Enforcement Report - Week of October 11, 2023

Class I Drugs Event

Event ID:
92952

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/26/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/04/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Dr. Berne's Whole Health Products
174 Tesuque Village Rd Unit 458
Tesuque NM United States

Distribution Pattern:
Nationwide and UK, Canada, Italy, India, Australia, Germany, Switzerland, Singapore, Netherlands, Ireland, South Korea, Belgium, Norway, Saudi-Arabia, Slovenia, Malta, Israel, Sweden, Latvia, Portugal, Hong Kong, Kuwait, Romania, South Africa, Thailand, Zambia, France, Finland, Mauritius, Barbados.

Associated Products

Product Description:
Dr. Berne's MSM DROPS 5% Solution, 30 mL/1.014 OZ bottle, Distributed by: Dr. Berne's Whole Health Products, Tesuque, NM, 87574, hello@drsamberne.com, UPC 00854582001111.

Product Quantity:

Reason for Recall:
Non-Sterility

Recall Number:
D-0037-2024

Code Information:
Lot: 6786, Exp: 03/31/25

Class II Drugs Event

Product Description:
Dr. Berne's MSM DROPS 15% Solution, 30 mL/1.014 OZ bottle, Distributed by: Dr. Berne's Whole Health Products, Tesuque, NM, 87574, hello@drsamberne.com, UPC 00854582001036

Product Quantity:
6060 bottles

Reason for Recall:
CGMP Deviations

Recall Number:
D-0033-2024

Code Information:
Lots: 6486, Exp: 11/23; 6536, Exp: 01/24; 6549, Exp: 02/24; 6561, Exp: 03/24; 6623, Exp: 06/24; 6630, Exp: 06/24; 6646, Exp: 07/24; 6675, Exp: 09/24; 6686, Exp: 09/24; 6695, Exp: 10/24; 6738, Exp: 11/24; 6767, Exp: 01/25; 6787, Exp: 03/25; 6799, Exp: 04/25; 6832 Exp: 05/25; 6844, Exp: 05/25; 6857, Exp: 06/25; 6888, Exp: 07/25.

Product Description:
Dr. Berne's MSM MIST 15% Solution, 30 mL/1.014 OZ bottle, Distributed by: Dr. Berne's Whole Health Products, Tesuque, NM, 87574, hello@drsamberne.com.

Product Quantity:
795 bottles

Reason for Recall:
CGMP Deviations

Recall Number:
D-0034-2024

Code Information:
Lot: 6617, Exp. 05/24; 6623, Exp 06/24; 6646, Exp 07/24; 6675, Exp 09/24; 6716, Exp 11/24.

Product Description:
Dr. Berne's Organic Castor Oil Eye Drops, Net WT 30 mL/1 fl oz bottle, Distributed by: Dr. Berne's Whole Health Products, Tesuque, NM, 87574, hello@drsamberne.com, Certified Organic by Organic Certifiers.

Product Quantity:
1744 bottles

Reason for Recall:
CGMP Deviations

Recall Number:
D-0035-2024

Code Information:
Lot: 6666, Exp. 11/30/25

Product Description:
Dr. Berne's MSM DROPS 5% Solution, 30 mL/1.014 OZ bottle, Distributed by: Dr. Berne's Whole Health Products, Tesuque, NM, 87574, hello@drsamberne.com, UPC 00854582001111.

Product Quantity:
3833 bottles

Reason for Recall:
CGMP Deviations

Recall Number:
D-0036-2024

Code Information:
Lot: 6485, Exp: 11/23: 6562, Exp: 03/24; 6624, Exp: 06/24; 6669, Exp: 08/24; 6688, Exp: 09/24; 6727, EXP: 11/24; 6771, Exp: 02/25; 6830, Exp: 03/25; 6887, Exp: 07/25.

