Enforcement Report - Week of March 3, 2021

Class I Drugs Event

Event ID:
86998

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/07/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/19/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
CareFusion 213, LLC
1550 Northwestern Dr
El Paso TX United States

Distribution Pattern:
Distributed in Puerto Rico and Oman

Associated Products

Product Description:
BD ChloraPrep Clear, 2% w/v chlorhexidine gluconate (CHG) and 70% v/v isopropyl alcohol (IPA) Sterile Solution, 0.10 fl. oz. (3 ml) each, 25 Applicators in carton, CareFusion 213, LLC, El Paso, TX 79912, subsidiary of Becton, Dickinson and Co, NDC 54365-400-32 REF 930400

Product Quantity:
988 cartons

Reason for Recall:
Non-sterility: Product is being recalled to climatic Zone IV regions of the world where at the labeled storage conditions of 30*C/75% Relative Humidity for more than 6 months, there is the potential for growth of Aspergillus penicillioides, a type of fungus, resulting in a breach of the package integrity.

Recall Number:
D-0265-2021

Code Information:
All lots including but not limited to the following lots distributed in Zone IV: Lot # 0161217 Exp. 05/31/2023; 0211068 Exp. 07/31/2023; 0176660 Exp. 06/30/2023; 0188805 Exp. 06/30/2023; 0175874 Exp. 06/30/2023; 0151977 Exp. 05/31/2023; 0149328 Exp. 04/30/2023; 0085419 Exp. 03/31/2023

Product Description:
ChloraPrep With Tint 2% w/v chlorhexidine gluconate (CHG) and 70% v/v isopropyl alcohol (IPA) Non-Sterile Solution - Hi-Lite Orange, 0.10 fl. oz. (3 ml) each, 25 applicators in carton, CareFusion El Paso, TX 79912, NDC 054365-400-11 Cat. No. 260415

Product Quantity:
36 cartons

Reason for Recall:
Microbial Contamination of Non-Sterile Products:Product is being recalled to climatic Zone IV regions of the world where at the labeled storage conditions of 30*C/75% Relative Humidity for more than 6 months, there is the potential for growth of Aspergillus penicillioides, a type of fungus, resulting in a breach of the package integrity.

Recall Number:
D-0266-2021

Code Information:
All lots including but not limited to the following lots distributed in Zone IV: Lot # 0038209, Exp. 01/31/2023; 0098528, Exp. 02/28/2023.

Product Description:
ChlroraPrep One-Step 2% w/v chlorhexidine gluconate (CHG) and 70% v/v isopropyl alcohol (IPA) Non-Sterile Solution -Clear, 0.10 fl. oz. (3ml) each, 25 applicators per carton. CareFusion El Paso, TX 79912, NDC 054365-400-01 Cat. No. 260400

Product Quantity:
280 cartons

Reason for Recall:
Non-sterility: Product is being recalled to climatic Zone IV regions of the world where at the labeled storage conditions of 30*C/75% Relative Humidity for more than 6 months, there is the potential for growth of Aspergillus penicillioides, a type of fungus, resulting in a breach of the package integrity.

Recall Number:
D-0267-2021

Code Information:
All lots including but not limited to the following lot distributed in Zone IV: Lot # 0192894, Exp. 06/30/2023; 9080812 Exp 03/31/2022

Product Description:
BD ChloraPrep Hi-Lite Orange 2% w/v chlorhexidine gluconate (CHG) and 70% v/v isopropyl alcohol (IPA), Sterile Solution, 0.01 fl. oz. (3 ml) each, 25 Applicators in carton, CareFusion El Paso, TX 79912, subsidiary of Becton, Dickinson and Co., NDC 54365-400-33 REF 930415

Product Quantity:
400 cartons

Reason for Recall:
Non-sterility: Product is being recalled to climatic Zone IV regions of the world where at the labeled storage conditions of 30*C/75% Relative Humidity for more than 6 months, there is the potential for growth of Aspergillus penicillioides, a type of fungus, resulting in a breach of the package integrity.

