Enforcement Report - Week of February 7, 2018

Class I Drugs Event

Event ID:
78634

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/29/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
02/01/2018

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Blue Fusion Natural
2942 E Chapman Ave # 132
Orange CA United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
BLUE PEARL capsules, 500mg, 1-count packets, Distributed by Blue Pearl Long Beach, CA UPC 8 4704600978 5

Product Quantity:
300 pill cards

Reason for Recall:
Marketed Without An Approved NDA/ANDA: FDA analysis found this product to contain undeclared sildenafil, an FDA approved drug for the treatment of erectile dysfunction, making this an unapproved drug for which safety and efficacy have not been established and therefore, subject to recall.

Recall Number:
D-0247-2018

Code Information:
All lots

Class II Drugs Event

Event ID:
78575

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/21/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
02/04/2018

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Nationwide USA, Puerto Rico, China, Chile, Guam, Honduras, India, Israel, Malaysia, Mexico, Turkey

Associated Products

Product Description:
Aplicare Povidone-Iodine Prep Pad, Antiseptic, Sterile Solution, Active Ingredient: Povidone-iodine USP 10%. Aplicare, INC., Meriden, CT 06450 USA. NDC: 52380-0111-1

Product Quantity:
11,750 cases

Reason for Recall:
Subpotent Drug:The titratable iodine contained in the Povidone-Iodine prep pads is below label claim of 0.85%.

Recall Number:
D-0252-2018

Code Information:
Part # P-1001; Lots: 58471; 59003; 59723; 60373; 60807; 61187; 61523; 61998; 63974; 64701; 65864 Part # P-1001-8S Lots: 58368; 58371; 58472; 58499; 58686; 58687; 58688; 58816; 58817; 58818; 59002; 59004; 59333; 59334; 59335; 59574; 59724; 59725; 60157; 60237; 60374; 60375; 60507; 60586; 61101; 61368; 61427; 61618; 61750; 61751; 61999; 62067; 62224; 62226; 62557; 62558; 62954; 62955; 63441; 63442; 63443; 63507; 63508; 64002; 64129; 64243; 64245; 64592; 64840; 65081; 65327; 65583; 65681; 65882; 66026; 66040; 66110; 66193; Part # P-1011 Lots: 66549; 66916 Part # P-1011-8S Lots: 66404; 66580; 66622; 66709; 66856

Product Description:
Medline CC Drawer 4 IV Circulation Pack, Contains Rx, Single Use Only, contains 2 Prep Pad PVPs. Packaged in USA for Medline Industries, Inc., Northfield, IL 60093

Product Quantity:
51 cases

Reason for Recall:
Subpotent Drug:The titratable iodine contained in the Povidone-Iodine prep pads is below label claim of 0.85%.

Recall Number:
D-0253-2018

Code Information:
Pack Number: ACC010254A; Lots: 17HD4376; 17HD1709; 17HD1709

Product Description:
Medline Vaginal Delivery CDS Pack, Single Use Only. Packaged in Mexico for Medline Industries, Inc., Northfield, IL 60093

Product Quantity:
2 cases

Reason for Recall:
Subpotent Drug:The titratable iodine contained in the Povidone-Iodine prep pads is below label claim of 0.85%.

Recall Number:
D-0254-2018

Code Information:
Pack Number: CDS830006I; Lots: 17IB3974

Product Description:
Medline Vitrectomy CDS Pack, Single Use Only. Packaged in Mexico for Medline Industries, Inc., Northfield, IL 60093

Product Quantity:
5 cases

Reason for Recall:
Subpotent Drug:The titratable iodine contained in the Povidone-Iodine prep pads is below label claim of 0.85%.

Recall Number:
D-0255-2018

Code Information:
Pack Number: CDS984258F; Lots: 177B1083

Product Description:
Medline RAD NECK ENT TRAY Pack, Single Use Only. Packaged in USA for Medline Industries, Inc., Northfield, IL 60093

Product Quantity:
4 cases

Reason for Recall:
Subpotent Drug:The titratable iodine contained in the Povidone-Iodine prep pads is below label claim of 0.85%.

Recall Number:
D-0256-2018

Code Information:
Pack Number: DYKA1220; Lots: 17FA1301

Product Description:
Medline Newborn Kit. Packaged for Medline Industries, Inc., Northfield, IL 60093

Product Quantity:
288 cases

Reason for Recall:
Subpotent Drug:The titratable iodine contained in the Povidone-Iodine prep pads is below label claim of 0.85%.

Recall Number:
D-0257-2018

Code Information:
Pack Number: DYKL1133; Lots: 17IA0348; 17GA0975; 17IA0348

Product Description:
Medline Concordia Trunk Kit. Packaged for Medline Industries, Inc., Northfield, IL 60093

Product Quantity:
21 cases

Reason for Recall:
Subpotent Drug:The titratable iodine contained in the Povidone-Iodine prep pads is below label claim of 0.85%.

Recall Number:
D-0258-2018

Code Information:
Pack Number: DYKM1403; Lots: 17BA1782

Product Description:
Medline Concordia Nurse Bag Kit. Packaged in USA for Medline Industries, Inc., Northfield, IL 60093

Product Quantity:
51 cases

Reason for Recall:
Subpotent Drug:The titratable iodine contained in the Povidone-Iodine prep pads is below label claim of 0.85%.

Recall Number:
D-0259-2018

Code Information:
Pack Number: DYKM1425; Lots: 17BA1030

Product Description:
Medline Pediatric IV Kit. Packaged in USA for Medline Industries, Inc., Northfield, IL 60093

Product Quantity:
50 cases

Reason for Recall:
Subpotent Drug:The titratable iodine contained in the Povidone-Iodine prep pads is below label claim of 0.85%.

Recall Number:
D-0260-2018

Code Information:
Pack Number: DYKP1000A; Lots: 17AA2252

Product Description:
Medline CNTRL Line Removal Kit Scripps. Packaged in USA for Medline Industries, Inc., Northfield, IL 60093

Product Quantity:
375 cases

Reason for Recall:
Subpotent Drug:The titratable iodine contained in the Povidone-Iodine prep pads is below label claim of 0.85%.

Recall Number:
D-0261-2018

Code Information:
Pack Number: DYKSCRIPPSCL1; Lots: 17HA1756

Product Description:
Medline Trunk Kit, Non-sterile. Packaged in USA for Medline Industries, Inc., Mundelein, IL 60060

Product Quantity:
231 cases

Reason for Recall:
Subpotent Drug:The titratable iodine contained in the Povidone-Iodine prep pads is below label claim of 0.85%.

Recall Number:
D-0262-2018

Code Information:
Pack Number: DYKTRUNK1; Lots: 17FA0227; 17FA0470; 17FA1431; 17HA0258; 17HA0259

Product Description:
Medline TRAY, CATHETER CARE, LIDDED. Packaged in USA for Medline Industries, Inc., Northfield, IL 60093

Product Quantity:
1,000 cases

Reason for Recall:
Subpotent Drug:The titratable iodine contained in the Povidone-Iodine prep pads is below label claim of 0.85%.

