Enforcement Report - Week of November 14, 2018

Class II Drugs Event

Event ID:
81199

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/08/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
11/02/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
ICU Medical Inc
600 N FIELD DRIVE
LAKE FOREST IL United States

Distribution Pattern:
Nationwide.

Associated Products

Product Description:
5% Dextrose Injection, USP, Rx Only, a) 25 mL NDC 0409-7923-20; b) 250 mL NDC 0409-7922-02, Hospira, Inc. Lake Forest, IL 60045

Product Quantity:
372,912 bags

Reason for Recall:
Lack of Assurance of Sterility; bags have the potential to leak

Recall Number:
D-0215-2019

Code Information:
Lots: a) 84-017-JT Exp. December 01, 2019; b) 84-012-JT Exp. June 01, 2019

Product Description:
0.9% Sodium Chloride Injection, USP Rx Only a) 250 mL NDC 0409-7983-02; b) 150 mL NDC 0409-7983-61; c) 50 mL NDC 0409-7984-36; d) 100 mL NDC 0409-7984-37, Hospira, Inc. Lake Forest, IL 60045

Product Quantity:
2,580,448 bags

Reason for Recall:
Lack of Assurance of Sterility; bags have the potential to leak

Recall Number:
D-0216-2019

Code Information:
Lots: a) 84-011-JT Exp. December 01, 2019 and 85-014-JT Exp. January 01, 2020; b) 84-015-JT Exp. December 01, 2019; c) 84-016-JT Exp. June 01, 2019; d) 84-005-JT Exp. December 01, 2019 and 84-014-JT Exp. December 01, 2019

Class II Drugs Event

Event ID:
81289

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/23/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
11/06/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Janssen Pharmaceuticals, Inc.
1125 Trenton-Harbourton Rd.
Titusville NJ United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Ortho-Novum 1/35 (norethindrone/ethinyl estradiol) Tablets, 1 mg/0.035 mg, 28-Day Regimen per pouch (NDC 50458-176-28), 6 Veridate Tablet Dispensers and 6 refills per carton (NDC 50458-176-06), Rx only, Manufactured by: Janssen Ortho, LLC, Manati, Puerto Rico 00674; Manufactured for: Janssen Pharmaceuticals, Inc., Titusville, New Jersey 08560.

Product Quantity:
1,777 cartons

Reason for Recall:
Labeling: Incorrect Instructions; Instructions included for use with the Veridate dispenser contained instructions for the Dialpak dispenser.

Recall Number:
D-0217-2019

Code Information:
Lot # 18BM114, Exp. 03/2020

Product Description:
Ortho-Novum 7/7/7 (norethindrone/ethinyl/estradiol) Tablets, 0.5 mg/0.035 mg, 0.75 mg/0.035 mg, 1 mg/0.035, 28-Day Regimen per pouch, packaged in a) 6 Veridate Tablet Dispensers and 6 Refill pouches (NDC 504-58-178-28) per carton (NDC 50458-178-06); and b) 12 Veridate Tablet Dispenser Refills (NDC 50458-178-12) per carton (NDC 50458-178-12), Clinic Package, , Rx Only, Manufactured by: Janssen Ortho, LLC, Manati, Puerto Rico 00674; Manufactured for: Janssen Pharmaceuticals, Inc., Titusville, New Jersey 08560.

Product Quantity:
a) 3,956 cartons; b) 1 carton

Reason for Recall:
Labeling: Incorrect Instructions; Instructions included for use with the Veridate dispenser contained instructions for the Dialpak dispenser.