Recall Number:
D-0268-2021

Code Information:
All lots including but not limited to the following lots distributed in Zone IV: Lot # 0107872, Exp. 04/30/2023; 0108556, Exp. 04/30/2023; 0148278, Exp. 04/30/2023; 0151978, Exp. 05/31/2023; 0155534, Exp. 05/31/2023; 0157085, Exp. 05/31/2023; 0160618, Exp. 05/31/2023; 0167907, Exp. 05/31/2023.

Class I Drugs Event

Event ID:
87101

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/17/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/19/2021

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
NDAL Mfg Inc.
23745 Spectacular Bid Ln
Monterey CA United States

Distribution Pattern:
Distributed Nationwide in the USA and Hong Kong

Associated Products

Product Description:
ManukaGuard Medical Grade Manuka Honey Allercleanse Nasal Spray, 1.3 FL OZ (40mL) bottle, 270 measured sprays, Distributed by Ndal Laboratories, 449 Alvarado St., Monterey, CA 93940 (bottle); NDAL MFG Inc., 80 Garden Court, Suite 100, Monterey, CA 93940 (carton); UPC 8 58631 00212 8. the Alvarado St. is for the bottle by putting "(bottle); NDAL MFG Inc., 80 Garden Court, Suite 100, Monterey, CA 93940 (carton); UPC 8 58631 00212 8." (according to the label)

Product Quantity:
4265 bottles

Reason for Recall:
Microbial Contamination of Non-Sterile Products: Product confirmed to have yeast

Recall Number:
D-0269-2021

Code Information:
LOT # 2010045; Best Before 10 2023

Class I Drugs Event

Event ID:
87224

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/27/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/22/2021

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

Recalling Firm:
Meitheal Pharmaceuticals Inc
8700 W Bryn Mawr Ave Ste 600
Chicago IL United States

Distribution Pattern:
Nationwide USA

Associated Products

Product Description:
Cisatracurium Besylate Injection, USP, 10mg per 5mL (2 mg per mL), Single-Dose Vial (NDC 71288-712-05), packaged as 10 x 5 mL Single-Dose Vials per carton (NDC 71288-712-06), Rx only, Mfd. for Meitheal Pharmaceuticals, Chicago, IL 60631.

Product Quantity:
34,860 vials

Reason for Recall:
Labeling: Label mix-up: Carton of Cisatracurium Besylate Injection, USP was observed to contain ten vials mislabeled as Phenylephrine Hydrochloride Injection, USP, but confirmed to contain Cisatracurium

Recall Number:
D-0286-2021

Code Information:
Lot C11507A

Class II Drugs Event

Event ID:
87298

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/10/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/21/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Teva Pharmaceuticals USA
400 Interpace Pkwy
Parsippany NJ United States

Distribution Pattern:
Product was distributed nationwide in the USA and Puerto Rico.

Associated Products

Product Description:
Dacarbazine for Injection USP, 200 mg, Single Use Vial (NDC 0703-5075-01), packaged in 10X20 ML Single Use Vials per tray (NDC 0703-5075-03); Rx only, TEVA Pharmaceuticals USA, INC., North Wales, PA 19454.

Product Quantity:
50 vials

Reason for Recall:
Lack of Assurance of Sterility: manufacturing areas for the recalled products exceeded acceptance levels for microbial recovery leading to a lack of sterility assurance for these sterile injectable products.

Recall Number:
D-0271-2021

Code Information:
Lot # 31326582B, exp. date 02/2022; Lot # 31326964B, exp. date 04/2022

Product Description:
Desmopressin Acetate Injection USP, 4 mcg/mL, 1 mL Preserved Vial (NDC 0703-5051-01), packaged in 10X1 mL Vials per Tray (NDC 0703-5051-03), Rx only, Teva Pharmaceuticals USA, Inc., North Wales, PA 19454.