Recall Number:
D-0263-2018

Code Information:
Pack Number: DYND12110; Lots: 16KA2117; 16LA1083; 15GA1298; 16KA0905; 16KA2117; 16BA0141

Product Description:
Medline Suture Removal Tray. Sterile. Single use only. Packaged in Mexico for Medline Industries, Inc., Mundelein, IL 60060

Product Quantity:
65,563 cases

Reason for Recall:
Subpotent Drug:The titratable iodine contained in the Povidone-Iodine prep pads is below label claim of 0.85%.

Recall Number:
D-0264-2018

Code Information:
Pack Number: DYND70900; Lots: 17GB6098; 16KB8714; 17GB5103; 17EB4268; 17BB3409; 17SB1821; 17OB8226; 16QB7895; 17EB7214; 16LB5336; 17QB4767; 17MB3722; 17PB7167; 17EB0

363; 17DB2103; 17FB2572 Pack Number: DYND70900H; Lots: 16KB8714; 16KB8714; 17EB4268; 17OB8226; 17OB8226; 17EB0363; 17EB0363; 17EB4268; 17EB4268; 16WB5947; 17GB6098; 17GB6098; 17QB4767; 17QB4767; 17MB3722; 17MB3722; 16SB7791; 16TB0404; 17GB6098; 17EB7214; 17EB0363; 17BB3409; 17PB7167; 17PB7167; 17EB7214; 17GB6098; 17PB7167; 17PB7167; 17EB4268; 17EB0363; 17PB7167; 17QB4767; 17QB4767; 17QB4767; 17EB7214; 17EB7214; 17OB8226; 17QB4767; 17BB3409; 17EB7214; 17QB4767; 17QB4767; 17QB4767; 17GB6098; 17GB6098; 17PB7167; 16TB0404; 17PB7167; 17QB4767; 17QB4767; 16WB5947; 17BB3409

Product Description:
Medline IV Start Kit, Sterile, Single use only. Packaged in Mexico for Medline Industries, Inc., Mundelein, IL 60060

Product Quantity:
10,375 cases

Reason for Recall:
Subpotent Drug:The titratable iodine contained in the Povidone-Iodine prep pads is below label claim of 0.85%.

Recall Number:
D-0265-2018

Code Information:
Pack Number: DYND74077; Lots: 16GB2754; 17GB3103; 16IB7722; 17EB6063 Pack Number: DYND74077H; Lots: 17EB6063; 17GB3103

Product Description:
Medline Central Line Dressing Change Tray Kit, Sterile, Single use only. Packaged in Mexico for Medline Industries, Inc., Mundelein, IL 60060

Product Quantity:
14,675 cases

Reason for Recall:
Subpotent Drug:The titratable iodine contained in the Povidone-Iodine prep pads is below label claim of 0.85%.

Recall Number:
D-0266-2018

Code Information:
Pack Number: DYND74661; Lots: 177B1602; 17RB9139; 16WB5199; 17CB7720; 17CB5841; 167B0074; 16GB8853; 16JB0621; 17EB4904; 16TB9798; 165B0465 Pack Number: DYND74661H; Lots: 17EB4904; 17CB5841; 17CB1032; 165B0465; 16WB5199; 17RB9139; 17CB7720; 16JB0621; 16TB9798; 177B1602;

Product Description:
Medline Incision and Drainage Tray Kit, Sterile, Single use only. Packaged in USA for Medline Industries, Inc., Mundelein, IL 60060

Product Quantity:
11 cases

Reason for Recall:
Subpotent Drug:The titratable iodine contained in the Povidone-Iodine prep pads is below label claim of 0.85%.

Recall Number:
D-0267-2018

Code Information:
Pack Number: DYNDA1046H; Lots: 16LA0907

Product Description:
Medline I&D Tray Kit, Sterile, Single use only. Packaged in Mexico for Medline Industries, Inc., Mundelein, IL 60060

Product Quantity:
40 cases

Reason for Recall:
Subpotent Drug:The titratable iodine contained in the Povidone-Iodine prep pads is below label claim of 0.85%.

Recall Number:
D-0268-2018

Code Information:
Pack Number: DYNDA1109; Lots: 178B0923

Product Description:
Medline Sheath Removal Kit, Sterile, Single use only. Packaged in Mexico for Medline Industries, Inc., Northfield, IL 60063

Product Quantity:
40 cases

Reason for Recall:
Subpotent Drug:The titratable iodine contained in the Povidone-Iodine prep pads is below label claim of 0.85%.

Recall Number:
D-0269-2018

Code Information:
Pack Number: DYNDA1356; Lots: 17DB2820

Product Description:
Medline Wound Closure Tray, Sterile, Single use only. Packaged in Mexico for Medline Industries, Inc., Northfield, IL 60093

Product Quantity:
80 cases

Reason for Recall:
Subpotent Drug:The titratable iodine contained in the Povidone-Iodine prep pads is below label claim of 0.85%.

Recall Number:
D-0270-2018

Code Information:
Pack Number: DYNDA1465; Lots: 17HB4903; 17CB8548

Product Description:
Medline General Purpose Kit, Sterile, Single use only. Packaged in Mexico for Medline Industries, Inc., Northfield, IL 60093

Product Quantity:
700 cases

Reason for Recall:
Subpotent Drug:The titratable iodine contained in the Povidone-Iodine prep pads is below label claim of 0.85%.

Recall Number:
D-0271-2018

Code Information:
Pack Number: DYNDA1591; Lots: 17GB5136; 17PB2138

Product Description:
Medline DC Line Kit, Sterile, Single use only. Packaged in Mexico for Medline Industries, Inc., Mundelein, IL 60060

Product Quantity:
363 cases

Reason for Recall:
Subpotent Drug:The titratable iodine contained in the Povidone-Iodine prep pads is below label claim of 0.85%.

Recall Number:
D-0272-2018

Code Information:
Pack Number: DYNDC1971; Lots: 175B1999; Pack Number: DYNDC1971H; Lots: 17OB8570; 175B1999

Product Description:
Medline Dressing Change Tray Kit, Sterile, Single use only. Packaged in Mexico for Medline Industries, Inc., Mundelein, IL 60060

Product Quantity:
280 cases

Reason for Recall:
Subpotent Drug:The titratable iodine contained in the Povidone-Iodine prep pads is below label claim of 0.85%.

Recall Number:
D-0273-2018

Code Information:
Pack Number: DYNDC2282; Lots: 16CB5897; 16PB9981

Product Description:
Medline INCISION AND DRAINAGE TRAY Kit, Sterile, Single use only. Packaged in Mexico for Medline Industries, Inc., Mundelein, IL 60060

Product Quantity:
60 cases

Reason for Recall:
Subpotent Drug:The titratable iodine contained in the Povidone-Iodine prep pads is below label claim of 0.85%.

Recall Number:
D-0274-2018

Code Information:
Pack Number: DYNDD1039; Lots: 17GB4725; 17HB4905

Product Description:
Medline Circumcision Tray Kit, Sterile, Single use only. Packaged in Mexico for Medline Industries, Inc., Northfield, IL 60093

Product Quantity:
80 cases

Reason for Recall:
Subpotent Drug:The titratable iodine contained in the Povidone-Iodine prep pads is below label claim of 0.85%.