Recall Number:
D-0218-2019

Code Information:
Lot #: a) 18CM120, Exp 03/2020; b) 18BM110, Exp. 03/2020

Class II Drugs Event

Event ID:
81337

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/28/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
11/07/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Tailor Made Compounding
200 Moore Dr
Nicholasville KY United States

Distribution Pattern:
Nationwide USA

Associated Products

Product Description:
Tesamorelin, 1mg/vial, 6mL vial, Lyophilized Powder for Reconstitution and Subcutaneous Injection, Rx Only, Tailor Made Compounding, Nicholasville, KY 40356

Product Quantity:
10,280 Vials

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Expiration Date; vial indicates a 1 year expiration date instead of a 6 month expiration date

Recall Number:
D-0223-2019

Code Information:
Lot, exp: 7101804, 7111807, 7131807, 7151801, 7161804, 7181805, 7191801, 7201803, 7211801, 7221801, 7231805, 7241803, 7251803, 7261802, 7271801, 7281801, 7301805, 7311805, exp 7/19; 8021801, 8031801, 8041801, 8081802, 8091804, 8101803, 8111810, 8121801, 8141801, 8161803, 8171803, 8201801, 8251801, exp 8/19

Class II Drugs Event

Event ID:
81346

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/17/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
11/07/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Qualgen, LLC
14844 Bristol Park Blvd
Edmond OK United States

Distribution Pattern:
Nationwide.

Associated Products

Product Description:
Estradiol 10mg pellet, 1 count (NDC 69761-010-01), 6 count (NDC 69761-010-06), 12 count (NDC 69761-010-12), and 30 count (NDC 69761-010-30) vials, Rx Only, Qualgen, LLC, Edmond, OK 73013

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0225-2019

Code Information:
Lots; C262 BUD: 12/20/2018; D067 BUD: 03/21/2019; D072 BUD: 03/28/2019

Product Description:
Estradiol 12.5mg pellet, 1 count (NDC 69761-012-01), 6 count (NDC 69761-012-06), 12 count (NDC 69761-012-12), and 30 count (NDC 69761-012-30) vials, Rx Only, Qualgen, LLC, Edmond, OK 73013

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0226-2019

Code Information:
Lots: C236 BUD: 11/13/2018

Product Description:
Estradiol 15mg pellet, 1 count (NDC 69761-015-01), 6 count (NDC 69761-015-06), 12 count (NDC 69761-015-12), and 30 count (NDC 69761-015-30) vials, Rx Only, Qualgen, LLC, Edmond, OK 73013

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0227-2019

Code Information:
Lots: C253 BUD: 12/12/2018; D016 BUD: 1/18/2019

Product Description:
Estradiol 18mg pellet, 1 count (NDC 69761-018-01), 6 count (NDC 69761-018-06), 12 count (NDC 69761-018-12), and 30 count (NDC 69761-018-30) vials, Rx Only, Qualgen, LLC, Edmond, OK 73013

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0228-2019

Code Information:
Lots: C255 BUD: 12/13/2018

Product Description:
Estradiol 25mg pellet, 1 count (NDC 69761-025-01), 6 count (NDC 69761-025-06), 12 count (NDC 69761-025-12), and 30 count (NDC 69761-025-30) vials, Rx Only, Qualgen, LLC, Edmond, OK 73013

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0229-2019

Code Information:
Lots: C238 BUD: 11/14/2018

Product Description:
Estradiol 6 mg pellet, 1 count (NDC 69761-006-01), 6 count (NDC 69761-006-06), 12 count (NDC 69761-006-12), and 30 count (NDC 69761-006-30) vials, Rx Only Qualgen, LLC, Edmond, OK 73013

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0230-2019

Code Information:
Lots: D007 BUD: 01/09/2019; D060 BUD: 3/14/2019

Product Description:
Testosterone 100mg pellet, 1 count (NDC 69761-110-01), 6 count (NDC 69761-110-06), 12 count (NDC 69761-110-12), and 30 count (NDC 69761-110-30) vials, Rx Only Qualgen, LLC, Edmond, OK 73013

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0231-2019

Code Information:
Lots: C232 BUD: 11/3/2018; C239 BUD: 11/14/2018; C246 BUD: 11/29/2018; C260 BUD: 12/19/2018; D004 BUD: 1/4/2019; D017 BUD: 1/18/2019; D023 BUD: 1/26/2019; D053 BUD: 3/6/2019

