

Enforcement Report - Week of December 8, 2021

Class II Drugs Event

Event ID:
89076

Status:
Ongoing

Recall Initiation Date:
11/17/2021

Center Classification Date:
11/26/2021

Recalling Firm:
ASP CARES
2414 Babcock Rd Ste 106
San Antonio TX United States

Distribution Pattern:
United States

Product Type:
Drugs

Date Terminated:

Voluntary / Mandated:
Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:
Letter

Associated Products

Product Description:

Methylcobalamin Solution for Injection, 1 mg/mL, 30 mL Multiple Dose Vial, For IM, SC or IV Use Only, Rx only, ASP Cares 2414 Babcock Rd Ste #106, San Antonio, TX 78229 NDC 72833-565-30

Product Quantity:

1605 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0260-2022

Code Information:

Lot: 082921565 BUD: 02/25/2022

Product Description:

Biotin Solution for Injection, 10 mg/mL, 30 mL Multiple Dose Vial, Sterile, For IM or IV use only, Rx only ASP Cares, 2414 Babcock Rd Ste #106, San Antonio, TX 78229 NDC 72833-0589-30

Product Quantity:

896 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0261-2022

Code Information:

Lot: 091721589 BUD: 03/16/2022

Product Description:

Ascorbic Acid Solution for Injection, 500 mg/mL, 50 mL Multiple Dose Vial, For IM, IV or SC Use Only, Rx only, ASP Cares, 2414 Babcock Rd Ste #106, San Antonio, TX 78229 NDC 72833-690-50

Product Quantity:

3077 vials

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0262-2022

Code Information:

Lots: 092321690 BUD: 03/22/2022; 093021690 BUD: 03/29/2022

Class II Drugs Event

Event ID:

89100

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

11/30/2021

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

12/02/2021

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Pfizer Inc.

235 East 42nd Street

New York NY United States

Distribution Pattern:

USA Nationwide

Associated Products

Product Description:

5% Dextrose Injection, USP, 50 mL ADD-Vantage Unit, Rx only, Distributed by Hospira, INC., Lake Forest, IL 60045 USA, NDC 0409-7100-68/0409-7100-66

Product Quantity:

765 bags

Reason for Recall:

Lack of sterility assurance: bag has the potential to leak.

Recall Number:

D-0265-2022

Code Information:

Lot: 4923608 Exp. 1MAY2022

Class III Drugs Event

Event ID:

89085

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

11/19/2021

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

12/01/2021

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Lupin Pharmaceuticals Inc.

Harborplace Tower 111 S Calvert St Fl 21st

Baltimore MD United States

Distribution Pattern:

nationwide within the United States

Associated Products

Product Description:

Tydemy (drospirenone, ethinyl estradiol & levomefolate calcium tablets, 3 mg/0.03 mg/0.451 mg and levomefolate calcium tablets, 0.451 mg), packaged in cartons containing 3 wallets of 28 Tablets each, Rx Only, Distributed by: Lupin Pharmaceuticals, Inc., Baltimore, Maryland 21202,

United States, Manufactured by: Lupin Limited, Pithampur, (M.P.) - 454775, India, 244896, The individual wallet NDC 68180-904-11 and the carton NDC 68180-904-13.

Product Quantity:

4113 cartons

Reason for Recall:

Subpotent Drug

Recall Number:

D-0264-2022

Code Information:

Lot #: L000784 and L000785, Exp. Date May 2022

Not Yet Classified Drugs Event

Event ID:

89033

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

11/09/2021

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:**Initial Firm Notification of Consignee or Public:**

Letter

Recalling Firm:

Sandoz Inc
100 College Rd W
Princeton NJ United States

Distribution Pattern:

CA, MS, OH and TX

Associated Products

Product Description:

Enoxaparin Sodium Injection, USP, 40 mg/0.4 mL syringes, 10 count carton, For Subcutaneous Injection, Rx Only, Manufactured for Sandoz Inc., Princeton, NJ 08540, NDC 00781-3246-64

Product Quantity:

45,036 cartons

Reason for Recall:

Temperature Abuse; temperature excursion during shipping

Recall Number:**Code Information:**

Lot #SAB06761A, exp 04/2023