Recall Number:
D-0275-2018

Code Information:
Pack Number: DYNDF1012E; Lots: 17SB5574

Product Description:
Medline Catheter Insertion Kit, Sterile. Packaged in Mexico for Medline Industries, Inc., Mundelein, IL 60060

Product Quantity:
4,100 cases

Reason for Recall:
Subpotent Drug:The titratable iodine contained in the Povidone-Iodine prep pads is below label claim of 0.85%.

Recall Number:
D-0276-2018

Code Information:
Pack Number: DYNDINSERTKIT; Lots: 17SB3347; 175B1052; 16JB3251; 16IB2940; 17CB4925

Product Description:
Medline All Purpose Instrument Tray, Sterile. Packaged in Mexico for Medline Industries, Inc., Mundelein, IL 60060

Product Quantity:
250 cases

Reason for Recall:
Subpotent Drug:The titratable iodine contained in the Povidone-Iodine prep pads is below label claim of 0.85%.

Recall Number:
D-0277-2018

Code Information:
Pack Number: DYNDL1488; Lots: 177B0657; 17QB3332

Product Description:
Medline General Purpose Tray, Sterile, Single Use Only. Packaged in USA for Medline Industries, Inc., Mundelein, IL 60060

Product Quantity:
56 cases

Reason for Recall:
Subpotent Drug:The titratable iodine contained in the Povidone-Iodine prep pads is below label claim of 0.85%.

Recall Number:
D-0278-2018

Code Information:
Pack Number: DYNDL1648; Lots: 17FA0144

Product Description:
Medline Laceration Tray, Sterile, Single Use Only. Packaged in USA for Medline Industries, Inc., Northfield, IL 60093

Product Quantity:
600 cases

Reason for Recall:
Subpotent Drug:The titratable iodine contained in the Povidone-Iodine prep pads is below label claim of 0.85%.

Recall Number:
D-0279-2018

Code Information:
Pack Number: DYNDL1688; Lots: 17HB3112

Product Description:
Medline Suture Removal Tray, Sterile, Single Use Only. Packaged in USA for Medline Industries, Inc., Mundelein, IL 60060

Product Quantity:
700 cases

Reason for Recall:
Subpotent Drug:The titratable iodine contained in the Povidone-Iodine prep pads is below label claim of 0.85%.

Recall Number:
D-0280-2018

Code Information:
Pack Number: DYNDR1018A; Lots: 17RB8658; 17HB1913

Product Description:
Medline GHS Suture Removal Tray, Sterile, Single Use Only. Packaged in USA for Medline Industries, Inc., Mundelein, IL 60060

Product Quantity:
1100 cases

Reason for Recall:
Subpotent Drug:The titratable iodine contained in the Povidone-Iodine prep pads is below label claim of 0.85%.

Recall Number:
D-0281-2018

Code Information:
Pack Number: DYNDR1056; Lots: 17RB9450

Product Description:
Medline Staple Remover Tray, Sterile, Single Use Only. Packaged in USA for Medline Industries, Inc., Northfield, IL 60060

Product Quantity:
248 cases

Reason for Recall:
Subpotent Drug:The titratable iodine contained in the Povidone-Iodine prep pads is below label claim of 0.85%.

Recall Number:
D-0282-2018

Code Information:
Pack Number: DYNDR1067; Lots: 17PB4605 Pack Number: DYNDR1067H; Lots: 17PB4605

Product Description:
Medline General Purpose Tray, Sterile, Single Use Only. Packaged in USA for Medline Industries, Inc., Mundelein, IL 60060

Product Quantity:
80 cases

Reason for Recall:
Subpotent Drug:The titratable iodine contained in the Povidone-Iodine prep pads is below label claim of 0.85%.

Recall Number:
D-0283-2018

Code Information:
Pack Number: DYNDR1071; Lots: 17FA1640

Product Description:
Medline Suture Removal Tray, Sterile, Single Use Only. Packaged in USA for Medline Industries, Inc., Mundelein, IL 60060

Product Quantity:
1,133 cases

Reason for Recall:
Subpotent Drug:The titratable iodine contained in the Povidone-Iodine prep pads is below label claim of 0.85%.

Recall Number:
D-0284-2018

Code Information:
Pack Number: DYNDR1109; Lots: 17NB0789; 17EB4269 Pack Number: DYNDR1109H; Lots 17EB4269

Product Description:
Medline Suture Removal Tray, Sterile, Single Use Only. Packaged in USA for Medline Industries, Inc., Mundelein, IL 60060

Product Quantity:
3800 cases

Reason for Recall:
Subpotent Drug:The titratable iodine contained in the Povidone-Iodine prep pads is below label claim of 0.85%.

Recall Number:
D-0285-2018

Code Information:
Pack Number: DYNDR1111; Lots: 17FB1191; 17HB1905 Pack Number: DYNDR1112A; Lots 177B0660; 175B2485

Product Description:
Medline Staple Remover Kit, Sterile, Single Use Only. Packaged in USA for Medline Industries, Inc., Mundelein, IL 60060

Product Quantity:
600 cases

Reason for Recall:
Subpotent Drug:The titratable iodine contained in the Povidone-Iodine prep pads is below label claim of 0.85%.

Recall Number:
D-0286-2018

Code Information:
Pack Number: DYNDR1118; Lots: 17SB4219; 175B2486

Product Description:
Medline Suture Removal Tray, Sterile, Single Use Only. Packaged in Mexico for Medline Industries, Inc., Mundelein, IL 60060

Product Quantity:
3,089 cases

Reason for Recall:
Subpotent Drug:The titratable iodine contained in the Povidone-Iodine prep pads is below label claim of 0.85%.

Recall Number:
D-0287-2018

Code Information:
Pack Number: DYNDR1157; Lots: 177B0661 Pack Number: DYNDR1157H; Lots: 177B0661; 17QB1693

Product Description:
Medline NICC Suture Removal Tray, Sterile, Single Use Only. Packaged in Mexico for Medline Industries, Inc., Mundelein, IL 60060

Product Quantity:
346 cases

Reason for Recall:
Subpotent Drug:The titratable iodine contained in the Povidone-Iodine prep pads is below label claim of 0.85%.

Recall Number:
D-0288-2018

Code Information:
Pack Number: DYNDR1161; Lots: 17RB9449 Pack Number: DYNDR1161H; Lots: 17RB9449

Product Description:
Medline Suture Removal Tray, Sterile, Single Use Only. Packaged in Mexico for Medline Industries, Inc., Mundelein, IL 60060

Product Quantity:
700 cases

Reason for Recall:
Subpotent Drug:The titratable iodine contained in the Povidone-Iodine prep pads is below label claim of 0.85%.

Recall Number:
D-0289-2018

Code Information:
Pack Number:DYNDR1165; Lots: 15HB6327; 15HB4355

Product Description:
Medline Skin Staple Remover Kit, Sterile, Single Use Only. Packaged in Mexico for Medline Industries, Inc., Mundelein, IL 60060

Product Quantity:
550 cases

Reason for Recall:
Subpotent Drug:The titratable iodine contained in the Povidone-Iodine prep pads is below label claim of 0.85%.