Product Quantity:
2,577 vials

Reason for Recall:
Lack of Assurance of Sterility: manufacturing areas for the recalled products exceeded acceptance levels for microbial recovery leading to a lack of sterility assurance for these sterile injectable products.

Recall Number:
D-0272-2021

Code Information:
Lot # 31326669B, exp. date 03/2021

Product Description:
Sterile Diluent for Epoprostenol Sodium for Injection, 50 mL vial (NDC 0703-9258-01), packaged in 2X50ML per tray (NDC 0703-9258-09), Rx only, TEVA PHARMACEUTICALS USA, INC., North Wales, PA 19454.

Product Quantity:
26,373 vials

Reason for Recall:
Lack of Assurance of Sterility: manufacturing areas for the recalled products exceeded acceptance levels for microbial recovery leading to a lack of sterility assurance for these sterile injectable products.

Recall Number:
D-0273-2021

Code Information:
Lot # 31326845B, exp. date 03/2021 Lot # 31327844B, exp. date 09/2021

Product Description:
Epoprostenol Sodium for Injection, 0.5 mg/vial (500,000 ng), 1X10ML vial, Rx only, Teva Pharmaceuticals USA, Inc., North Wales, PA 19454, NDC 0703-1985-01.

Product Quantity:
12,629 vials

Reason for Recall:
Lack of Assurance of Sterility: manufacturing areas for the recalled products exceeded acceptance levels for microbial recovery leading to a lack of sterility assurance for these sterile injectable products.

Recall Number:
D-0274-2021

Code Information:
Lot # 31327537B, exp. date 09/2021

Product Description:
MethylPREDNISolone Acetate Injectable Suspension USP, 40 mg/mL, 1 mL Single-Dose Vial (NDC 0703-0031-01), packaged in 25X1ML per tray (NDC 0703-0031-04), Rx only, TEVA PHARMACEUTICALS USA, INC., North Wales, PA 19454.

Product Quantity:
5,086 vials

Reason for Recall:
Lack of Assurance of Sterility: manufacturing areas for the recalled products exceeded acceptance levels for microbial recovery leading to a lack of sterility assurance for these sterile injectable products.

Recall Number:
D-0275-2021

Code Information:
Lot # 31327742B, exp. date 02/2021 Lot # 31328408B, exp. date 07/2021

Product Description:
Leucovorin Calcium for Injection, USP, 100 mg/vial, Single-Dose Vial, Rx only, Teva Parenteral Medicines, Inc., Irvine, CA 92618, NDC 0703-5140-01.

Product Quantity:
248,565 vials

Reason for Recall:
Lack of Assurance of Sterility: manufacturing areas for the recalled products exceeded acceptance levels for microbial recovery leading to a lack of sterility assurance for these sterile injectable products.

Recall Number:
D-0276-2021

Code Information:
Lot # 31326364B, exp. date 01/2022 31327120B, exp. date 05/2022 31327963B, exp. date 10/2022

Product Description:
Metoclopramide Injection USP, 10 mg/2 mL (5 mg/mL), 2 mL Single-Use Vial NDC 0703-4502-01), packaged in 25 x 2 mL Single-Use Vials per tray (NDC 0703-4502-04), Rx only, Teva Parenteral Medicines, Inc., Irvine, CA 92618.

Product Quantity:
29,357 vials

Reason for Recall:
Lack of Assurance of Sterility: manufacturing areas for the recalled products exceeded acceptance levels for microbial recovery leading to a lack of sterility assurance for these sterile injectable products.

Recall Number:
D-0277-2021

Code Information:
Lot # 31325042B, exp. date 06/2021 31325336B, exp. date 07/2021 31326042B, exp. date 10/2021 31326137B, exp. date 11/2021 31326230B, exp. date 12/2021 31323816B, exp. date 02/2021

Product Description:
Toposar (etoposide injection USP), 1 gram/50 mL (20 mg/mL), 50 mL Multiple-dose Vial, Rx only, Teva Pharmaceuticals USA, Inc., North Wales, PA 19454, NDC 0703-5657-01.

