Enforcement Report - Week of January 5, 2022

Class I Drugs Event

Event ID:
89135

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/30/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/28/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Teligent Pharma, Inc.
105 Lincoln Avenue
Buena NJ United States

Distribution Pattern:
Distributed to a wholesaler in CO who further distributed Nationwide in the USA

Associated Products

Product Description:
Lidocaine Hydrochloride, Topical Solution USP, 4% (40 mg/mL), packaged in 50 mL screw cap bottles, Rx Only, Manufactured by Teligent Pharma, Inc., Buena, NJ 08310, Distributed by: McKesson Corporation dba Sky Packaging, 4971 Southridge Blvd., Suite 101, Memphis, TN 38141, NDC 63739-997-64

Product Quantity:
6,816 bottles

Reason for Recall:
Superpotent Drug

Recall Number:
D-0295-2022

Code Information:
Lot #: 16345, Exp. Date 01/2024

Class I Drugs Event

Event ID:
89138

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/30/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/28/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Aroma Release Technologies Inc
7026 Discovery Dr
Chattanooga TN United States

Distribution Pattern:
Distributed in the states of Texas and New York.

Associated Products

Product Description:

Klean Touch Hand Sanitizer (Ethyl Alcohol 70%) Ingredients Ethanol and Methanol, in 55-gallon drums, Aroma Release Technology, Inc., 7026 Discovery Drive, Chattanooga, TN 37416

Product Quantity:
37 55-gallon drums

Reason for Recall:
Marketed Without an Approved NDA/ANDA: Product labeled to contain methanol making it an unapproved new drug and contains methanol

Recall Number:
D-0298-2022

Code Information:
Lots: 1620-1, 1620-3, 1620-4, 1820-4, 1820-5, 1920-1, 1920-2, No Expiration Date

Class I Drugs Event

Event ID:
89153

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/03/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/28/2021

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Gilead Sciences, Inc.
333 Lakeside Dr
Foster City CA United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Veklury (remdesivir) for injection, 100 mg/vial, Single-Dose Vial, Rx only, Manufactured for: Gilead Sciences, Inc., Foster City, CA 94404, NDC 61958-2901-2

Product Quantity:
53,473 vials

Reason for Recall:
Presence of Particulate Matter: investigation into a customer complaint confirmed the presence of glass particulates.

Recall Number:
D-0299-2022

Code Information:
Lots: 2141001-1A, 2141002-1A, Exp. 01/2024

Class II Drugs Event

Event ID:
88550

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/23/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/28/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:

Teligent Pharma, Inc.
105 Lincoln Avenue
Buena NJ United States

Distribution Pattern:
Distributed Nationwide in the USA

Associated Products

Product Description:
Betamethasone Dipropionate Lotion USP, 0.05% (Augmented), 30 mL bottle, (29 g), Rx Only, Teligent Pharma Inc., Buena, NJ, 08310, NDC 52565-023-29

Product Quantity:
3,792 bottles

Reason for Recall:
Failed Stability Specifications: lot did not meet specification for the Active Pharmaceutical Ingredient (API) particle test, which was determined through routine stability testing

Recall Number:
D-0297-2022

Code Information:
Lot # 16569, Exp 9/2022

Class II Drugs Event

Event ID:
89059

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/12/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/29/2021

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
SterRx, LLC
141 Idaho Ave
Plattsburgh NY United States

Distribution Pattern:
U.S.A. Nationwide

Associated Products

Product Description:
Midazolam in 0.9% Sodium Chloride Injection, 50 mg per 50 mL (1 mg per mL), Rx only, SterRx, 141 Idaho Ave. Plattsburgh, NY 12003, NDC #70324-102-01.

Product Quantity:
15660 bags

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0300-2022

Code Information:
Lots S21131/BSP, 10-Nov-21 S21132/BSQ, 11-Nov-21 S21139/BSX, 18-Nov-21 S21150/BTI, 24-Nov-21 S21158/BTP, 1-Dec-21 S21160/BTR, 2-Dec-21 & S21170/BUB, 9-Dec-21.

