Enforcement Report - Week of November 9, 2022

Class II Drugs Event

Event ID:
90982

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/07/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/02/2022

Initial Firm Notification of Consignee or Public:
Telephone

Recalling Firm:
Pharmacy Plus, Inc. dba Vital Care Compounder
115 S 40th Ave
Hattiesburg MS United States

Distribution Pattern:
AL, LA, MS, and TN

Associated Products

Product Description:
ACETYLCYSTEINE OPTH 10% Solution, 15 mL droptainers, Rx only, Vital Care Compounder, 115 S. 40th Ave., Hattiesburg, MS 39402

Product Quantity:
1 droptainer

Reason for Recall:
Lack of Assurance of Sterility: FDA inspection found the recalled products were produced in a manner than cannot guarantee the sterility of the products purported to be sterile.

Recall Number:
D-0026-2023

Code Information:
Lot: 66895, BUD: 11/19/2022

Product Description:
ACETYLCYSTEINE OPTH 5% Solution, 15 mL droptainers, Rx only, Vital Care Compounder, 115 S. 40th Ave., Hattiesburg, MS 39402

Product Quantity:
2 droptainers

Reason for Recall:
Lack of Assurance of Sterility: FDA inspection found the recalled products were produced in a manner than cannot guarantee the sterility of the products purported to be sterile.

Recall Number:
D-0027-2023

Code Information:
Lots: 66017, BUD: 10/13/2022; 66177, BUD: 10/19/2022

Product Description:
AUTOLOGUS TEARS SERUM SOLN FULL STRENGTH, 3 mL droptainers, Rx only, Vital Care Compounder, 115 S. 40th Ave., Hattiesburg, MS 39402

Product Quantity:
168 droptainers

Reason for Recall:
Lack of Assurance of Sterility: FDA inspection found the recalled products were produced in a manner than cannot guarantee the sterility of the products purported to be sterile.

Recall Number:
D-0028-2023

Code Information:
Lots: 65521, BUD: 10/15/2022; 65545, BUD: 10/15/2022; 65605, BUD: 10/16/2022; 65658, BUD: 10/17/2022; 65733, BUD: 10/21/2022; 65894, BUD: 10/24/2022; 66019, BUD: 10/28/2022; 66120, BUD: 10/30/2022; 66388, BUD: 11/6/2022; 66755, BUD: 11/14/2022; 66870, UD: 11/18/2022; 66928, BUD: 11/19/2022

Product Description:
BRILLIANT BLUE G, 0.04% Solution, 2 mL vials, Rx only, Vital Care Compounder, 115 S. 40th Ave., Hattiesburg, MS 39402

Product Quantity:
86 vials

Reason for Recall:
Lack of Assurance of Sterility: FDA inspection found the recalled products were produced in a manner than cannot guarantee the sterility of the products purported to be sterile.

Recall Number:
D-0029-2023

Code Information:
Lot: 60448 BUD: 10/31/2022

Product Description:
CEFTAZIDIME INTRAVITREAL 2.25MG/0.1ML Solution, 0.5 mL syringe, Rx only, Vital Care Compounder, 115 S. 40th Ave., Hattiesburg, MS 39402

Product Quantity:
12 syringes

Reason for Recall:
Lack of Assurance of Sterility: FDA inspection found the recalled products were produced in a manner than cannot guarantee the sterility of the products purported to be sterile.

Recall Number:
D-0030-2023

Code Information:
Lots: 65434, BUD: 10/13/2022; 66349, BUD: 11/05/2022; 66868, BUD: 11/18/2022

Product Description:
CEFUROXIME INTRAVITREAL SYR 1MG/0.1ML Solution in 1 mL syringe, Rx only, Vital Care Compounder, 115 S. 40th Ave., Hattiesburg, MS 39402

Product Quantity:
460 syringes

Reason for Recall:
Lack of Assurance of Sterility: FDA inspection found the recalled products were produced in a manner than cannot guarantee the sterility of the products purported to be sterile.

