

Enforcement Report - Week of February 22, 2023

Class II Drugs Event

Event ID:

91466

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

12/27/2022

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

02/15/2023

Initial Firm Notification of Consignee or Public:

Telephone

Recalling Firm:

Sentara Infusion Services
535 Independence Pkwy Ste 300
Chesapeake VA United States

Distribution Pattern:

Dispensed to Patients Nationwide.

Associated Products

Product Description:

0.9% Sodium Chloride, used as a diluent or hydration, packaged volume of (a)1000ML (b)2000ML (c) 720ML, used with Curlin pump, no pump or gravity. Sentara Home Infusion Pharmacy Services, 535 Independence Pkwy, Ste 300, Chesapeake, VA 23320

Product Quantity:

114 bags total

Reason for Recall:

Lack of sterility assurance

Recall Number:

D-0272-2023

Code Information:

Beyond Use date December 24 - December 31, 2022

Product Description:

Amikacin 450MG IN NS 45ML, Antibiotic, used in a HOME PUMP, Sentara Home Infusion Pharmacy Services, 535 Independence Pkwy, Ste 300 Chesapeake, VA 23320,

Product Quantity:

7 bags

Reason for Recall:

Lack of sterility assurance

Recall Number:

D-0273-2023

Code Information:

Beyond Use date: December 28 - December 30, 2022

Product Description:

AMPICILLIN 12GM IN NS 600M, used with a Curlin pump, Sentara Home Infusion Pharmacy Services, 535 Independence Pkwy, Ste 300, Chesapeake, VA 23320,

Product Quantity:

19 bags

Reason for Recall:

Lack of sterility assurance

Recall Number:

D-0274-2023

Code Information:

Beyond Use date: December 25 - December 29, 2022

Product Description:

AMPICILLIN 8GM IN NS 400ML, antibiotic, used with Curlin pump, Sentara Home Infusion Pharmacy Services, 535 Independence Pkwy, Ste 300, Chesapeake, VA 23320,

Product Quantity:

14 bags

Reason for Recall:

Lack of sterility assurance

Recall Number:

D-0275-2023

Code Information:

Beyond Use Date: December 25-December 30, 2022

Product Description:

Ampicillin/Sulbactam 3GM IN NS 100ML, antibiotic, Rx only, used with a home pump, Sentara Home Infusion Pharmacy Services, 535 Independence Pkwy, Ste 300, Chesapeake, VA 23320,

Product Quantity:

20 bags

Reason for Recall:

Lack of sterility assurance

Recall Number:

D-0276-2023

Code Information:

Beyond Use Date: December 25-December 30, 2022

Product Description:

CASPOFUNGIN 50MG IN NS 100ML, used with a HOMEPUMP, Sentara Home Infusion Pharmacy Services, 535 Independence Pkwy, Ste 300, Chesapeake, VA 23320

Product Quantity:

7 bags

Reason for Recall:

Lack of sterility assurance

Recall Number:

D-0277-2023

Code Information:

Beyond Use Date: December 30-31, 2023

Product Description:

CEFAZOLIN (a) 12GM IN NS 600ML, (b) 2GM IN NS 100ML, (c) 2GM/20ML SW SYRINGE, (d) 3GM IN NS 150ML, antibiotic, used with a curlin, home or no pump assigned. Sentara Home Infusion Pharmacy Services, 535 Independence Pkwy, Ste 300, Chesapeake, VA 23320

Product Quantity:

111 bags total 21 syringes total

Reason for Recall:

Lack of sterility assurance

Recall Number:

D-0278-2023

Code Information:

Beyond Use By: December 25-31, 2022

Product Description:

CEFAZOLIN 5mg/mL/HEPARIN 100unit/ml 1.5ML SYR, antibiotic, Sentara Home Infusion Pharmacy Services, 535 Independence Pkwy, Ste 300,

Chesapeake, VA 23320

Product Quantity:

8 syringes

Reason for Recall:

Lack of sterility assurance

Recall Number:

D-0279-2023

Code Information:

Beyond Use Date: December 29-31, 2022

Product Description:

CEFEPIME, (a) 2GM IN NS 100ML (b)8GM IN NS 400ML (c) 12GM IN NS 600ML, used with a Curlin or Home pump, Sentara Home Infusion Pharmacy Services, 535 Independence Pkwy, Ste 300, Chesapeake, VA 23320

Product Quantity:

71 bags total

Reason for Recall:

Lack of sterility assurance

Recall Number:

D-0280-2023

Code Information:

