Enforcement Report - Week of September 2, 2020

Class I Drugs Event

Event ID:
86095

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/22/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/21/2020

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Fresenius Kabi USA, LLC
3 Corporate Dr
Lake Zurich IL United States

Distribution Pattern:
U.S.A. Nationwide

Associated Products

Product Description:
Dexmedetomididne HCl in 0.9% Sodium Chloride Injection, 200 mcg per 50 mL (4 mcg per mL), for intravenous infusion, preservative free, 50 mL Single Dose Bottle, Rx only, Fresenius Kabi Lake Zurich, IL 60047, NDC 63323-671-05

Product Quantity:
25,100 bottles

Reason for Recall:
Cross Contamination with other products: trace amounts of lidocaine

Recall Number:
D-1537-2020

Code Information:
Lot #: 6121853, Exp 05/2021; 6122207, Exp 06/2021

Class I Drugs Event

Event ID:
86193

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/29/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/27/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
SCA Pharmaceuticals
755 Rainbow Rd Ste B
Windsor CT United States

Distribution Pattern:
Nationwide within the U.S.

Associated Products

Product Description:
Heparin Sodium 2,500 units in 0.9% Sodium Chloride 500 mL, Single Dose Container, Rx Only Injection for Intravenous Use (5 units/mL), SCA Pharmaceuticals, 755 Rainbow Rd., Windsor, CT 06095, NDC#: 70004-0655-44, Bar Code 70004065544.

Product Quantity:
1,097 Containers

Reason for Recall:
Cross Contamination with Other Product(s): containers labeled as having methylparaben and propylparaben as preservatives, actually contained undeclared benzyl alcohol and did not contain any parabens.

Recall Number:
D-1550-2020

Code Information:
Lot #: 1220019269, 1220019278, Exp 08/21/2020; 1220019386, Exp 08/25/2020.

Product Description:
Heparin Sodium 5,000 units in 0.9% Sodium Chloride 500 mL, Single Dose Container, Rx Only Injection for Intravenous Use (10 units/mL), SCA Pharmaceuticals, 755 Rainbow Rd., Windsor, CT 06095, NDC#: 70004-0650-44, Bar Code 70004065044.

Product Quantity:
366 Containers

Reason for Recall:
Cross Contamination with Other Product(s): containers labeled as having methylparaben and propylparaben as preservatives, actually contained undeclared benzyl alcohol and did not contain any parabens.

Recall Number:
D-1551-2020

Code Information:
Lot #: 1220019289, Exp 08/21/2020.

Product Description:
Heparin Sodium 5,000 units in 0.9% Sodium Chloride 1000 mL, Single Dose Container, Rx Only Injection for Intravenous Use (5 units/mL), SCA Pharmaceuticals, 755 Rainbow Rd., Windsor, CT 06095, NDC#: 70004-0650-46, Bar Code 70004065046.

Product Quantity:
1,527 Containers

Reason for Recall:
Cross Contamination with Other Product(s): containers labeled as having methylparaben and propylparaben as preservatives, actually contained undeclared benzyl alcohol and did not contain any parabens.

Recall Number:
D-1552-2020

Code Information:
Lot #: 1220019243, Exp 08/20/2020; 1220019439,1220019279, 1220019392, Exp 08/24/2020; 1220019488, Exp 08/26/2020.

Product Description:
Heparin Sodium 10,000 units in 0.9% Sodium Chloride 1000 mL, Single Dose Container, Rx Only Injection for Intravenous Use (10 units/mL), SCA Pharmaceuticals, 755 Rainbow Rd., Windsor, CT 06095, NDC#: 70004-0652-46, Bar Code 70004065246.

Product Quantity:
362 Containers

Reason for Recall:
Cross Contamination with Other Product(s): containers labeled as having methylparaben and propylparaben as preservatives, actually contained undeclared benzyl alcohol and did not contain any parabens.