Product Description:
Morphine Sulfate in 0.9% Sodium Chloride Injection, 100 mg per 100 mL (1 mg per mL), Rx only, SterRx, 141 Idaho Avenue, Plattsburgh, NY, 12903, NDC 70324-427-02.

Product Quantity:

880 units

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0301-2022

Code Information:
S21317/BZE

Product Description:
dilTIAZem HCl 125 mg per 125 mL (1 mg per mL) in 0.7% Sodium Chloride Injection, Rx only, SterRx, 141 Idaho Ave., Plattsburgh, NY, 12903, NDC 70324-976-01.

Product Quantity:
24300 bags

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0302-2022

Code Information:
Lots S21164/BTV, 3-Dec-21; S21191/BUU, 18-DEC-21; S21197/BUZ, 31-Dec-21; S21220/BVV, 13-Jan-22; S21271/BX0, 27-Jan-22; S21272/BXP, 28-Jan-22; S21299/BYP, 18-Fev-22; S21300/BYQ, 19-Feb-22

Product Description:
NOREPINEPHRINE 4 mg per 250 mL (16 mcg per mL) in 5% Dextrose Injection, Rx only, SterRx, 141 Idaho Ave., Plattsburgh, NY 12903, NDC 70324-451-01.

Product Quantity:
9360 bags

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0303-2022

Code Information:
S21192/BUV 18-Apr-22 S21205/BVH 23-Apr-22 S21402/CCK 21-Aug-22

Product Description:
EPINEPHrine, 2 mg per 250 mL (8 mcg per mL) in 0.9% Sodium Chloride Injection, Rx only, SterRx, 141 Idaho Ave., Plattsburgh, NY, 12903, NDC 70324-027-01.

Product Quantity:
2779 bags

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0304-2022

Code Information:
S21257/BXC

Product Description:
PHENYLepherine HCL in 0.9% Sodium Chloride, 20 mg per 250 mL (80 mcg per mL), Rx only, SterRx, 141 Idaho Avenue, Plattsburgh, NY 12903, NDC 70324-701-01.

Product Quantity:
18,948 bags

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0305-2022

Code Information:
S21086/BQW 14-Dec-21 S21149/BTH 23-Jan-22 S21159/BTQ 30-Jan-22 S21265/BXI 3-Apr-22 S21305/BYU 24-Apr-22 S21311/BZA 26-

Apr-22

Product Description:
Sodium Bicarbonate in 5% Dextrose Injection, 150 mEq per 1000 mL (12.6 mg per mL), Rx only, SterRx, 141 Idaho Ave., Plattsburgh, NY 12903, NDC 70324-326-01.