Beyond Use Date December 24-31, 2022

Product Description:

CEFOXITIN (a) 1GM IN NS 50ML,(b) 2GM IN NS 100ML, used with a home pump. Sentara Home Infusion Pharmacy Services, 535 Independence Pkwy, Ste 300, Chesapeake, VA 23320,

Product Quantity:

3 bags

Reason for Recall:

Lack of sterility assurance

Recall Number:

D-0281-2023

Code Information:

Beyond Use date December 30, 2022

Product Description:

CEFTRIAZONE (a) 1GM IN NS 50ML, (b)4GM IN NS 200ML, (c) 8GM IN NS 400ML, antibiotic, Rx only, used in a Curlin or Home pump, Sentara Home Infusion Pharmacy Services, 535 Independence Pkwy, Ste 300, Chesapeake, VA 23320,

Product Quantity:

bags

Reason for Recall:

Lack of sterility assurance

Recall Number:

D-0282-2023

Code Information:

Beyond Use Date: December 25-30, 2022

Product Description:

CEFTRIAZONE (a) 2GM in NS 100ml, (b) 4GM IN NS 200ML, Antibiotic, used with a Curlin or Home pump, Sentara Home Infusion Pharmacy Services, 535 Independence Pkwy, Ste 300, Chesapeake, VA 23320,

Product Quantity:

72 bags

Reason for Recall:

Lack of sterility assurance

Recall Number:

D-0283-2023

Code Information:

Beyond Use Date: December 24-31, 2022

Product Description:

D5 NS 2300ML, Sentara Home Infusion Pharmacy Services, 535 Independence Pkwy, Ste 300, Chesapeake, VA 23320,

Product Quantity:

2

Reason for Recall:

Lack of sterility assurance

Recall Number:

D-0284-2023

Code Information:

Beyond Use Date: December 26, 2022

Product Description:

D5W1/2NS W/ 77MEQ OF SOD ACETATE 1000ML, Hydration, Sentara Home Infusion Pharmacy Services, 535 Independence Pkwy, Ste 300, Chesapeake, VA 23320

Product Quantity:

8 bags

Reason for Recall:

Lack of sterility assurance

Recall Number:

D-0285-2023

Code Information:

Beyond Use Date: December 29-31, 2022

Product Description:

DAPTOMYCIN (a)360MG in NS 18ML syringe (b)580MG IN NS 29ML syringe(c) 630MG IN NS 31.5ML used with a home pump; antibiotic, Rx only, Sentara Home Infusion Pharmacy Services, 535 Independence Pkwy, Ste 300, Chesapeake, VA 23320

Product Quantity:

17 bags

Reason for Recall:

Lack of sterility assurance

Recall Number:

D-0286-2023

Code Information:

Beyond Use Date: December 25-30, 2022

Product Description:

DAPTOMYCIN (a) 400MG IN NS 20ML, (b) 550MG IN NS 27.5ML, antibiotic, Rx only, used with a home pump. Sentara Home Infusion Pharmacy Services, 535 Independence Pkwy, Ste 300, Chesapeake, VA 23320

Product Quantity:

17 bags

Reason for Recall:

Lack of sterility assurance

Recall Number:

D-0287-2023

Code Information:

Beyond Use Date: December 24-31, 2022

Product Description:

Dextrose 10% 720ML, TPN, Rx only, use with a home pump, Sentara Home Infusion Pharmacy Services, 535 Independence Pkwy, Ste 300,

Chesapeake, VA 23320

Product Quantity:

1 bag

Reason for Recall:

Lack of sterility assurance

Recall Number:

D-0288-2023

Code Information:

Beyond Use Date: December 28, 2022

Product Description:

Diphenhydramine 18mg in 3.6ML NS SYRINGE, antihistamine, Rx Only, Sentara Home Infusion Pharmacy Services, 535 Independence Pkwy, Ste 300, Chesapeake, VA 23320,

Product Quantity:

15 bags

Reason for Recall:

Lack of sterility assurance

Recall Number:

D-0289-2023

Code Information:

Beyond Use Date: December 29, 2022

Product Description:

DOBUTAMINE, (a) 1080MG IN D5W 270ML, (b) 760MG IN D5W 190ML, ionotrop, used with a home pump, Rx only, Sentara Home Infusion Pharmacy Services, 535 Independence Pkwy, Ste 300, Chesapeake, VA 23320

Product Quantity:

4

Reason for Recall:

Lack of sterility assurance

Recall Number:

D-0290-2023

Code Information:

