

Enforcement Report - Week of July 5, 2023

Class II Drugs Event

Event ID:

92425

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

05/30/2023

Voluntary / Mandated:**Center Classification Date:**

06/29/2023

Initial Firm Notification of Consignee or Public:**Recalling Firm:**

SUN PHARMACEUTICAL INDUSTRIES INC

2 Independence Way

Princeton NJ United States

Distribution Pattern:

USA nationwide

Associated Products

Product Description:

Amphotericin B Liposome for Injection, 50mg/vial, Rx only, Distributed by Sun Pharmaceutical Industries, Inc. Cranbury, NJ 08512, Manufactured by Sun Pharmaceutical Medicare Limited, Baska Ujeti Road, Ujeti, Halol-389350, Gujarat, India, NDC 62756-0233-01

Product Quantity:

12960 vials

Reason for Recall:

Subpotent drug

Recall Number:

D-0891-2023

Code Information:

Lot # BAD0089A, Exp 01/2025; BAD0330A, Exp 07/2025

Class II Drugs Event

Event ID:

92453

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

06/05/2023

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

06/26/2023

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Homeocare Laboratories, Inc.

7 Odell Plz Ste 142-146

Yonkers NY United States

Distribution Pattern:

Product was distributed USA nationwide.

Associated Products

Product Description:

Kanjo Arnica Cream, 2 oz. gel & cream NDC# 80551-201-02 Mfg. For: Acutens, Inc. Sheridan, WY 82801

Product Quantity:

921 bottles

Reason for Recall:

cGMP deviations

Recall Number:

D-0880-2023

Code Information:

Lot # 2446, exp. date Mar-24

Product Description:

Arnica Cream, 2 oz. NDC# 61727-114-02 Mfg. For: Brazmedics, LLC New York, NY 10021

Product Quantity:

2,376 bottles

Reason for Recall:

cGMP deviations

Recall Number:

D-0881-2023

Code Information:

Lot # 2446, exp. Mar-24

Product Description:

Bebelyn Colics, 0.50 fl. oz. distributed by Pharmadel LLC New Castle, DE 19720 NDC# 55758-036-01

Product Quantity:

5,956 bottles

Reason for Recall:

cGMP deviations

Recall Number:

D-0882-2023

Code Information:

Lot # 2414, exp. date Sep-24

Product Description:

Babelyn Diarrhea, 0.50 fl. oz. distributed by Pharadel LLC NDC# 55758-035-01

Product Quantity:

5957 bottles

Reason for Recall:

cGMP deviations

Recall Number:

D-0883-2023

Code Information:

Lot # 2413, exp. date Sep-24

Product Description:

DoloEar, 0.50 fl. oz. distributed by Pharadel LLC NDC# 55758-035-15

Product Quantity:

12,850 bottles

Reason for Recall:

cGMP deviations

Recall Number:

D-0884-2023

Code Information:

Lot # 2423, exp. date Nov-24; 2445, exp. date Apr-25

Product Description:

SnoreStop Naso Spray Bulk, liquid distributed by Green Pharma NDC# 61152-199-99

Product Quantity:

200 liters/55 gallon drum

Reason for Recall:

cGMP deviations

Recall Number:

D-0885-2023

Code Information:

Lot # 2436, exp. date: unknown

Product Description:

StellaLife Peppermint Dental Rinse, 16 oz. bottles NDC# 69685-103-16

Product Quantity:

130,762/16 oz. bottles

Reason for Recall:

cGMP deviations

Recall Number:

D-0886-2023

Code Information:

Lot # 2357B,2333, exp. date Sep-2; 2367C, 2367D, exp. date Nov-23; 2367E, 2367F, exp. date Jan-24; 2395A, 2406, exp. date Feb-2; 2395B, exp. date Mar-24; 2395C, exp. date Apr-24

Product Description:

StellaLife Coconut Dental Rinse, 16 oz. bottles NDC# 69685-113-16

Product Quantity:

16,587 bottles

Reason for Recall:

cGMP deviations

Recall Number:

D-0887-2023

Code Information:

Lot # 2396, exp. date Apr-24

Product Description:

StellaLife Dental Spray, 1 fl. oz. NDC# 69685-101-02

Product Quantity:

40,034/1 fl. oz tubes

Reason for Recall:

cGMP deviations

Recall Number:

D-0888-2023

Code Information:

Lot # 2335, exp. date Sep-23; 2364, exp. date Nov-23; 2408, exp. date Feb-24

Product Description:

StellaLife Dental Gel, 1 fl. oz. NDC# 69685-102-02

Product Quantity:

38,105/1 fl. oz. tubes

Reason for Recall:

cGMP deviations

Recall Number:

D-0889-2023

Code Information:

Lot #2334, exp. date Sep-23; 2363, exp. date Nov-23; 2365, exp. date Jan-24

Product Description:

StellaLife Dental Gel, 1 fl. oz. NDC# 69685-112-01

Product Quantity:

33,109/1 fl. oz. tubes

Reason for Recall:

cGMP deviations

Recall Number:

D-0890-2023

Code Information:

Lot #2407, exp. date Feb-24; 2409A, exp. date Apr-24; 2409B, exp. date May-24

Class II Drugs Event

Event ID:

92494

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

06/12/2023

Voluntary / Mandated:**Center Classification Date:**

06/26/2023

Initial Firm Notification of Consignee or Public:**Recalling Firm:**

Ferring Pharmaceuticals Inc
100 Interpace Pkwy
Parsippany NJ United States

Distribution Pattern:

USA Nationwide

Associated Products

Product Description:

Endometrin (progesterone) Vaginal Insert 100mg, packaged in a carton of 21 vaginal inserts with 21 disposable vaginal applicators, Manufactured for: Ferring Pharmaceuticals Inc., Parsippany, NJ

Product Quantity:**Reason for Recall:**

cGMP deviations: potential for Microbial Contamination of Non-Sterile Products

Recall Number:

D-0879-2023

Code Information:

AA200A, AA201A, Exp. 12/2025

Class II Drugs Event

Event ID:

92524

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

06/16/2023

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

06/26/2023

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

The Harvard Drug Group
341 Mason Rd
La Vergne TN United States

Distribution Pattern:

Nationwide in the U.S.

Associated Products

Product Description:

Tramadol Hydrochloride Tablets, USP 50 mg, Unit Dose 100-Count Tablets Rx only, Manufactured by: Sun Pharmaceutical Industries Ltd. Survey No. 259/15, Dadra-396 191, (U.T. of D & NH), India. Distributed by: Sun Pharmaceutical Industries, Inc. Cranbury, NJ 08512, Distributed by: Major Pharmaceuticals Livonia, MI 48152 USA, NDC 0904-7179-61

Product Quantity:

3876 cartons

Reason for Recall:

Packaging defect: blister packaging inadequately sealed.

Recall Number:

D-0878-2023

Code Information:

Lot #: M04343, Exp. 04/2024