Recall Number:
D-0031-2023

Code Information:
Lots: 63265, BUD: 01/24/2023; 66085, BUD: 04/03/2023

Product Description:
CYCLOSPORIN 0.07% OPTH 0.07% Solution in 10 mL bottles, Rx only, Vital Care Compounder, 115 S. 40th Ave., Hattiesburg, MS 39402

Product Quantity:
67 bottles

Reason for Recall:
Lack of Assurance of Sterility: FDA inspection found the recalled products were produced in a manner than cannot guarantee the sterility of the products purported to be sterile.

Recall Number:
D-0032-2023

Code Information:
Lots: 59638, BUD: 11/25/2022; 64261, BUD: 04/30/2023

Product Description:
GLYCERIN OPHTHALMIC DROPS 98.5% Solution, 10 mL droptainer, Rx only, Vital Care Compounder, 115 S. 40th Ave., Hattiesburg, MS 39402

Product Quantity:
1 droptainer

Reason for Recall:
Lack of Assurance of Sterility: FDA inspection found the recalled products were produced in a manner than cannot guarantee the sterility of the products purported to be sterile.

Recall Number:
D-0033-2023

Code Information:
Lot: 65416, BUD: 10/13/2022

Product Description:
LAURETH-9 INJ 2% Solution, 30 ML vial, Rx only, Vital Care Compounder, 115 S. 40th Ave., Hattiesburg, MS 39402

Product Quantity:
3 vials

Reason for Recall:
Lack of Assurance of Sterility: FDA inspection found the recalled products were produced in a manner than cannot guarantee the sterility of the products purported to be sterile.

Recall Number:
D-0034-2023

Code Information:
Lot: 66513, BUD: 11/10/2022

Product Description:
LIDOCAINE/PHENYLEPHRINE PF SYR 1%/1.5% Solution, 3 mL syringes, Rx only, Vital Care Compounder, 115 S. 40th Ave., Hattiesburg, MS 39402

Product Quantity:
389 syringes

Reason for Recall:
Lack of Assurance of Sterility: FDA inspection found the recalled products were produced in a manner than cannot guarantee the sterility of the products purported to be sterile.

Recall Number:
D-0035-2023

Code Information:
Lot: 65972, BUD: 10/27/2022

Product Description:
LIDOCAINE EPINEPHRINE BUFFERED 2%/1:1000 Solution, 10 mL syringe, Rx only, Vital Care Compounder, 115 S. 40th Ave., Hattiesburg, MS 39402

Product Quantity:
7 syringes

Reason for Recall:
Lack of Assurance of Sterility: FDA inspection found the recalled products were produced in a manner than cannot guarantee the sterility of the products purported to be sterile.

Recall Number:
D-0036-2023

Code Information:
Lot: 66591, BUD: 11/12/2022

Product Description:
MEDROXYPROGESTERONE ACETATE 300 MG/ML Suspension, 10 mL vial, Rx only, Vital Care Compounder, 115 S. 40th Ave., Hattiesburg, MS

39402

Product Quantity:
40 vials

Reason for Recall:
Lack of Assurance of Sterility: FDA inspection found the recalled products were produced in a manner than cannot guarantee the sterility of the products purported to be sterile.

Recall Number:
D-0037-2023

Code Information:
Lot: 55786, BUD: 12/31/2022

Product Description:
METHYLCOBALAMIN PF 1 ML Injection Solution 5,000 MCG/ML Solution, 1 mL vials, Rx only, Vital Care Compounder, 115 S. 40th Ave., Hattiesburg, MS 39402

Product Quantity:
514 vials

Reason for Recall:
Lack of Assurance of Sterility: FDA inspection found the recalled products were produced in a manner than cannot guarantee the sterility of the products purported to be sterile.

Recall Number:
D-0038-2023

Code Information:
Lot: 57997, BUD: 02/25/2023; 64941, BUD: 03/08/2023

Product Description:
MITOMYCIN INJECTION 0.375 mg/mL SYR, 0.375 mg/mL solution, 1 mL syringe, Rx only, Vital Care Compounder, 115 S. 40th Ave., Hattiesburg, MS 39402

Product Quantity:
185 syringes

Reason for Recall:
Lack of Assurance of Sterility: FDA inspection found the recalled products were produced in a manner than cannot guarantee the sterility of the products purported to be sterile.

