry dispensed 12/01/2017 through 02/12/2018

Product Description:
Cyclophosphamide 50 mg cap NDC 00054-0383-25 28 days supply

Product Quantity:
Unknown

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0785-2018

Code Information:
All lots remaining within expiry dispensed 12/01/2017 through 02/12/2018

Product Description:
Dexamethasone 4 mg tablet NDC 49884-0087-01 28 days supply

Product Quantity:
Unknown

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0786-2018

Code Information:
All lots remaining within expiry dispensed 12/01/2017 through 02/12/2018

Product Description:
Sutent 37.5 mg capsules x28 NDC 00069-0830-38 28 days supply

Product Quantity:
Unknown

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0787-2018

Code Information:
All lots remaining within expiry dispensed 12/01/2017 through 02/12/2018

Product Description:
Sutent 50 mg capsules x28 NDC 00069-0550-38 42 days supply

Product Quantity:
Unknown

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0788-2018

Code Information:
All lots remaining within expiry dispensed 12/01/2017 through 02/12/2018

Product Description:
Imatinib Mesylate Tablet 400 mg NDC 60505-2901-03 30 days supply

Product Quantity:
Unknown

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0789-2018

Code Information:
All lots remaining within expiry dispensed 12/01/2017 through 02/12/2018

Product Description:
Capecitabine 150 mg Tablet NDC 00378-2511-91 28 days supply

Product Quantity:
Unknown

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0790-2018

Code Information:
All lots remaining within expiry dispensed 12/01/2017 through 02/12/2018

Product Description:
Capecitabine 500 mg Tablet NDC 00378-2512-78 28 days supply and 21 days supply

Product Quantity:
Unknown

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0791-2018

Code Information:
All lots remaining within expiry dispensed 12/01/2017 through 02/12/2018

Product Description:
Bendeka 25 mg/mL 4 mL MDVPF NDC 63459-0348-04 28 days supply

Product Quantity:
Unknown

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0792-2018

Code Information:
All lots remaining within expiry dispensed 12/01/2017 through 02/12/2018

Product Description:
Ondansetron 8 mg tablet NDC 57237-0076-30 28 days supply

Product Quantity:
Unknown

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0793-2018

Code Information:
All lots remaining within expiry dispensed 12/01/2017 through 02/12/2018

Product Description:
Letrozole 2.5 mg tab NDC 51991-0759-33 30 days supply

Product Quantity:
Unknown

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0794-2018

Code Information:
All lots remaining within expiry dispensed 12/01/2017 through 02/12/2018

Product Description:
Perjeta 420 mg/14 mL SDV Vials 50242-0145-01 21 days supply

Product Quantity:
Unknown

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0795-2018

Code Information:
All lots remaining within expiry dispensed 12/01/2017 through 02/12/2018

Product Description:
Zarxio 300 mcg/0.5 mL PFS NDC 14 days supply

Product Quantity:
Unknown

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0796-2018

Code Information:
All lots remaining within expiry dispensed 12/01/2017 through 02/12/2018

Product Description:
Tasigna Capsules 150 mg NDC 00078-0592-87 28 days supply

Product Quantity:
Unknown

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0797-2018

Code Information:
All lots remaining within expiry dispensed 12/01/2017 through 02/12/2018

Product Description:
OPDIVO 40 mg/4 mL SDV NDC 00003-3772-11 28 days supply

Product Quantity:
Unknown

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0798-2018

Code Information:
All lots remaining within expiry dispensed 12/01/2017 through 02/12/2018

Product Description:
Kisqali 600 Dose 63 tablet 200 mg NDC 00078-0874-63 28 days supply

Product Quantity:
Unknown

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0799-2018

Code Information:
All lots remaining within expiry dispensed 12/01/2017 through 02/12/2018

Product Description:
Lupron Depot 22.5 mg 3 month Kit NDC 00074-3346-03 84 days supply

Product Quantity:
Unknown

Reason for Recall:
Lack of Processing Controls.