Product Quantity:
127,260 bags

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0306-2022

Code Information:
S20483/BNJ 23-Nov-21 S20484/BNK 24-Nov-21 S20485/BNL 25-Nov-21 S21008/BNV 3-Dec-21 S21010/BNX 9-Dec-21 S21025/BOM 10-Dec-21 S21026/BON 15-Dec-21 S21027/BOO 16-Dec-21 S21035/BOW 17-Dec-21 S21045/BPF 18-Dec-21 S21046/BPG 21-Dec-21 S21050/BPK 22-Dec-21 S21054/BPO 24-Dec-21 S21055/BPQ 25-Dec-21 S21061/BPW 28-Dec-21 S21062/BPX 29-Dec-21 S21063/BPY 30-Dec-21 S21064/BPZ 31-Dec-21 S21069/BQE 31-Dec-21 S21073/BQI 4-Jan-22 S21074/BQJ 5-Jan-22 S21076/BQL 6-Jan-22 S21077/BQM 7-Jan-22 S21081/BQQ 20-Jan-22 S21083/BQS 22-Jan-22 S21084/BQT 25-Jan-22 S21110/BRU 26-Jan-22 S21111/BRV 27-Jan-22 S21112/BRW 27-Jan-22 S21113/BRX 28-Jan-22 S21114/BRY 1-Feb-22 S21115/BRZ 1-Feb-22 S21123/BSH 2-Feb-22 S21124/BSI 3-Feb-22 S21126/BSK 3-Feb-22 S21127/BSL 4-Feb-22 S21128/BSM 4-Feb-22 S21129/BSN 5-Feb-22 S21168/BTZ 10-Mar-22 S21169/BUA 11-Mar-22 S21176/BUH 15-Mar-22 S21181/BUL 17-Mar-22 S21182/BUM 17-Mar-22 S21270/BXN 26-May-22 S21274/BXR 26-May-22 S21321/BZH 1-Jun-22 S21322/BZI 2-Jun-22 S21323/BZJ 3-Jun-22 S21324/BZK 3-Jun-22 S21325/BZL 7-Jun-22 S21329/BZP 8-Jun-22 S21336/BZW 14-Jun-22 S21337/BZX 15-Jun-22 S21338/BZY 16-Jun-22 S21341/CAB 17-Jun-22 S21343/CAD 18-Jun-22 S21348/CAH 23-Jun-22 S21350/CAJ 24-Jun-22 S21351/CAK 28-Jun-22 S21357/CAQ 1-Jul-22 S21360/CAT 2-Jul-22 S21363/CAW 5-Jul-22 S21366/CAZ 7-Jul-22 S21374/CBH 8-Jul-22 S21376/CBJ 8-Jul-22 S21377/CBK 12-Jul-22 S21381/CBO 13-Jul-22 S21384/CBR 13-Jul-22 S21387/CBU 13-Jul-22 S21390/CBX 14-Jul-22 S21392/CBZ 14-Jul-22 S21393/CCA 15-Jul-22 S21396/CCD 15-Jul-22 S21397/CCF 19-Jul-22 S21399/CCH 19-Jul-22 S21401/CCJ 20-Jul-22 S21404/CCM 21-Jul-22

Product Description:
Succinylcholine Chloride Injection, 200 mg per 10 mL (20 mg per mL), 1,000 mL, Rx only, SterRx, 141 Idaho Avenue, Plattsburgh, NY 12903, NDC 70324-826-01.

Product Quantity:
3540 bags

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0307-2022

Code Information:
S21367/CBA 18-Nov-21 S21403/CCL 9-Dec-21

Product Description:
EPINEPHIrine in 0.9% Sodium Chloride Injection, 4 mg per 250 mL (16 mcg per mL), Rx only, SterRx, 141 Idaho Ave., Plattsburgh, NY 12903, NDC 70324-227-01.

Product Quantity:
26,928 bags

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0308-2022

Code Information:
S21254/BWZ 22-Nov-21 S21263/BXG 30-Nov-21 S21333/BZT 11-Jan-22 S21398/CCG 19-Feb-22

Product Description:
EPINEPHIrine in 0.9% Sodium Chloride Injection, 5 mg per 250 mL (20 mcg per mL), Rx only, SterRx, 141 Idaho Ave., Plattsburgh, NY 12903, NDC 70324-052-01.

Product Quantity:
7548 bags

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:

D-0309-2022

Code Information:
S21255/BXA 22-Jan-22 S21264/BXH 29-Jan-22 S21328/BZO 10-Mar-22

Product Description:
EPINEPHIrine in 0.9% Sodium Chloride Injection, 8 mg per 250 mL (32 mcg per mL), Rx only, SterRx, 141 Idaho Ave., Plattsburgh, NY 12903, NDC 70324-077-01.