Recall Number:
D-0290-2018

Code Information:
Pack Number: DYNDR1184; Lots: 175B2484; 17HB1903

Product Description:
Medline Straight Suture Removal Tray, Sterile, Single Use Only. Packaged in Mexico for Medline Industries, Inc., Mundelein, IL 60060

Product Quantity:
10,298 cases

Reason for Recall:
Subpotent Drug:The titratable iodine contained in the Povidone-Iodine prep pads is below label claim of 0.85%.

Recall Number:
D-0291-2018

Code Information:
Pack Number: DYNDR1186; Lots: 17EB0360; 177B1719 Pack Number: DYNDR1186H; Lots: 16PB7974; 17EB0360

Product Description:
Medline Suture Removal Tray, Sterile, Single Use Only. Packaged in Mexico for Medline Industries, Inc., Mundelein, IL 60060

Product Quantity:
100 cases

Reason for Recall:
Subpotent Drug:The titratable iodine contained in the Povidone-Iodine prep pads is below label claim of 0.85%.

Recall Number:
D-0292-2018

Code Information:
Pack Number: DYNDR1195; Lots: 17AB1899

Product Description:
Medline Suture Removal Kit, Sterile, Single Use Only. Packaged in Mexico for Medline Industries, Inc., Northfield, IL 60093

Product Quantity:
100 cases

Reason for Recall:
Subpotent Drug:The titratable iodine contained in the Povidone-Iodine prep pads is below label claim of 0.85%.

Recall Number:
D-0293-2018

Code Information:
Pack Number: DYNDR1199; Lots 16XB4041; 175B2487; 17PB8309

Product Description:
Medline Suture Removal Kit, Sterile, Single Use Only. Packaged in Mexico for Medline Industries, Inc., Mundelein, IL 60060

Product Quantity:
1,250 cases

Reason for Recall:
Subpotent Drug:The titratable iodine contained in the Povidone-Iodine prep pads is below label claim of 0.85%.

Recall Number:
D-0294-2018

Code Information:
Pack Number: DYNDS1010; Lots 15EB9408

Product Description:
Medline General Purpose Instrument Set, Sterile, Single Use Only. Packaged in Mexico for Medline Industries, Inc., Mundelein, IL 60060

Product Quantity:
3,300 cases

Reason for Recall:
Subpotent Drug:The titratable iodine contained in the Povidone-Iodine prep pads is below label claim of 0.85%.

Recall Number:
D-0295-2018

Code Information:
Pack Number: DYNDS1014; Lots 17GB3416; 176B2045

Product Description:
Liberator Medical Supply Catheter Insertion Tray, Sterile, Single Use Only. Distributed by: Liberator Medical Supply, INC. Packaged in Mexico for Medline Industries, Inc., Mundelein, IL 60060

Product Quantity:
20,430 cases

Reason for Recall:
Subpotent Drug:The titratable iodine contained in the Povidone-Iodine prep pads is below label claim of 0.85%.

Recall Number:
D-0296-2018

Code Information:
Pack Number: DYNDT1022E; Lots 17QB4402; 17TB1979

Product Description:
Medline Irrigation W/Piston SYR Tray, Sterile, Single Use Only. Packaged in Mexico for Medline Industries, Inc., Northfield, IL 60093

Product Quantity:
2,336 cases

Reason for Recall:
Subpotent Drug:The titratable iodine contained in the Povidone-Iodine prep pads is below label claim of 0.85%.

Recall Number:
D-0297-2018

Code Information:
Pack Number: DYNDT1094 and DYNDT1094H

Product Description:
Medline IV Start Kit, Sterile, Single Use Only. Packaged in Mexico for Medline Industries, Inc., Northfield, IL 60093

Product Quantity:
350 cases

Reason for Recall:
Subpotent Drug:The titratable iodine contained in the Povidone-Iodine prep pads is below label claim of 0.85%.

Recall Number:
D-0298-2018

Code Information:
Pack Number: DYNDV1609; Lots 17GB1216

Product Description:
Medical Equipment Affiliates IV Start Kit, Sterile, Single Use Only. Packaged in Mexico for Medical Equipment Affiliates., Tahlequah, OK 74464

Product Quantity:
5,400 cases

Reason for Recall:
Subpotent Drug:The titratable iodine contained in the Povidone-Iodine prep pads is below label claim of 0.85%.

Recall Number:
D-0299-2018

Code Information:
Pack Number: DYNDV39010; Lots 17QB8612

Product Description:
Medline Debridement Tray, Sterile, Single Use Only. Assembled in USA by Medline Industries, Inc., Mundelein, IL 6060

Product Quantity:
90 cases

Reason for Recall:
Subpotent Drug:The titratable iodine contained in the Povidone-Iodine prep pads is below label claim of 0.85%.

Recall Number:
D-0300-2018

Code Information:
Pack Number: DYNDW1032

Product Description:
Medline Skin Biopsy Pack-LF, Sterile, Single Use Only. Packaged in USA by Medline Industries, Inc., Northfield, IL 60093

Product Quantity:
120 cases

Reason for Recall:
Subpotent Drug:The titratable iodine contained in the Povidone-Iodine prep pads is below label claim of 0.85%.

Recall Number:
D-0301-2018

Code Information:
Pack Number: DYNJ0394028; Lots 17HK3191

Product Description:
Medline Incision and Drainage Tray, Sterile, Single Use Only. Packaged in Mexico by Medline Industries, Inc., Mundelein, IL 60060

Product Quantity:
2,369 cases

Reason for Recall:
Subpotent Drug:The titratable iodine contained in the Povidone-Iodine prep pads is below label claim of 0.85%.

Recall Number:
D-0302-2018

Code Information:
Pack Number: DYNJ07147; Lots 1160B1635; 17RB8957; 16WB2198; 16GB6023; 16KB1547; 17DB1855 Pack Number: DYNJ07147H; Lots 17DB1855; 16WB2198; 17RB8957

Product Description:
Medline Pacemaker Implant Pack, Sterile, Single Use Only. Packaged in Mexico by Medline Industries, Inc., Mundelein, IL 60060

Product Quantity:
66 cases

Reason for Recall:
Subpotent Drug:The titratable iodine contained in the Povidone-Iodine prep pads is below label claim of 0.85%.

Recall Number:
D-0303-2018

Code Information:
Pack Number: DYNJ32856C; Lots 17SB6210; 17FB5359; 17SB6208

Product Description:
Medline Hip Replacement, Kit, Sterile, Single Use Only. Packaged in Mexico by Medline Industries, Inc., Northfield, IL 60093

Product Quantity:
88 cases

Reason for Recall:
Subpotent Drug:The titratable iodine contained in the Povidone-Iodine prep pads is below label claim of 0.85%.

Recall Number:
D-0304-2018

Code Information:
Pack Number: DYNJ48244B; Lots 17FB2504; 17HB2544

Product Description:
Medline Incision Drainage Kit, Sterile, Single Use Only. Packaged in Mexico by Medline Industries, Inc., Mundelein, IL 60060

Product Quantity:
149 cases

Reason for Recall:
Subpotent Drug:The titratable iodine contained in the Povidone-Iodine prep pads is below label claim of 0.85%.