Beyond Use Date: December 29, 2022

Product Description:

Ertapenem (Invanz) 1GM NS 100ML, antibiotic, use with home pump, Rx Only, Sentara Home Infusion Pharmacy Services, 535 Independence Pkwy, Ste 300, Chesapeake, VA 23320

Product Quantity:

22 bags

Reason for Recall:

Lack of sterility assurance

Recall Number:

D-0291-2023

Code Information:

Beyond Use Date: December 24-31, 2022

Product Description:

ETHANOL 70% 0.5ML SYRINGE, Cathcare, Sentara Home Infusion Pharmacy Services, 535 Independence Pkwy, Ste 300, Chesapeake, VA 23320

Product Quantity:

17 syringes

Reason for Recall:

Lack of sterility assurance

Recall Number:

D-0292-2023

Code Information:

Beyond Use Date: December 25-31, 2022

Product Description:

FLUCONAZOLE 200MG NS 100ML, antifungal, Rx only, Sentara Home Infusion Pharmacy Services, 535 Independence Pkwy, Ste 300, Chesapeake, VA 23320

Product Quantity:

13 bags

Reason for Recall:

Lack of sterility assurance

Recall Number:

D-0293-2023

Code Information:

Beyond Use Date: December 2-31, 2022

Product Description:

GANCICLOVIR (CYTOVENE) (a)1480MG IN NS 296ML, (b) 740 MG IN NS 336 ML, antiviral, Rx Only, use with a Curlin pump, Sentara Home Infusion Pharmacy Services, 535 Independence Pkwy, Ste 300, Chesapeake, VA 23320

Product Quantity:

5 bags

Reason for Recall:

Lack of sterility assurance

Recall Number:

D-0294-2023

Code Information:

Beyond Use Date: December 24-29, 2022

Product Description:

HYDROCORTISONE 9a) 2MG IN NS 0.2ML SYRINGE, 9MG IN NS 2ML SYRINGE, steroid, Rx Only, Sentara Home Infusion Pharmacy Services, 535 Independence Pkwy, Ste 300, Chesapeake, VA 23320, NDC# 00009-0011-04

Product Quantity:

32 syringes

Reason for Recall:

Lack of sterility assurance

Recall Number:

D-0295-2023

Code Information:

Beyond Use Date: December 24-31, 2022

Product Description:

HYDROMORPHONE (a) 1MG/ML IN NS, 50ML, 75 ML, 100ML, 175ML(NDC 00703-0018-01 and NDC 00409-2634-50) ; (b) 5MG/ML IN NS 60ML, 100ML, 250ML; pain, Rx only, used with a Curlin pump or no pump, Sentara Home Infusion Pharmacy Services, 535 Independence Pkwy, Ste 300, Chesapeake, VA 23320, NDC# 00409-2634-50

Product Quantity:

37 bags

Reason for Recall:

Lack of sterility assurance

Recall Number:

D-0296-2023

Code Information:

Beyond Use Date: December 24-31, 2022

Product Description:

IMIPENEM/CILASTATIN 2000MG IN NS 400ML, antibiotic, Rx Only, use with a Curlin Pump, Sentara Home Infusion Pharmacy Services, 535 Independence Pkwy, Ste 300, Chesapeake, VA 23320, NDC# 63323-0322-25

Product Quantity:

7 bags

Reason for Recall:

Lack of sterility assurance

Recall Number:

D-0297-2023

Code Information:

Beyond Use Date: December 25-30, 2022

Product Description:

INTRALIPID 18GM, TPN, Rx Only, use with a Curlin pump, Sentara Home Infusion Pharmacy Services, 535 Independence Pkwy, Ste 300, Chesapeake, VA 23320,

Product Quantity:

7 bags

Reason for Recall:

Lack of sterility assurance

Recall Number:

D-0298-2023

Code Information:

Beyond Use Date: December 29-30, 2022

Product Description:

KYTRIL 350MCG IN 3.5ML NS SYRINGE, antimetic, Rx Only, Sentara Home Infusion Pharmacy Services, 535 Independence Pkwy, Ste 300, Chesapeake, VA 23320

Product Quantity:

14 syringes

Reason for Recall:

Lack of sterility assurance

Recall Number:

D-0299-2023

Code Information:

Beyond Use Date: December 29, 2022

Product Description:

Lactated Ringers packaged in volume of 1000ML, 2500ML, 3000 ML, 3600 ML, 500ML (NDC 00338-0117-03)hydration, Rx Only, use with Curlin pump, Sentara Home Infusion Pharmacy Services, 535 Independence Pkwy, Ste 300, Chesapeake, VA 23320