Product Description:
Testosterone 12.5mg pellet, 1 count (NDC 69761-112-01), 6 count (NDC 69761-112-06), 12 count (NDC 69761-112-12), and 30 count (NDC 69761-112-30) vials, Rx Only Qualgen, LLC, Edmond, OK 73013

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0232-2019

Code Information:
Lots: C261 BUD: 12/20/2018

Product Description:
Testosterone 200mg pellet, 1 count (NDC 69761-120-01), 6 count (NDC 69761-120-06), 12 count (NDC 69761-120-12), and 30 count (NDC 69761-120-30) vials, Rx Only Qualgen, LLC, Edmond, OK 73013

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0233-2019

Code Information:
Lots: C230 BUD: 11/1/2018; C233 BUD: 11/3/2018; C234 BUD: 11/9/2018; C237 BUD: 11/13/2018; C240 BUD: 11/15/2018; C242 BUD: 11/20/2018; C244 BUD: 11/27/2018; C248 BUD: 12/4/2018; C250 BUD: 12/6/2018; C252 BUD: 12/12/2018; C256 BUD: 12/14/2018; C258 BUD: 12/18/2018; C264 BUD: 12/27/2018; D006 BUD: 1/8/2019; D009 BUD: 1/10/2019; D013 BUD: 1/15/2019; D015 BUD: 1/17/2019; D019 BUD: 1/22/2019; D024 BUD: 1/29/2019; D028 BUD: 2/1/2019; D034 BUD: 2/8/2019; D041 BUD: 2/20/2019; D059 BUD: 3/13/2019; D063 BUD: 3/15/2019; D070 BUD: 3/26/2019

Product Description:
Testosterone 25 mg pellet, 1 count (NDC: 69761-125-01) and 30 count vials (NDC: 69761-125-30), Rx Only Qualgen, LLC, Edmond, OK 73013

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0234-2019

Code Information:
Lots: C235 BUD: 11/10/2018; C241 BUD: 11/17/2018; C251 BUD: 12/8/2018; C265 BUD: 12/28/2018; D008 BUD: 1/9/2019; D018 BUD: 1/19/2019; D022 BUD: 1/25/2019; D032 BUD: 2/7/2019; D037 BUD: 2/13/2019; D057 BUD: 3/8/2019; D061 BUD: 3/14/2019; D069 BUD: 3/23/2019

Product Description:
Testosterone 37.5 mg pellet, 1 count (NDC 69761-137-01), 6 count (NDC 69761-137-06), 12 count (NDC 69761-137-12) and 30 count (NDC 69761-137-30) vials, Rx Only, Qualgen, LLC, Edmond, OK 73013

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0235-2019

Code Information:
Lots: C245 BUD: 11/28/2018; D005 BUD: 1/5/2019; D027 BUD: 1/31/2019; D035 BUD: 2/9/2019; D058 BUD: 3/9/2019

Product Description:
Testosterone 50mg pellet, 1 count (NDC 69761-150-01), 6 count (NDC 69761-150-06), 12 count (NDC 69761-150-12), and 30 count (NDC 69761-

150-30) vials, Rx Only Qualgen, LLC, Edmond, OK 73013

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0236-2019

Code Information:
Lots: C247 BUD: 11/30/2018; C249 BUD: 12/5/2018; C266 BUD: 12/29/2018; D012 BUD: 1/12/2019; D029 BUD: 2/2/2019

Product Description:
Testosterone 87.5mg pellet, 1 count (NDC 69761-187-01), 6 count (NDC 69761-187-06), 12 count (NDC 69761-187-12), and 30 count (NDC 69761-187-30) vials, Rx Only Qualgen, LLC, Edmond, OK 73013

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0237-2019

Code Information:
Lots: C243 BUD: 11/21/2018; D010 BUD: 1/11/2019; D025 BUD: 1/30/2019