Recall Number:
D-0305-2018

Code Information:
Pack Number: P888943; Lots 17RB8662 Pack Number: P888943H; Lots 17RB8662

Product Description:
Medline Anesthesia Kit, Single Use Only. Packaged in Mexico by Medline Industries, Inc., Northfield, IL 60093

Product Quantity:
60 cases

Reason for Recall:
Subpotent Drug:The titratable iodine contained in the Povidone-Iodine prep pads is below label claim of 0.85%.

Recall Number:
D-0306-2018

Code Information:
Pack Number: DYNJAA6606; Lots 178B1823; 17HB2055

Product Description:
Medline Suture Removal Tray, Sterile, Single Use Only. Packaged in Mexico by Medline Industries, Inc., Mundelein, IL 60060

Product Quantity:
49,587 cases

Reason for Recall:
Subpotent Drug:The titratable iodine contained in the Povidone-Iodine prep pads is below label claim of 0.85%.

Recall Number:
D-0307-2018

Code Information:
Pack Number: MDS701550; Lots 16GB7687; 17HB5153; 16IB0427; 17GB3906; 17AB1937; 17CB7737; 16JB1136; 16JB1137 Pack Number: MDS701550H; Lots 16QB4583; 16IB0427; 17CB7737; 16MB6165; 17GB3906; 17AB1937; 16GB7687; 16JB1137; 17HB5153

Product Description:
Medline Incision and Drainage Tray, Sterile, Single Use Only. Packaged in Mexico by Medline Industries, Inc., Mundelein, IL 60060

Product Quantity:
808 cases

Reason for Recall:
Subpotent Drug:The titratable iodine contained in the Povidone-Iodine prep pads is below label claim of 0.85%.

Recall Number:
D-0308-2018

Code Information:
Pack Number: MDS70815; Lots 16LB2959; 173B1289; 17HB4108; 17FB6679; 16JB8627 Pack Number: MDS70815H; Lots 17FB6679

Product Description:
Medline Suture Removal Tray, Sterile, Single Use Only. Packaged in Mexico by Medline Industries, Inc., Mundelein, IL 60060

Product Quantity:
98,901 cases

Reason for Recall:
Subpotent Drug:The titratable iodine contained in the Povidone-Iodine prep pads is below label claim of 0.85%.

Recall Number:
D-0309-2018

Code Information:
Pack Number: MDS708550; Lots 17GB4997; 17TB7125; 17RB7896; 17HB3784; 17HB4133; 17RB7895; 17FB1724; 17FB2572; Pack Number: MDS708550H; Lots 17GB4997; 17RB7896; 17PB5544; 17FB1724; 16JB1135; 17TB7125; 16SB9345; 17FB2572; 17FB2571; 17RB7895; 17HB3784; 16NB7654; 17FB1721; 16LB8439; 17HB4133; 16WB1269; 16NB8410; 15VB7079

Product Description:
Medline Suture Removal Tray, Sterile, Single Use Only. Packaged in Mexico by Medline Industries, Inc., Mundelein, IL 60060

Product Quantity:
195,448 cases

Reason for Recall:
Subpotent Drug:The titratable iodine contained in the Povidone-Iodine prep pads is below label claim of 0.85%.

Recall Number:
D-0310-2018

Code Information:
Pack Number: MDS708555; Lots 17SB5603; 17PB8319; 177B2065; 17DB2104; 17RB9448; 17RB9451; 17PB8314; 17HB5104; 16XB1090; 17QB0860; 16OB0307; 17DB2777; 16UB2803; Pack Number: MDS708555H; Lots 17PB8319; 173B2496; 16UB2803; 16XB1090; 16SB4453; 16RB1126; 17DB2777; 17QB0860; 16TB8928; 17PB8314; 16IB3745; 17RB9451; 17DB2104; 164B2214; 16KB5659

Product Description:
Professional Hospital Supply Suture Removal Kit, Sterile, Single Use Only. Packaged in Mexico for Professional Hospital Supply, Inc., 41980 Winchester Rd., Temecula, CA 92590

Product Quantity:
450 cases

Reason for Recall:
Subpotent Drug:The titratable iodine contained in the Povidone-Iodine prep pads is below label claim of 0.85%.

Recall Number:
D-0311-2018

Code Information:
Pack Number: P524151; Lots 17HB5103; 17RB8741

Product Description:
Medline Suture Removal Pack Latex Safe, Sterile, Single Use Only. Packaged in Mexico for Medline Industries, Inc., Northfield, IL 60093

Product Quantity:
663 cases

Reason for Recall:
Subpotent Drug:The titratable iodine contained in the Povidone-Iodine prep pads is below label claim of 0.85%.

Recall Number:
D-0312-2018

Code Information:
Pack Number: P734457; Lots 17GB5158; 17RB8681; 17FB0926

Product Description:
Professional Hospital Supply Suture Removal Kit, Sterile, Single Use Only. Packaged in Mexico for Professional Hospital Supply, Inc., 41980 Winchester Rd., Temecula, CA 92590

Product Quantity:
779 cases

Reason for Recall:
Subpotent Drug:The titratable iodine contained in the Povidone-Iodine prep pads is below label claim of 0.85%.

Recall Number:
D-0313-2018

Code Information:
Pack Number: P888899; Lots 17RB8659; 17GB5162 Pack Number: P888899H; Lots 17RB8659

Product Description:
Medline Skin Stapler RMVR, Tray Sterile, Single Use Only. Packaged in Mexico for Medline Industries, Inc., Mundelein, IL 60060

Product Quantity:
592 ases

Reason for Recall:
Subpotent Drug:The titratable iodine contained in the Povidone-Iodine prep pads is below label claim of 0.85%.

Recall Number:
D-0314-2018

Code Information:
Pack Number: P888937; Lots 177B0658; 17QB8268 Pack Number: P888937H; Lots 17QB8268

Product Description:
Medline Incision Drainage Tray, Sterile, Single Use Only. Packaged in Mexico for Medline Industries, Inc., Mundelein, IL 60060

Product Quantity:

Reason for Recall:
Subpotent Drug:The titratable iodine contained in the Povidone-Iodine prep pads is below label claim of 0.85%.

Recall Number:
D-0315-2018

Code Information:
Pack Number: P888943; Lots 17RB8662 Pack Number: P888937H; Lots 17QB8268

Product Description:
Medline Abdominal Surgery II Pack-LF, Sterile, Single Use Only. Packaged in USA for Medline Industries, Inc., Northfield, IL 60093

Product Quantity:
144 cases

Reason for Recall:
Subpotent Drug:The titratable iodine contained in the Povidone-Iodine prep pads is below label claim of 0.85%.

Recall Number:
D-0316-2018

Code Information:
Pack Number: PHS541637005

Product Description:
Medline Suture Removal Tray, Sterile, Single Use Only. Packaged in USA for Medline Industries, Inc., Mundelein, IL 60060

Product Quantity:
9,000 cases

Reason for Recall:
Subpotent Drug:The titratable iodine contained in the Povidone-Iodine prep pads is below label claim of 0.85%.

Recall Number:
D-0317-2018

Code Information:
Pack Number: SD-1010; Lots 17CB8694; 17MB4778; 16KB5621

Product Description:
Medline Suture Removal Tray, Sterile, Single Use Only. Packaged in USA for Medline Industries, Inc., Mundelein, IL 60060

Product Quantity:
34,495 cases

Reason for Recall:
Subpotent Drug:The titratable iodine contained in the Povidone-Iodine prep pads is below label claim of 0.85%.