Recall Number:
D-0800-2018

Code Information:
All lots remaining within expiry dispensed 12/01/2017 through 02/12/2018

Class II Drugs Event

Event ID:
79980

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/23/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
05/09/2018

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:
Nationwide

Associated Products

Product Description:
Metoprolol Succinate Extended-Release Tablets, USP, 100 mg, 100 Tablets bottle, Rx only, Manufactured by: Dr. Reddy's Laboratories Limited Bachupally-500 090 India\ NDC 55111-468-01

Product Quantity:
8160 bottles

Reason for Recall:
Presence of Foreign Tablets/Capsules: One foreign tablet identified as Clopidogrel 75 mg was found in a 100 count bottle of Metoprolol Succiante Extended-Release Tablets.

Recall Number:
D-0727-2018

Code Information:
Batch # C706254, 08/2019

Class II Drugs Event

Event ID:
80005

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/26/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
05/10/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Coast Quality Pharmacy LLC
5710 Hoover Blvd
Tampa FL United States

Distribution Pattern:
AL, CA, FL, MI, SC, TX

Associated Products

Product Description:
Macroaggregated albumin (MAA) kit (for the preparation of Tc99m MAA), Aggregated and non-Aggregated Human Serum Albumin 2.5-5 mg Sodium Acetate Sol 200 mL/0.125 mL lyophilized powder in 10 mL glass vial, Rx only, AnazaoHealth, Tampa, FL

Product Quantity:
52 vials

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0801-2018

Code Information:
Lot: MAA-171219BM BUD: 4/19/18; MAA-180226BM BUD: 06/26/18

Not Yet Classified Drugs Event

Event ID:
79976

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/13/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:

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

Recalling Firm:
Septodont Inc.
416 S Taylor Ave
Louisville CO United States

Distribution Pattern:
US and International

Associated Products

Product Description:
OraVerse (Phentolamine Mesylate) Injection, 0.4 mg/1.7mL, packaged in a box of 10 cartridges of 0.4mg/1.7mL each, Rx only, Distributed by Septodont, Inc., Louisville, CO 80027, Made in Canada by Novocol Pharmaceutical of Canada, Inc., NDC 0362-0101-10

Product Quantity:
8509 boxes

Reason for Recall:
Failed Impurities/Degradation: This recall has been initiated due to an out of specification (OOS) result that was obtained for related substance (Phentolamide), a known degradation product impurity at the 15 month stability test point.

Recall Number:

Code Information:
Lot #'s D01894E and D01894G

Not Yet Classified Drugs Event

Event ID:
79996

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/01/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Nationwide in the USA and Puerto Rico

Associated Products

Product Description:
Ampicillin and Sulbactam for Injection, USP, 3 gram*s/vial, packaged in 10-count vials per carton, Rx only, Distributed by: AuroMedics Pharma LLC, 279 Princeton-Hightstown Rd., E. Windsor, NJ 08520, NDC 55150-117-20.

Product Quantity:
54,720 vials

Reason for Recall:
Presence of Particulate Matter: confirmed customer report of the presence of visible particulate matter believed to be red rubber particles from the manufacturing process of the active ingredients.

Recall Number:

Code Information:
Lot #: AS0317041-A, AS0317035-A; Exp August 2019

Not Yet Classified Drugs Event

Event ID:
80033

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/04/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Noven Pharmaceuticals, Inc.
11960 SW 144th St
Miami FL United States

Distribution Pattern:
Nationwide within the US.

Associated Products

Product Description:
Minivelle (estradiol transdermal system) 0.1 mg/day, packaged in 8-systems per box, Rx only, Mfd. by: Noven Pharmaceuticals, Inc. Miami, Florida 33186 Dist. by: Noven Therapeutics, LLC Miami, Florida 33186, NDC 68968-6610-8

Product Quantity:
61960 boxes

Reason for Recall:
Defective Delivery System: Product is out of specification for shear

Recall Number:

Code Information:
Lot #: 81391, 81638 Exp. 10/2018

Product Description:
Minivelle (estradiol transdermal system) 0.0375 mg/day, packaged in 8-systems per box, Rx only, Mfd. by: Noven Pharmaceuticals, Inc. Miami, Florida 33186 Dist. by: Noven Therapeutics, LLC Miami, Florida 33186, NDC 68968-6637-8

Product Quantity:
70870 boxes

Reason for Recall:
Defective Delivery System: Product is out of specification for shear

Recall Number:

Code Information:
Lot #: 81896, Exp. 03/2019; 82264 Exp. 12/2018