

# Enforcement Report - Week of August 21, 2019

## Class II Drugs Event

**Event ID:**

83136

**Product Type:**

Drugs

**Status:**

Ongoing

**Date Terminated:****Recall Initiation Date:**

06/12/2019

**Voluntary / Mandated:**

Voluntary: Firm initiated

**Center Classification Date:**

08/15/2019

**Initial Firm Notification of Consignee or Public:**

Letter

**Recalling Firm:**

Infusion Options, Inc.  
5924 13th Ave  
Brooklyn NY United States

**Distribution Pattern:**

NY only

## Associated Products

**Product Description:**

Oxytocin 60 units/1000 mL Lactated Ringers Intravenous Solution, Rx Only, Infusion Options, Inc. 5924 13th Ave, Brooklyn, NY 11219-4934, 718-283-7233

**Product Quantity:**

820 60 units/bag

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1744-2019

**Code Information:**

All lots within expiry

**Product Description:**

Abraxane 170 MG / 34 ML IVPB; Abraxane 200 MG / 40 ML IVPB; Abraxane 180 MG / 36 ML IVPB, Rx Only, Infusion Options, Inc. 5924 13th Ave, Brooklyn, NY 11219-4934, 718-283-7233

**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1745-2019

**Code Information:**

All lots within expiry

**Product Description:**

Adcetris 96 MG/100 ML NS IVPB, Rx Only, Infusion Options, Inc. 5924 13th Ave, Brooklyn, NY 11219-4934, 718-283-7233

**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1746-2019

**Code Information:**

All lots within expiry

**Product Description:**

ADO-TRASTUZUMAB 210 MG/250 ml NS; ADO-TRASTUZUMAB E 213 MG / 250 ML NS; ADO-TRASTUZUMAB 242 MG/250 ml NS; ADO-TRASTUZUMAB EMT 168 mg / 250 ml NS; ADO-TRASTUZUMAB E 160 MG / 250 ML NS ADO-TRASTUZUMAB 150 mg / 250 ml NS; ADO-TRASTUZUMAB EMT 301 mg / 250 ml NS; ADO-TRASTUZUMAB EMTANSINE 230mg/250ml NS IV Rx Only, Infusion Options, Inc. 5924 13the Ave, Brooklyn, NY 11219-4934, 718-283-7233

**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1747-2019

**Code Information:**

All lots within expiry

**Product Description:**

ALIMTA 785 mg QS 100 ml 0.9% NACL IVPB; ALIMTA 1000 mg QS 100 ml 0.9% NACL IVPB; Rx Only, Infusion Options, Inc. 5924 13the Ave, Brooklyn, NY 11219-4934, 718-283-7233

**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1748-2019

**Code Information:**

All lots within expiry

**Product Description:**

ATEZOLIZUMAB 1200 MG / 250 ML 0.9% NACL, Rx Only, Infusion Options, Inc. 5924 13the Ave, Brooklyn, NY 11219-4934, 718-283-7233

**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1749-2019

**Code Information:**

All lots within expiry

**Product Description:**

AVASTIN 630 MG / 100 ML 0.9% NACL IVPB; AVASTIN 2.5 mg/ 0.1ML Syringe; AVASTIN 587.5 MG/100 ML 0.9% NACL IVPB; AVASTIN 350 MG/100 ML 0.9% NACL IVPB; AVASTIN 325 MG / 100 ML 0.9% NACL IVPB; AVASTIN 3.75 mg/ 0.15 ML Syringe; AVASTIN 416 MG / 100 ML 0.9% NACL IVPB; AVASTIN 360 MG/100 ML 0.9% NACL IVPB; AVASTIN 250 MG / 100 ML 0.9% NACL IVPB; AVASTIN 693.125 MG/100 ML 0.9% NACL IVPB; AVASTIN 1020 MG/100 ML NS IVPB; AVASTIN 811.875 MG/100 ML 0.9% NACL IVPB; AVASTIN 1006.25 MG/100 ML NS IVPB, Rx Only, Infusion Options, Inc. 5924 13the Ave, Brooklyn, NY 11219-4934, 718-283-7233

**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1750-2019

**Code Information:**

All lots within expiry

**Product Description:**

AZACITIDINE 125 MG / 5 ML SUB-Q SYRINGE; AZACITIDINE 75 MG (3 ML) SYRINGE, AZACITIDINE 135 MG / 5.4 ML SUB-Q SYRINGE, Rx Only, Infusion Options, Inc. 5924 13the Ave, Brooklyn, NY 11219-4934, 718-283-7233

**Product Quantity:**

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1751-2019

**Code Information:**

All lots within expiry

**Product Description:**

BEVACIZUMAB 784 MG / 100 ML NS IVPB; BEVACIZUMAB 350 MG/100 ml NS IVPB; BEVACIZUMAB 425 MG/ 100 ml NS IVPB; BEVACIZUMAB 420 MG/100 ml 0.9% NACL IVPB; BEVACIZUMAB 556 mg/100 ml NS IVPB BEVACIZUMAB 330 MG / 100 ML NS IVPB; BEVACIZUMAB 790 MG / 100 ML NS IVPB; BEVACIZUMAB 470 MG / 100 ML NS IVPB; BEVACIZUMAB 758 MG / 100 ML NS IVPB; BEVACIZUMAB 690 MG / 100 ML NS IVPB BEVACIZUMAB 599 MG/100 ml NS IVPB; BEVACIZUMAB 1113 MG / 100 ML NS IVPB; BEVACIZUMAB 660 MG /100 ml NS IVPB; BEVACIZUMAB 590 MG / 100 ML NS IVPB; BEVACIZUMAB 620 MG / 100 ML NS IVPB BEVACIZUMAB 800 MG / 100 ML NS IVPB, Rx Only, Infusion Options, Inc. 5924 13the Ave, Brooklyn, NY 11219-4934, 718-283-7233

**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1752-2019

**Code Information:**

all lots within expiry

**Product Description:**

BLEOMYCIN 18 UNITS / 100 ML NS IVPB, Rx Only, Infusion Options, Inc. 5924 13the Ave, Brooklyn, NY 11219-4934, 718-283-7233

**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1753-2019

**Code Information:**

All lots within expiry

**Product Description:**

BORTEZOMIB 2.5 mg / 1 ML SQ SYRINGE; BORTEZOMIB 2.88 MG / 1.15 ML SQ SYRINGE; BORTEZOMIB 2.31 MG / 0.92 ml SQ SYRINGE; BORTEZOMIB 2.7 mg / 1.08 ML SQ SYRINGE; BORTEZOMIB 1.45 mg / 0.58 ml SQ SYRINGE; BORTEZOMIB 2.25 mg (0.9 ML) SQ SYRINGE; BORTEZOMIB 1.98 mg / 0.79 ml SQ SYRINGE, Rx Only, Infusion Options, Inc. 5924 13the Ave, Brooklyn, NY 11219-4934, 718-283-7233

**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1754-2019

**Code Information:**

All lots within expiry

**Product Description:**

CALCIUM GLUCONATE 1 GM /100 ML NACL 0.9% IVPB, Rx Only, Infusion Options, Inc. 5924 13the Ave, Brooklyn, NY 11219-4934, 718-283-7233

**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1755-2019

**Code Information:**

All lots within expiry

**Product Description:**

CARBOPLATIN 174 MG / 250ml NS IVPB; CARBOPLATIN 240 MG / 250 ML NS IVPB; CARBOPLATIN 750 MG / 250 ML NACL 0.9% IVPB; CARBOPLATIN 895 MG / 250 ML NACL 0.9% IVPB; CARBOPLATIN 235 MG / 250ml NS IVPB CARBOPLATIN 716 MG / 250 ML D5W IVPB; CARBOPLATIN 400 MG / 500 ML NS IVPB; CARBOPLATIN 500 MG / 100 ML NACL 0.9% IVPB; CARBOPLATIN 575 MG / 500 ML NS IVPB; CARBOPLATIN 307 MG / 100 ML NACL 0.9% IVPB; CARBOPLATIN 766 MG / 500 ML NS IVPB; CARBOPLATIN 684 / 250 ML NACL 0.9% IVPB; CARBOPLATIN 260 MG / 100 ML D5W IVPB CARBOPLATIN 360 MG /100 ML NACL 0.9% IVPB; CARBOPLATIN 274 MG / 250 ML D5W IVPB; CARBOPLATIN 240 MG / 100 ML D5W IVPB; CARBOPLATIN 750 MG / 250 ML NS IVPB; CARBOPLATIN 260 MG / 250 ML NS IVPB; CARBOPLATIN 460 MG / 250 ML NS IVPB; CARBOPLATIN 175 MG / 250 ML NS IVPB; CARBOPLATIN 229.4 MG / 500 ML NS IVPB CARBOPLATIN 780 MG / 100 ML NACL 0.9% IVPB; CARBOPLATIN 140 MG / 250 ML NS IVPB; CARBOPLATIN 408 MG / 500 ML NS IVPB CARBOPLATIN 847 MG / 250 ML D5W IVPB; CARBOPLATIN 560 MG / 250 ML D5W IVPB; CARBOPLATIN 180 MG / 250 ML NS IVPB; CARBOPLATIN 200 MG / 250 ML D5W IVPB; CARBOPLATIN 238 MG / 500 ML NS IVPB, Rx Only, Infusion Options, Inc. 5924 13the Ave, Brooklyn, NY 11219-4934, 718-283-7233