Product Quantity:

25 bags

Reason for Recall:

Lack of sterility assurance

Recall Number:

D-0300-2023

Code Information:

Beyond Use Date: December 24-31, 2022

Product Description:

Levaquin 750MG IN D5W 150ML, antibiotic, Rx Only, use with home pump, Sentara Home Infusion Pharmacy Services, 535 Independence Pkwy, Ste 300, Chesapeake, VA 23320,

Product Quantity:

14 bags

Reason for Recall:

Lack of sterility assurance

Recall Number:

D-0301-2023

Code Information:

Beyond Use Date: December 24-31, 2022

Product Description:

LEVOTHYROXINE 25MCG IN NS 1.25ML SYRINGE, Thyroid, Rx Only, Sentara Home Infusion Pharmacy Services, 535 Independence Pkwy, Ste 300, Chesapeake, VA 23320

Product Quantity:

7 syringes

Reason for Recall:

Lack of sterility assurance

Recall Number:

D-0302-2023

Code Information:

Beyond Use Date: December 29, 2022

Product Description:

MEROPENEM (a) 1000MG IN NS 250ML, (b) 2GM IN NS 100ML, (c) 500mg IN NS 125ML, antibiotic, Rx Only, use with home pump or no pump, Sentara Home Infusion Pharmacy Services, 535 Independence Pkwy, Ste 300, Chesapeake, VA 23320

Product Quantity:

91 bags

Reason for Recall:

Lack of sterility assurance

Recall Number:

D-0303-2023

Code Information:

Beyond Use Date: December 24-31, 2022

Product Description:

METHADONE (a) 2.5MG IN 5ML NS SYRINGE, (b) 4MG IN 5ML NS SYRINGE, pain, Rx Only, Sentara Home Infusion Pharmacy Services, 535 Independence Pkwy, Ste 300, Chesapeake, VA 23320

Product Quantity:

19 syringes

Reason for Recall:

Lack of sterility assurance

Recall Number:

D-0304-2023

Code Information:

Beyond Use Date: December 28-29, 2022

Product Description:

Methylprednisolone 12MG IN NS 1.2ML SYRINGE, steroid, Rx Only, Sentara Home Infusion Pharmacy Services, 535 Independence Pkwy, Ste 300, Chesapeake, VA 23320

Product Quantity:

27 syringes

Reason for Recall:

Lack of sterility assurance

Recall Number:

D-0305-2023

Code Information:

Beyond Use Date: December 29-31, 2022

Product Description:

METRONIDAZOLE 500MG 100ML, antibiotic, Rx Only, use with a home pump or no pump, Sentara Home Infusion Pharmacy Services, 535 Independence Pkwy, Ste 300, Chesapeake, VA 23320

Product Quantity:

30 bags

Reason for Recall:

Lack of sterility assurance

Recall Number:

D-0306-2023

Code Information:

Beyond Use Date: December 24-29, 2022

Product Description:

Milrinone (a) 104MG IN 0.45% NS 130ML,(b) 108MG IN 0.45% NS 135ML, (c) 120MG IN 0.45% NS 150ML, (d) 136MG IN 0.45% NS 170ML, (e) 144MG IN 0.45% NS 180ML, (f) 160MG IN 0.45% NS 200ML, (g) 168MG IN 0.45% NS 210ML, (h) 192MG IN 0.45% NS 240ML, (i) 44MG IN 0.45% NS 55 ML, (j) 52MG IN 0.45% NS 65ML, (k) 56MG IN 0.45% NS 70ML, (l) 68MG IN 0.45% NS 85ML, (m) 84MG IN 0.45% NS 105ML, (n) 88MG IN 0.45% NS 110ML, (o) 92MG IN 0.45% NS 115ML, (p) 96MG IN 0.45% NS 120ML, ionotrop, Rx Only, use with a Curlin or no pump, Sentara Home Infusion Pharmacy Services, 535 Independence Pkwy, Ste 300, Chesapeake, VA 23320

Product Quantity:

83 bags

Reason for Recall:

Lack of sterility assurance

Recall Number:

D-0307-2023

Code Information:

Beyond Use Date: December 24-31, 2022

Product Description:

MORPHINE Sulfate (a) 1MG/ML IN NS 350ML, (b) 5MG/ML IN NS 200ML, pain, Rx Only, use with Curlin pump, Sentara Home Infusion Pharmacy Services, 535 Independence Pkwy, Ste 300, Chesapeake, VA 23320