Recall Number:
D-0318-2018

Code Information:
Pack Number: Z302-R; Lots 177B2075; 17RB9452; 17QB2640; 17CB4220 Pack Number: Z302-RH; Lots 177B2075; 17QB2640; 17RB9452; 17CB4220; 17NB1933; 17MB0084; 16LB3367

Product Description:
Medline Incision & Drainage Tray, Sterile, Single Use Only. Packaged in USA for Medline Industries, Inc., Northfield, IL 60093

Product Quantity:
73 cases

Reason for Recall:
Subpotent Drug:The titratable iodine contained in the Povidone-Iodine prep pads is below label claim of 0.85%.

Recall Number:
D-0319-2018

Code Information:
Pack Numbers: DYNDA1076, DYNDA1076H

Class II Drugs Event

Event ID:
78610

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/07/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
01/29/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Johnson & Johnson
199 Grandview Rd
Skillman NJ United States

Distribution Pattern:
Product was distributed nationwide

Associated Products

Product Description:
Neutrogena Acne Proofing whipped foam cleanser, (Salicylic Acid 2%), aerosolized product in a can, NET WT. 5 OZ (141 g) , Distributed by Johnson & Johnson Consumer Inc. Skillman, NJ 08558, UPC 0 70501 11131 4

Product Quantity:
67,260 units

Reason for Recall:
Defective Container: products showed leakage (bubbles, foaming) of propellant and product from the container valve cup area.

Recall Number:
D-0243-2018

Code Information:
Lot #: 16217F70, 16317F70, 18317F56, 18417F56, 18517F56, 18617F56, 19517F57 19617F57,19717F57, 19817F57, Exp. 05/2019.

Product Description:
Neutrogena deep clean purifying whipped foam cleanser, (Salicylic Acid 0.5%), aerosolized product in a can, NET WT. 5 OZ. (141 g) Distributed By: Johnson & Johnson Consumer Inc. Skillman, NJ 08558. UPC: 0 70501 10053 0

Product Quantity:

Reason for Recall:
Defective Container: products showed leakage (bubbles, foaming) of propellant and product from the container valve cup area.

Recall Number:
D-0244-2018

Code Information:
Lot #:15917F54, 16017F54, Exp. 05/2019; 15817F69,15917F69, Exp. 04/2019; 20017F55, 20117F55, Exp. 06/2019.

Product Description:
Neutrogena Elevated 4-Holiday Trays (contains Neutrogena Deep Clean Purifying Whipped Foam Cleanser) Case Code: 00070501302866

Product Quantity:

Reason for Recall:
Defective Container: products showed leakage (bubbles, foaming) of propellant and product from the container valve cup area.

Recall Number:
D-0245-2018

Code Information:
Lot #: 2617RT1, 2617RT2, 2627RT2, 2637RT1, 2647RT1, 2657RT1, 2627RT2, EXP 05/2019

Class II Drugs Event

Event ID:
78775

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/14/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
01/26/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Boehringer Ingelheim Pharmaceuticals, Inc.
900 Ridgebury Rd
Ridgefield CT United States

Distribution Pattern:
Distributed nationwide

Associated Products

Product Description:
SPIRIVA HandiHaler (tiotropium bromide inhalation powder) 18 mcg/capsule (90 capsules (unit dose blisters) per box, Rx Only, Made in Germany, Distributed by: Boehringer Ingelheim (BI) Pharmaceuticals, Inc., Ridgefield, CT 06877, NDC 0597-0075-47

Product Quantity:
45,008 units/90 capsules each unit

Reason for Recall:
Failed Stability Specifications

Recall Number:
D-0242-2018

Code Information:
Lot # 606478; Exp. 03/18

Class II Drugs Event

Event ID:
78928

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/11/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
02/02/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Premier Pharmacy Labs Inc
8265 Commercial Way
Weeki Wachee FL United States

Distribution Pattern:
Nationwide.

Associated Products

Product Description:
Mitomycin 40 mg/mL Preservative Free Irrigation Volume: 10 mL SDV , Compounded by: Premier Pharmacy Labs 8265 Commercial Way, Weeki Wachee, FL 34613, NDC: 69623-160-35.

Product Quantity:
193 vials

Reason for Recall:
Labeling: Label Error on Declared Strength

Recall Number:
D-0251-2018

Code Information:
Lot: MIT100217SVDS BUD: 03/01/2018

Class III Drugs Event

Event ID:
78962

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/24/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
01/30/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
JCB Laboratories LLC
7335 W 33rd St N
Wichita KS United States

Distribution Pattern:
Nationwide within USA

Associated Products

Product Description:
Cefuroxime, Ophthalmic Solution for Injection, 10 mg/mL, 0.3 mL single-use syringe. This is a Compounded Drug, Hospital & Office Use Only, Not for Resale. Fagron Sterile Services/JCB Laboratories, 7335 W. 33rd St. N., Wichita, KS 67205

Product Quantity:
6,510 syriges

Reason for Recall:
Subpotent Drug: The product is sub-potent prior to its 90-day beyond use date.

Recall Number:
D-0246-2018

Code Information:
Lot #: C274-000002725, BUD 1/21/2018; C274-000002790, BUD 1/28/2018; C274-000002989, BUD 2/13/2018; C274-000003008, BUD 2/14/2018; C274-000003077, BUD 2/20/2018

Class III Drugs Event

Event ID:
78990

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/22/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
02/01/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Ascent Pharmaceuticals, Inc.
550 S Research Pl
Central Islip NY United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Oxycodone Hydrochloride Tablets, USP 15 mg, 100 count bottles, Rx only, Manufactured for Camber Pharmaceuticals, Inc., Piscataway, NJ, Manufactured by: Ascent Pharmaceuticals, Inc., Central Islip, NY --- NDC 31722-917-01

Product Quantity:
45,875 bottles

Reason for Recall:
Labeling; Label Error Not Elsewhere Classified; label missing controlled substance CII symbol

Recall Number:
D-0248-2018

Code Information:
Lot Numbers: 17080591 and 17080619, exp 07/19; 17110907 and 17110908, exp 10/19; and 17120986, exp 11/19

Class III Drugs Event

Event ID:
79029

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/21/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
02/01/2018

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:
Nationwide

Associated Products

Product Description:
Clobetasol Propionate Cream USP, 0.05% 60 g tube, Rx only Mfd. by: Taro Pharmaceutical Industries Ltd., Haifa Bay, Israel 2624761 Dist. by : Taro Pharmaceuticals U.S.A., Inc., Hawthorne, NY 10532 UPC 351672125837 NDC 51672-1258-3

Product Quantity:
27,792 tubes

Reason for Recall:
Failed Content Uniformity Specifications

Recall Number:
D-0249-2018

Code Information:
Lot 311235, exp Sept 2018

Not Yet Classified Drugs Event

Event ID:
76644

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/07/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
A&H Focal Inc.
119 Linwood Ave
Staten Island NY United States

Distribution Pattern:
NY and NJ through six retail stores named "Asian Food Markets"

Associated Products

Product Description:
Black Ant capsules, 4600mg, 4-count blister pack, labeling is in foreign language

Product Quantity:
unknown

Reason for Recall:
Marked Without An Approved NDA/ANDA: FDA analysis found these products to contain sildenafil, an FDA approved drug for the treatment of erectile dysfunction, making these products unapproved drugs for which safety and efficacy have not been establish and therefore, subject to recall.