Product Quantity:
5832 bags

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0310-2022

Code Information:
S21255/BXA 22-Jan-22 S21264/BXH 29-Jan-22 S21328/BZO 10-Mar-22

Product Description:
EPINEPHrine in 0.9% Sodium Chloride Injection, 16 mg per 250 mL (64 mcg per mL), Rx only, SterRx, 141 Idaho Ave., Plattsburgh, NY 12903, NDC 70324-627-01.

Product Quantity:
684 bags

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0311-2022

Code Information:
S21335/BZV

Product Description:
Midazolam in 0.9% Sodium Chloride Injection, 100 mg per 100 mL (1 mg per mL), Rx only, SterRx, 141 Idaho Ave., Plattsburgh, NY 12903, NDC 70324-102-02.

Product Quantity:
36360 bags

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0312-2022

Code Information:
S21065/BQA 12-Nov-21 S21066/BQB 19-Nov-21 S21142/BTA 19-Nov-21 S21143/BTB 20-Nov-21 S21146/BTE 21-Nov-21 S21147/BTF 25-Nov-21 S21148/BTG 25-Nov-21 S21153/BTL 26-Nov-21 S21154/BTM 27-Nov-21 S21171/BUC 10-Dec-21 S21172/BUD 11-Dec-21 S21173/BUE 15-Dec-21 S21190/BUT 16-Dec-21 S21201/BVD 22-Dec-21 S21202/BVE 24-Dec-21 S21203/BVF 29-Dec-21 S21204/BVG 19-Jan-22 S21258/BXD 20-Jan-22 S21275/BXS 30-Jan-22 S21276/BXT 2-Feb-22 S21277/BXU 3-Feb-22 S21278/BXV 3-Feb-22 S21284/BYB 4-Feb-22 S21285/BYC 5-Feb-22 S21286/BYD 11-Feb-22 S21287/BYE 12-Feb-22 S21290/BYH 16-Feb-22 S21304/BYT 23-Feb-22 S21306/BYV 24-Feb-22 S21308/BYX 25-Feb-22 S21310/BYZ 26-Feb-22 S21379/CBM 14-Apr-22 S21382/CBP 14-Apr-22 S21385/CBS 15-Apr-22

Product Description:
Morphine Sulfate in 5% Dextrose Injection, 100 mg per 100 mL (1 mg per mL), Rx only, SterRx, 141 Idaho Ave., Plattsburgh, NY 12903, NDC 70324-452-01.

Product Quantity:
40 bags

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0313-2022

Code Information:
S21293/BYJ

Product Description:
NOREPINEPHRINE in 5% Dextrose Injection, 8 mg per 250 mL (32 mg per mL) Injection, Rx only, SterRx, 141 Idaho Ave., Plattsburgh, NY 12903, NDC 70324-476-01.

Product Quantity:
1428 bags

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0314-2022

Code Information:
S21409/CCR

Product Description:
dilTIAZem HCl in 5% Dextrose Injection, 125 mg per 125 mL, (32 mcg per mL), Rx only, SterRx, 141 Idaho Ave., Plattsburgh, NY 12903, NDC 70324-951-01.

Product Quantity:
8946 bags

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0315-2022

Code Information:
S21200/BVC 15-Nov-21 S21296/BYM 19-Dec-21 S21320/BZG 4-Jan-22 S21164/BTV 3-Dec-21 S21191/BUU 18-Dec-21 S21197/BUZ 31-Dec-21 S21220/BVV 13-Jan-22 S21271/BXO 27-Jan-22 S21272/BXP 28-Jan-22 S21299/BYP 18-Feb-22 S21300/BYQ 19-Feb-22

Product Description:
Fentanyl Citrate, in 0.9% Sodium Chloride Injection, 1 mg per 100 mL, (10 mcg per mL), Rx Only, SterRx, 141 Idaho Ave., Plattsburgh, NY 12903, NDC 70324-327-01.