Product Quantity:

11 bags

Reason for Recall:

Lack of sterility assurance

Recall Number:

D-0308-2023

Code Information:

Beyond Use Date: December 24-31, 2022

Product Description:

MYCAMINE 100MG IN NS 100ML, antifungal, Rx Only, use with a homepump, Sentara Home Infusion Pharmacy Services, 535 Independence Pkwy, Ste 300, Chesapeake, VA 23320

Product Quantity:

5 bags

Reason for Recall:

Lack of sterility assurance

Recall Number:

D-0309-2023

Code Information:

Beyond Use Date: December 25-29, 2022

Product Description:

NAFCILLIN 24GM IN NS 1200ML, antibiotic, Rx Only, use with a Curlin pump, Sentara Home Infusion Pharmacy Services, 535 Independence Pkwy, Ste 300, Chesapeake, VA 23320

Product Quantity:

16 bags

Reason for Recall:

Lack of sterility assurance

Recall Number:

D-0310-2023

Code Information:

Beyond Use Date: December 25-31, 2022

Product Description:

NALBUPHINE (a) 1.5MG IN 1.5ML NS, (b) 2.5MG IN 2.5ML NS, SYRINGE, pain, Rx Only, Sentara Home Infusion Pharmacy Services, 535 Independence Pkwy, Ste 300, Chesapeake, VA 23320

Product Quantity:

31 syringes

Reason for Recall:

Lack of sterility assurance

Recall Number:

D-0311-2023

Code Information:

Beyond Use Date: December 29, 2022

Product Description:

ONDANSETRON 8MG IN NS 100ML, antimetic, Rx Only, Sentara Home Infusion Pharmacy Services, 535 Independence Pkwy, Ste 300, Chesapeake, VA 23320

Product Quantity:

15 bags

Reason for Recall:

Lack of sterility assurance

Recall Number:

D-0312-2023

Code Information:

Beyond Use Date: December 29-30, 2022

Product Description:

PANTOPRAZOLE 30MG IN NS 7.5ML, SYRINGE, antimetic, Rx only, Sentara Home Infusion Pharmacy Services, 535 Independence Pkwy, Ste 300, Chesapeake, VA 23320

Product Quantity:

14 bags

Reason for Recall:

Lack of sterility assurance

Recall Number:

D-0313-2023

Code Information:

Beyond Use Date: December 29, 2022

Product Description:

PENICILLIN (a) 40MU IN D5W 400ML(CONTINUOUS), (b) 40U IN D5W 400ML(CONTINUOUS), (c) 48MU IN D5W 480ML, antibiotic, Rx Only, use with a Curlin pump, Sentara Home Infusion Pharmacy Services, 535 Independence Pkwy, Ste 300, Chesapeake, VA 23320

Product Quantity:

8 bags

Reason for Recall:

Lack of sterility assurance

Recall Number:

D-0314-2023

Code Information:

Beyond Use Date: December 25-31, 2022

Product Description:

PIPERACILLIN / TAZOBACTAM (a) 4.5GM IN NS 100 ML, (b)18GM IN NS 267M, (c) 27GM IN NS 400ML, (d) 3.375 GM IN NS 50ML, (e) 36 GM IN NS 533 ML, antibiotic, Rx only, use with a Curlin or home pump or no pump, Sentara Home Infusion Pharmacy Services, 535 Independence Pkwy, Ste 300, Chesapeake, VA 23320

Product Quantity:

78 bags

Reason for Recall:

Lack of sterility assurance

Recall Number:

D-0315-2023

Code Information:

Beyond Use Date: December 25-31, 2022

Product Description:

Sodium Chloride 0.9 % (a) 100ML (MAGNESIUM) (b) 69.3ML, (c) 71.4ML, (d) 77.7ML, (e) 130ML, (f) 210ML, (g) 190ML, (h) 220ML: diluent, Rx Only, use with Curlin or Sapphire pump, Sentara Home Infusion Pharmacy Services, 535 Independence Pkwy, Ste 300, Chesapeake, VA 23320

Product Quantity:

11 bags

Reason for Recall:

Lack of sterility assurance

Recall Number:

D-0316-2023

Code Information:

Beyond Use Date: December 24- 30, 2022

Product Description:

TOBRAMYCIN 660MG IN NS 66ML, antibiotic, Rx Only, use with homepump, Sentara Home Infusion Pharmacy Services, 535 Independence Pkwy, Ste 300, Chesapeake, VA 23320,

