Enforcement Report - Week of December 21, 2022

Class I Drugs Event

Event ID:
91197

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/28/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/13/2022

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Exela Pharma Sciences LLC
1245 Blowing Rock Blvd
Lenoir NC United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
8.4% Sodium Bicarbonate Injection, USP 50 mEq/50 mL (1 mEq/mL) 50 mL Single Dose Vials, packaged in cartons of 20 vials, Rx only, Manufactured and Distributed by: Exela Pharma Sciences, LLC Lenoir, NC 28645. Carton NDC 51754-5001-5, vial NDC 51754-5001-1.

Product Quantity:
489,600 vials

Reason for Recall:
Defective Container: Complaints received of vial breakage and glass flying when pressurized while preparing the product for administration.

Recall Number:
D-0079-2023

Code Information:
Lots: P0001178 Exp. 05/2023; P0001298, P0001301, P0001313, P0001314, P0001317 Exp. 08/2023; P0001330, P0001464 Exp. 09/2023; P0001442 Exp. 11/2023; P0001467, P0001472, P0001486, P0001532 Exp. 12/2023.

Product Description:
8.4% Sodium Bicarbonate Injection, USP 50 mEq/50 mL (1 mEq/mL) 50 mL Single Dose Vials, packaged in cartons of 20 vials, Rx Only, Mfd for: Civica, Inc. Lehi, Utah 84043, Mfd by: Exela Pharma Sciences, LLC, Lenoir, NC 28645, Carton NDC 72572-740-20, vial NDC 72572-740-1.

Product Quantity:
37,320 vials

Reason for Recall:
Defective Container: Complaints received of vial breakage and glass flying when pressurized while preparing the product for administration.

Recall Number:
D-0080-2023

Code Information:
Lot: P0001490 Exp. 12/2023

Class II Drugs Event

Event ID:
91229

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/29/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/09/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
OurPharma LLC
2512 S City Lake Rd
Fayetteville AR United States

Distribution Pattern:
MO

Associated Products

Product Description:
FentaNYL Citrate 2.5 mg/50 mL (50mcg/ml) Injection Solution, Preservative Free, Single Use 50 ml Cassette, Rx Only, Repackaged by OurPharma, LLC. 2512 S. City Lake Rd. Fayetteville, AR 72701, 1-833-290-2654, NDC 73013-001-01

Product Quantity:
691 cassettes

Reason for Recall:
Underfilled units.

Recall Number:
D-0078-2023

Code Information:
Lots: 100122060007 Exp. 12/17/2022; 100122060008 Exp. 12/18/2022; 100122070002 Exp. 01/09/2023.

Class II Drugs Event

Event ID:
91243

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/12/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/13/2022

Initial Firm Notification of Consignee or Public:
Telephone

Recalling Firm:
Atlantic Management Resources Ltd.
39 Harvey Ln
Westborough MA United States

Distribution Pattern:
Nationwide and Australia

Associated Products

Product Description:
Neuroquell Plus, Advanced Formula, A Homeopathic Drug, Calendula Oil packaged in 0.22 Fl. oz. (6.6 mL) bottles, Mfg. for/Dist. By Claire Ellen Topicals, P.O. Box 901 Westborough, MA 01581, USA, NDC# 66233712-01.

Product Quantity:
461 bottles

Reason for Recall:
cGMP Deviations

Recall Number:
D-0081-2023

Code Information:
Lot Code B-02

Product Description:
Neuroquell, A Homeopathic Drug, Calendula Oil, packaged in1/8 Fl. oz. (3.5 g) bottles, Mfg. for/Dist. By Claire Ellen Topicals, P.O. Box 901 Westborough, MA 01581, USA, NDC# 66233712-01.

Product Quantity:
51 bottles

Reason for Recall:
cGMP Deviations

Recall Number:
D-0082-2023

Code Information:
Lot Code B-02

Product Description:
ProSirona, A Homeopathic Formula, Calendula Oil packaged in 1/8 Fl. oz. (3.5 g) bottles, Dist. by: Endometriosis Assoc. Inc. (International), Mfg. by Claire Ellen Topicals, P.O. Box 901 Westborough, MA 01581, USA, NDC# 66233-712-01.

Product Quantity:
72 bottles

Reason for Recall:
cGMP Deviations

Recall Number:
D-0083-2023

Code Information:
Lot Code B-02

Product Description:
Menastil, A Homeopathic Formula, Calendula Oil packaged in 1/8 Fl. oz. (3.5 g) bottles, Mfg. for/Dist. By Claire Ellen Topicals, P.O. Box 901 Westborough, MA 01581, USA, NDC# 66233-711-01.

Product Quantity:
26 bottles

Reason for Recall:
cGMP Deviations

Recall Number:
D-0084-2023

Code Information:
Lot Code A-01

Not Yet Classified Drugs Event

Event ID:
91283

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/01/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Two or more of the following: Email, Fax, Letter, Press Release, Telephone, Visit

Recalling Firm:
BayCare Integrated Service Center, LLC /dba BayCare Central Pharmacy

7802 E Telecom Pkwy
Temple Terrace FL United States

Distribution Pattern:
BayCare Health System hospitals in FL

Associated Products

Product Description:
Omnipaque (iohexol) 300 mg Iodine/ml, 2.4g Iodine/8 ml in a 10 mL syringe, packaged in 5-count syringes per bag, Rx Only, Baycare Central Pharmacy 7802 E. Telecom Parkway, Temple Terrace, FL 33637

Product Quantity:
250 syringes

Reason for Recall:
Labeling: Label Error on Declared Strength: syringes mislabeled as 300 mg iodine/mL contained product 350 mg iodine/mL

Recall Number:

Code Information:
Lot: IOHE2.420221128, Exp. 12/7/2022