Enforcement Report - Week of June 16, 2021

Class II Drugs Event

Event ID:
87907

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/28/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/09/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Fresenius Medical Care Holdings, Inc.
920 Winter St Bld 950
Waltham MA United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Sodium Chloride 0.9%, USP, 1000 mL, Mfg by: Fresenius Medical Care North America, Waltham, MA 02451, NDC 46163-0300-10

Product Quantity:
48 cases

Reason for Recall:
Temperature Abuse: Product exposed to temperature outside specified limits.

Recall Number:
D-0603-2021

Code Information:
Lot #: 20NG02095, Exp. Date October 2021

Class III Drugs Event

Product Description:
DELFLEX Peritoneal Dialysis Solution with 1.5% Dextrose, 5000 mL bags, 2-pack, Rx Only, Fresenius Medical Care NA, Waltham, MA 02451, NDC 49230-0188-50

Product Quantity:
25 cases

Reason for Recall:
Temperature Abuse: Product exposed to temperature outside specified limits.

Recall Number:
D-0604-2021

Code Information:
Lot #: 20JU01001, Exp. Date February 2022

Product Description:
DELFLEX Peritoneal Dialysis Solution with 2.5 % Dextrose, Low Magnesium, Low Calcium, packaged in a) 3000 mL 2 packs (NDC 49230-0209-23), b) 3000 mL (NDC 49230-209-30) and c) 5000 mL (NDC 49230-209-50) Rx only, Fresenius Medical Care NA Waltham, MA 02451

Product Quantity:
672 cases

Reason for Recall:
Temperature Abuse: Product exposed to temperature outside specified limits.

Recall Number:
D-0605-2021

Code Information:
Lot #: a) 20PU03043, Exp. Date June 2022; b) 20SU03036, Exp. date July 2022; c) 20Su07012, Exp. date July 2022; 21AU07021, 21AU02037, 21AU01007, 21AU01006, 21AU01019, Exp. date August 2022

Product Description:
DELFELX Peritoneal Dialysis Solution with 4.25% Dextrose, Low Magnesium, Low Calcium, 5000 mL, Fresenius Medical Care, Waltham, MA 02451, NDC 49230-0212-50

Product Quantity:
49 cases

Reason for Recall:
Temperature Abuse: Product exposed to temperature outside specified limits.

Recall Number:
D-0606-2021

Code Information:
Lot #: 21AK01022, Exp. date July 2022; 20SK01022, Exp. date June 2022

Product Description:
DELFLEX Peritoneal Dialysis Solution with 1.5% Dextrose, Low magnesium, Low Calcium and attached stay safe Exchange set, 2000 mL Fresenius Medical Care NA, Waltham, MA 02451, NDC 49230-206-92

Product Quantity:
5 cases

Reason for Recall:
Temperature Abuse: Product exposed to temperature outside specified limits.

Recall Number:
D-0607-2021

Code Information:
Lot #: 20SU02032, Exp. date July 2022

Product Description:
DELFLEX Peritoneal Dialysis Solution with 2.5% Dextrose, Low magnesium, Low Calcium and attached stay safe Exchange set, packaged in a) 2500 mL (NDC 49230-209-94) and b) 2000mL, packs of 5 (NDC 49230-209-92) Fresenius Medical Care NA, Waltham, MA 02451,

Product Quantity:
39 cases

Reason for Recall:
Temperature Abuse: Product exposed to temperature outside specified limits.

Recall Number:
D-0608-2021

Code Information:
Lot #: a) 20PU02010, Exp. date June 2022 and b) 20SU04033, Exp. date July 2022

Product Description:
DELFLEX Peritoneal Dialysis Solution with 4.25% Dextrose, Low magnesium, Low Calcium and attached stay safe Exchange set, 2000 mL, packs of 5, Rx only, Fresenius Medical Care NA, Waltham, MA 02451, NDC 49230-212-92

Product Quantity:
4 cases

Reason for Recall:
Temperature Abuse: Product exposed to temperature outside specified limits.

Recall Number:
D-0609-2021

Code Information:
Lot #: 20PU04030, Exp. date June 2022

Product Description:
DELFLEX Peritoneal Dialysis Solution with 1.5% Dextrose, Low magnesium, Low Calcium, packaged in a) 3000 mL bags (NDC 49230-206-30) and b) 5000mL bags, 2 packs (NDC 49230-206-50), Rx only, Fresenius Medical Care NA, Waltham, MA 02451

Product Quantity:
285 cases

Reason for Recall:
Temperature Abuse: Product exposed to temperature outside specified limits.

Recall Number:
D-0610-2021

Code Information:
Lot #: a) 20SU03060, Exp Date. July 2022; b) 21AU02015, 21AU02038, Exp. Date August 2022

Class III Drugs Event

Event ID:
88005

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/14/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/10/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Medline Industries Inc
3 Lakes Dr
Northfield IL United States

Distribution Pattern:
Distributed Nationwide in the USA and Isreal

Associated Products

Product Description:
READYPREP CHG, 2% Chlorhexidine Gluconate Cloth, 2 9x10.5 in (22.9x26.7 cm) Disposable Cloths, Non-Sterile, Single Use Only, Manufactured by Medline Industries, Inc., Northfield, IL 60093 USA. NDC: 53329-244-01

Product Quantity:
231,936 packs

Reason for Recall:
Superpotent Drug: Product is above specification for active ingredient, 2% Chlorhexidine Gluconate.

Recall Number:
D-0624-2021

Code Information:
Lot #:: 19EEA027, Exp May 2021; 19GEA049, Exp August 2021; 19HEA044, Exp Sept 2021

Class III Drugs Event

Event ID:
88008

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/26/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/15/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
McKesson Corporation dba McKesson Drug Company
4853 Crumpler Rd
Memphis TN United States

Distribution Pattern:
Nationwide in the US

Associated Products

Product Description:
Levetiracetam Tablets USP, 250 mg UD 100 Tablets (10x10) boxes, Rx Only, Distributed By: McKesson Corporation 4971 Southridge Blvd., Suite 101 Memphis, TN 38141 Manufactured by: Aurobindo Pharma Limited Hyderabad-500 090, India NDC 63739-795-10

Product Quantity:
210 cartons

Reason for Recall:
Labeling; Wrong Barcode; error in the machine-readable barcode which could result in some units being read as Naproxen Tablets 500 mg. Product is labeled correctly as Levetiracetam

Recall Number:
D-0630-2021

Code Information:
Lot: 0000124916 Exp. 09/30/2022