Product Quantity:

2 bags

Reason for Recall:

Lack of sterility assurance

Recall Number:

D-0317-2023

Code Information:

Beyond Use Date, eceember 24, 2022

Product Description:

TPN (a) 100GM/AA, 285GM/DEX, (b)55GM/LIP 2300ML, (c)55GM/AA 285GM/DEX 50GM/LIP1800ML, (d)TPN AA:100GM DEX:250GM LIP:50GM 2400ML, (e) 55GM DEX:285GM 1800ML, Rx Only, use with Curlin pump or no pump, Sentara Home Infusion Pharmacy Services, 535 Independence Pkwy, Ste 300, Chesapeake, VA 23320

Product Quantity:

26 bags

Reason for Recall:

Lack of sterility assurance

Recall Number:

D-0318-2023

Code Information:

Beyond Use Date: December 24-3 , 2022

Product Description:

TPN 107gm/AA, 200gm/DEX, 50gm/LIP 2250mL, (b) 108GM/AA, 330GM/DEX 3000ML, (c) 108GM/AA, 330GM/DEX, 60GM/LIP 3000ML, (d) 37GM/AA, 160GM/DEX 1450ML, (e) 37GM/AA, 160GM/DEX, 25GM/LIP 1450ML, (f) 74-100GM OF PROTEIN B4197 74 Gm, (g) 75GM/AA, 200GM/DEX, 43GM/LIP 2500ML, (h) 90GM/AA ; 255GM/DEX ; 50GM/LIP 3500 ml, (i) 90GM/AA ; 255GMDEX 3500 ml, (j) TPN AA 100GM DEX: 320GM LIP: 50GM 2400ML, (k) TPN AA 30GM DEX: 145GM 1210ML, (l) TPN AA 30GM DEX: 145GM LIP: 35GM 1210ML, (m)TPN AA 42GM DEX: 432GM 2070ML, (n) TPN AA 50GM DEX: 130GM 2500ML, (o) TPN AA 55GM DEX:180GM 1000ML, (p) TPN AA 70GM DEX:290GM 2100ML, (q) TPN AA 70GM DEX:290GM 2500ML, (r) TPN AA 80GM DEX:200GM 1900ML, (s) TPN AA 80GM DEX:200GM LIP:38GM 1900ML, (t) TPN AA 30GM ; DEX 82GM ; IN 890 ml, (u) TPN AA 30GM ; DEX 82GM ; LIP 18GM IN 890 ml, Rx Only, use with Curlin pump, Sentara Home Infusion Pharmacy Services, 535 Independence Pkwy, Ste 300, Chesapeake, VA 23320

Product Quantity:

111 bags

Reason for Recall:

Lack of sterility assurance

Recall Number:

D-0319-2023

Code Information:

Beyond Use Date: December 24-31, 2022

Product Description:

TPN (a) 115GM/AA, 215GM/DEX, 25GM/LIP 1150ML, (b)90GM/AA, 215GM/DEX, 25GM/LIP 1150ML, (c) TPN AA: 100GM DEX: 105GM 2700ML, (d) TPN AA: 100GM DEX: 105GM LIP: 45GM 2700ML, (e) TPN: AA100GM ; DEX185GM ; LIP50GM IN 1500ML, (f) TPN: AA 150GM ; DEX 220GM ; LIP 45GM IN 2400 ml, (g) TPN: AA 60GM ; DEX 200GM ; LIP 30GM IN 1500 ml, Rx only, use with Curlin pump, Sentara Home Infusion Pharmacy Services, 535 Independence Pkwy, Ste 300, Chesapeake, VA 23320

Product Quantity:

31 bags

Reason for Recall:

Lack of sterility assurance

Recall Number:

D-0320-2023

Code Information:

Beyond Use Date: December 24-31, 2022

Product Description:

TPN (a) 95GM/AA, 385/DEX, 50GM/LIP 1800ML, (b)TPN AA:100GM DEX:250GM LIP:50GM 2400ML, (c) TPN: AA 80GM ; DEX 320GM ; LIP 50GM IN 2300 ml, Rx only, use with Curlin pump, Sentara Home Infusion Pharmacy Services, 535 Independence Pkwy, Ste 300, Chesapeake, VA 23320

Product Quantity:

24 bags

Reason for Recall:

Lack of sterility assurance

Recall Number:

D-0321-2023

Code Information:

Beyond Use Date: December 25-31, 2022

Product Description:

Vancomycin (a) 1.25GM IN NS 250ML, (b) 1.5GM IN NS 300ML, (c) 1000MG IN NS 200ML (d) 2GM IN 400ML NS, (e) 900MG IN NS 180ML, (f) 500 MG NS 100ML, (g) 750 MG NS 150ML, antibiotic, Rx only, use with home pump, Sentara Home Infusion Pharmacy Services, 535 Independence Pkwy, Ste 300, Chesapeake, VA 23320

Product Quantity:

155 bags

Reason for Recall:

Lack of sterility assurance

Recall Number:

D-0322-2023

Code Information:

Beyond Use Date: December 24-31, 2022

Product Description:

VANCOMYCIN (a)700 MG NS 140ML, (b) 1000MG IN NS 200ML, antibiotic, Rx only, use with home pump, Sentara Home Infusion Pharmacy Services, 535 Independence Pkwy, Ste 300, Chesapeake, VA 23320

Product Quantity:

18 bags

Reason for Recall:

Lack of sterility assurance

Recall Number:

D-0323-2023

Code Information:

Beyond Use Date: December 28-31, 2022

Product Description:

VITAMIN K(PHYTONADIONE) 2.5MG(0.25ML) SYRINGE, Rx only, Sentara Home Infusion Pharmacy Services, 535 Independence Pkwy, Ste 300, Chesapeake, VA 23320,

Product Quantity:

1 bag

Reason for Recall:

Lack of sterility assurance

Recall Number:

D-0324-2023

Code Information:

Beyond Use Date: December 29, 2022

Class II Drugs Event

Event ID:

91498

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

12/08/2022

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

02/10/2023

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

McGuff Compounding Pharmacy Services, Inc.

2921 W Macarthur Blvd Ste 142

Santa Ana CA United States

Distribution Pattern:

Nationwide in the USA

Associated Products

Product Description:

Thiamine Hydrochloride 200 mg/2mL (100mg/mL), Riboflavin 2 mg/2mL (1mg/mL) Injection, FOR INTRAMUSCULAR OR SLOW INTRAVENOUS USE, 2 mL Sterile Single Use Vial, Preservative-Free, Rx Only, Compounded for a licensed professional or patient use by: McGuff Compounding Pharmacy Services, Inc, Santa Ana, CA 92704.

Product Quantity:

11 vials

Reason for Recall:

Presence of Particulate Matter: Presence of foreign substances were reported in vials at the pharmacy.

Recall Number:

D-0266-2023

Code Information:

Lot: 22K1681, initial BUD: 12/18/2022, extended BUD: 1/27/2023.

Product Description:

Thiamine Hydrochloride 3000 mg/30 mL (100mg/mL), Riboflavin 30 mg/30 mL (1mg/mL) Injection, FOR INTRAMUSCULAR OR SLOW INTRAVENOUS USE, 30 mL Sterile Multiple Use Vial, Rx Only, Compounded for a licensed professional or patient use by: McGuff Compounding Pharmacy Services, Inc, Santa Ana, CA 92704.

Product Quantity:

255 vials

Reason for Recall:

Presence of Particulate Matter: Presence of foreign substances were reported in vials at the pharmacy.

Recall Number:

D-0267-2023

Code Information:

Lot: 22K1661, initial BUD: 12/18/2022, extended BUD: 1/27/2023; 22J2401, BUD: 12/19/2022.

Class II Drugs Event

Event ID:

91521

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

01/10/2023

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

02/15/2023

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Consolidated Chemical, Inc
3224 S Kingshighway Blvd
Saint Louis MO United States

Distribution Pattern:

Nationwide in the USA

Associated Products

Product Description:

Techni-Care Chloroxylenol 3%, [4 fl oz /118 mL or 8 fl oz/236 mL] per bottle, Care-Tech Laboratories, Inc., Saint Louis, Missouri 63139. NDC 4 oz bottle: 46706-222-01; NDC 8 oz: 46706-222-02

Product Quantity:

4 oz: 6580 bottles; 8 oz: 1248 bottles

Reason for Recall:

CGMP Deviations: initiated due to violations of CGMP manufacturing practices

Recall Number:

D-0325-2023

Code Information:

Lots 3217A and 3217B, exp 06/23

Product Description:

Humatrix Microclysmic Gel, 8 oz per bottle, Care-Tech Laboratories, Inc., Saint Louis, Missouri 63139.