**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1756-2019

**Code Information:**

All lots within expiry

**Product Description:**

CARFILZOMIB 65 MG IN 50 ML D5W IVPB; CARFILZOMIB 75 MG IN 50 ML D5W IVPB; CARFILZOMIB 50 MG IN 50 ML D5W IVPB; CARFILZOMIB 45 MG IN 50 ML D5W IVPB; CARFILZOMIB 46.2 MG IN 50 ML D5W IVPB, Rx Only, Infusion Options, Inc. 5924 13the Ave, Brooklyn, NY 11219-4934, 718-283-7233

**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1757-2019

**Code Information:**

All lots within expiry

**Product Description:**

CETUXIMAB 335 MG / 167.5 ML IVPB, Rx Only, Infusion Options, Inc. 5924 13the Ave, Brooklyn, NY 11219-4934, 718-283-7233

**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1758-2019

**Code Information:**

All lots within expiry

**Product Description:**

Cisplatin 40 MG / 500 ml NS IVPB WITH Mannitol 40 G; Cisplatin 80 MG / 250 ml 0.9% NACL; Cisplatin 44 MG QS 500 ml NS IVPB; Cisplatin 40 MG / 500 ml 0.9% NACL; Cisplatin 36 MG / 500 ML NS IVPB; Cisplatin 73 MG QS 500 ml 0.9% NACL WITH Mannitol 12.5 G; Cisplatin 70 MG / 500 ml NS WITH Magnesium 1 G and Mannitol 12.5 G; Cisplatin 60 MG /250 ml 0.9% NACL Cisplatin 47 MG /250 ml 0.9% NACL WITH Mannitol 12.5 G; Cisplatin 150 MG / 250 ml 0.9% NACL; Cisplatin 115 MG /250 ml NS IVPB; Cisplatin 80 MG QS 500 ml NS IVPB WITH Mannitol 12.5 G; Cisplatin 120 MG / 500 ML NS IVPB Cisplatin 157 MG /250 ml 0.9% NACL WITH Mannitol 12.5 G; Cisplatin 43 MG QS 1000 ml 0.9% NACL WITH Mannitol 12.5 G, Rx Only, Infusion Options, Inc. 5924 13the Ave, Brooklyn, NY 11219-4934, 718-283-7233

**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1759-2019

**Code Information:**

All lots within expiry

**Product Description:**

Cisplatin 40 MG / 500 ml NS IVPB WITH Mannitol 40 G; Cisplatin 80 MG / 250 ml 0.9% NACL; Cisplatin 44 MG QS 500 ml NS IVPB; Cisplatin 40 MG / 500 ml 0.9% NACL; Cisplatin 36 MG / 500 ML NS IVPB; Cisplatin 73 MG QS 500 ml 0.9% NACL WITH Mannitol 12.5 G; Cisplatin 70 MG / 500 ml NS WITH Magnesium 1 G and Mannitol 12.5 G; Cisplatin 60 MG /250 ml 0.9% NACL Cisplatin 47 MG /250 ml 0.9% NACL WITH Mannitol 12.5 G; Cisplatin 150 MG / 250 ml 0.9% NACL; Cisplatin 115 MG /250 ml NS IVPB; Cisplatin 80 MG QS 500 ml NS IVPB WITH Mannitol 12.5 G; Cisplatin 120 MG / 500 ML NS IVPB Cisplatin 157 MG /250 ml 0.9% NACL WITH Mannitol 12.5 G; Cisplatin 43 MG QS 1000 ml 0.9% NACL WITH Mannitol 12.5 G, Rx Only, Infusion Options, Inc. 5924 13the Ave, Brooklyn, NY 11219-4934, 718-283-7233

**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1760-2019

**Code Information:**

All lots within expiry

**Product Description:**

Cyclophosphamide 840 MG / 250 ML NS IVPB; Cyclophosphamide 1112 MG / 250 ML NS IVPB; Cyclophosphamide 1248 MG / 50 ML NS IVPB; Cyclophosphamide 1125 MG / 100 ML NS IVPB; Cyclophosphamide 1000 MG / 500 ML NS IVPB; Cyclophosphamide 1400 MG / 100 ML NS IVPB; Cyclophosphamide 1056 MG / 250 ML NS IVPB; Cyclophosphamide 980 MG / 500 ML NS IVPB; Cyclophosphamide 580 mg / 500 ML NS IVPB; Cyclophosphamide 880 MG / 500 ML NS IVPB; Cyclophosphamide 501 MG / 250 ML NS IVPB; Cyclophosphamide 1163 MG / 50 ML NS IVPB; Cyclophosphamide 1100 MG / 500 ML NS IVPB; Cyclophosphamide 1152 MG / 250 ML NS IVPB; Cyclophosphamide 1116 MG / 250 ML NS IVPB; Cyclophosphamide 894 MG / 250 ML NS IVPB; Cyclophosphamide 1210 MG / 500 ML NS IVPB; Cyclophosphamide 1010 MG/ 500 ML NS IVPB; Cyclophosphamide 1030 MG / 500 ML NS IVPB; Cyclophosphamide 500 MG / 250 ML NS IVPB, Rx Only, Infusion Options, Inc. 5924 13the Ave, Brooklyn, NY 11219-4934, 718-283-7233

**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1761-2019

**Code Information:**

All lots within expiry

**Product Description:**

Cytarabine 128 MG/250 ML D5W IVPB; Cytarabine 20 MG / 1 ML SQ SYRINGE Cytarabine 70 MG QS 6 ML PF NS SYRINGE; Cytarabine 100 MG QS 3 ML PF NS SYRINGE, Rx Only, Infusion Options, Inc. 5924 13the Ave, Brooklyn, NY 11219-4934, 718-283-7233

**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1762-2019

**Code Information:**

All lots within expiry

**Product Description:**

DACARBAZINE 680 MG in 250 ml NS; DACARBAZINE 675 MG in 250 ml NS, Rx Only, Infusion Options, Inc. 5924 13the Ave, Brooklyn, NY 11219-4934, 718-283-7233

**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1763-2019

**Code Information:**

All lots within expiry

**Product Description:**

DARATUMUMAB 904 MG QS 500 ML NS IVPB; DARATUMUMAB 668 MG QS 1000 ML NS IVPB, Rx Only, Infusion Options, Inc. 5924 13the Ave,

Brooklyn, NY 11219-4934, 718-283-7233

**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1764-2019

**Code Information:**

All lots within expiry

**Product Description:**

DARZALEX 1008 MG / 500 ML NS IVPB, Rx Only, Infusion Options, Inc. 5924 13th Ave, Brooklyn, NY 11219-4934, 718-283-7233

**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1765-2019

**Code Information:**

All lots within expiry

**Product Description:**

DECITABINE 40 MG / 100 ml NS IVPB, Rx Only, Infusion Options, Inc. 5924 13th Ave, Brooklyn, NY 11219-4934, 718-283-7233

**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1766-2019

**Code Information:**

All lots within expiry

**Product Description:**

DEXAMETHASONE 10 MG / 50 ML NS IVPB; DEXAMETHASONE 5 MG / 50 ML NS; DEXAMETHASONE 5 MG / 50 ML NS IVPB; Rx Only, Infusion Options, Inc. 5924 13th Ave, Brooklyn, NY 11219-4934, 718-283-7233

**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1767-2019

**Code Information:**

All lots within expiry

**Product Description:**

DIPHENHYDRAMINE 25 MG/50 ML NS, Rx Only, Infusion Options, Inc. 5924 13th Ave, Brooklyn, NY 11219-4934, 718-283-7233

**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1768-2019

**Code Information:**

All lots within expiry

**Product Description:**

DOCETAXEL 60 MG / 250 ml D5W IVPB; DOCETAXEL 71 MG/ 250 ML NS IVPB; DOCETAXEL 155 MG/ 250 ml NS IVPB; DOCETAXEL 110 mg / 250 ml NS IVPB; DOCETAXEL 150 MG / 250 ml NS IVPB; DOCETAXEL 137 mg / 250 ml 0.9% NAACL IVPB; DOCETAXEL 130 MG/ 250 ml NS IVPB; DOCETAXEL 140 MG/ 250 ml NS IVPB; DOCETAXEL 144 MG/ 250 ML NS IVPB; DOCETAXEL 117 MG/ 250 ML NS IVPB; DOCETAXEL 30

mg / 250 ml D5W IVPB; DOCETAXEL 125 MG/ 250 ml NS IVPB; DOCETAXEL 135 MG / 250 ml NS IVPB, Rx Only, Infusion Options, Inc. 5924 13the Ave, Brooklyn, NY 11219-4934, 718-283-7233