Recall Number:
D-0039-2023

Code Information:
Lots: 60618, BUD: 5/6/2023; 66536, BUD: 7/8/2023

Product Description:
MOXIFLOXACIN PRESERVATIVE FREE SYR, 0.15 mg/0.1 mL, Sterile Solution, 1 mL syringes, Rx only, Vital Care Compounder, 115 S. 40th Ave., Hattiesburg, MS 39402

Product Quantity:
106 syringes

Reason for Recall:
Lack of Assurance of Sterility: FDA inspection found the recalled products were produced in a manner than cannot guarantee the sterility of the products purported to be sterile.

Recall Number:
D-0040-2023

Code Information:
Lot: 66470, BUD: 11/10/2022

Product Description:
PAP/PHEN/PROSTAG/ATROPINE INJ 150MG/7.5MG/75MCG/1MG bottle solution, 5 mL vials, Rx only, Vital Care Compounder, 115 S. 40th Ave., Hattiesburg, MS 39402

Product Quantity:
2 vials

Reason for Recall:
Lack of Assurance of Sterility: FDA inspection found the recalled products were produced in a manner than cannot guarantee the sterility of the products purported to be sterile.

Recall Number:
D-0041-2023

Code Information:
Lots: 66369, BUD: 11/06/2022; 66540, BUD: 11/09/2022

Product Description:
PAPAVERINE / PHENTOLAMINE / PROSTAGLANDIN 150MG / 2.5MG / 50MCG SOLUTION, 5 mL vials, Rx only, Vital Care Compounder, 115 S. 40th Ave., Hattiesburg, MS 39402

Product Quantity:
56 vials

Reason for Recall:
Lack of Assurance of Sterility: FDA inspection found the recalled products were produced in a manner than cannot guarantee the sterility of the products purported to be sterile.

Recall Number:
D-0042-2023

Code Information:
Lots: 64409, BUD: 04/08/2023; 60849, BUD: 05/23/2023

Product Description:
PAPAVERINE / PHENTOLAMINE / PROSTAGLANDIN INJ 150MG/10MG/100MCG/ BOTTLE SOLUTION, 5 ML vial, Rx only, Vital Care Compounder, 115 S. 40th Ave., Hattiesburg, MS 39402

Product Quantity:
1 vial

Reason for Recall:
Lack of Assurance of Sterility: FDA inspection found the recalled products were produced in a manner than cannot guarantee the sterility of the products purported to be sterile.

Recall Number:
D-0043-2023

Code Information:
Lot: 66576, BUD: 11/09/2022

Product Description:
PAPAVERINE / PHENTOLAMINE / PROSTAGLANDIN INJ 75MG/2.5MG/50MCG/ BOTTLE SOLUTION, 5 ML vial, Rx only, Vital Care Compounder, 115 S. 40th Ave., Hattiesburg, MS 39402

Product Quantity:
1 vial

Reason for Recall:
Lack of Assurance of Sterility: FDA inspection found the recalled products were produced in a manner than cannot guarantee the sterility of the products purported to be sterile.

Recall Number:
D-0044-2023

Code Information:
Lot: 65425, BUD: 10/13/2022

Product Description:
PAPAVERINE / PHENTOLAMINE / PROSTAGLANDIN INJ 90MG/3MG/29.4MCG/ BOTTLE SOLUTION, 5 ML vial, Rx only, Vital Care Compounder, 115 S. 40th Ave., Hattiesburg, MS 39402

Product Quantity:
2 vials

Reason for Recall:
Lack of Assurance of Sterility: FDA inspection found the recalled products were produced in a manner than cannot guarantee the sterility of the products purported to be sterile.

Recall Number:
D-0045-2023

Code Information:
Lots: 66450, BUD: 11/07/2022; 66527, BUD: 11/09/2022

Product Description:
PAPAVERINE / PHENTOLAMINE INJECTION 150MG / 5MG / VIAL SOLUTION, 10 mL vials, Rx only, Vital Care Compounder, 115 S. 40th Ave., Hattiesburg, MS 39402

Product Quantity:
242 vials

Reason for Recall:
Lack of Assurance of Sterility: FDA inspection found the recalled products were produced in a manner than cannot guarantee the sterility of the products purported to be sterile.