Recall Number:
D-1553-2020

Code Information:
Lot #: 1220019457, Exp 08/24/2020

Class II Drugs Event

Event ID:
85814

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/03/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/24/2020

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Yusef Manufacturing Laboratories, LLC
Freeport West, F-4, #3
Clearfield UT United States

Distribution Pattern:
Shipped to one distributer located in Colorado

Associated Products

Product Description:
Rocky Mountain Sunscreen SPF30 Kiwi Flavored Lip Balm (Oxybenzone 5%, Meradimate 5%, Octinoxate 7.5%, Octisalate 5%) 0.15 Oz Tube, Rocky Mtn. Sunscreen, UPC 7 54018 20004 3

Product Quantity:
2,558 pieces

Reason for Recall:
Superpotent Drug: Active Ingredient Octisalate found at 15% above label claim.

Recall Number:
D-1540-2020

Code Information:
Part ID 9PRKY01, Batch #13852

Class II Drugs Event

Event ID:
86125

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/27/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/27/2020

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
RESOURCE RECOVERY & TRADING LLC
4275 Executive Sq Ste 200
La Jolla CA United States

Distribution Pattern:
AL, GA

Associated Products

Product Description:
Hand Sanitizer Disinfectant Gel 70% Ethyl Alcohol, packaged in 6.7 FL Oz. (200 mL) bottles, Distributed by: Access USA, Miami, FL 33308, UPC 650240025020

Product Quantity:
17,280 bottles

Reason for Recall:
cGMP deviations

Recall Number:
D-1548-2020

Code Information:
All lots.

Product Description:
HAND SANITIZER Non-sterile Solution 70% Topical Solution, packaged in 20L (5.28 Gal) plastic containers, Distributed by: Resource Recovery & Trading LLC 4275 Executive Square, Ste. 200 La Jolla, CA 92037, UPC 37710600013

Product Quantity:
115 bottles

Reason for Recall:
cGMP deviations

Recall Number:
D-1549-2020

Code Information:
All lots.

Class II Drugs Event

Event ID:
86190

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/10/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/21/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Aurobindo Pharma USA Inc.
279 Princeton Hightstown Rd
East Windsor NJ United States

Distribution Pattern:
Nationwide in the U.S.

Associated Products

Product Description:
Sulfamethoxazole and Trimethoprim Tablets, USP, 800 mg/160 mg Double Strength, 500 Tablets per bottle, Rx Only, Distributed by: Aurobindo Pharma USA, Inc. 279 Princeton-Hightstown Road, East Windsor, NJ 08520, Made in India, NDC: 65862-420-05.

Product Quantity:
5748 bottles

Reason for Recall:
Presence of Foreign Substance: product complaints were received by the firm for the presence of metal wire in the tablet(s).

Recall Number:
D-1535-2020

Code Information:
Lot #s: STSD19109-A, Exp. 05/31/2022; SP1D19083AA3, SP1D19084AA3, Exp. 08/31/2022.

Class II Drugs Event

Event ID:
86191

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/06/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/26/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Hetero Labs Limited (Unit V)
458 Surv No 439 - 441 Polepally Village
Badepalle India

Distribution Pattern:
Product was distributed to major wholesalers/distributors throughout the United States.

Associated Products

Product Description:
Losartan Potassium Tablets USP, 50 mg, 90 count bottles, Rx only, Manufactured for: Camber Pharmaceuticals, Inc., Piscataway, NJ by Hetero Labs, Limited, Mahabubragar, India

Product Quantity:
43,512 bottles

Reason for Recall:
Failed Tablet/Capsule Specification; complaint of bulging tablet

Recall Number:
D-1545-2020

Code Information:
Batch # LOA19357A, exp. date 09/2021

Class II Drugs Event

Event ID:
86202

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/10/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/25/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Par Pharmaceutical Inc.
1 Ram Ridge Rd
Chestnut Ridge NY United States

Distribution Pattern:
Product was distributed to 9 major distributors throughout the United States.

Associated Products

Product Description:
BusPIRone Hydrochloride Tablets, USP 7.5 mg NDC# 49884-725-01

Product Quantity:
11,347 bottles

Reason for Recall:
Failed Impurity /Degradation Specifications

Recall Number:
D-1542-2020

Code Information:
Lot # 32091002, exp. date May 2021

Class II Drugs Event

Event ID:
86243

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/14/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/21/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Hikma Pharmaceuticals USA Inc.
2 Esterbrook Ln
Cherry Hill NJ United States

Distribution Pattern:
Nationwide in the U.S.