Class II Drugs Event

Event ID:
93100

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/21/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/04/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Zydus Pharmaceuticals (USA) Inc
73 Route 31 N
Pennington NJ United States

Distribution Pattern:
Nationwide in the USA.

Associated Products

Product Description:
Oxybutynin Chloride Extended-Release Tablets USP 10 mg, a) 100 tablets (NDC 68382-256-01) and b) 500 tablets (NDC 68382-256-05) bottles, Rx Only, Manufactured by: Cadila Healthcare Ltd., Ahmedabad, India, Distributed by: Zydus Pharmaceuticals (USA) Inc., Pennington, NJ 08534

Product Quantity:
7,248 bottles

Reason for Recall:
Failed Dissolution Specifications

Recall Number:
D-0038-2024

Code Information:
Lot#: M300652 and M300651, exp. Dec 2024

Class II Drugs Event

Event ID:
93128

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/28/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/05/2023

Initial Firm Notification of Consignee or Public:

Recalling Firm:
Eugia US LLC
279 Princeton Hightstown Rd
East Windsor NJ United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Triamcinolone Acetonide Injectable Suspension, USP, 400 mg per 10 mL (40mg/mL), 10 mL Multiple Dose Vial, Rx Only, For Intramuscular or Intra-articular use only, Shake Well, Not for IV/ID, intraocular, epidural, or intrathecal use, Mfd. in India for Auromedics Pharma LLC., E Windsor, NJ, 08520, NDC 55150-385-01.

Product Quantity:
1,626 vials

Reason for Recall:
Presence of Particulate Matter: A product complaint of a piece of glass was identified in a vial. The piece of glass appears to be roughly 1 cm x 0.5 cm inside the vial.

Recall Number:
D-0041-2024

Code Information:
Lot #: 3TC22010, Exp 11/30/2024

Class III Drugs Event

Event ID:
93089

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:

Voluntary / Mandated:

09/01/2023

Center Classification Date:
10/05/2023

Recalling Firm:
Amerisource Health Services LLC
2550 John Glenn Ave Ste A
Columbus OH United States

Distribution Pattern:
Nationwide in the USA

Voluntary / Mandated:
Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:
Letter

Associated Products

Product Description:
HydrALAZINE Hydrochloride Tablets, USP, 10 mg, 100 Tablets (10 x 10) per carton, Rx Only, Distributed by: American Health Packaging, Columbus, Ohio 43217. Carton NDC#: 68084-447-01; Individual Dose NDC: 68084-447-11

Product Quantity:
3,344 cartons

Reason for Recall:
Failed Impurities/Degradation Specifications: Out of Specification results in the repackaged product for impurities at the 12-month time point.

Recall Number:
D-0039-2024

Code Information:
Lot#: 1007002, Exp 12/31/2023

Class III Drugs Event

Event ID:
93160

Status:
Ongoing

Recall Initiation Date:
10/03/2023

Center Classification Date:
10/05/2023

Recalling Firm:
Imprimis NJOF, LLC
1705 Route 46 Ste 6B
Ledgewood NJ United States

Distribution Pattern:
Nationwide

Product Type:
Drugs

Date Terminated:

Voluntary / Mandated:
Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:
Letter

Associated Products

Product Description:
Epinephrine-Lidocaine HCl (0.25mg/mL and 7.5mg/mL) 1mL Single Use Intraocular injection Preservative Free NDC 71384-640-01 Not for resale. Office use only. Lot: 23APR018 Date Compounded: 24APR2023 Expires on: 17APR2024. In case of adverse event contact: www.fda.gov/medwatch or (800)-FDA-1088 Imprimis NJOF, LLC. 1705 Route 46 West, Unit 6B, Ledgewood, NJ, 07852 (844) 446-6979

Product Quantity:
364 bags (1 mL filled in 2 mL glass amber vials; 20 vials shipped in a bag)

Reason for Recall:
Subpotent: Failing Test Results for Epinephrine

Recall Number:
D-0040-2024

Code Information:
23APR018