Recall Number:
D-0046-2023

Code Information:
Lots: 55092, BUD: 10/22/2022; 59100, BUD: 10/30/2022; 62038, BUD: 04/08/2023; 66533, BUD: 04/08/2023

Product Description:
PAPAVERINE HCL STOCK SOLUTION 30MG/ML SOLUTION, 10 mL vial, Rx only, Vital Care Compounder, 115 S. 40th Ave., Hattiesburg, MS 39402

Product Quantity:
28 vials

Reason for Recall:
Lack of Assurance of Sterility: FDA inspection found the recalled products were produced in a manner than cannot guarantee the sterility of the products purported to be sterile.

Recall Number:
D-0047-2023

Code Information:
Lot: 60552, BUD: 03/12/2023

Product Description:
PAPAVERINE/PHENTOLAMINE/PROSTAGLANDIN INJ 150/5/50MCG / VIAL SOLUTION, 10 mL vials, Rx only, Vital Care Compounder, 115 S. 40th Ave., Hattiesburg, MS 39402

Product Quantity:
5 vials

Reason for Recall:
Lack of Assurance of Sterility: FDA inspection found the recalled products were produced in a manner than cannot guarantee the sterility of the products purported to be sterile.

Recall Number:
D-0048-2023

Code Information:
Lot: 65594, BUD: 10/16/2022

Product Description:
PAPAVERINE/PHENTOLAMINE/PROSTAGLANDIN INJ 150MG/5MG/10MCG/VIAL SOLUTION, 5 ML vial, Rx only, Vital Care Compounder, 115 S. 40th Ave., Hattiesburg, MS 39402

Product Quantity:
1 vial

Reason for Recall:
Lack of Assurance of Sterility: FDA inspection found the recalled products were produced in a manner than cannot guarantee the sterility of the products purported to be sterile.

Recall Number:
D-0049-2023

Code Information:
Lot: 65976, BUD: 10/27/2022

Product Description:
PHENTOLAMINE 10MG/ML INJECTION, 10MG/ML SOLUTION, 10 mL vial, Rx only, Vital Care Compounder, 115 S. 40th Ave., Hattiesburg, MS 39402

Product Quantity:
10 vials

Reason for Recall:
Lack of Assurance of Sterility: FDA inspection found the recalled products were produced in a manner than cannot guarantee the sterility of the products purported to be sterile.

Recall Number:
D-0050-2023

Code Information:
Lots: 60586, BUD: 11/01/2022; 64203, BUD: 01/28/2023

Product Description:
PRED ACETATE / GATIFLOXACIN 1% / 0.5% SUSP, 10 mL droptainers, Rx only, Vital Care Compounder, 115 S. 40th Ave., Hattiesburg, MS 39402

Product Quantity:
378 droptainers

Reason for Recall:
Lack of Assurance of Sterility: FDA inspection found the recalled products were produced in a manner than cannot guarantee the sterility of the products purported to be sterile.

Recall Number:
D-0051-2023

Code Information:
Lots: 65056, BUD: 11/18/2022; 66246, BUD: 11/19/2022

Product Description:
PROSTAGLANDIN E1 INJECTION SOLUTION 500MCG/ML SOLUTION, 1 ML vials, Rx only, Vital Care Compounder, 115 S. 40th Ave., Hattiesburg, MS 39402

Product Quantity:
50 vials

Reason for Recall:
Lack of Assurance of Sterility: FDA inspection found the recalled products were produced in a manner than cannot guarantee the sterility of the products purported to be sterile.

Recall Number:
D-0052-2023

Code Information:
Lots: 59993 BUD: 10/18/2022; 60932 BUD: 11/09/2022

Product Description:
SEMAGLUTIDE INJECTION 5MG/ML (0.25MG/0.05ML) SOLN, various amounts in unit dose vials, Rx only, Vital Care Compounder, 115 S. 40th Ave., Hattiesburg, MS 39402

Product Quantity:
800.5 mL in unit dose vials

Reason for Recall:
Lack of Assurance of Sterility: FDA inspection found the recalled products were produced in a manner than cannot guarantee the sterility of the products purported to be sterile.