Product Quantity:
10660 bags

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0316-2022

Code Information:
S21349/CAI 23-Mar-22 S21356/CAP 1-Apr-22 S21361/CAU 2-Apr-22

Product Description:
Fentanyl Citrate, in 0.9% Sodium Chloride Injection, 2.5 mg per 250 mL, (10 mcg per mL), Rx Only, SterRx, 141 Idaho Ave., Plattsburgh, NY 12903, NDC 70324-327-02.

Product Quantity:
5000 bags

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0317-2022

Code Information:
S21353/CAM 26-Mar-22 S21358/CAR 30-Mar-22 S21364/CAX 6-Apr-22

Product Description:
MORPHINE SULFATE, in 0.9% Sodium Chloride Injection, 50 mg per 50 mL, (1 mg per mL), Rx only, SterRx, 141 Idaho Ave., Plattsburgh, NY 12903, NDC 70324-427-01.

Product Quantity:
880 bags

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0318-2022

Code Information:
S21292/BYI

Product Description:
NOREPINEPHRINE, 16 mg per 250 mL, (64 mcg per mL) in 5% Dextrose Injection, Rx only, SterRx, 141 Idaho Ave., Plattsburgh, NY 12903, NDC 70324-002-01.

Product Quantity:
1044 bags

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0319-2022

Code Information:
S21194/CDW

Product Description:
NOREPINEPHRINE, 4 mg per 250 mL, (18 mcg per mL) in 0.9% Sodium Chloride Injection, Rx only, SterRx, 141 Idaho Ave., Plattsburgh, NY 12903, NDC 70324-651-01.

Product Quantity:
121,584 bags

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0320-2022

Code Information:
S20415/BKY 12-Nov-21 S20418/BLB 13-Nov-21 S20452/BMI 5-Dec-21 S20463/BMT 9-Dec-21 S20464/BMU 18-Dec-21 S20478/BNF 23-Dec-21 S21021/BOI 6-Jan-22 S21033/BOU 20-Jan-22 S21047/BPH 21-Jan-22 S21059/BPU 28-Jan-22 S21094/BRE 18-Feb-22 S21117/BSB 3-Mar-22 S21118/BSC 10-Mar-22 S21138/BSW 17-Mar-22 S21227/BWA 7-May-22 S21239/BWK 12-May-22 S21279/BXW 5-Jun-22 S21295/BYL 16-Jun-22 S21298/BYO 18-Jun-22 S21339/BZZ 16-Jul-22 S21346/CAF 21-Jul-22 S21355/CAO 28-Jul-22 S21370/CBD 4-Aug-22 S21372/CBF 7-Aug-22 S21438/CDS 4-Sep-22

Product Description:
NOREPINEPHRINE, 8 mg per 250 mL, (32 mcg per mL) in 0.9% Sodium Chloride Injection, Rx only, SterRx, 141 Idaho Ave., Plattsburgh, NY 12903, NDC 70324-676-01.

Product Quantity:
74,508 bags

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0321-2022

Code Information:
S21162/BTT 13-Nov-21 S21163/BTU 13-Nov-21 S21167/BTY 19-Nov-21 S21174/BUF 20-Nov-21 S21175/BUG 21-Nov-21 S21217/BVS 12-Dec-21 S21218/BVT 12-Dec-21 S21219/BVU 16-Dec-21 S21241/BWL 24-Dec-21 S21281/BXY 20-Jan-22 S21282/BXZ 23-Jan-22 S21283/BYA 22-Jan-22 S21297/BYN 28-Jan-22 S21340/CAA 27-Feb-22 S21342/CAC 5-Mar-22 S21352/CAL 6-Mar-22 S21359/CAS 11-Mar-22 S21362/CAV 12-Mar-22 S21368/CBB 13-Mar-22 S21369/CBC 19-Mar-22 S21415/CCX 7-Apr-22 S21419/CDB 7-Apr-22 S21434/CDP 16-Apr-22

Product Description:
NOREPINEPHRINE, 16 mg per 250 mL, (64 mcg per mL) in 0.9% Sodium Chloride Injection, SterRx, 141 Idaho Ave., Plattsburgh, NY 12903, NDC 70324-926-01.