**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1769-2019

**Code Information:**

All lots within expiry

**Product Description:**

Doxorubicin 110 MG / 55 ML IVP SYRINGE; Doxorubicin 56 MG / 28 ML IVP SYRINGE; Doxorubicin 75 MG / 37.5 ML IVP SYRINGE; Doxorubicin 125 MG / 62.5 ML SYRINGE IVP; Doxorubicin 93 MG / 46.5 ML IV SYRINGE; Doxorubicin 112 MG / 56 ML IVP SYRINGE; Doxorubicin 50 MG / 25 ML IVP SYRINGE; Doxorubicin 120 MG / 60 ML IVP SYRINGE; Doxorubicin 106 MG / 53 ML IVP SYRINGE; Doxorubicin 90 MG / 45 ML IVP SYRINGE; Doxorubicin 14 MG/500 ML NS IV WITH Vincristine 0.7 MG and Etoposide 70 MG; Doxorubicin 100 MG / 50 ML IVP SYRINGE; Doxorubicin 16 MG/1000 ML NS IV WITH Vincristine 0.6 MG and Etoposide 78 MG; Doxorubicin 45 MG / 22.5 ML IVP SYRINGE, Rx Only, Infusion Options, Inc. 5924 13the Ave, Brooklyn, NY 11219-4934, 718-283-7233

**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1770-2019

**Code Information:**

All lots within expiry

**Product Description:**

Doxorubicin Liposomal 71 MG / 250 ML D5W IVPB; Doxorubicin Liposomal 66 MG/250 ML D5W, Rx Only, Infusion Options, Inc. 5924 13the Ave, Brooklyn, NY 11219-4934, 718-283-7233 Doxorubicin 16 MG/1000 ML NS IV WITH Vincristine 0.6 MG and Etoposide 78 MG Doxorubicin 16 MG/1000 ML NS IV WITH Vincristine 0.6 MG and Etoposide 78 MG Duplicate Doxorubicin 45 MG / 22.5 ML IVP SYRINGE

**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1771-2019

**Code Information:**

All lots within expiry

**Product Description:**

Durvalumab 651 mg/ 250 ml NS IVPB; Durvalumab 650 mg/ 250 ml NS IVPB, Rx Only, Infusion Options, Inc. 5924 13the Ave, Brooklyn, NY 11219-4934, 718-283-7233

**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1772-2019

**Code Information:**

All lots within expiry

**Product Description:**

ENTYVIO 300 MG /250 ML 0.9% NACL, Rx Only, Infusion Options, Inc. 5924 13the Ave, Brooklyn, NY 11219-4934, 718-283-7233

**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1773-2019

**Code Information:**

All lots within expiry

**Product Description:**

ERBITUX 770 MG/ 385 ML IVPB; ERBITUX 440 MG/ 220 ml IVPB; ERBITUX 850 MG/ 425 ml IVPB, Rx Only, Infusion Options, Inc. 5924 13th Ave, Brooklyn, NY 11219-4934, 718-283-7233

**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1774-2019

**Code Information:**

All lots within expiry

**Product Description:**

ERIBULIN 1.12 MG / 100 ML NS IVPB; ERIBULIN 1.87 MG / 100 ML NS IVPB; ERIBULIN 1.89 MG / 100 ML NS IVPB, Rx Only, Infusion Options, Inc. 5924 13th Ave, Brooklyn, NY 11219-4934, 718-283-7233

**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1775-2019

**Code Information:**

All lots within expiry

**Product Description:**

Etoposide 184 MG / 500 ml NS IVPB; Etoposide 176 MG/ 500 ml 0.9% NACL IVPB; Etoposide 170 MG / 500 ml 0.9% NACL IVPB; Etoposide 152 MG / 500 ml 0.9% NACL IVPB; Etoposide 275 MG / 500 ml NS IVPB; Etoposide 270 MG / 500 ml NS IVPB; Etoposide 90 MG / 500 ml NS IVPB; Etoposide 160 MG / 500 ml NS IVPB; Etoposide 178 MG/ 500 ml 0.9% NACL IVPB; Etoposide 214 MG / 500 ml NS IVPB; Etoposide 290 MG / 500 ml NS IVPB, Rx Only, Infusion Options, Inc. 5924 13th Ave, Brooklyn, NY 11219-4934, 718-283-7233

**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1776-2019

**Code Information:**

All lots within expiry

**Product Description:**

Fluorouracil 560 MG / 11.2 ML IVP; Fluorouracil 3340 MG QS 92 ML 0.9% NACL; Fluorouracil 3920 MG QS 92 ML 0.9% NACL; Fluorouracil 3760 mg QS 100 ml NS CASS; Fluorouracil 4000 MG QS 92 ml 0.9% NACL; Fluorouracil 3140 MG QS 240 ML NS PUMP; Fluorouracil 2400 MG QS 96 ML 0.9% NACL Fluorouracil 5000 MG QS 101 ml 0.9% NACL; Fluorouracil 750 MG / 15 ML IVP Fluorouracil 4500 mg QS 100 ml NS CASS; Fluorouracil 4100 mg QS 100 ml NS CASS; Fluorouracil 690 mg / 13.8 ml IVP; Fluorouracil 2400 MG QS 96 ML NS IV; Fluorouracil 812 MG/16.24 ML IVP; Fluorouracil 4872 MG QS 240 ML NS PUMP; Fluorouracil 4200 mg QS 100 ml NS CASS; Fluorouracil 1110 MG QS 96 ml NS IVPB; Fluorouracil 370 MG/ 50 ML NS; Fluorouracil 620 MG/ 12.4 ML SYRINGE IVP; Fluorouracil 3160 MG QS 92 ML 0.9% NACL; Fluorouracil 1050 mg QS 92 ml NS IVPB; Fluorouracil 370 MG /100 ML NS IVPB; Fluorouracil 4080 MG QS 1000 ML NS IVPB; Fluorouracil 5 MG / 0.1 ML SYRINGE; Fluorouracil 5040 MG QS 101 ml NS CADD; Fluorouracil 4224 MG QS 100 ml NS CASS; Fluorouracil 700 MG / 14 ML IVP; Fluorouracil 3550 mg QS 92 ML 0.9% NACL IV; Fluorouracil 760 MG / 15.2 ML IVP; Fluorouracil 4560 MG QS 240 ML NS PUMP; Fluorouracil 796 MG / 15.92 ML IVP Fluorouracil 4776 MG QS 240 ML NS PUMP; Fluorouracil 930 MG QS 240 ML NS PUMP; Fluorouracil 730 MG / 14.6 ML IVP SYR; Fluorouracil 4400 MG QS 100 ml NS CADD; Fluorouracil 2430 MG QS 96 ml 0.9% NACL; Fluorouracil 4728 MG QS 100 ml NS CASS; Fluorouracil 3550 MG QS 92 ML 0.9% NACL Fluorouracil 588 MG / 11.76 ML IVP; Fluorouracil 3528 MG QS 240 ML NS PUMP; Fluorouracil 2520 mg QS 96 ml NS IVPB; Fluorouracil 790 MG / 15.8 ml IVP; Fluorouracil 4750 mg QS 97 ml 0.9% NACL IV; Fluorouracil 2660 MG QS 96 ml NS IVPB; Fluorouracil 720 MG/ 14.4 ML IVP; Fluorouracil 4370 mg QS 92 ml 0.9% NACL IV; Fluorouracil 3280 MG QS 92 ML 0.9% NACL; Fluorouracil 780 MG / 15.6 ML IVP; Fluorouracil 4660 MG QS 97 ml 0.9% NACL Fluorouracil 3620 MG QS 100 ml NS CASS; Fluorouracil 2370 MG QS 92 ML 0.9% NACL; Fluorouracil 800 MG / 16 ML IVP; Fluorouracil 4800 MG QS 101 ml NS CADD; Fluorouracil 4000 mg QS 92 ML 0.9% NACL IV; Fluorouracil 2480 MG QS 96 ML 0.9% NACL; Fluorouracil 688 MG / 13.76 ml IVP Fluorouracil 4128 MG QS 1000 ML D5W IVPB; Fluorouracil 6000 MG QS 250 ml NS CASS;



Fluorouracil 672 MG / 13.44 ML IVP; Fluorouracil 4032 MG / 1000 ML D5W IVPB; Fluorouracil 894 MG / 17.88 ml IVP; Fluorouracil 400 MG / 50 ML NS IVPB; Fluorouracil 840 MG / 16.8 ml IVP; Fluorouracil 590 MG/ 11.8 ML IVP, Rx Only, Infusion Options, Inc. 5924 13the Ave, Brooklyn, NY 11219-4934, 718-283-7233

**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1777-2019

**Code Information:**

All lots within expiry

**Product Description:**

FOSAPREPITANT 150 mg/150 ml NS IVPB, Rx Only, Infusion Options, Inc. 5924 13the Ave, Brooklyn, NY 11219-4934, 718-283-7233