Recall Number:
D-0053-2023

Code Information:
Lots: 65680, BUD: 10/11/2022; 66043, BUD: 10/15/2022; 66372, BUD: 10/23/2022; 66597, BUD: 10/29/2022

Product Description:
SERUM TEARS IN NSAL 20% OPTH SOLUTION, 3 mL droptainers, Rx only, Vital Care Compounder, 115 S. 40th Ave., Hattiesburg, MS 39402

Product Quantity:
45 droptainers

Reason for Recall:
Lack of Assurance of Sterility: FDA inspection found the recalled products were produced in a manner than cannot guarantee the sterility of the products purported to be sterile.

Recall Number:
D-0054-2023

Code Information:
Lots: 65490, BUD: 10/14/2022; 65584, BUD: 10/16/2022; 66013, BUD: 10/28/2022

Product Description:
TALC, STERILE POWDER, 5 GM vial, Rx only, Vital Care Compounder, 115 S. 40th Ave., Hattiesburg, MS 39402

Product Quantity:
1 vial

Reason for Recall:
Lack of Assurance of Sterility: FDA inspection found the recalled products were produced in a manner than cannot guarantee the sterility of the products purported to be sterile.

Recall Number:
D-0055-2023

Code Information:
Lot: 65995, BUD: 10/28/2022

Product Description:
VANCOMYCIN INTRAVITREAL 1MG/0.1ML SOLUTION, 0.5 mL syringes, Rx only, Vital Care Compounder, 115 S. 40th Ave., Hattiesburg, MS 39402

Product Quantity:
12 syringes

Reason for Recall:
Lack of Assurance of Sterility: FDA inspection found the recalled products were produced in a manner than cannot guarantee the sterility of the products purported to be sterile.

Recall Number:
D-0056-2023

Code Information:
Lots: 65432, BUD: 10/13/2022; 66347, BUD: 11/05/2022; 66864, BUD: 11/18/2022

Product Description:
VORICONAZOLE OPTH SOLUTION 2% STERILE SOLN, 10 ML droptainer, Rx only, Vital Care Compounder, 115 S. 40th Ave., Hattiesburg, MS 39402

Product Quantity:
1 droptainer

Reason for Recall:
Lack of Assurance of Sterility: FDA inspection found the recalled products were produced in a manner than cannot guarantee the sterility of the products purported to be sterile.

Recall Number:
D-0057-2023

Code Information:
Lot: 66757, BUD: 10/14/2022

Class II Drugs Event

Event ID:
91033

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/18/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/31/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
SUN PHARMACEUTICAL INDUSTRIES INC
2 Independence Way
Princeton NJ United States

Distribution Pattern:
Nationwide with the United States

Associated Products

Product Description:
Buprenorphine and Naloxone Sublingual Tablets 8 mg/2 mg, 30-count bottles, Rx only, Distributed by: Sun Pharmaceutical Industries, Inc. Cranbury, NJ 08512 Manufactured by: Sun Pharmaceutical Industries Ltd. Survey No. 259/15, Dadra-396 191, (U.T. of D & NH), India; NDC 62756-970-83

Product Quantity:

Reason for Recall:
Presence of Foreign Substance

Recall Number:
D-0024-2023

Code Information:
Lot #: DNC1129A, Exp 06/2023 Lot #: DNC1740A, Exp 09/2023

Class III Drugs Event

Event ID:
90959

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/18/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/01/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Genentech Inc
1 Dna Way
South San Francisco CA United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Susvimo (ranibizumab injection), 100mg/mL, sold together as a) carton containing One Susvimo single-dose vial and One Susvimo initial fill needle, NDC 50242-078-55; and b) carton labeled as Susvimo Ocular Implant with Insertion Tool Assembly, containing One carrier with implant and One insertion Tool, UDI 81004259001, GTIN 00810042590014, Rx only, Genentech, Inc., A Member of the Roche Group, South San Francisco, CA 94080-4990.

Product Quantity:
452 vials and implants

Reason for Recall:
Defective Delivery System: Commercial implants do not meet the filed specification for the intended use, a few patients have experienced an issue with the implants that renders it non-functioning.

Recall Number:
D-0025-2023

Code Information:
Lot/Exp: a) 3499188, Exp 10/31/2022; Lot 3523071, Exp 6/30/2023; b) 3456735, Exp 10/23/2026; 3456737; Exp 10/29/2026; 3477671, Exp 10/31/2026; 3480781, Exp 12/19/2026; 3506526, Exp 02/25/2027; 3506531, Exp 04/15/2027