Enforcement Report - Week of November 1, 2023

Class I Drugs Event

Event ID:
93150

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/29/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/24/2023

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Biomic Sciences, LLC dba ION Intelligence of Nature
4351 Seminole Trl
Charlottesville VA United States

Distribution Pattern:
Nationwide in the United States and to Canada, New Zealand, Australia, Indonesia, Malaysia, Great Britain, and the Netherlands

Associated Products

Product Description:
ION*Sinus Spray, 1 fl oz/ 30 mL, Manufactured by: ION* Biome Charlottesville, VA

Product Quantity:

Reason for Recall:
Microbial contamination of Non-Sterile Products

Recall Number:
D-0067-2024

Code Information:
All lots within expiry.

Class II Drugs Event

Product Description:
ION* Sinus Support Nasal Spray, 1 fl oz/30 ml bottles, Manufactured by: ION* Intelligence of Nature Charlottesville, VA

Product Quantity:

Reason for Recall:
Microbial contamination of Non-Sterile Products

Recall Number:
D-0068-2024

Code Information:
All lots within expiry.

Product Description:
Restore Sinus Spray, Manufactured by: Biomic Sciences, LLC Charlottesville, VA

Product Quantity:

Reason for Recall:
Microbial contamination of Non-Sterile Products

Recall Number:
D-0069-2024

Code Information:
All lots within expiry.

Class III Drugs Event

Event ID:
93178

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/04/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/26/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Denver Solutions, LLC DBA Leiters Health
13796 Compark Blvd
Englewood CO United States

Distribution Pattern:
USA Nationwide

Associated Products

Product Description:
Oxytocin synthetic, 30 Units added to 0.9% Sodium Chloride 500mL IV Bag (0.06 Units per mL), Rx only, Leiter Compounding Health, 13796 Compark Blvd, Englewood, CO 80112, NDC 71449-157-70

Product Quantity:
6,276 IV bags

Reason for Recall:
Labeling: Not Elsewhere Classified

Recall Number:
D-0070-2024

Code Information:
Lot#: 2330956, Exp. 10/23/2023; 2330964, Exp. 10/24/2023; 2331014, Exp. 11/6/2023; 2331033, Exp. 11/8/2023

Product Description:
VANCOmycin HCl PF, 1.25 g added to 0.9% Sodium Chloride 250 mL IV Bag, Rx only, Leiters Compounding Health, 13796 Compark Blvd, Englewood, CO 80112, NDC 71449-028-68.

Product Quantity:
33,480 IV Bags

Reason for Recall:
Labeling: Not Elsewhere Classified

Recall Number:
D-0071-2024

Code Information:
Lot#: 2330781, Exp. 10/19/23; 2330791, Exp. 10/29/23; 2330795, Exp. 11/02/23; 2330800, Exp. 11/09/23; 2330807, Exp. 11/11/23; 2330812, Exp. 11/16/23; 2330816, Exp. 11/19/23; 2330822, 10/20/23; 2330897,11/23/23; 2330899, 11/25/23; 2330901, 11/26/23; 2330918, 11/30/23; 2330943, 01/12/24; 2331050, 01/14/24; 2331064, 01/21/24; 2331102, Exp. 01/25/24.

Product Description:
VANCOmycin HCl PF, 1.5 g added to 0.9% Sodium Chloride 250 mL IV Bag, Rx only, Leiters Compounding Health, 13796 Compark Blvd, Englewood, CO 80112, NDC 71449-029-68.

Product Quantity:
25,908 IV bags

Reason for Recall:

Labeling: Not Elsewhere Classified

Recall Number:
D-0072-2024

Code Information:
Lot#: 2330792, Exp. 12/17/23; 2330801, Exp. 12/26/23; 2330821, 10/15/23; 2330823, Exp. 10/21/23; 2330825, Exp. 10/27/23; 2330846, Exp. 10/28/23; 2330847, Exp. 11/03/23; 2330856, 11/17/23; 2330858, Exp. 12/03/23; 2330860, 12/15/23; 2330866, Exp. 12/29/23; 2331053, Exp. 01/13/24.

Class III Drugs Event

Event ID:
93223

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/22/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/23/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
West-Ward Columbus Inc
1809 Wilson Rd
Columbus OH United States

Distribution Pattern:
MS, OH

Associated Products

Product Description:
Methotrexate Tablets, USP, 2.5 mg, 10x10 Unit-Dose Tablets per carton, Rx only, Distributed by: West-Ward Pharmaceuticals Corp., Eatontown, NJ 07724. NDC: 0054-8550-25

Product Quantity:
2,673 cartons

Reason for Recall:
Failed Tablet/Capsule Specifications: Tablets were observed to have an unsmooth surface with two tablets demonstrating illegible tablet identification and scoring.

Recall Number:
D-0066-2024

Code Information:
Lot, expiry: Lot AB7486B, exp Dec 2023; Lot AB8766B, exp April 2024; Lot AB9484B, exp Aug 2024