Product Quantity:
4,806 vials

Reason for Recall:
Lack of Assurance of Sterility: manufacturing areas for the recalled products exceeded acceptance levels for microbial recovery leading to a lack of sterility assurance for these sterile injectable products.

Recall Number:
D-0278-2021

Code Information:
Lot # 31327600B, exp. date 08/2022

Product Description:
Vecuronium Bromide for Injection, 10 mg, 1 mg/mL when reconstituted to 10 mL, 10 mL Vial (NDC 0703-2914-01), packaged in 10 x 10 mL Vials per tray (NDC 0703-2914-03), Rx only, Teva Pharmaceuticals USA, Inc., North Wales, PA 19454.

Product Quantity:
33,6697 vials

Reason for Recall:
Lack of Assurance of Sterility: manufacturing areas for the recalled products exceeded acceptance levels for microbial recovery leading to a lack of sterility assurance for these sterile injectable products.

Recall Number:
D-0279-2021

Code Information:
Lot # 31325712B, exp. date 12/2021 31326320B, exp. date 02/2022 31326457B, exp. date 02/2022 31327880B, exp. date 10/2022

Product Description:
Epoprostenol Sodium for Injection, 1.5 mg/vial (1,500,000 ng), 10 mL vial, Rx only, Teva Pharmaceuticals USA, Inc., North Wales, PA 19454, NDC 0703-1995-01.

Product Quantity:
12,609 vials

Reason for Recall:
Lack of Assurance of Sterility: manufacturing areas for the recalled products exceeded acceptance levels for microbial recovery leading to a lack of sterility assurance for these sterile injectable products.

Recall Number:
D-0280-2021

Code Information:
Lot # 31326456B, exp. date 02/28/2021

Product Description:
MethylPREDNISolone Acetate Injectable Suspension USP, 80 mg/mL, 1 mL Single-Dose Vial (NDC 0703-0051-01), packaged in 25X1ML vials per tray (NDC 0703-0051-04), Rx only, Teva Pharmaceuticals USA, Inc., North Wales, PA 19454.

Product Quantity:
5,378 vials

Reason for Recall:
Lack of Assurance of Sterility: manufacturing areas for the recalled products exceeded acceptance levels for microbial recovery leading to a lack of sterility assurance for these sterile injectable products.

Recall Number:
D-0281-2021

Code Information:
Lot # 31327909B, exp. date 04/2021 Lot # 31328352B, exp. date 07/2021

Product Description:
MethylPREDNISolone Acetate Injectable Suspension USP, 400 mg/10 mL (40 mg/mL), 10 mL Multiple-Dose Vial, Rx only, Teva Pharmaceuticals USA, Inc., North Wales, PA 19454, NDC 0703-0045-01.

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility: manufacturing areas for the recalled products exceeded acceptance levels for microbial recovery leading to a lack of sterility assurance for these sterile injectable products.

Recall Number:
D-0282-2021

Code Information:
Lot # 31327725B, exp. date 02/2021 Lot # 31327906B, exp. date 03/2021

Product Description:
MethylPREDNISolone Acetate Injectable Suspension USP, 200 mg/5 mL (0 mg/mL), 5 mL Multiple-Dose Vial, Rx only, Teva Pharmaceuticals USA, Inc., North Wales, PA 19454, NDC 0703-0043-01.

Product Quantity:
6,710 vials

Reason for Recall:
Lack of Assurance of Sterility: manufacturing areas for the recalled products exceeded acceptance levels for microbial recovery leading to a lack of

sterility assurance for these sterile injectable products.

Recall Number:
D-0283-2021

Code Information:
Lot # 31328768B, exp. date 09/2021

Product Description:
MethylPREDNISolone Acetate Injectable Suspension USP, 400 mg/5 mL (80 mg/mL), 5 mL Multiple-Dose Vial, Rx only, Teva Pharmaceuticals USA, Inc., North Wales, PA 19454, NDC 0703-0063-01.