Recall Number:

Code Information:
All Lots

Product Description:
Indian God Lotion Spray Bottle, labeling is in foreign language

Product Quantity:
unknown

Reason for Recall:
Marked Without An Approved NDA/ANDA: FDA analysis found this product to contain diethyl phthalate, an inactive ingredient in several modified release solid oral dosage forms, making this product unapproved drug for which safety and efficacy have not been establish and therefore, subject to recall.

Recall Number:

Code Information:
All Lots

Product Description:
Miraculous Evil Root capsules, 1200 mg, 6-count bottle, labeling is in foreign language

Product Quantity:
unknown

Reason for Recall:
Marked Without An Approved NDA/ANDA: FDA analysis found these products to contain sildenafil, an FDA approved drug for the treatment of erectile dysfunction, making these products unapproved drugs for which safety and efficacy have not been establish and therefore, subject to recall.

Recall Number:

Code Information:
All Lots

Product Description:
GERMANY BLACK GOLD tablets, 2800 mg, 8-count bottle, labeling is in foreign language

Product Quantity:
unknown

Reason for Recall:
Marked Without An Approved NDA/ANDA: FDA analysis found these products to contain sildenafil, an FDA approved drug for the treatment of erectile dysfunction, making these products unapproved drugs for which safety and efficacy have not been establish and therefore, subject to recall.

Recall Number:

Code Information:
All Lots

Product Description:
GERMANY NIUBIAN tablets, 3000mg, 10-count bottle, labeling is in foreign language

Product Quantity:
unknown

Reason for Recall:
Marked Without An Approved NDA/ANDA: FDA analysis found these products to contain sildenafil, an FDA approved drug for the treatment of erectile dysfunction, making these products unapproved drugs for which safety and efficacy have not been establish and therefore, subject to recall.

Recall Number:

Code Information:
All Lots

Product Description:
HARD TEN DAYS capsules, 4500mg, 6-count bottle, labeling is in foreign language

Product Quantity:
unknown

Reason for Recall:
Marked Without An Approved NDA/ANDA: FDA analysis found these products to contain sildenafil, an FDA approved drug for the treatment of erectile dysfunction, making these products unapproved drugs for which safety and efficacy have not been establish and therefore, subject to recall.

Recall Number:

Code Information:
All Lots

Product Description:
LANG YI HAO CHAONONGSUOPIAN tablets, 500 mg, 8-count bottle, labeling is in foreign language

Product Quantity:
unknown

Reason for Recall:
Marked Without An Approved NDA/ANDA: FDA analysis found these products to contain sildenafil, an FDA approved drug for the treatment of erectile dysfunction, making these products unapproved drugs for which safety and efficacy have not been establish and therefore, subject to recall.

Recall Number:

Code Information:
All Lots

Product Description:
GOLD VIGRA capsules, 50mg, 6-count bottle, labeling is in foreign language

Product Quantity:
unknown

Reason for Recall:
Marked Without An Approved NDA/ANDA: FDA analysis found these products to contain sildenafil, an FDA approved drug for the treatment of erectile dysfunction, making these products unapproved drugs for which safety and efficacy have not been establish and therefore, subject to recall.

Recall Number:

Code Information:
All Lots

Product Description:
Clalis capsules, 50mg, 6-count bottle, labeling is in foreign language

Product Quantity:
unknown

Reason for Recall:
Marked Without An Approved NDA/ANDA: FDA analysis found these products to contain sildenafil, an FDA approved drug for the treatment of erectile dysfunction, making these products unapproved drugs for which safety and efficacy have not been establish and therefore, subject to recall.

Recall Number:

Code Information:
All Lots

Product Description:
Ye Lang Shen capsules, 5000 mg, 8-count bottle, labeling is in foreign language

Product Quantity:
unknown

Reason for Recall:
Marked Without An Approved NDA/ANDA: FDA analysis found these products to contain sildenafil, an FDA approved drug for the treatment of

Recall Number:

erectile dysfunction, making these products unapproved drugs for which safety and efficacy have not been establish and therefore, subject to recall.

Code Information:
All Lots

Product Description:
ZHANSHENG WEIGE CHAOYUE XILISHI tablets, 2000 mg, 6-count bottle, labeling is in foreign language

Product Quantity:
unknown

Reason for Recall:
Marked Without An Approved NDA/ANDA: FDA analysis found these products to contain sildenafil, an FDA approved drug for the treatment of erectile dysfunction, making these products unapproved drugs for which safety and efficacy have not been establish and therefore, subject to recall.

Recall Number:

Code Information:
All Lots

Product Description:
Zhonghua Niubian tablets, 2000mg, 6-count bottle, labeling is in foreign language

Product Quantity:
unknown

Reason for Recall:
Marked Without An Approved NDA/ANDA: FDA analysis found these products to contain sildenafil, an FDA approved drug for the treatment of erectile dysfunction, making these products unapproved drugs for which safety and efficacy have not been establish and therefore, subject to recall.

Recall Number:

Code Information:
All Lots

Product Description:
STREE OVERLORD capsules, 3800 mg, 4-count bottle, labeling is in foreign language

Product Quantity:
unknown

Reason for Recall:
Marked Without An Approved NDA/ANDA: FDA analysis found these products to contain sildenafil, an FDA approved drug for the treatment of erectile dysfunction, making these products unapproved drugs for which safety and efficacy have not been establish and therefore, subject to recall.

Recall Number:

Code Information:
All Lots

Product Description:
MAX MAN capsules, 3000 mg, 6-count bottle, labeling is in foreign language

Product Quantity:
unknown

Reason for Recall:
Marked Without An Approved NDA/ANDA: FDA analysis found these products to contain sildenafil, an FDA approved drug for the treatment of erectile dysfunction, making these products unapproved drugs for which safety and efficacy have not been establish and therefore, subject to recall.

Recall Number:

Code Information:
All Lots

Product Description:
HU HU SHENG WEI capsules, 3000 mg, 2-count bottle, labeling is in foreign language

Product Quantity:
unknown

Reason for Recall:
Marked Without An Approved NDA/ANDA: FDA analysis found these products to contain sildenafil, an FDA approved drug for the treatment of erectile dysfunction, making these products unapproved drugs for which safety and efficacy have not been establish and therefore, subject to recall.

Recall Number:

Code Information:
All Lots

Product Description:
YANSHIJIAONANG capsules, 2000mg, 8-count bottle, labeling is in foreign language

Product Quantity:
unknown

Reason for Recall:
Marked Without An Approved NDA/ANDA: FDA analysis found these products to contain sildenafil, an FDA approved drug for the treatment of erectile dysfunction, making these products unapproved drugs for which safety and efficacy have not been establish and therefore, subject to recall.

