Enforcement Report - Week of December 14, 2022

Class II Drugs Event

Event ID:
91194

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/25/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/05/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
B. Braun Medical, Inc.
901 Marcon Blvd
Allentown PA United States

Distribution Pattern:
FL, NJ, PA

Associated Products

Product Description:
0.9% Sodium Chloride Injection USP 1000 mL Single-dose container Rx only NDC 0264-5802-00 B. Braun Medical Inc. Bethlehem, PA 18018-3524 USA 1-800-227-2862

Product Quantity:
756 bags

Reason for Recall:
Lack of sterility assurance: Bags have the potential to leak.

Recall Number:
D-0076-2023

Code Information:
Lot: 0061832446 Exp. 31 Oct 2024

Class II Drugs Event

Event ID:
91226

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/22/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/02/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Fresenius Medical Care Holdings, Inc.
920 Winter St Bld 950
Waltham MA United States

Distribution Pattern:
Product was distributed Nationwide in the USA.

Associated Products

Product Description:
0.9% Sodium Chloride Injection, USP, Each 100 mL contains: SODIUM CHLORIDE, USP - 900 mg, WATER FOR INJECTION, USP - qs, 1000mL Bag, 12 PK, Rx Only, Fresenius Medical Care North America, Waltham, MA 02451, NDC 49230-300-10

Product Quantity:
4,097 cases/12 bags per case

Reason for Recall:
Lack of Assurance of Sterility: Leakage of 0.9% Sodium Chloride for Injection, 1L, 12pk Saline Solution.

Recall Number:
D-0075-2023

Code Information:
Lot # 22HU05062, 22HU06059, 22HU05035, EXP 06/30/2023; 22JU05001, EXP 07/31/2023

Class II Drugs Event

Event ID:
91263

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/05/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/07/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
RemedyRepack Inc.
625 Kolter Dr Ste 4
Indiana PA United States

Distribution Pattern:
Product was distributed to two different customers in MI.

Associated Products

Product Description:
Desmopressin Acetate Tablet, 0.2 mg, 100-count box, Rx only, Source NDC: 23155-0490-01; MFG: Avet Pharmaceuticals Inc., East Brunswick, NJ 08816; Repackaged by: RemedyRepack Inc., Indiana, PA 15701, NDC #: 70518-3493-00.

Product Quantity:
9 boxes

Reason for Recall:
Subpotent Drug: repackaged product was recalled by the manufacturer for subpotency.

Recall Number:
D-0077-2023

Code Information:
Lot # B1817019-082222, Exp. 02/24/2023; B1819127-082322, Exp. 02/26/2023