Product Quantity:
36,576 bags

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0322-2022

Code Information:
S21082/BQV 13-Nov-21 S21102/BRM 28-Nov-21 S21135/BST 14-Dec-21 S21166/BTX 7-Jan-22 S21178/BUJ 28-Jan-22 S21226/BVZ 5-Feb-22 S21237/BWI 7-Feb-22 S21242/BWM 13-Feb-22 S21280/BXX 11-Mar-22 S21302/BYS 21-Mar-22 S21345/CAE 23-Apr-22 S21424/CDG 28-May-22

Product Description:
PHENYLephrine HCl, 40 mg per 250 mL, (160 mcg per mL) in 0.9% Sodium Chloride Injection, Rx Only, SterRx, 141 Idaho Ave., Plattsburgh, NY 12903, NDC 70324-252-01.

Product Quantity:
20640 bags

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0323-2022

Code Information:
S21087/BQX 16-Dec-21 S21151/BTJ 24-Jan-22 S21186/BUQ 14-Feb-22 S21189/BUS 16-Feb-22 S21266/BXJ 3-Apr-22 S21307/BYW 24-Apr-22 S21313/BZC 27-Apr-22

Product Description:
PHENYLephrine HCl, 50 mg per 250 mL, (200 mg per mL) in 0.9% Sodium Chloride Injection, Rx Only, SterRx, 141 Idaho Ave., Plattsburgh, NY 12903, NDC 70324-901-01.

Product Quantity:
23,136 bags

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0324-2022

Code Information:
S21088/BQY 19-Dec-21 S21152/BTK 25-Jan-22 S21161/BTS 31-Jan-22 S21289/BYG 4-Apr-22 S21309/BYY 25-Apr-22 S21314/BZD 2-May-22 S21378/CBL 12-Jun-22

Product Description:
Sodium Bicarbonate in 5% Dextrose Injection, Rx Only, SterRx, 141 Idaho Ave., Plattsburgh, NY 12903, NDC 70324-326-03

Product Quantity:
2886 bags

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0325-2022

Code Information:
S20459/BMP 17-Nov-21 S20472/BMZ 18-Nov-21 S20473/BNA 18-Nov-21

Class II Drugs Event

Event ID:
89135

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/30/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/28/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Teligent Pharma, Inc.

105 Lincoln Avenue
Buena NJ United States

Distribution Pattern:
Distributed to a wholesaler in CO who further distributed Nationwide in the USA

Associated Products

Product Description:
Lidocaine Hydrochloride, Topical Solution USP, 4% (40 mg/mL), packaged in 50 mL screw cap bottles, Rx Only, Manufactured by Teligent Pharma, Inc., Buena, NJ 08310, Distributed by: McKesson Corporation dba Sky Packaging, 4971 Southridge Blvd., Suite 101, Memphis, TN 38141, NDC 63739-997-64

Product Quantity:
7,176 bottles

Reason for Recall:
Superpotent Drug: Minimally superpotent

Recall Number:
D-0296-2022

Code Information:
Lot #: 15594, Exp Date 05/2023

Not Yet Classified Drugs Event

Event ID:
89186

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/06/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Valisa MFG LLC
131 Executive Blvd
Farmingdale NY United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
kleantouch HAND SANITIZER (ethyl alcohol 70%), 8.0 FL OZ (236 ML), Distributed by: Valisa MFG, LLC, Farmingdale, NY, 11735, Made in USA, UPC 6 86162 99246 1.

Product Quantity:
7704 bottles

Reason for Recall:
Marketed Without an Approved NDA/ANDA: Product labeled to contain methanol making it an unapproved new drug and contains methanol

Recall Number:

Code Information:
Lot #: 1260-1, 1260-2, 1260-3, 1260-4. Exp. 04/2022