Product Quantity:

3186 bottles

Reason for Recall:

CGMP Deviations: initiated due to violations of CGMP manufacturing practices

Recall Number:

D-0326-2023

Code Information:

Lot, expiry: Lot 3216, exp 04/23 and 3218, exp 10/23

Class II Drugs Event

Event ID:

91528

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

01/11/2023

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

02/15/2023

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Amerisource Health Services LLC
2550 John Glenn Ave Ste A
Columbus OH United States

Distribution Pattern:

Nationwide USA

Associated Products

Product Description:

Metoprolol Succinate Extended-Release Tablets, USP, 50 mg, packaged in (a) 100-count bottle, NDC 68001-501-00; (b) 500-count bottle, NDC 68001-501-03. Manufactured by Alkem Laboratories Ltd., India. For BluePoint Laboratories

Product Quantity:

(a) 6670 100-count (b) 2666 500-count bottles

Reason for Recall:

Failed Dissolution Specifications: This recall is being initiated in support of the recall by the manufacturer which included lots that were packaged for BluePoint Laboratories.

Recall Number:

D-0269-2023

Code Information:

Lots: (a) 21143211, EXP 03/31/2023; (b) 21143185, 21143193, EXP 02/28/2023

Class II Drugs Event

Event ID:

91609

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

12/27/2022

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

02/16/2023

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Amerisource Health Services LLC
2550 John Glenn Ave Ste A
Columbus OH United States

Distribution Pattern:

Nationwide within the USA

Associated Products**Product Description:**

BuPROPion Hydrochloride Tablets, USP 75 mg, 100 Tablets (10 x 10) per carton, Rx Only, Distributed by: American Health Packaging, Columbus, Ohio 43217. NDC carton: 60687-340-01; NDC Blister Pack: 60687-340-11

Product Quantity:

1,416 cartons

Reason for Recall:

Failed Impurities/Degradation Specifications

Recall Number:

D-0328-2023

Code Information:

Lot #: 1003837, Exp. Date 01/31/2023

Class II Drugs Event**Event ID:**

91643

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

02/03/2023

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

02/15/2023

Initial Firm Notification of Consignee or Public:

E-Mail

Recalling Firm:

Leadiant Biosciences, Inc.
9841 Washingtonian Blvd Ste 500
Gaithersburg MD United States

Distribution Pattern:

Nationwide USA

Associated Products**Product Description:**

Abelcet (Amphotericin B Lipid Complex) Injection, 5 mg/mL, 100 mg vial, Rx only, Manufactured by Exelead, Inc., Indianapolis, IN 46268; Distributed by Leadiant Biosciences, Inc., Gaithersburg, MD 20878, NDC 57665-101-41

Product Quantity:

31,879 vials

Reason for Recall:

Lack of assurance of sterility: Medial fill with presence of Cupriavidus pauculus.

Recall Number:

D-0327-2023

Code Information:

Lot#: 1203A, Exp. 5/11/2024

Class II Drugs Event

Event ID:

91694

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

02/09/2023

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

02/15/2023

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

HTO Nevada, Inc.
6400 Rosewood St
Lake Oswego OR United States

Distribution Pattern:

Nationwide in the USA and Canada.

Associated Products

Product Description:

New & Improved Blue Gel Anesthetic, to reduce pain and swelling during pain sensitive procedures, 1 oz bottle, distributed by Dermal Source, Portland, OR, www.dermalsource.com 1-888-568-3223. NDC Code: 80069-008-01. Drug Facts- For use by licensed professionals only, Active Ingredients -Lidocaine HCL (5%), Tetracaine HCL (1%) and epinephrine (0.1%).

Product Quantity:

4709 bottles

Reason for Recall:

cGMP Deviation: Raw material recalled by repackager, due to discoloration of the epinephrine API.

Recall Number:

D-0270-2023

Code Information:

Lot #s: 796CP-0006, Exp 02/2024; 796CP-0007, Exp 03/2024.

Product Description:

Maximum Zone2 Topical Analgesic, 1oz bottle, for use during a pain sensitive procedure, distributed by: DERMAL SOURCE, Portland, OR, www.dermalsource.com, 1-866-568-3223, NDC code: 80069-012-01, Drug Facts- For use by licensed professionals only' Active Ingredients- Lidocaine HCL (5%), Epinephrine (0.01%).

Product Quantity:

1,571 bottles

Reason for Recall:

cGMP Deviation: Raw material recalled by repackager, due to discoloration of the epinephrine API.

Recall Number:

D-0271-2023

Code Information:

Lot #: 795CP-0003, Exp 07/2024.