Recall Number:

Code Information:
All Lots

Product Description:
Power V8 Viagra tablets, 200mg, 10-Grain bottle, labeling is in foreign language

Product Quantity:
unknown

Reason for Recall:
Marked Without An Approved NDA/ANDA: FDA analysis found these products to contain sildenafil, an FDA approved drug for the treatment of erectile dysfunction, making these products unapproved drugs for which safety and efficacy have not been establish and therefore, subject to recall.

Recall Number:

Code Information:
All Lots

Product Description:
DADIYONGSHI XIANGGANGTIANLONGSHENGWU tablets, 6-count bottle, labeling is in foreign language

Product Quantity:
unknown

Reason for Recall:
Marked Without An Approved NDA/ANDA: FDA analysis found these products to contain sildenafil, an FDA approved drug for the treatment of erectile dysfunction, making these products unapproved drugs for which safety and efficacy have not been establish and therefore, subject to recall.

Recall Number:

Code Information:
All Lots

Product Description:
LIEN CHAN FOR SEVEN DAYS capsules, labeling is in foreign language

Product Quantity:
unknown

Reason for Recall:
Marked Without An Approved NDA/ANDA: FDA analysis found these products to contain sildenafil, an FDA approved drug for the treatment of erectile dysfunction, making these products unapproved drugs for which safety and efficacy have not been establish and therefore, subject to recall.

Recall Number:

Code Information:
All Lots

Product Description:
MACA gold tablets, 6800 mg, 10-count bottle, labeling is in foreign language

Product Quantity:
unknown

Reason for Recall:
Marked Without An Approved NDA/ANDA: FDA analysis found these products to contain sildenafil, an FDA approved drug for the treatment of erectile dysfunction, making these products unapproved drugs for which safety and efficacy have not been establish and therefore, subject to recall.

Recall Number:

Code Information:
All Lots

Product Description:
Tiger King tablets, labeling is in foreign language

Product Quantity:
unknown

Reason for Recall:
Marked Without An Approved NDA/ANDA: FDA analysis found these products to contain sildenafil, an FDA approved drug for the treatment of erectile dysfunction, making these products unapproved drugs for which safety and efficacy have not been establish and therefore, subject to recall.

Recall Number:

Code Information:
All Lots

Not Yet Classified Drugs Event

Event ID:
78531

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/10/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Nationwide within USA and Puerto Rico

Associated Products

Product Description:
Nexterone (amiodarone HCl) Premixed Injection, 150mg/100mL, 100-mL bag, Rx Only, Sterile, Baxter Healthcare Corporation, Deerfield, IL. NDC 43066-150-10

Product Quantity:
35,628 single-dose containers

Reason for Recall:
Presence of Particulate Matter:Particulate identified as polyethylene, the primary constituent of the film and ports used to manufacture the bag in which product is packaged

Recall Number:

Code Information:
Lot #, Expiry: NC109925, Exp 6/1/2019; NC109123, 5/2019

Not Yet Classified Drugs Event

Event ID:
78605

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/20/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Glenmark Pharmaceuticals Inc., USA
750 Corporate Dr
Mahwah NJ United States

Distribution Pattern:
Product was distributed throughout the United States.

Associated Products

Product Description:
Glenmark Mometasone Furoate Cream, USP, 0.1%, 45 g Rx Only Manufactured by: Glenmark Pharmaceuticals Ltd. Village Manufactured for: Glenmark Pharmaceuticals Inc., USA Mahwah, NJ 07430 NDC 68462019255 UPC 3684620192559

Product Quantity:
5136 tubes

Reason for Recall:
Glenmark Pharmaceuticals is recalling Mometasone Furoate Cream, USP, 0.1%, 45 g. due market complaints related to "gritty texture".

Recall Number:

Code Information:
Batch Number: 05170598

Not Yet Classified Drugs Event

Event ID:
78913

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/04/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
International Laboratories, Inc.
6950 Bryan Dairy Rd Ste A
Seminole FL United States

Distribution Pattern:
Nationwide within the US

Associated Products

Product Description:
Clopidogrel Tablets, USP 75 mg, 30-count bottles, Rx only, Packaged for: International Laboratories, LLC St. Petersburg, FL 33710, NDC 54458-888-16

Product Quantity:
218772 bottles

Reason for Recall:
LABELING: LABEL MIX-UP. Simvastatin tablets, USP 10 mg were found in bottles labeled as Clopidogrel tablets, USP 75 mg.

Recall Number:

Code Information:
Lot #: 117099A, Exp. 08/19

Not Yet Classified Drugs Event

Event ID:
79023

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/25/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
PD-Rx Pharmaceuticals, Inc.
727 N Ann Arbor Ave
Oklahoma City OK United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
PD-Rx Pharmaceuticals Incorporated Ibuprofen 200 mg tablets a) 24 tablets NDC 55289-673-24; b) 30 tablets NDC 55289-673-30; c) 50 tablets NDC 55289-673-50; d) 60 tablets NDC 55289-673-60

Product Quantity:
7174 bottles

Reason for Recall:
cGMP deviations.

Recall Number:

Code Information:
Lots: K16E92 Exp. 5/31/18; B17A87 Exp. 5/31/18; E17A51 Exp. 5/31/18; L16B59 Exp. 1/31/18; K16E01 Exp. 5/31/18; A17F21 Exp. 5/31/18; B17D71 Exp. 5/31/18; D17E92 Exp. 5/31/18; J16D13 Exp. 1/31/18; A17D63 Exp. 5/31/18; E17A18 Exp. 5/31/18; F17B87 Exp. 5/31/18; C17C58 Exp. 5/31/18

Not Yet Classified Drugs Event

Event ID:
79065

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

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Atorvastatin Calcium Tablets 10 mg, a) 90 count and b) 500 count bottles, Rx only, Mfd by: Dr. Reddy's Laboratories, Ltd., Srikakulam, INDIA --- NDC 55111-121-05

Product Quantity:
a) 34,125; b) 3,540 bottles

Reason for Recall:
Failed Impurities/Degradations Specifications; out-of-specification results observed for Total Degradation Impurities during stability

Recall Number:

Code Information:
Lot numbers: a) T600125, 3/2018; T600201, T600248 5/2018, b) T600125, 3/2018; T600201, and T600248, 5/2018

Product Description:
Atorvastatin Calcium Tablets 20 mg, a) 90 count and b) 500 count bottles, Rx only, Mfd by: Dr. Reddy's Laboratories, Ltd., Srikakulam, INDIA --- NDC 55111-122-05

Product Quantity:
a) 28,941 and b) 2,928 bottles

Reason for Recall:
Failed Impurities/Degradations Specifications; out-of-specification results observed for Total Degradation Impurities during stability

Recall Number:

Code Information:
Lot numbers: a) T600126, 3/2018; T600202 and T600247 5/2018, b) T600126, 3/2018; T600202, and T600247, 5/2018

Product Description:
Atorvastatin Calcium Tablets 40 mg, 90 count bottles, Rx only, Mfd by: Dr. Reddy's Laboratories, Ltd., Srikakulam, INDIA --- NDC 55111-123-05

Product Quantity:
12,579 bottles

Reason for Recall:
Failed Impurities/Degradations Specifications; out-of-specification results observed for Total Degradation Impurities during stability

Recall Number: