Enforcement Report - Week of December 16, 2020

Class I Drugs Event

Event ID:
86766

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/17/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/08/2020

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
USA Nationwide

Associated Products

Product Description:
Dexmedetomidine HCl in 0.9% Sodium Chloride Injection, 200 mcg / 50 mL (4 mcg / mL), 50 mL Single Dose Bottle, Rx only, Fresenius Kabi, Lake Zurich, IL 60047, NDC 63323-671-05

Product Quantity:
13,525 bottles

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

Recall Number:
D-0120-2021

Code Information:
Lot #: 6123925

Class II Drugs Event

Event ID:
86327

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/25/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/07/2020

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Asiaticon, SA de CV
Conkal No. 62
Ciudad De Mexico Mexico

Distribution Pattern:
Distributed in Texas

Associated Products

Product Description:
V-Klean Hand Sanitizer Gel Alcohol 70% packaged as a)8.5 fl oz (250 ml), UPC 7 16053 70499 3; b) 16.9 fl oz (500 ml), UPC 7 16053 70499 3; c) 33.8 fl. oz. (1000 ml) bottles: 716053704993; Manufactured by: Asiaticon S.A. de C.V. Conkar 62, Jardines del Ajusco. Tlalpan Cuidad de Mexico. 14200 ;

Product Quantity:
111,500 units

Reason for Recall:
Lack of CGMPs:

Recall Number:
D-0116-2021

Code Information:
All lots.

Product Description:
Protz real protection Antibacterial Hand Sanitizer, Ethyl Alcohol 70%, 13.5 FL OZ (400 mL), Distributed by: Safety-Med Products, Inc. Burlington, WI 53105 Made in Mexico by Asiaticon S.A. de C.V. Conkal No. 62, Mexico, Ciudad de Mexico 14200, Mexico NDC: 75192-600-02 UPC 7 503019 005002

Product Quantity:
111,500 units

Reason for Recall:
Lack of CGMPs:

Recall Number:
D-0117-2021

Code Information:
All lots.

Class II Drugs Event

Event ID:
86749

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/17/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/09/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Shilpa Medicare Limited
S-20 To S-26, Pharm. Formulation Sez Tsiic, Green Industrial Park
Polepally, Jadcherla India

Distribution Pattern:
Nationwide in the U.S.

Associated Products

Product Description:
Busulfan Injection 60 mg/10 mL (6 mg/mL), For Intravenous Infusion Only, Must be diluted before use, Single Dose Vial, Sterile, Cytotoxic Agent, Rx Only, 10 mL vial, Manufactured by: Shilpa Medicare Limited, India, Distributed by: Armas Pharmaceuticals, Inc., Manalapan, NJ 07726, Vial NDC 72485-210-01, Carton NDC 72485-210-08.

Product Quantity:
2,064 vials

Reason for Recall:
GMP Deviations

Recall Number:
D-0121-2021

Code Information:
Lot #: 7S10008B, Exp. 12/31/2020

Product Description:
Azacitidine for Injection 100 mg/vial, For Subcutaneous and Intravenous Use Only, Rx Only, One Single Dose Vial, Cytotoxic Agent, Manufactured by: Shilpa Medicare Limited, India, Distributed by: Celltrion USA, Inc., Jersey City, NJ 07302, NDC 72485-201-01.

Product Quantity:
52,234 vials

Reason for Recall:
GMP Deviations

Recall Number:
D-0122-2021

Code Information:
Lot #s: 7S10115A, Exp. 07/31/2021; 7S10143A, 7S10182B, Exp. 09/30/2021; 7S10185A, Exp. 10/31/2021; 7S10255A, 7S10256A, 7S10263A, Exp. 11/30/2021; 7T10028A, 12/31/2021; 7T10040A, Exp. 01/31/2022.

Product Description:
Azacitidine for Injection 100 mg/vial, For Subcutaneous and Intravenous Use Only, Rx Only, One Single Dose Vial, Cytotoxic Agent, Manufactured by: Shilpa Medicare Limited, India, Distributed by: Celltrion USA, Inc., Jersey City, NJ 07302, NDC 72606-558-01.

Product Quantity:
6,560 vials

Reason for Recall:
GMP Deviations

Recall Number:
D-0123-2021

Code Information:
Lot #: 7S10227A, Exp. 10/31/2021

Product Description:
Imatinib Mesylate Tablets 100 mg, Rx Only, 90-count Bottle, Manufactured by: Shilpa Medicare Limited, India, Distributed by: Armas Pharmaceuticals Inc., Manalapan, NJ 07726, NDC 72485-202-90.

Product Quantity:
2611 bottles

Reason for Recall:
GMP Deviations

Recall Number:
D-0124-2021

Code Information:
Lot #s: 7S10033B, 7S10033A, 7S10031A, Exp. 02/28/2021.

Product Description:
Imatinib Mesylate Tablets 400 mg, Rx Only, 30-count Bottle, Manufactured by: Shilpa Medicare Limited, India, Distributed by: Armas Pharmaceuticals Inc., Manalapan, NJ 07726, NDC 72485-203-30.

Product Quantity:
4166 bottles

Reason for Recall:
GMP Deviations

Recall Number:
D-0125-2021

Code Information:
Lot #s: 7S10032A, 7S10034A, Exp. 02/28/2021

Product Description:
Docetaxel Injection USP 160 mg/8mL (20 mg/mL), For Intravenous Infusion Only, Rx Only, 8 mL Single Use Vial, Cytotoxic Agent, Manufactured by:

Shilpa Medicare Limited, India, Distributed by: Armas Pharmaceuticals, Inc., Manalapan, NJ 07726, NDC 72485-216-08.

Product Quantity:
2008 vials

Reason for Recall:
GMP Deviations

Recall Number:
D-0126-2021

Code Information:
Lot #: 7S10185A, Exp. 10/31/2021

Class III Drugs Event

Event ID:
86867

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/20/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/09/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Novocol Pharmaceutical of Canada, Inc.
25 Wolseley Crt
Cambridge Canada

Distribution Pattern:
U.S. nationwide.

Associated Products

Product Description:
Scandonest 3% Plain (Mepivacaine Hydrochloride 3% without Vasoconstrictor), packaged in cartons of 50 cartridges (1.7 mL each), Rx only, Manufactured for SEPTODONT, Inc., Louisville, CO 80027, by Novocol Pharmaceutical of Canada, Inc., Cambridge, ON N1R 6X3, Canada, NDC 0362-1098-90

Product Quantity:
15,398 cartridges

Reason for Recall:
Labeling: Label mix-up

Recall Number:
D-0127-2021

Code Information:
Batch # D03050E, D03032F, Exp 28-Feb-2022; D02983D, Exp 30-Nov-2021; D02865C, Exp 31-Aug-2021; D02894G, Exp 30-Sep-2021; D02701G, Exp 31-Jan-2021; D02766E, Exp 30-Apr-2021