Product Description:
Testosterone 200 mg/Anastrozole 20 mg pellet, 1 count (NDC 69761-222-01), 6 count (NDC 69761-222-06), 12 count (NDC 69761-222-12), and 30 count (NDC 69761-222-30) vials, Rx Only, Qualgen, Edmond, OK 73013

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0238-2019

Code Information:
Lot: C254 BUD: 12/13/2018

Class II Drugs Event

Event ID:
81453

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/26/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
11/06/2018

Initial Firm Notification of Consignee or Public:
Telephone

Recalling Firm:
S.C. Johnson Professional
2815 Coliseum Centre Dr Ste 600
Charlotte NC United States

Distribution Pattern:
NC

Associated Products

Product Description:
deb stoko, Refresh AntiBac FOAM (benzalkonium chloride), 0.13%, 1 L (33.8 fl. oz.) cartridge packaged in 8 cartridges per case, Made in the USA, Deb USA, Inc., Charlotte, NC 28217, NDC 11084-010-27.

Product Quantity:
869 cases

Reason for Recall:
CGMP Deviations: Product was released to market prior to microbiological testing.

Recall Number:
D-0220-2019

Code Information:
Lot 9131

Product Description:
Alcohol Free Foaming Hand Sanitizer (benzalkonium chloride), 0.13%, 1 L (33.8 fl. oz.) cartridge packaged in 8 cartridges per case, Safe-T-Fresh Inc., USA, 2530 Xenium Lane North, Minneapolis, MN 55441.

Product Quantity:
258 cases

Reason for Recall:
CGMP Deviations: Product was released to market prior to microbiological testing.

Recall Number:
D-0221-2019

Code Information:
Lot 9085

Class II Drugs Event

Event ID:
81466

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/31/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
11/07/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Avella of Deer Valley, Inc. Store 38
24416 N 19th Ave
Phoenix AZ United States

Distribution Pattern:
Product was distributed throughout the United States.

Associated Products

Product Description:
BEVACIZUMAB 2.5 MG/0.1ML, pre-filled syringe (deliverable dose of 1.25MG in normject syringe) Repackaged by Avella Specialty Pharmacy, 24416 N 19th Avenue, Pheonix, AZ 85085. NDC 42852-001-24

Product Quantity:
911 syringes

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0224-2019

Code Information:
Lot # 138-20182408@58 BUD 12/22/2018

Class III Drugs Event

Event ID:
81353

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/15/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
11/07/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Baxter Healthcare Corporation
1 Baxter Pkwy
Deerfield IL United States

Distribution Pattern:
Distributed nationwide in the USA and Puerto Rico

Associated Products

Product Description:
Metoprolol Tartrate Injection, USP, 5 mg/ 5 mL (1 mg/mL), 5 mL per sterile single use glass vial, Rx Only, Manufactured for: Claris Lifesciences, Inc., North Brunswick, NJ 08902. By: Claris Injectables Ltd., Gujarat, India. NDC: 36000-033-10

Product Quantity:
402,165 vials

Reason for Recall:
Failed pH Specifications: Upward shift in the pH of the solution within the shelf life of the impacted lots.

Recall Number:
D-0222-2019

Code Information:
Lot #S: A061267, A061273,EXP 10/2018; A061392, A061395, A061398, A061403, A061407, EXP 11/2018; A0A0070, A0A0073, A0A0079, A0A0081, A0A0083, EXP 12/2018; A0A0119, A0A0124, A0A0125, A0A0133, A0A0141, A0A0145, A0A0152, EXP 1/2019; A0A0247, A0A0252, A0A0253, A0A0292, A0A0293, EXP 2/2019; A0A0361, A0A0367, A0A0390, EXP 3/2019; A0A0438, A0A0445, A0A0453, A0A0459, EXP 4/2019; A0A0547, A0A0551, A0A0554, A0A0630, A0A0631, A0A0637, A0A0638, EXP 5/2019; A0A0777, EXP 7/2019; A0A0915, A0A0919, A0A0924, A0A0930, EXP 8/2019; A0A1094, A0A1097, A0A1110, EXP 11/2019;

Class III Drugs Event

Event ID:
81505

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/05/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
11/06/2018

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:
Within the United States

Associated Products

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

Product Quantity:
18,895 bottles

Reason for Recall:
Container packaging defect.

