Enforcement Report - Week of February 17, 2021

Class II Drugs Event

Event ID:
87255

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/21/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/10/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Stanley Specialty Pharmacy Compounding and Wellness Center
3120 Latrobe Dr Ste 200
Charlotte NC United States

Distribution Pattern:
Distributed Nationwide in the USA

Associated Products

Product Description:
Lidocaine/Tetracaine (LIPO110)* 23%/7% Ointment 100 GMS per 4 ounce plastic ointment jar, Rx Only, Stanley Specialty Pharmacy 3120 Latrobe Dr. Suite 200 Charlotte, NC 28211

Product Quantity:
4400 grams (44 jars)

Reason for Recall:
Superpotent Drug. Lidocaine higher concentration than listed

Recall Number:
D-0252-2021

Code Information:
Lot: 195789 Exp. Apr. 17 2021

Class III Drugs Event

Event ID:
87233

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/28/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/08/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Accord Healthcare, Inc.
1009 Slater Rd Ste 210B
Durham NC United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Glycopyrrolate Injection, USP 0.4 mg/2 mL (0.2 mg/mL) 25 x 2 mL Single Dose Vials Rx Only, Manufactured for: Accord Healthcare, Inc. Durham, NC 27703, USA. Manufactured by: Intas Pharmaceuticals Limited, Ahmedabad-382 210, India NDC 16729-472-08 (Vial NDC 16729-472-30)

Product Quantity:
502 cartons

Reason for Recall:
Labeling; Label Mix-up; correctly labeled 2 mL vials were packaged into blister strips labeled for 1 mL vials

Recall Number:
D-0250-2021

Code Information:
Lot: M2013645 Exp. Aug. 2022

Class III Drugs Event

Event ID:
87260

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/05/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/09/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
SUN PHARMACEUTICAL INDUSTRIES INC
2 Independence Way
Princeton NJ United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Pantoprazole Sodium for Injection 40mg/vial For I.V. infusion only Distributed by: Sun Pharmaceutical Industries, Inc. Cranbury, NJ 08512 Manufactured by: Sun Pharmaceutical Industries Ltd. Halol-Baroda Highway, Halol-389 350, Gujarat, India NDC 62756-129-40

Product Quantity:
20,475 vials

Reason for Recall:
Failed Impurity/Degradation Specifications

Recall Number:
D-0251-2021

Code Information:
JKU3595A, JKU3596A, JKU3597A, and JKU3629A; Exp 02/2021

Not Yet Classified Drugs Event

Event ID:
87269

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/02/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:

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

Recalling Firm:
Apotex Corp.
2400 N Commerce Pkwy Ste 400
Weston FL United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Enoxaparin Sodium Injection, USP 100 mg/mL Single Dose Syringes with Automatic Safety Device For Subcutaneous Injection 10 x 1 mL Single Dose Syringes Rx Only, Manufactured by: Gland Pharma Ltd. Hyderabad, India Manufactured for: Apotex Corp. Weston, FL 33326 NDC 60505-0795-4 UPC 360505079544 (carton) NDC 60505-0795-1 UPC (01)10360505079510 (label)

Product Quantity:
6670 cartons

Reason for Recall:
Labeling; Label Mixup; syringe barrels may containing markings for 150 mg/mL (corresponding to 120 mg/0.8mL strength) instead of 100 mg/mL markings (corresponding to 100 mg/mL strength)

Recall Number:

Code Information:
Batch: CS008 Exp. 04/2022

Product Description:
Enoxaparin Sodium Injection, USP 120 mg/ 0.8 mL Single Dose Syringes with Automatic Safety Device For Subcutaneous Injection 10 x 0.8 mL Single Dose Syringes Rx Only,Manufactured by: Gland Pharma Ltd. Hyderabad, India Manufactured for: Apotex Corp. Weston, FL 33326 NDC 60505-0796-4 UPC 360505079543 (carton) NDC 60505-0796-0 UPC (01)10360505079602 (label)

Product Quantity:
6832 cartons

Reason for Recall:
Labeling; Label Mixup; syringe barrels may contain markings for 100 mg/mL (corresponding to 100 mg/mL strength) instead of 150 mg/mL (corresponding to 120 mg/0.8mL strength)

Recall Number:

Code Information:
Batch: CT003 Exp. 05/2022