Associated Products

Product Description:
Buprenorphine HCl Injection, 0.3 mg/mL, 1 mL vial, For Intramuscular or Intravenous Use Only, Rx Only, Manufactured by: Hikma Farmaceutica, Portugal S.A., Distributed by: Hikma Pharmaceuticals, Eatontown, NJ 07724, USA Inc., NDC: 0143-9246-01.

Product Quantity:
97,890 vials

Reason for Recall:
Sub-potent Drug: Out-of-Specification assay results found at 3 month stability testing.

Recall Number:
D-1533-2020

Code Information:
Lot #s: 2005023.1, 2005024.1, 2005025.1, Exp 02/28/2021

Class II Drugs Event

Event ID:
86246

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/30/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/24/2020

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Ecolab Inc
1 Ecolab Pl
Saint Paul MN United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Hand Sanitizer (Alcohol 80% v/v) topical solution, 55 US GAL (208 L) EcoLab Inc 1 EcoLab Place St. Paul, MN 55102 USA, NDC 47593-624-21

Product Quantity:
305 drums

Reason for Recall:
Discoloration and Presence of Foreign Substance

Recall Number:
D-1539-2020

Code Information:
Lot #: BP0D3091A0, BP0D3203A0, CR0D0553A0, CR0D0571A0, CR0D0577A0, CR0D0584A0, CR0E0482A0, CR0E0490A0, CR0E0499A0, CR0E0501A0, CR0E0520A0, FO0D0358A0, FO0D0440A0, FO0D0456A0, FO0D0464A0, FO0D0480A1, FO0D0490A0, FO0D0502A1, FO0D0517A1, FO0E0044A1, FO0E0061A1, FO0E0075A1, FO0E0094A0, FO0E0111A0, FO0E0119A1, FO0E0241A1, FO0E0256A1; Exp. Date April 2021

Class II Drugs Event

Event ID:
86280

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/19/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/25/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
BAYSHORE PHARMACEUTICALS
788 Morris Tpke Ste 200
Short Hills NJ United States

Distribution Pattern:
nationwide

Associated Products

Product Description:
Metformin Hydrochloride Extended-Release Tablets USP, 500 mg 1000 Tablets Rx Only Manufactured by: Beximco Pharmaceuticals, LTD. 126, Kathaldia, Tongi, Gazipur, 1711, Bangladesh NDC 76385-129-01

Product Quantity:
594 bottles

Reason for Recall:
CGMP Deviations

Recall Number:
D-1543-2020

Code Information:
Lot #18641; Exp. 05/2021

Product Description:
Metformin Hydrochloride Extended-Release Tablets USP, 750 mg 100 Tablets Rx Only Manufactured by: Beximco Pharmaceuticals, LTD. 126, Kathaldia, Tongi, Gazipur, 1711, Bangladesh NDC 76385-129-01

Product Quantity:
3984 bottles

Reason for Recall:
CGMP Deviations

Recall Number:
D-1544-2020

Code Information:
Lot #18657, Exp. 05/2021

Class III Drugs Event

Event ID:
86154

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/31/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/24/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
The Mentholatum Company
707 Sterling Dr
Orchard Park NY United States

Distribution Pattern:
Nationwide within the U.S.

Associated Products

Product Description:
Red Cross Oral Pain (Oral Anesthetic benzocaine 20%), Maximum Strength, 1/8 Fl. Oz. (3.7 mL) bottle with Cotton Pellets box packaged in a blister pack, Distributed by: Mentholatum Company, Orchard Park, NY 14127 NDC 10742-8902-1, UPC 3 10742 09509 8

Product Quantity:
31,732 Blister Packs

Reason for Recall:
Labeling; Not Elsewhere Classified: The Mentholatum Company is initiating a voluntary recall due to an error in the labeling of the cotton pellet box found within the Red Cross Oral Pain blister pack. The cotton pellet box states that the product contains "Natural Eugenol Oil" in which it does not.

Recall Number:
D-1541-2020

Code Information:
Item Number: 95090007 Lot #: 66572