Product Quantity:
15,043 vials

Reason for Recall:
Lack of Assurance of Sterility: manufacturing areas for the recalled products exceeded acceptance levels for microbial recovery leading to a lack of sterility assurance for these sterile injectable products.

Recall Number:
D-0284-2021

Code Information:
Lot # 31327738B, exp. date 03/2021

Product Description:
Leucovorin Calcium for Injection, USP, 350 mg/vial, Rx only, labeled as a) Teva Parenteral Medicines, Inc., Irvine, CA 92618, and b) Manufactured By: Teva Pharmaceuticals USA, Inc., North Wales, PA 19454, novaplus+, NDC 0703-5145-01.

Product Quantity:
705,745 vials

Reason for Recall:
Lack of Assurance of Sterility: manufacturing areas for the recalled products exceeded acceptance levels for microbial recovery leading to a lack of sterility assurance for these sterile injectable products.

Recall Number:
D-0285-2021

Code Information:
Lot # a) 31324653B, exp. date 03/2021; 31326066B, exp. date 11/2021; 31326428B, exp. date 02/2022; 31327949B, exp. date 10/2022; 31327995B, exp. date 10/2022; 31328031B, exp. date 11/2022; 31328217B, exp. date 12/2022; 31328325B, exp. date 12/2022; 31328425B, exp. date 07/2021; Lot # b) 31324480B, exp. date 02/2021; Lot # 31327396B, exp. date 08/2022

Class II Drugs Event

Event ID:
87339

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/17/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/24/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Dr. Reddy's Laboratories, Inc.
107 College Rd E
Princeton NJ United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Imatinib Mesylate Tablets 100mg, packaged as a) 90-count bottles (NDC 43598-344-90); and b) For Institutional Use Only 30-count (3 x 10 unit-

dose) tablets per carton (NDC 43598-344-31); Rx only, Distributor: Dr. Reddy's Laboratories Inc., Princeton, NJ 08540; Made in India.

Product Quantity:
a) 1350 bottles; b) 147 cartons

Reason for Recall:
Failed Dissolution Specifications

Recall Number:
D-0287-2021

Code Information:
Lot #: a) H2000206, Exp 06/22; b) H2000138, Exp 06/22

Class II Drugs Event

Event ID:
87363

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/19/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/21/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Areva Pharmaceuticals Inc
7112 Areva Dr Ne
Georgetown IN United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Irinotecan Hydrochloride Injection, USP, 40 mg/2 mL (20 mg/mL), 2 mL Single-Dose Vial, Rx Only, Distributed by: Areva Pharmaceuticals, Inc., Gerogetown, IN 47122, Made in India, NDC 59923-714-02.

Product Quantity:
3287 vials

Reason for Recall:
CGMP Deviations: based on a Warning Letter received by the manufacturer of the recalled product for inadequate out-of specification investigations, complaint and the investigation conclusions.

Recall Number:
D-0270-2021

Code Information:
Lot 7S10022A, Exp Jan-21

Class II Drugs Event

Event ID:
87384

Product Type:
Drugs

Status:
Completed

Date Terminated:

Recall Initiation Date:
02/17/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/24/2021

Initial Firm Notification of Consignee or Public:
Telephone

Recalling Firm:
The General Hospital Corporation
55 Fruit St
Boston MA United States

Distribution Pattern:
Product was distributed to one direct account.

Associated Products

Product Description:
Fludeoxyglucose F 18 Injection, 20-300 mCi/mL at End of Synthesis (EOS) Solution, 50 mL glass vial, Rx only, Manufactured by Massachusetts General Hospital PET Center, Boston, MA NDC 76318-334-50

Product Quantity:
50 mL vial

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0288-2021

Code Information:
Lot # P01-021721, exp 02/17/2021