Enforcement Report - Week of October 26, 2022

Class II Drugs Event

Event ID:
90896

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/26/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/18/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
AuroMedics Pharma LLC
279 Princeton Hightstown Rd
East Windsor NJ United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Acyclovir Sodium Injection, 500mg/10mL (50mg/mL), 10 mL Single Dose Vial, Rx only, Distributed by: AuroMedics Pharma LLC, 279 Princeton-Hightstown Rd., E. Windsor, NJ 08520; Made in India, NDC 55150-154-10.

Product Quantity:
89400 vials

Reason for Recall:
Presence of Particulate Matter: Customer complaint for a dark red, brown and black particulate floating inside vial.

Recall Number:
D-0013-2023

Code Information:
Lot: AC22006, Exp 08/2023

Class II Drugs Event

Event ID:
90934

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/30/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/17/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Ingenus Pharmaceuticals Llc
4190 Millenia Blvd
Orlando FL United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Flunisolide Nasal Solution, USP 0.025%, 25 mL bottles, Rx only, Manufactured for: Ingenus Pharmaceuticals, LLC Orlando, FL 32839-6408; NDC 50742-317-25 UPC 3 50742 31725 7

Product Quantity:
6176 bottles

Reason for Recall:
Out of specification for related substances (impurities).

Recall Number:
D-0010-2023

Code Information:
Lot #: 22E040 Exp. 07/2023; 22F038 Exp. 08/2023

Class II Drugs Event

Event ID:
90992

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/06/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/17/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Golden State Medical Supply Inc.
5187 Camino Ruiz
Camarillo CA United States

Distribution Pattern:
USA nationwide

Associated Products

Product Description:
Rifampin Capsules, USP, 300 mg, packaged in a) 30-count bottle (NDC 51407-323-30), b) 60-count bottle (NDC 51407-323-60), c) 100-count bottle (NDC 51407-323-01), Rx only, Manufactured by Patheon Pharmaceuticals Inc., OH, Packaged by GSMS, Incorporated, CA.

Product Quantity:

Reason for Recall:
Failed impurities/degradation specifications: Finished product exceeds the 5 ppm interim limit for 1-Methyl-4-Nitrosopoperazine (MNP).

Recall Number:
D-0011-2023

Code Information:
Lot#: a) GS041430, GS041941, Exp 1/31/2023; GS041315, GS042991, GS043027, GS043367, GS043501, GS044421, Exp 3/31/2023; b) GS041431, GS041799, GS042287, GS042414, GS042879, Exp: 1/31/2023; GS041316, GS042992, GS043368, GS043579, Exp 3/31/2023; c) GS041429, GS041877, Exp 1/31/2023; GS041317, GS043028, GS043366, GS044422, Exp 3/31/2023

Product Description:
Rifampin Capsules, USP, 150 mg, 30-count bottle, Rx only, Manufactured by Patheon Pharmaceuticals Inc., OH, Packaged by GSMS, Incorporated, CA, NDC 51407-322-30

Product Quantity:

Reason for Recall:
Failed impurities/degradation specifications: Finished product exceeds the 5 ppm interim limit for 1-Methyl-4-Nitrosopoperazine (MNP).

Recall Number:
D-0012-2023

Code Information:
Lot #: GS036715, GS037569, GS038132, GS038665, GS038750, GS039565, GS039997, GS040673, Exp 10/31/2022; GS040674, GS041237, GS041652, GS042152, GS043365, Exp 3/31/2023; GS045441, GS045677, GS046111, Exp 2/29/2024.

Class II Drugs Event

Event ID:
90997

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/11/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/20/2022

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

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

Distribution Pattern:
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:
16,006 cases of twelve bags each

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

Recall Number:
D-0015-2023

Code Information:
Lot # 22EU05043, EXP 5/21/2023; 22HU05018, EXP 6/9/2023; 22HU05019, EXP 6/10/2023; 22HU05025, 22HU05026, EXP 6/12/2023; 22HU05049, EXP 6/22/2023; 22HU05053, EXP 6/24/2023; 22HU05054, 22HU05055, EXP 6/25/2023; 22HU06027, EXP 6/11/2023; 22HU06049, EXP 6/23/2023; 22HU06055, EXP 6/24/2023; 22HU06056, EXP 6/25/2023; 22JU05008, EXP 7/4/2023; 22KU06036, EXP 8/19/2023; 22JU06023, EXP 7/8/2023

Class III Drugs Event

Event ID:
90983

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/11/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/18/2022

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
LNK International, Inc.
55 Arkay Dr
Hauppauge NY United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
NDC 0363-6171-09 Walgreens Sinus Pressure, Pain & Cough ACETAMINOPHEN/ PAIN RELIEVER DEXTROMETHORPHAN HBr/ COUGH SUPPRESSANT GUAIFENESIN/ EXPECTORANT PHENYLEPHRINE HCl/ NASAL DECONGESTANT Maximum Strength Decongestant Free DISTRIBUTED BY: WALGREENS CO. 200 WILMOT RD., DEERFIELD, IL 60015 walgreens.com

Product Quantity:
66,384 boxes of twenty tablets each

Reason for Recall:
Boxes mislabeled to read "Decongestant Free", but the product contains Phenylephrine HCl 5mg

Recall Number:
D-0014-2023

Code Information:
P129910 P129911 P130240