Enforcement Report - Week of September 1, 2021

Class I Drugs Event

Event ID:
88220

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/02/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/26/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
KVK-Tech, Inc.
110 Terry Dr
Newtown PA United States

Distribution Pattern:
Product was distributed to one distributor who may have further distributed Nationwide in the USA.

Associated Products

Product Description:
Atovaquone Oral Suspension, USP, 750 mg/5 mL, 210 mL bottle, Rx Only, Mfd. By: KVK-Tech, Inc., Newtown, PA 18940, NDC 10702-223-21.

Product Quantity:
1,692 bottles

Reason for Recall:
Temperature abuse: the firm received customer complaints of unusual grittiness in the product.

Recall Number:
D-0772-2021

Code Information:
Batch # 16653A, 16654A, Exp 12/2022

Class I Drugs Event

Event ID:
88436

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/10/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/25/2021

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
SterRx, LLC
141 Idaho Ave
Plattsburgh NY United States

Distribution Pattern:
Nationwide in the US

Associated Products

Product Description:
Sodium Bicarbonate in 5% Dextrose Injection, 150 mEq per 1,000 mL (12.6 mg per mL), 1,000 mL bags, Rx only, SterRx, 141 Idaho Ave., Plattsburgh, NY 12903 NDC 70324-326-01

Product Quantity:
1098 bags

Reason for Recall:
Non-Sterility: firm's third party lab confirmed microbial contamination.

Recall Number:
D-0767-2021

Code Information:
Lot Number: BUP, exp. date 03/23/22

Class II Drugs Event

Event ID:
88303

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/20/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/26/2021

Initial Firm Notification of Consignee or Public:

Recalling Firm:
HIS ENTERPRISE INC
460 Bergen Blvd Ste 222
Palisades Park NJ United States

Distribution Pattern:
USA nationwide.

Associated Products

Product Description:
Miss Slim, capsules, packaged in 10-count and 30-count box, Distributed by : His Enterprise Made in USA UPC 742137605030

Product Quantity:

Reason for Recall:
Marketed without ANDA/NDA approval

Recall Number:
D-0770-2021

Code Information:
all lots

Class II Drugs Event

Event ID:
88326

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/23/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/20/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Professional Disposables International, Inc
400 Chestnut Ridge Rd
Woodcliff Lake NJ United States

Distribution Pattern:
Distributed Nationwide in the US

Associated Products

Product Description:
PDI Povidone-Iodine Prep Pad MEDIUM, 1 Prep Pad [2.0x2.5 in (5.1x6.4 cm)], Professional Disposables International Inc., Orangeburg, NY

10962-1376 Reorder No. B40600; UPC (01)00310819000147, NDC 10819-3883-1,

Product Quantity:
53588 cases

Reason for Recall:
SubPotent: Out of Specification

Recall Number:
D-0758-2021

Code Information:
Lot #'s EXP date 11800977, 2021-07-31; 11800978 2021-08-02; 11800979 2021-08-04; 11801123 2021-08-06; 11801124 2021-08-09; 11801125 2021-08-15; 11801126 2021-08-16; 11801228 2021-08-28; 11801230 2021-09-11; 11801231 2021-09-13; 11801232 2021-09-18; 11801234 2021-10-25; 11801417 2021-10-28; 11801418 2021-11-01; 11801419 2021-11-07; 11801420 2021-11-15; 11801421 2021-11-20; 11801709 2021-11-29; 11801710 2021-12-04; 11900195 2022-02-19; 11900196 2022-02-21; 11900197 2022-02-25; 11900370 2022-04-01; 11900372 2022-04-03; 11900371 2022-04-05; 11900647 2022-05-04; 11900623 2022-05-21; 11900624 2022-05-24; 11900646 2022-05-29; 11900967 2022-08-13; 11900968 2022-08-26; 11900969 2022-08-28; 11901043 2022-09-11; 11901044 2022-09-18; 11901318 2022-10-03; 11901330 2022-10-08; 11901331 2022-10-16; 11901446 2022-10-28; 11901447 2022-11-19; 11901448 2022-12-19; 11901739 2023-01-02; 11901752 2023-01-09; 12000045 2023-01-14; 12000048 2023-01-18; 12000046 2023-01-21; 12000047 2023-01-24; 12000333 2023-01-25; 12000675 2023-02-16; 12000334 2023-02-27; 12000335 2023-02-27; 12000336 2023-02-28; 12000676 2023-03-16; 12000815 2023-03-29; 12000816 2023-05-05; 12000914 2023-05-13; 12000915 2023-05-18; 12000951 2023-05-22; 12000950 2023-06-01; 12001366 2023-08-12; 12001367 2023-08-14; 12001368 2023-08-17; 12001370 2023-08-21; 12001369 2023-08-21; 12001371 2023-08-25; 12001372 2023-09-30; 12001818 2023-09-30; 12001820 2023-09-30; 12001819 2023-11-30; 12001821 2023-11-30; 12001822 2023-11-30; 12001972 2023-12-31; 12001973 2023-12-31; 12001974 2023-12-31; 12001975 2023-12-31; 12001976 2023-12-31; 12001977 2023-12-31; 12001978 2023-12-31; 12100080 2023-12-31; 12100081 2023-12-31; 12100082 2024-02-29; 12100084 2024-02-29; 12100447 2024-03-31; 11800978, 11800979, 11801123, 11801124, 11801125, 11801126, 11801228, 11801230, 11801231, 11801232, 11801234, 11801417,11801418, 11801419, 11801420, 11801421, 11801709, 11801710, 11900195, 11900196, 11900197, 11900370, 11900371, 11900372, 11900623, 11900624, 11900646, 11900647, 11900967, 11900968, 11900969, 11901043, 11901044, 11901318, 11901330, 11901331, 11901446, 11901447, 11901448, 11901739, 11901752, 12000045, 12000046, 12000047, 12000048, 12000333, 12000334, 12000335, 12000336, 12000675, 12000676, 12000815, 12000816, 12000914, 12000915, 12000950, 12000951, 12001366, 12001367, 12001368, 12001369, 12001370, 12001371, 12001372, 12001818, 12001819, 12001820, 12001821, 12001822, 12001972, 12001973, 12001974, 12001975, 12001976, 12001977, 12001978, 12100080, 12100081, 12100082, 12100084 and 12100447

Product Description:
PDI Povidone-Iodine Prep Pad Large, 1 Prep Pad, Professional Disposable International, Inc., Orangeburg, NY 10962 -1376 USA Reorder No C12400 NDC 10819-3883-3, UPC (01)00310819000154

Product Quantity:
1982 cases

Reason for Recall:
SubPotent: Out of Specification

Recall Number:
D-0759-2021

Code Information:
Lot #'s 11801215, EXP 2021-08-22; 11801504, EXP 2021-11-06; 11801717,EXP 2021-12-07; 11900421, EXP 2022-04-04; 11901076, EXP 2022-08-29; 11901571, EXP 2022-11-19; 12000388, EXP 2023-03-13; 12001533 EXP 2023-07-28; 12100459 EXP 2024-03-31;

Product Description:
PDI Povidine Iodine Swabstick (1's), 1 swabstick, Professional Disposable International, Inc. Orangeburg, NY 10962 -1376 Reorder No S41350 NDC 10819-3885-1, UPC (01)00310819000178.

Product Quantity:
41,105 cases

Reason for Recall:
SubPotent: Out of Specification

Recall Number:
D-0760-2021

Code Information:
Lot #'s 11900790, EXP 2021-07-25; 11900919, EXP 2021-07-28; 11900920, EXP 2021-08-12; 11900921, EXP 2021-08-15; 11901106, EXP 2021-08-27; 11901107, EXP 2021-08-30; 11901128, EXP 2021-09-05; 11901129, EXP 2021-09-12;11901249, EXP 2021-09-25; 11901250, EXP 2021-10-17; 11901391, EXP 2021-10-19; 11901392, EXP 2021-10-22; 11901438, EXP 2021-10-24; 11901439, EXP 2021-10-08; 11901457, EXP 2021-11-07; 11901541, EXP 2021-11-18; 11901603, EXP 2021-11-19; 11901604, EXP 2021-12-19; 11901669, EXP 2021-12-19; 11901670, EXP 2021-11-16; 11901702, EXP 2021-12-02; 11901703, EXP 2021-12-14; 12000082, EXP 2021-12-19; 12000083, EXP 2022-01-24; 12000118, EXP 2022-01-03; 12000119, EXP 2022-01-30; 12000249, EXP 2022-01-10; 12000250, EXP 2022-01-10; 12000348, EXP 2022-02-13; 12000349, EXP 2022-02-28; 12000398, EXP 2022-02-05; 12000456, EXP 2022-03-12; 12000457, EXP 2022-03-12; 12000683, EXP 2022-03-23; 12000684, EXP 2022-03-30; 12000685, EXP 2022-04-04; 12000922, EXP 2022-05-15; 12000923, EXP 2022-05-19; 12000927, EXP 2022-05-21; 12000989, EXP 2022-06-15; 12000990, EXP 2022-06-05; 12000991, EXP 2022-06-10; 12001154, EXP 2022-06-

26; 12001155, EXP 2022-06-24; 12001231, EXP 2022-07-26; 12001232, EXP 2022-07-21; 12001243, EXP 2022-07-03; 12001244, EXP 2022-07-04; 12001537, EXP 2022-08-31; 12001538, EXP 2022-08-31; 12001539, EXP 2022-08-31; 12001540, EXP 2022-09-30; 12001666, EXP 2022-09-30; 12001667, EXP 2022-09-30; 12001668, EXP 2022-09-30; 12001669, EXP 2022-09-30; 12001841, EXP 2022-10-31; 12001842, EXP 2022-10-31; 12001959, EXP 2022-10-31; 12002072, EXP 2022-11-30; 12100123, EXP 2023-02-28; 12100124, EXP 2023-02-28; 12100454, EXP 2023-03-31; 12100455, EXP 2023-03-31; 12100590, EXP 2023-04-30; 12100591, EXP 2023-04-30;

Product Description:
PDI Povidone-Iodine Swabstick (3's), 3 Swabsticks, Professional Disposable International, Inc., Orangeburg, NY 10962 -1376 Reorder No S41125 NDC 10819-3885-2, UPC (01)00310819000185

Product Quantity:
51,926 cases

Reason for Recall:
SubPotent: Out of Specification

Recall Number:
D-0761-2021

Code Information:
Lot #'s 11900761, EXP 2022-11-03; 11900917, EXP 2022-11-04; 11900918, EXP 2022-11-05; 11901008, EXP 2022-11-06; 11901009, EXP 2022-11-07; 11901124, EXP 2022-11-08; 11901125, EXP 2022-11-09; 11901126, EXP 2022-11-10;11901127, EXP 2022-11-11; 11901179, EXP 2022-11-12; 11901180, EXP 2022-11-13; 11901247, EXP 2022-11-14; 11901248, EXP 2022-11-15; 11901388, EXP 2022-11-16;11901389, EXP 2022-11-17; 11901390, EXP 2022-11-18; 11901419, EXP 2022-11-19; 11901420, EXP 2022-11-20; 11901480, EXP 2022-11-21; 11901558, EXP 2022-11-22;11901590, EXP 2022-11-23; 11901591, EXP 2022-11-24; 11901592, EXP 2022-11-25; 11901691, EXP 2022-11-26; 11901692, EXP 2022-11-27; 12000054, EXP 2022-11-28; 12000055, EXP 2022-11-29; 12000116, EXP 2022-11-30; 12000117, EXP 2022-12-01; 12000172, EXP 2022-12-02; 12000173, EXP 2022-12-03; 12000189, EXP 2022-12-04; 12000190, EXP 2022-12-05; 12000287, EXP 2022-12-06; 12000288, EXP 2022-12-07; 12000346, EXP 2022-12-08; 12000347, EXP 2022-12-09; 12000452, EXP 2022-12-10; 12000453, EXP 2022-12-11; 12000454, EXP 2022-12-12; 12000455, EXP 2022-12-13; 12000679, EXP 2022-12-14; 12000680, EXP 2022-12-15; 12000681, EXP 2022-12-16; 12000682, EXP 2022-12-17; 12000881, EXP 2022-12-18; 12000882, EXP 2022-12-19; 12000883, EXP 2022-12-20; 12000884, EXP 2022-12-21; 12001003, EXP 2022-12-22; 12001004, EXP 2022-12-23; 12001005, EXP 2022-12-24; 12001006, EXP 2022-12-25; 12001150, EXP 2022-12-26; 12001151, EXP 2022-12-27; 12001184, EXP 2022-12-28; 12001283, EXP 2022-12-29; 12001284, EXP 2022-12-30; 12001285, EXP 2022-12-31; 12001510, EXP 2023-01-01; 12001513, EXP 2023-01-02; 12001514, EXP 2023-01-03; 12001515, EXP 2023-01-04; 12001598, EXP 2023-01-05; 12001599, EXP 2023-01-06; 12001600, EXP 2023-01-07; 12001786, EXP 2023-01-08; 12001789, EXP 2023-01-09; 12001790, EXP 2023-01-10; 12001843, EXP 2023-01-11; 12001844, EXP 2023-01-12; 12001981, EXP 2023-01-13; 12001982, EXP 2023-01-14; 12002006, EXP 2023-01-15; 12002007, EXP 2023-01-16; 12002148, EXP 2023-01-17; 12002149, EXP 2023-01-18; 12100119, EXP 2023-01-19; 12100120, EXP 2023-01-20; 12100237, EXP 2023-01-21; 12100238, EXP 2023-01-22; 12100239, EXP 2023-01-23; 12100240, EXP 2023-01-24; 12100456, EXP 2023-01-25; 12100457, EXP 2023-01-26; 12100537, EXP 2023-01-27;

Product Description:
PDI Povidone-Iodine Cleansing Scrub Swabstick (1's), 1 Swabstick, Professional Disposable International, Inc., Orangeburg, NY 10962 -1376 Reorder No S48050, NDC 10819-3891-2, UPC (01)00310819000192.

Product Quantity:
5,477 cases

Reason for Recall:
SubPotent: Out of Specification

Recall Number:
D-0762-2021

Code Information:
Lot #'s 11901081, EXP 2023-04-04; 11901340, EXP 2023-04-05; 11901593, EXP 2023-04-06; 11901594, EXP 2023-04-07; 12000784, EXP 2023-04-08; 12000992, EXP 2023-04-09; 12001492, EXP 2023-04-10; 12001699, EXP 2023-04-11; 12100121, EXP 2023-04-12; 12100453, EXP 2023-04-13;

Product Description:
PDI Povidone-Iodide Cleansing Scrub Swabstick (3's), 3 Swabsticks, Professional Disposable International, Inc., Orangeburg, NY 10962 -1376, Reorder No S82125, NDC 10819-3891-3, UPC (01)00310819000208.

Product Quantity:
3,113 cases

Reason for Recall:
SubPotent: Out of Specification

Recall Number:
D-0763-2021

Code Information:
Lot #'s 11901080, EXP 2023-04-14; 11901339, EXP 2023-04-15; 11901755, EXP 2023-04-16; 12000016, EXP 2023-04-17; 12000397, EXP 2023-04-18; 12000987, EXP 2023-04-19; 12001578, EXP 2023-04-20; 12001814, EXP 2023-04-21;

Product Description:
PDI Duo-Swab Povidone-Iodine Cleansing Scrub Swabstick, (1's), Step 1, packaged as a) Step 1 Scrub, 1 Swabstick, NDC 10819-3891-1, b) Step 2 Prep, 1 Swabstick, NDC 10819-3890-1, Professional Disposable International, Inc., Orangeburg, NY 10962 -1376 Reorder No S23125, UPC (01)00318019000161

Product Quantity:
11,039 cases

Reason for Recall:
SubPotent: Out of Specification

Recall Number:
D-0764-2021

Code Information:
SKU S23125 Lot #'s 11900971, 11901517, 11901756, 12000199, 12000286, 12000459, 12000686, 12000751, 12001009, 12001316, 12001795, 12001809, 12001862, 12001863, 12002140, 12002141, 12100392 and 12100393

Class II Drugs Event

Event ID:
88371

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/12/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/20/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
ANHUI WELCOME FOREIGN TRADE CO.,LTD.
Changhe Kechuang Mansion Room 1602 No. 677 Changjiang West Rd
Hefei China

Distribution Pattern:
Distributed to: INTERNATIONAL NATURE NUTRACEUTICALS.INC. 39 BOWERY PMB 193,NEW YORK,NY 10002,U.S.A.

Associated Products

Product Description:
Pi yen chin Ophthalmic Redness Reliever Drops Made in China, Net Wt.: 10 ml (0.34 fl/oz) Exclusive U.S. Distributor: (Chinese writing)International Nature Nutraceuticals, Inc. New York, NY 10002 www.INNHERB.com. Konzon NDC 51367-008-10

Product Quantity:
63,750

Reason for Recall:
Labeling: Not Elsewhere Classified; The packaging states these are ophthalmic drops. However, they are manufactured as nasal drops and sterility cannot be assured.

Recall Number:
D-0755-2021

Code Information:
Lot 180901 Exp: 8/2021 Lot 190601 Exp: 5/2022 Lot 191201 Exp: 11/2022 Lot 200701 Exp:6/2023 Lot 201101 Exp: 10/2023 Lot 210501 Exp: 4/2024

Class II Drugs Event

Event ID:
88377

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/29/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/25/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Teligent Pharma, Inc.
105 Lincoln Avenue
Buena NJ United States

Distribution Pattern:
USA Nationwide

Associated Products

Product Description:
Erythromycin Topical Solution USP, 2%, 60mL bottle, Rx only, Teligent Pharma, Inc. Buena, NJ 08310, NDC 52565-027-59

Product Quantity:
7488 bottles

Reason for Recall:
Defective container: possibility for lack of seal integrity.

Recall Number:
D-0769-2021

Code Information:
Lot #: 14892, Exp 1/2022

Class II Drugs Event

Event ID:
88436

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/10/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/25/2021

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
SterRx, LLC
141 Idaho Ave
Plattsburgh NY United States

Distribution Pattern:
Nationwide in the US

Associated Products

Product Description:
Sodium Bicarbonate in 5% Dextrose Injection, 150 mEq per 1,000 mL (12.6 mg per mL), 1,000 mL bags, Rx only, SterRx, 141 Idaho Ave., Plattsburgh, NY 12903

Product Quantity:
3378 bags

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0768-2021

Code Information:
Lot Numbers: BTW, exp. date 03/08/22 BUI, exp. date 03/16/22

Class II Drugs Event

Event ID:
88457

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/06/2021

Center Classification Date:
08/20/2021

Recalling Firm:
XELLIA PHARMACEUTICALS USA, LLC
2150 E Lake Cook Rd
Buffalo Grove IL United States

Distribution Pattern:
Nationwide USA

Voluntary / Mandated:
Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:
Letter

Associated Products

Product Description:
Micafungin for Injection, 50 mg/vial, Single-Dose Vial, Sterile, Rx Only, For Intravenous Infusion Only, Manufactured for: Xellia Pharmaceuticals USA, LLC, Buffalo Grove, IL 60089. NDC 70594-036-01

Product Quantity:
9,161 vials 50 mg and 100 mg vials total

Reason for Recall:
Labeling; Incorrect or Missing Package Insert: The package insert provided with the product does not include all required sections approved for this product. This includes aspects of Adverse Reactions, Drug Interactions and Use in Specific Populations.

Recall Number:
D-0756-2021

Code Information:
Lot 467111, exp 1/2023

Product Description:
Micafungin for Injection, 100 mg/vial, Single-Dose Vial, Sterile, Rx Only, For Intravenous Infusion Only, Manufactured for: Xellia Pharmaceuticals USA, LLC, Buffalo Grove, IL 60089. NDC 70594-037-01

Product Quantity:
9,161 (50mg and 100 mg vials total)

Reason for Recall:
Labeling; Incorrect or Missing Package Insert: The package insert provided with the product does not include all required sections approved for this product. This includes aspects of Adverse Reactions, Drug Interactions and Use in Specific Populations.

Recall Number:
D-0757-2021

Code Information:
Lot 467111, exp 1/2023

Class II Drugs Event

Event ID:
88474

Status:
Ongoing

Recall Initiation Date:
08/13/2021

Center Classification Date:
08/24/2021

Recalling Firm:
SigmaPharm Laboratories LLC
3375 Progress Dr
Bensalem PA United States

Distribution Pattern:
Disttibuted Nationwide in the USA.

Product Type:
Drugs

Date Terminated:

Voluntary / Mandated:
Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:
Letter

Associated Products

Product Description:
Sodium Phenylbutyrate POWDER, 250 grams bottle, Rx Only, Sigmapharm Laboratories, LLC Bensalem, PA 19020 NDC 42794-086-14 UPC Code# 3 42794 086 14 4

Product Quantity:
1,993 bottles

Reason for Recall:
Failed Impurities Specifications: Out of Specification impurity results obtained during routine testing.

Recall Number:
D-0766-2021

Code Information:
Lot Numbers: 1813001, 1813101, 1813201, EXP. May 2023; 1822601, 1822701, EXP Nov 2023; 1905701, 1905801, 1906501, 1906601, 1906701, EXP May 2024

Class II Drugs Event

Event ID:
88489

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/30/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/23/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Custopharm, Inc.
2325 Camino Vida Roble
Carlsbad CA United States

Distribution Pattern:
Distributed Nationwide in the USA

Associated Products

Product Description:
FLUDARABINE PHOSPHATE FOR INJECTION, USP, 50 mg per vial, Single dose vial, Rx Only, Mfd for: Leucadia Pharmaceuticals Carlsbad, CA 92011 U.S.A, NDC 24201-237-01

Product Quantity:
19,384 vials

Reason for Recall:
Lack of Assurance of Sterility: the manufacturing firm had microbial recoveries during environmental monitoring in aseptic areas of manufacturing.

Recall Number:
D-0765-2021

Code Information:
Lot# 31327913C, Exp. Date 10/2022

Class II Drugs Event

Event ID:
88505

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/19/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/26/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Eli Lilly & Company
839 S Delaware St
Indianapolis IN United States

Distribution Pattern:
USA Nationwide

Associated Products

Product Description:
Trulicity (dulaglutide), 0.75 mg/0.5 mL, 4 Single-Dose Pens per box, Rx only, Eli Lilly and Company, Indianapolis, IN 46285, NDC 0002-1433-80

Product Quantity:
119,539 4-packs

Reason for Recall:
Labeling: Label error on declared strength - autoinjector devices labeled as 0.75 mg / 0.5 mL actually contain 1.5 mg / 0.5 mL of product.

Recall Number:
D-0773-2021

Code Information:
Lot number: D396436C

Class II Drugs Event

Event ID:
88536

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/17/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/20/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
RemedyRepack Inc.
625 Kolter Dr Ste 4
Indiana PA United States

Distribution Pattern:
Product was distributed to two medical facilities in VA and FL.

Associated Products

Product Description:
Carvedilol 25 mg, 180-count bottle, Rx only, Manufactured by Zydus Pharm, Pennington, NJ 08534, NDC 68382-0095-05, Repackaged by RemedyRepack Inc., Indiana, PA 15701, NDC 70518-1826-01

Product Quantity:
4

Reason for Recall:
A 500 count bottle of Carvedilol 25 mg tablets contained two Paroxetine Tablets, 40 mg. Product was repackaged into 180 count bottles.

Recall Number:
D-0754-2021

Code Information:
Lot # B1273286-071521, Exp 07/31/2022

Class III Drugs Event

Event ID:
88402

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/05/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/26/2021

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
USA nationwide

Associated Products

Product Description:
Bleomycin for Injection, USP, packaged in 15 units per single dose vial, Rx only, Manufactured by Thymoorgan Pharmazie GmbH Schiffgraben 23, 38690 Gosfar, Germany Distributed by Hikma USA Inc. Berkeley Heights, NJ 07922, NDC 0143-9240-01

Product Quantity:
1,152 vials

Reason for Recall:
Labeling: Not elsewhere classified: Mislabeling

Recall Number:
D-0771-2021

Code Information:
BL0018