Recall Number:
D-0219-2019

Code Information:
Lot #: ZYCY, Exp. 04/11/2021

Not Yet Classified Drugs Event

Event ID:
81228

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/03/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Silver Star Brands
2155 S Oakwood Rd
Oshkosh WI United States

Distribution Pattern:
Nationwide USA

Associated Products

Product Description:
Native Remedies VertiFree Oral Spray, 2 fl oz (59 mL) per bottle, Distributed by: Silver Star Brands, Oshkosh, WI 54906. NDC: 35403-253-02

Product Quantity:
67 bottles

Reason for Recall:
Microbial Contamination of Non-Sterile Products

Recall Number:

Code Information:
Lot K061417B

Product Description:
Native Remedies HypoSlim Oral Spray, 2 fl oz (59 mL) per bottle, Distributed by: Silver Star Brands, Oshkosh, WI 54906. NDC: 68703-275-02

Product Quantity:
95 bottles

Reason for Recall:
Microbial Contamination of Non-Sterile Products

Recall Number:

Code Information:
Lot K051818A

Product Description:
Native Remedies VaricoGo Oral Spray, 2 fl oz (59 mL) per bottle, Distributed by: Silver Star Brands, Oshkosh, WI 54906. NDC: 68703-105-59

Product Quantity:
53 bottles

Reason for Recall:
Microbial Contamination of Non-Sterile Products

Recall Number:

Code Information:
Lot K111717A

Product Description:
Native Remedies EyeClear Pro Oral Spray, 2 fl oz (59 mL) per bottle, Distributed by: Silver Star Brands, Oshkosh, WI 54906. NDC: 68703-151-59

Product Quantity:
931 bottles

Reason for Recall:
Microbial Contamination of Non-Sterile Product

Recall Number:

Code Information:
Lot K022317A and K022317B

Product Description:
Healthful Naturals, DizziFree, 2 fl oz (59 mL) per bottle, Distributed by: Silver Star Brands, Oshkosh, WI 54906. NDC: 68703-204-02

Product Quantity:
247 bottles

Reason for Recall:
Microbial Contamination of Non-Sterile Products

Recall Number:

Code Information:
Lot K022616D

Product Description:
Healthful Naturals, Leg Cramp Support, 2 fl oz (59 mL) per bottle, Distributed by: Silver Star Brands, Oshkosh, WI 54906. NDC: 68703-206-02

Product Quantity:
247 bottles

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

Recall Number:

Code Information:
Lot K022216C

Not Yet Classified Drugs Event

Event ID:
81381

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/17/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Medline Industries Inc
Three Lakes Drive
Northfield IL United States

Distribution Pattern:
Nationwide USA and Puerto Rico

Associated Products

Product Description:
SparkleFresh Fluoride Toothpaste, Sodium Monofluorophosphate 0.76%, a) 17 g tube (NDC 53329-083-92, product number NONTP6I), b) 24 g tube (NDC 53329-083-93, product number NONTP85I), c) 42.5 g (NDC 53329-083-21, product number NONTP15I), d) 24 g tube (NDC 53329-081-93, product number DGN1000), Made in Malaysia for Medline Industries, Inc., Three Lakes Drive, Northfield, IL 60093 USA

Product Quantity:
994,756 tubes

Reason for Recall:
Microbial Contamination of Non-Sterile Product

Recall Number:

Code Information:
a) Lot 102920C, exp 10/29/2020 and 111220C, exp 11/11/2020; b) 111620D, exp 11/16/2020; c) 111420D, exp 11/14/2020; d) 111720C, exp 11/17/2020