**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1778-2019

**Code Information:**

All lot within expiry

**Product Description:**

Fluorouracil 560 MG / 11.2 ML IVP Fluorouracil 3340 MG QS 92 ML 0.9% NACL Fluorouracil 3920 MG QS 92 ML 0.9% NACL Fluorouracil 3760 mg QS 100 ml NS CASS Fluorouracil 4000 MG QS 92 ml 0.9% NACL Fluorouracil 3140 MG QS 240 ML NS PUMP Fluorouracil 2400 MG QS 96 ML 0.9% NACL Fluorouracil 5000 MG QS 101 ml 0.9% NACL Fluorouracil 750 MG / 15 ML IVP Fluorouracil 4500 mg QS 100 ml NS CASS Fluorouracil 4100 mg QS 100 ml NS CASS Fluorouracil 690 mg / 13.8 ml IVP Fluorouracil 2400 MG QS 96 ML NS IV Fluorouracil 812 MG/16.24 ML IVP Fluorouracil 4872 MG QS 240 ML NS PUMP Fluorouracil 4200 mg QS 100 ml NS CASS Fluorouracil 1110 MG QS 96 ml NS IVPB Fluorouracil 370 MG/ 50 ML NS Fluorouracil 620 MG/ 12.4 ML SYRINGE IVP Fluorouracil 3160 MG QS 92 ML 0.9% NACL Fluorouracil 1050 mg QS 92 ml NS IVPB Fluorouracil 370 MG /100 ML NS IVPB Fluorouracil 4080 MG QS 1000 ML NS IVPB Fluorouracil 5 MG / 0.1 ML SYRINGE Fluorouracil 5040 MG QS 101 ml NS CADD Fluorouracil 4224 MG QS 100 ml NS CASS Fluorouracil 700 MG / 14 ML IVP Fluorouracil 3550 mg QS 92 ML 0.9% NACL IV Fluorouracil 760 MG / 15.2 ML IVP Fluorouracil 4560 MG QS 240 ML NS PUMP Fluorouracil 796 MG / 15.92 ML IVP Fluorouracil 4776 MG QS 240 ML NS PUMP Fluorouracil 930 MG QS 240 ML NS PUMP Fluorouracil 730 MG / 14.6 ML IVP SYR Fluorouracil 4400 MG QS 100 ml NS CADD Fluorouracil 2430 MG QS 96 ml 0.9% NACL Fluorouracil 4728 MG QS 100 ml NS CASS Fluorouracil 3550 MG QS 92 ML 0.9% NACL Fluorouracil 588 MG / 11.76 ML IVP Fluorouracil 3528 MG QS 240 ML NS PUMP Fluorouracil 2520 mg QS 96 ml NS IVPB Fluorouracil 790 MG / 15.8 ml IVP Fluorouracil 4750 mg QS 97 ml 0.9% NACL IV Fluorouracil 2660 MG QS 96 ml NS IVPB Fluorouracil 720 MG/ 14.4 ML IVP Fluorouracil 4370 mg QS 92 ml 0.9% NACL IV Fluorouracil 3280 MG QS 92 ML 0.9% NACL Fluorouracil 780 MG / 15.6 ML IVP Fluorouracil 4660 MG QS 97 ml 0.9% NACL Fluorouracil 3620 MG QS 100 ml NS CASS Fluorouracil 2370 MG QS 92 ML 0.9% NACL Fluorouracil 800 MG / 16 ML IVP Fluorouracil 4800 MG QS 101 ml NS CADD Fluorouracil 4000 mg QS 92 ML 0.9% NACL IV Fluorouracil 2480 MG QS 96 ML 0.9% NACL Fluorouracil 688 MG / 13.76 ml IVP Fluorouracil 4128 MG QS 1000 ML D5W IVPB Fluorouracil 6000 MG QS 250 ml NS CASS Fluorouracil 672 MG / 13.44 ML IVP Fluorouracil 4032 MG / 1000 ML D5W IVPB Fluorouracil 894 MG / 17.88 ml IVP Fluorouracil 400 MG / 50 ML NS IVPB Fluorouracil 840 MG / 16.8 ml IVP Fluorouracil 590 MG/ 11.8 ML IVP

**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1779-2019

**Code Information:**

All lots within expiry

**Product Description:**

GAZYVA 100 MG IN 250 ML NS IVPB; GAZYVA 900 MG IN 250 ML NS IVPB, Rx Only, Infusion Options, Inc. 5924 13the Ave, Brooklyn, NY 11219-4934, 718-283-7233

**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1780-2019

**Code Information:**

All lots within expiry

**Product Description:**

Gemcitabine 1910 MG / 250 ML NS IVPB; Gemcitabine 1140 MG / 250 ML NS 0.9% IVPB; Gemcitabine 1290 MG /250 ML NS IVPB; Gemcitabine 460 MG / 250 ML NS IVPB; Gemcitabine 880 MG / 250 ML NS IVPB; Gemcitabine 810 MG / 250 ML NS IVPB; Gemcitabine 820 MG / 250 ML NS IVPB; Gemcitabine 1748 MG / 250 ML NS IVPB; Gemcitabine 890 MG /250 ML NS IVPB Gemcitabine 2000 MG /250 ML 0.9% NACL IVPB; Gemcitabine 660 MG / 250 ML NS IVPB; Gemcitabine 1880 MG /250 ML NS IVPB; Gemcitabine 1180 MG / 250 ML NS IVPB; Gemcitabine 1400 MG / 250 ML NS IVPB Gemcitabine 1300 MG / 250 ML NS IVPB; Gemcitabine 1406 MG /250 ML NS IVPB; Gemcitabine 1672 MG / 250 ML NS IVPB; Gemcitabine 2050 MG / 250 ML NS IVPB; Gemcitabine 1260 MG / 250 ML NS IVPB; Gemcitabine 1710 MG / 250 ML NS IVPB; Gemcitabine 1320 MG / 250 ML NS IVPB; Gemcitabine 1200 MG /250 ML NS IVPB, Rx Only, Infusion Options, Inc. 5924 13the Ave, Brooklyn, NY 11219-4934, 718-283-7233

**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1781-2019

**Code Information:**

All lots within expiry

**Product Description:**

GRANISETRON 1000 MCG / 50 ML NS, Rx Only, Infusion Options, Inc. 5924 13the Ave, Brooklyn, NY 11219-4934, 718-283-7233

**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1782-2019

**Code Information:**

All lots within expiry

**Product Description:**

HERCEPTIN 400 MG / 250 ML NS IVPB; HERCEPTIN 340 MG /250 ml 0.9% NACL IVPB; HERCEPTIN 553 MG / 250 ml NS IVPB; HERCEPTIN 305 MG / 250 ml NS IVPB; HERCEPTIN 526 MG / 250 ML NS IVPB; HERCEPTIN 162 MG / 250 ML NS IVPB; HERCEPTIN 354 MG/ 250 ml 0.9% NACL IVPB; HERCEPTIN 440 MG / 250 ML NS IVPB; HERCEPTIN 650 MG / 250 ML NS IVPB; HERCEPTIN 472 MG / 250 ML NS IVPB, Rx Only, Infusion Options, Inc. 5924 13the Ave, Brooklyn, NY 11219-4934, 718-283-7233

**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1783-2019

**Code Information:**

All lots within expiry

**Product Description:**

IFOSFAMIDE 9200 MG / 1 L NS IVPB WITH MESNA 9200 MG, Rx Only, Infusion Options, Inc. 5924 13the Ave, Brooklyn, NY 11219-4934, 718-283-7233

**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1784-2019

**Code Information:**

All lots within expiry

**Product Description:**

InFLIXimab 300 mg / 250 ml 0.9% NACL IVPB, Rx Only, Infusion Options, Inc. 5924 13the Ave, Brooklyn, NY 11219-4934, 718-283-7233

**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1785-2019

**Code Information:**

All lots within expiry

**Product Description:**

INJECTAFER 720 MG in 100 ml NS IVPB; INJECTAFER 210 MG in 100 ml NS IVPB, Rx Only, Infusion Options, Inc. 5924 13the Ave, Brooklyn, NY 11219-4934, 718-283-7233

**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1786-2019

**Code Information:**

All lots within expiry

**Product Description:**

IRINOTECAN 250 MG /500 ml D5W IVPB; IRINOTECAN 110 MG /250 ML D5W IVPB; IIRINOTECAN 250 MG/250 ML NS IVPB; IRINOTECAN 315 MG / 250 ML NS IVPB; IRINOTECAN 155 MG / 500 ml D5W IVPB; IRINOTECAN 75 MG / 250 ML NS IVPB; IRINOTECAN 140 MG / 250 ML NS IVPB; IRINOTECAN 317 MG /500 ML D5W IVPB; IRINOTECAN 135 mg / 500 ml D5W IVPB; IRINOTECAN 265 MG / 500 ML D5W IVPB; IRINOTECAN 140 MG / 500 ml D5W IVPB; IRINOTECAN 195 mg / 500 ml D5W IVPB; IRINOTECAN 245 mg / 500 ml D5W IVPB; IRINOTECAN 130 MG / 500 ML D5W IVPB, Rx Only, Infusion Options, Inc. 5924 13the Ave, Brooklyn, NY 11219-4934, 718-283-7233

**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1787-2019

**Code Information:**

All lots within expiry

**Product Description:**

IRON SUCROSE 200 mg / 100 ML NS IVPB, Rx Only, Infusion Options, Inc. 5924 13the Ave, Brooklyn, NY 11219-4934, 718-283-7233

**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1788-2019

**Code Information:**

All lots within expiry

**Product Description:**

LEUCOVORIN 560 MG / 250 ML NS IVPB; LEUCOVORIN 830 MG / 250 ml NS IVPB; LEUCOVORIN 300 MG / 50 ml D5W IVPB; LEUCOVORIN 840 MG / 250 ml NS IVPB; LEUCOVORIN 750 MG / 250 ml NS IVPB; LEUCOVORIN 690 MG / 250 ml NS IVPB; LEUCOVORIN 314 mg / 50 ml NS IVPB; LEUCOVORIN 620 MG / 250 ml D5W IVPB; LEUCOVORIN 420 MG / 50 ML D5W IVPB; LEUCOVORIN 700 MG / 250 ml D5W IVPB; LEUCOVORIN 592 mg / 250 ml D5W IVPB; LEUCOVORIN 760 mg / 250 ml D5W IVPB; LEUCOVORIN 796 MG / 250 ml D5W IVPB; LEUCOVORIN 730 MG / 250 ml D5W IVPB; LEUCOVORIN 324 mg / 50 ml NS IVPB; LEUCOVORIN 590 MG / 250 ml D5W IVPB; LEUCOVORIN 336 MG / 50 ml NS IVPB; LEUCOVORIN 398 MG/ 250 ml D5W IVPB; LEUCOVORIN 354 MG / 50 ml NS IVPB; LEUCOVORIN 720 MG / 250 ml D5W IVPB; LEUC; VORIN 328 mg / 50 ml NS IVPB; LEUCOVORIN 776 MG / 250 ml D5W IVPB; LEUCOVORIN 339 MG / 250 ml D5W IVPB; LEUCOVORIN 800 mg / 250 ml D5W IVPB; LEUCOVORIN 330 MG / 50 ml D5W IVPB; LEUCOVORIN 330 MG / 50 ml NS IVPB; LEUCOVORIN 688 MG in 250 ML D5W IVPB; LEUCOVORIN 350 MG / 250 ml NS IVPB; LEUCOVORIN 672 MG / 250 ml D5W IVPB; LEUCOVORIN 588 mg / 250

ml D5W IVPB; LEUCOVORIN 812 MG / 250 ML D5W IVPB; LEUCOVORIN 300 MG / 100 ml NS IVPB, Rx Only, Infusion Options, Inc. 5924 13the Ave, Brooklyn, NY 11219-4934, 718-283-7233

**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1789-2019

**Code Information:**

All lots within expiry

**Product Description:**

METHOTREXATE 25 MG / 1 ML IM SYR; METHOTREXATE 12 mg QS 5 ml PF 0.9% NACL; METHOTREXATE 98 MG / 3.92 ML IM SYR; METHOTREXATE 55 MG / 2.2 ML IVP; METHOTREXATE 59.5 MG / 2.38 ML IVP; METHOTREXATE 12 mg QS 6 ml 0.9% NACL; METHOTREXATE 150 MG / 50 ML NS IVPB; METHOTREXATE 112.5 MG/ 4.5 ML IM SYR, Rx Only, Infusion Options, Inc. 5924 13the Ave, Brooklyn, NY 11219-4934, 718-283-7233

**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1790-2019

**Code Information:**

All lots within expiry

**Product Description:**

METHYLPREDNISOLONE 10 MG / 0.16 ML IVP, Rx Only, Infusion Options, Inc. 5924 13the Ave, Brooklyn, NY 11219-4934, 718-283-7233

**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1791-2019

**Code Information:**

All lots within expiry

**Product Description:**

MITOMYCIN 10 MG /20 ML IVP SYRINGE, Rx Only, Infusion Options, Inc. 5924 13the Ave, Brooklyn, NY 11219-4934, 718-283-7233

**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1792-2019

**Code Information:**

All lots within expiry

**Product Description:**

NIVOLUMAB 480 MG / 100 ML NS IVPB; NIVOLUMAB 200 mg / 100 ML NS IVPB; NIVOLUMAB 165 mg / 100 ML NS IVPB; NIVOLUMAB 240 mg / 100 ML NS IVPB, Rx Only, Infusion Options, Inc. 5924 13the Ave, Brooklyn, NY 11219-4934, 718-283-7233

**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1793-2019

**Code Information:**

All lots within expiry

**Product Description:**

ONDANSETRON 8 MG / 50 ml NS IVPB, Rx Only, Infusion Options, Inc. 5924 13the Ave, Brooklyn, NY 11219-4934, 718-283-7233

**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1794-2019

**Code Information:**

All lots within expiry

**Product Description:**

OPDIVO 200 mg /100 ML NS VPB; OPDIVO 480 mg/100 ML NS IVPB, Rx Only, Infusion Options, Inc. 5924 13the Ave, Brooklyn, NY 11219-4934, 718-283-7233

**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1795-2019

**Code Information:**

All lots within expiry

**Product Description:**

ORENCIA 750 mg QS 100 ml 0.9% NACL IVPB, Rx Only, Infusion Options, Inc. 5924 13the Ave, Brooklyn, NY 11219-4934, 718-283-7233

**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1796-2019

**Code Information:**

All lots within expiry

**Product Description:**

OXALIPLATIN 145 MG /250 ML D5W IVPB; OXALIPLATIN 154 MG / 250 ML D5W IVPB; OXALIPLATIN 130 MG / 250 ML D5W IVPB; OXALIPLATIN 140 MG / 250 ml D5W IVPB; OXALIPLATIN 162 MG / 250 ML D5W IVPB; OXALIPLATIN 169 MG / 250 ML D5W IVPB; OXALIPLATIN 90 MG / 500 ML D5W IVPB; OXALIPLATIN 50 MG / 250 ML D5W IVPB; OXALIPLATIN 70 MG / 500 ML D5W IVPB; OXALIPLATIN 40 MG / 250 ML D5W IVPB; OXALIPLATIN 155 MG / 250 ML D5W IVPB; OXALIPLATIN 85 MG / 250 ML D5W IVPB OXALIPLATIN 146 MG / 250 ML D5W IVPB; OXALIPLATIN 246 MG / 500 ML D5W IVPB; OXALIPLATIN 143 MG / 250 ML D5W IVPB; OXALIPLATIN 65 MG / 500 ML D5W IVPB; OXALIPLATIN 80 MG / 500 ML D5W IVPB; OXALIPLATIN 100 MG / 250 ML D5W IVPB; OXALIPLATIN 150 MG / 250 ML D5W IVPB; OXALIPLATIN 125 MG / 250 ML D5W IVPB; OXALIPLATIN 170 MG / 250 ML D5W IVPB, Rx Only, Infusion Options, Inc. 5924 13the Ave, Brooklyn, NY 11219-4934, 718-283-7233

**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1797-2019

**Code Information:**

All lots within expiry

**Product Description:**

PACLITAXEL 258 MG / 500 ML NS IVPB; PACLITAXEL 318 MG / 500 ML NS IVPB; PACLITAXEL 385 MG / 500 ML NS IVPB; PACLITAXEL 340 MG / 500 ML NS IVPB; PACLITAXEL 332 MG / 500 ML NS IVPB; PACLITAXEL 250 MG / 500 ML NS IVPB; PACLITAXEL 117 MG / 250 ML NACL 0.9% IVPB PACLITAXEL 90 MG / 250 ML NS IVPB; PACLITAXEL 290 MG / 500 ML NS IVPB; PACLITAXEL 168 MG / 250 ML NS IVPB; PACLITAXEL 157 MG / 250 ML NS IVPB; PACLITAXEL 350 MG / 500 ML NS IVPB; PACLITAXEL 280 mg / 500 ML NS IVPB; PACLITAXEL 282 mg / 500 ML NS IVPB; PACLITAXEL 90 MG / 250 ML D5W IVPB; PACLITAXEL 255 MG / 500 ML NS IVPB; PACLITAXEL 100 MG / 250 ML NS IVPB; PACLITAXEL 80 MG / 250 ML D5W IVPB; PACLITAXEL 117 MG / 250 ML NS IVPB; PACLITAXEL 159 MG / 250 ML NS IVPB; PACLITAXEL 330 MG / 500 ML NS IVPB; PACLITAXEL 135 MG / 250 ML NS IVPB; PACLITAXEL 200 MG / 500 ML NS IVPB; PACLITAXEL 150 MG / 250 ML NS

IVPB; PACLITAXEL 130 MG / 250 ML NS IVPB; PACLITAXEL 144 MG / 250 ML NS IVPB; PACLITAXEL 300 MG / 500 ML NS IVPB; PACLITAXEL 120 MG / 250 ML NS IVPB; PACLITAXEL 140 MG / 250 ML NS IVPB, Rx Only, Infusion Options, Inc. 5924 13th Ave, Brooklyn, NY 11219-4934, 718-283-7233

**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1798-2019

**Code Information:**

All lots within expiry

**Product Description:**

PACLITAXEL ALBUMIN 185 mg /100 ml NS IVPB; PACLITAXEL ALBUMIN 160 MG / 100 ml NS IVPB; PACLITAXEL ALBUMIN 145 MG / 100 ml NS IVPB PACLITAXEL ALBUMIN 165 mg / 100 ml NS IVPB; PACLITAXEL ALBUMIN 150 mg /100 ml NS IVPB, Rx Only, Infusion Options, Inc. 5924 13th Ave, Brooklyn, NY 11219-4934, 718-283-7233

**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1799-2019

**Code Information:**

All lots within expiry

**Product Description:**

PACLITAXEL PROTEIN 175 MG/100 ML NS IVPB; PACLITAXEL PROTEIN 190 MG/100 ML NS IVPB; PACLITAXEL PROTEIN 355 MG/100 ML NS IVPB, Rx Only, Infusion Options, Inc. 5924 13th Ave, Brooklyn, NY 11219-4934, 718-283-7233

**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1800-2019

**Code Information:**

All lots within expiry

**Product Description:**

PEMBROLIZUMAB 200 MG / 100 ML NS IVPB, Rx Only, Infusion Options, Inc. 5924 13th Ave, Brooklyn, NY 11219-4934, 718-283-7233

**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1801-2019

**Code Information:**

All lots within expiry

**Product Description:**

PANITUMUMAB 400 MG / 100 ml NS IVPB, Rx Only, Infusion Options, Inc. 5924 13th Ave, Brooklyn, NY 11219-4934, 718-283-7233

**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1802-2019

**Code Information:**

All lots within expiry

**Product Description:**

PEMETREXED 910 MG QS 100 ML NS IVPB; PEMETREXED 940 mg QS 100 ml NS IVPB; PEMETREXED 1000 mg QS 100 ml 0.9% NACL IVPB; PEMETREXED 490 MG /100 ml NS IVPB; PEMETREXED 800 mg/ 100 ml NS IVPB, Rx Only, Infusion Options, Inc. 5924 13the Ave, Brooklyn, NY 11219-4934, 718-283-7233

**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1803-2019

**Code Information:**

All lots within expiry

**Product Description:**

PERJETA 420 MG/250 ml 0.9% NACL IVPB, Rx Only, Infusion Options, Inc. 5924 13the Ave, Brooklyn, NY 11219-4934, 718-283-7233

**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1804-2019

**Code Information:**

All lots within expiry

**Product Description:**

PERTUZUMAB 840 MG/250 ml 0.9% NACL IVPB, Rx Only, Infusion Options, Inc. 5924 13the Ave, Brooklyn, NY 11219-4934, 718-283-7233

**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1805-2019

**Code Information:**

All lots within expiry

**Product Description:**

PRESERVATIVE FREE 0.9% NACL 5 ML SYR, Rx Only, Infusion Options, Inc. 5924 13the Ave, Brooklyn, NY 11219-4934, 718-283-7233

**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1806-2019

**Code Information:**

All lots within expiry

**Product Description:**

RAMUCIRUMAB 457 MG QS 250 ML NS IVPB; AMUCIRUMAB 1182 MG QS 250 ML NS IVPB; Rx Only, Infusion Options, Inc. 5924 13the Ave, Brooklyn, NY 11219-4934, 718-283-7233

**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1807-2019

**Code Information:**

All lots within expiry

**Product Description:**

REMICADE 680 MG QS 250 ML 0.9% NACL IVPB; REMICADE 270 MG QS 250 ML 0.9% NACL IV; REMICADE 730 MG QS 250 ML 0.9% NACL IVPB; REMICADE 330 MG QS 250 ML 0.9% NACL IVPB; REMICADE 740 MG IN 250 ML NS IVPB; REMICADE 650 MG / 250 ml 0.9% NACL; REMICADE 1200 MG/250 ml 0.9% NACL IVPB; REMICADE 800 MG/250 ml 0.9% NACL IVPB; REMICADE 600 MG / 250 ml 0.9% NACL IVPB, Rx Only, Infusion Options, Inc. 5924 13th Ave, Brooklyn, NY 11219-4934, 718-283-7233

**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1808-2019

**Code Information:**

All lots within expiry

**Product Description:**

RITUXAN 728 MG QS 728 mL 0.9% NACL IVPB; RITUXAN 560 MG / 306 ml 0.9% NACL; RITUXAN 562 MG IN 562 ml 0.9% NACL; RITUXAN 700 MG QS 700 mL 0.9% NACL IVPB; RITUXAN 1000 MG / 350 mL 0.9% NACL IVPB; RITUXAN 730 MG / 730 mL 0.9% NACL IVPB; RITUXAN 1000 MG QS 1000 ml NS; RITUXAN 1000 MG QS 200 ml 0.9% NACL; RITUXAN 500 MG / 300 ml 0.9% NACL; RITUXAN 660 MG QS 660 ml 0.9% NACL; RITUXAN 770 MG QS 770 mL 0.9% NACL IVPB, Rx Only, Infusion Options, Inc. 5924 13th Ave, Brooklyn, NY 11219-4934, 718-283-7233

**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1809-2019

**Code Information:**

All lots within expiry

**Product Description:**

RITUXIMAB 575 MG / 250 ml 0.9% NACL IVPB; RITUXIMAB 675 MG / 250 ml 0.9% NACL IVPB; RITUXIMAB 1000 MG / 1000 ml NS IVPB, Rx Only, Infusion Options, Inc. 5924 13th Ave, Brooklyn, NY 11219-4934, 718-283-7233

**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1810-2019

**Code Information:**

All lots within expiry

**Product Description:**

RomiPLOstim 700 MCG/ 1.4 ML SQ SYR, Rx Only, Infusion Options, Inc. 5924 13th Ave, Brooklyn, NY 11219-4934, 718-283-7233

**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1811-2019

**Code Information:**

All lots within expiry

**Product Description:**

Sodium Chloride 0.9% 1 LITER WITH Potassium Chloride 20 mEq, Mannitol 12.5 G, Magnesium Sulfate 2 G, Rx Only, Infusion Options, Inc. 5924 13th Ave, Brooklyn, NY 11219-4934, 718-283-7233

**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility



**Recall Number:**

D-1812-2019

**Code Information:**

All lots within expiry

**Product Description:**

SOLIRIS 1200 MG QS 240 ML NAACL0.9% IVPB; SOLIRIS 900 MG QS 180 ML NAACL 0.9% IVPB, Rx Only, Infusion Options, Inc. 5924 13the Ave, Brooklyn, NY 11219-4934, 718-283-7233

**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1813-2019

**Code Information:**

All lots within expiry

**Product Description:**

TOPOTECAN 1.24 MG / 100 ML NS IVPB, Rx Only, Infusion Options, Inc. 5924 13the Ave, Brooklyn, NY 11219-4934, 718-283-7233

**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1814-2019

**Code Information:**

All lots within expiry

**Product Description:**

TRASTUZUMAB 427 MG / 250 ml NS IVPB; TRASTUZUMAB 531 MG / 250 ML NS IVPB; TRASTUZUMAB 276 MG / 250 ML NS IVPB; TRASTUZUMAB 360 MG / 250 ML NS IVPB; TRASTUZUMAB 757 MG / 250 ML NS IVPB TRASTUZUMAB 450 MG / 250 ML NS IVPB; TRASTUZUMAB 120 MG / 250 ML NS IVPB; TRASTUZUMAB 164 MG / 250 ML NS IVPB; TRASTUZUMAB 444 MG / 250 ml NS IVPB; TRASTUZUMAB 634 MG / 250 ML NS IVPB; TRASTUZUMAB 330 MG / 250 ML NS IVPB; TRASTUZUMAB 781 MG / 250 ML NS IVPB; TRASTUZUMAB 376 mg / 250 ML NS IVPB; TRASTUZUMAB 114 MG / 250 ML NS IVPB; TRASTUZUMAB 266 MG / 250 ML NS IVPB TRASTUZUMAB 323 MG / 250 ML NS IVPB; Rx Only, Infusion Options, Inc. 5924 13the Ave, Brooklyn, NY 11219-4934, 718-283-7233

**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1815-2019

**Code Information:**

All lots within expiry

**Product Description:**

VELCADE 2.1 mg / 0.84 ml SQ SYRINGE; VELCADE 2.5 MG/ 1 ML SUB-Q SYRINGE; VELCADE 2.2 MG/ 0.88 ML SUB-Q SYRINGE; VELCADE 2.6 MG (1.04 ML) Sub Q SYRINGE; VELCADE 4 mg / 1.6 ml SQ SYRINGE; VELCADE 2.75 mg / 1.1 ml SQ SYRINGE; VELCADE 2.6 mg / 1.04 ml SQ SYRINGE VELCADE 1.7 mg / 0.68 ml SQ SYRINGE; VELCADE 3.5 mg / 1.4 ML SQ SYRINGE; VELCADE 2.2 mg / 0.88 ml SQ SYRINGE; VELCADE 2.33 MG/ 0.93 ML SUB-Q SYRINGE; VELCADE 2.4 MG/ 0.96 ML SUB-Q SYRINGE VELCADE 2.63 MG/ 1.052 ML SUB-Q SYRINGE, Rx Only, Infusion Options, Inc. 5924 13the Ave, Brooklyn, NY 11219-4934, 718-283-7233

**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1816-2019

**Code Information:**

All lots within expiry

**Product Description:**

VINBLASTINE 10.9 MG / 100 ML D5W IVPB; VINBLASTINE 10.8 MG / 100 ML D5W IVPB, Rx Only, Infusion Options, Inc. 5924 13th Ave, Brooklyn, NY 11219-4934, 718-283-7233

**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1817-2019

**Code Information:**

All lots within expiry

**Product Description:**

VINCRIStINE 1 MG /50 ML NS IVPB; VINCRIStINE 1.2 MG /50 ML NAcl 0.9% IVPB; VINCRIStINE 1 MG / 1 ML IVP SYRINGE; VINCRIStINE 2 MG /100 ML D5W IVPB, Rx Only, Infusion Options, Inc. 5924 13th Ave, Brooklyn, NY 11219-4934, 718-283-7233

**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1818-2019

**Code Information:**

All lots within expiry

**Product Description:**

FERRIC CARBOXYMALTOSE 750mg/50ml NS IVPB, Rx Only, Infusion Options, Inc. 5924 13th Ave, Brooklyn, NY 11219-4934, 718-283-7233

**Product Quantity:****Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-1819-2019

**Code Information:**

All lots within expiry

## Class II Drugs Event

**Event ID:**

83316

**Status:**

Ongoing

**Recall Initiation Date:**

07/11/2019

**Center Classification Date:**

08/13/2019

**Recalling Firm:**

US Pharmaceuticals Inc.  
681 Main St Ste 27  
Belleville NJ United States

**Distribution Pattern:**

Distributed 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:**

CVS Health Glycerin Suppositories, 50-count box, Distributed by: CVS Pharmacy, Inc. One CVS Drive Woonsocket, RI 02895. UPC 0 50428 33106

4

**Product Quantity:**

144 cases

**Reason for Recall:**

CGMP Deviations: Out of Specification results for either total microbial count or total organic carbon in the purified water utilized in the manufacturing process.

**Recall Number:**

D-1724-2019

**Code Information:**

Lot #'s 52J17, 53J17, 54J17, 55J17, 59J17, 60J17 EXP 07/2019

**Product Description:**

Eczema Lotion Hydrocortisone 1% / Anti-Itch Lotion, 3.5 oz (99.2 g) Distributed By: Walgreen Co. 200 Wilmot Rd. Deerfield, IL, 60015. NDC 0363-0670-04, UPC 3 11917 19308 3

**Product Quantity:**

533 cases

**Reason for Recall:**

CGMP Deviations: Out of Specification results for either total microbial count or total organic carbon in the purified water utilized in the manufacturing process.

**Recall Number:**

D-1725-2019

**Code Information:**

Lot #36P17 EXP 11/2019

**Product Description:**

CVS Therapeutic Menthol Gel, 8 FL OZ (227 g) Distributed by: CVS Pharmacy, Inc. One CVS Drive Woonsocket, RI 02895. UPC 0 50428 48136 3

**Product Quantity:**

5017 cases

**Reason for Recall:**

CGMP Deviations: Out of Specification results for either total microbial count or total organic carbon in the purified water utilized in the manufacturing process.

**Recall Number:**

D-1726-2019

**Code Information:**

Lot #'s 28L17, 31L17, 36L17, 40L17, 44L17 EXP 09/2019; 05M17, 09M17, 12M17, 13M17, 23M17 EXP 10/2019; 69P17, 72P17 EXP 11/2019; 42S17, 46S17 EXP 12/2019; 85C18, 86C18 EXP 03/2020; 31J18, 43J18, 55J18, 58J18, 18L18 EXP 07/2020.

**Product Description:**

Children Glycerin Suppositories Laxative for ages 2 to 5. Package Size 25-count. Distributed by Walgreen CO. 200 Wilmot Rd. Deerfield IL 60015. NDC#0363-0440-25,

**Product Quantity:**

76 cases

**Reason for Recall:**

CGMP Deviations: Out of Specification results for either total microbial count or total organic carbon in the purified water utilized in the manufacturing process.

**Recall Number:**

D-1727-2019

**Code Information:**

Lot #88J17 EXP 07/2019

**Product Description:**

Adult Glycerin Suppositories, Package Size 25-count suppositories, Distributed By: Walgreen Co. 200 Wilmot Rd. Deerfield, IL 60015. NDC#0363-0445-25,

**Product Quantity:**

98 cases

**Reason for Recall:**

CGMP Deviations: Out of Specification results for either total microbial count or total organic carbon in the purified water utilized in the manufacturing process.

**Recall Number:**

D-1728-2019

**Code Information:**

Lot # 01K17, 02K17 -Exp 08/2019

**Product Description:**

Adult Glycerin Suppositories, Package Size 50-count suppositories, Distributed By: Walgreen Co. 200 Wilmot Rd. Deerfield, IL 60015. NDC#0363-0441-50

**Product Quantity:**

196 cases

**Reason for Recall:**

CGMP Deviations: Out of Specification results for either total microbial count or total organic carbon in the purified water utilized in the manufacturing process.

**Recall Number:**

D-1729-2019

**Code Information:**

Lot #'s 39P17, 42P17, 43P17, 44P17, EXP 11/2019

**Product Description:**

Adult Glycerin Suppositories, Package Size 100-count suppositories, Distributed By: Walgreen Co. 200 Wilmot Rd. Deerfield, IL 60015. NDC#0363-0441-00

**Product Quantity:**

880 cases

**Reason for Recall:**

CGMP Deviations: Out of Specification results for either total microbial count or total organic carbon in the purified water utilized in the manufacturing process.

**Recall Number:**

D-1730-2019

**Code Information:**

Lot #'s 68J17, 71J17, 72J17, 73J17, 77J17, 78J17, 79J17, 81J17, 82J17 - EXP 07/2019; 27P17, 28P17, 29P17, 30P17, 31P17, 32P17, 33P17, 37P17, 38P17, EXP 11/2019.

**Product Description:**

Hydrocortisone Cream With Aloe, Hydrocortisone 1% / Anti-Itch Cream with Aloe, 1 OZ (28 g) tube. Distributed By: Walgreen Co. 200 Wilmot Rd., Deerfield, IL 60015. NDC #0363-0620-03, UPC 3 11917 17935 3

**Product Quantity:**

3114 cases

**Reason for Recall:**

CGMP Deviations: Out of Specification results for either total microbial count or total organic carbon in the purified water utilized in the manufacturing process.

**Recall Number:**

D-1731-2019

**Code Information:**

Lot #63J17 EXP 07/2019, 11P17 EXP 11/2019

**Product Description:**

Hydrocortisone Cream With Aloe, Hydrocortisone 1% / Anti-Itch Cream with Aloe, 2 OZ (56 g) tube. Distributed By: Walgreen Co. 200 Wilmot Rd., Deerfield, IL 60015. NDC #0363-0620-04, UPC 3 11917 17934 6

**Product Quantity:**

1223 cases

**Reason for Recall:**

CGMP Deviations: Out of Specification results for either total microbial count or total organic carbon in the purified water utilized in the manufacturing process.

**Recall Number:**

D-1732-2019

**Code Information:**

Lot #'s 11P17, 20P17 EXP 11/2019

**Product Description:**

Hydrocortisone Cream, Hydrocortisone 1% / Anti-Itch Cream, 1 OZ (28 g) tube. Distributed By: Walgreen Co. 200 Wilmot Rd., Deerfield, IL 60015. NDC #0363-0638-03, UPC 3 11917 18245 2 .

**Product Quantity:**

305 cases

**Reason for Recall:**

CGMP Deviations: Out of Specification results for either total microbial count or total organic carbon in the purified water utilized in the manufacturing process.

**Recall Number:**

D-1733-2019

**Code Information:**

Lot #56J17 EXP 07/2019

**Product Description:**

Hydrocortisone Cream, Hydrocortisone 1% / Anti-Itch Cream, 2 OZ (56 g) tube. Distributed By: Walgreen Co. 200 Wilmot Rd., Deerfield, IL 60015. NDC #0363-0638-04, UPC 3 11917 18247 6

**Product Quantity:**

651 cases

**Reason for Recall:**

CGMP Deviations: Out of Specification results for either total microbial count or total organic carbon in the purified water utilized in the manufacturing process.

**Recall Number:**

D-1734-2019

**Code Information:**

Lot #56J17 EXP 07/2019

**Product Description:**

Soothe&Cool Protect Moisture Guard Skin Protectant, 3.5 oz. (99 g), tube, Manufactured for Medline industries, Inc., Mundelein, IL 60060. NDC 53329-303-22

**Product Quantity:**

830 tubes

**Reason for Recall:**

CGMP Deviations: Out of Specification results for either total microbial count or total organic carbon in the purified water utilized in the manufacturing process.

**Recall Number:**

D-1735-2019

**Code Information:**

Lot #57J17 EXP 07/2019

**Product Description:**

CVS Health Glycerin Suppositories, 100- count box, Distributed by:Distributed by: CVS Pharmacy, Inc. One CVS Drive Woonsocket, RI 02895. UPC 0 50428 42738 5

**Product Quantity:**

1174 cases

**Reason for Recall:**

CGMP Deviations: Out of Specification results for either total microbial count or total organic carbon in the purified water utilized in the manufacturing process.

**Recall Number:**

D-1736-2019

**Code Information:**

Lot #'s 61J17, 62J17, 65J17, 66J17, 67J17, 83J17, 86J17, 87J17 EXP 07/2019; Lot #'s 06P17, 08P17, 09P17, 10P17, 12P17, 13P17, 15P17,

16P17, 17P17, 18P17, 19P17, 21P17, 22P17, 23P17, 24P17, 26P17 EXP 11/2019

**Product Description:**

CRYO-273 Cold Pain Relieving Gel Roll-On 3 FL. OZ. (89 mL) Distributed By: CRYO-273.com Tampa, FL 33629. UPC 8 15290 01529 6

**Product Quantity:**

167 cases

**Reason for Recall:**

CGMP Deviations: Out of Specification results for either total microbial count or total organic carbon in the purified water utilized in the manufacturing process.

**Recall Number:**

D-1737-2019

**Code Information:**

Lot #'s 09K17, 13K17 EXP 08/2019

**Product Description:**

Cool Hot Ice Analgesic Gel, 8 oz (227 g) Distributed by: Unipack Inc. Pittsburg, PA 15239, USA. UPC 7 51393 00608 6

**Product Quantity:**

246 cases

**Reason for Recall:**

CGMP Deviations: Out of Specification results for either total microbial count or total organic carbon in the purified water utilized in the manufacturing process.

**Recall Number:**

D-1738-2019

**Code Information:**

Lot # 14L18, EXP 09/2020

**Product Description:**

Kool Comfort Cooling Pain Relief, 5% Menthol, Packaged in a) 3 OZ./85 g (UPC 0 52301 35903 5); b) 4 OZ/ 113 g (UPC 0 52301 36504 3); c) 32 OZ/ 907 g (UPC 0 52301 36532 6); d) 16 OZ/ 454 g (UPC 0 52301 36516 6); e) 128 OZ/ 3629 g (UPC 0 52301 36512 8) Manufactured for: Dee Cee Laboratories, Inc. 304 Dee Cee Rd., White House, TN 37188.

**Product Quantity:**

2192 cases

**Reason for Recall:**

CGMP Deviations: Out of Specification results for either total microbial count or total organic carbon in the purified water utilized in the manufacturing process.

**Recall Number:**

D-1739-2019

**Code Information:**

Lot # 27H18, EXP 06/2021; 32H18, EXP 06/2021; 42H18, EXP 06/2021; 21J18, EXP 07/2021

**Product Description:**

Wonder Freeze Pain Relieving Gel with ILEX, Menthol 5%, packaged in a) 3 OZ /85 g (UPC 0 99528 35903 5); b) 4 OZ / 113 g (UPC 0 99528 31504 8); c) 16 OZ / 454 g (UPC 0 99528 31516 1); Manufactured For: Wonder Laboratories, 115 S.C.T. Ct., White House TN. 37188.

**Product Quantity:**

147 cases

**Reason for Recall:**

CGMP Deviations: Out of Specification results for either total microbial count or total organic carbon in the purified water utilized in the manufacturing process.

**Recall Number:**

D-1740-2019

**Code Information:**

Lot # a) 21J18, EXP 07/2021 b) 42H18, EXP 06/2021; c) 32H18, EXP 6/2021

**Product Description:**

CRYO-273 Cold Pain Relieving Gel 128 FL. OZ. Distributed By: CRYO-273.com Tampa, FL 33629. UPC 8 15290 01550 2

**Product Quantity:**

314 cases

**Reason for Recall:**

CGMP Deviations: Out of Specification results for either total microbial count or total organic carbon in the purified water utilized in the manufacturing process.

**Recall Number:**

D-1741-2019

**Code Information:**

Lot #'s 13K17 EXP 08/2019, 03L17 EXP 09/2019, 74H18 EXP 06/2020, 18J18 EXP 06/2020

## Class II Drugs Event

**Event ID:**

83354

**Product Type:**

Drugs

**Status:**

Ongoing

**Date Terminated:****Recall Initiation Date:**

07/17/2019

**Voluntary / Mandated:**

Voluntary: Firm initiated

**Center Classification Date:**

08/09/2019

**Initial Firm Notification of Consignee or Public:**

Letter

**Recalling Firm:**

Lupin Pharmaceuticals Inc.  
111 S Calvert St Fl 21ST  
Baltimore MD United States

**Distribution Pattern:**

Product was distributed to wholesalers/distributors and supermarket and drug chains throughout the United States.

## Associated Products

**Product Description:**

Lisinopril and Hydrochlorothiazide Tablets USP, 10 mg/12.5 mg, 100 tablet bottle, Rx only, Manufactured by for: Lupin Pharmaceuticals, Inc., Baltimore, MD, Manufactured by: Lupin Limited, Pithampur, INDIA NDC 68180-518-01

**Product Quantity:**

39,216 bottles

**Reason for Recall:**

Presence of Foreign Substance; Product complaints received related to brownish/blackish stains on the tablets and brownish/blackish powder observed inside the bottles.

**Recall Number:**

D-1720-2019

**Code Information:**

Batch# H900575, exp. date 01/2022

## Class II Drugs Event

**Event ID:**

83434

**Product Type:**

Drugs

**Status:**

Ongoing

**Date Terminated:****Recall Initiation Date:**

07/24/2019

**Voluntary / Mandated:**

Voluntary: Firm initiated

**Center Classification Date:**

08/12/2019

**Initial Firm Notification of Consignee or Public:**

Letter

**Recalling Firm:**

Alvogen, Inc  
10 Bloomfield Ave Bldg B Ste 2  
Pine Brook NJ United States

**Distribution Pattern:**

Natonwide, PR

**Associated Products****Product Description:**

Nitrofurantoin Monohydrate/Macrycrystals Capsules, 100 mg, 100-count bottle, Rx Only, Distributed by: Alvogen, Inc. Pine Brook, NY 07058 USA, NDC 47781-303-01

**Product Quantity:**

2784 bottles

**Reason for Recall:**

Failed dissolution specifications

**Recall Number:**

D-1722-2019

**Code Information:**

Lot # 471976, Exp 03/2020

**Product Description:**

Macrobid Urinary Tract Anitbacterial, 100 mg, 100-count bottle, Rx Only, Mfg. by: Norwich Pharmaceuticals, Inc. Norwich, NY 13815 USA Dist. by: Almatica Pharma, Inc. Pine Brook, NJ 07058 USA, NDC 52427-285-01

**Product Quantity:**

4272 bottles

**Reason for Recall:**

Failed dissolution specifications

**Recall Number:**

D-1723-2019

**Code Information:**

Lot # 472990, Exp 03/2020

**Class II Drugs Event****Event ID:**

83479

**Product Type:**

Drugs

**Status:**

Ongoing

**Date Terminated:****Recall Initiation Date:**

03/01/2019

**Voluntary / Mandated:**

Voluntary: Firm initiated

**Center Classification Date:**

08/15/2019

**Initial Firm Notification of Consignee or Public:**

Letter

**Recalling Firm:**

American Health Packaging  
2550 John Glenn Ave Ste A  
Columbus OH United States

**Distribution Pattern:**

Nationwide USA

**Associated Products****Product Description:**

Aspirin and Extended-release Dipyridamole Capsules, 25 mg/200 mg, 20 capsules per carton (5 blister cards x 4 unit doses), Rx Only, Distributed by: American Health Packaging, Columbus, Ohio 43217. NDC Carton: 60687-305-32; NDC Blister Pack: 60687-305-33



**Product Quantity:**

13,229 cartons

**Reason for Recall:**

Failed Impurities/Degradation Specifications; out of specification result for an unknown impurity in stability samples.

**Recall Number:**

D-1820-2019

**Code Information:**

Lot, expiry: Lot 174262, exp. 03/31/2019; Lot 176469, exp. 06/30/2019; Lot 177897, exp. 08/31/2019; Lots 178318 and 178436, exp. 09/30/2019; Lot 179547 and 179656, exp. 11/30/2019

## Class II Drugs Event

**Event ID:**

83559

**Status:**

Ongoing

**Recall Initiation Date:**

08/09/2019

**Center Classification Date:**

08/15/2019

**Recalling Firm:**American Health Packaging  
2550 John Glenn Ave Ste A  
Columbus OH United States**Distribution Pattern:**

Nationwide USA

**Product Type:**

Drugs

**Date Terminated:****Voluntary / Mandated:**

Voluntary: Firm initiated

**Initial Firm Notification of Consignee or Public:**

Letter

## Associated Products

**Product Description:**

Carbamazepine, Extended-Release Tablets, USP, 400 mg, 30 Tablets (3 blister cards x 10 unit doses), Rx Only, Distributed by: American Health Packaging, Columbus, Ohio 43217. NDC Carton: 68084-562-21; NDC Unit Dose: 68084-562-11

**Product Quantity:**

457 cartons

**Reason for Recall:**

Failed Dissolution Specifications

**Recall Number:**

D-1821-2019

**Code Information:**

Lot 181677, exp 11/30/2020

## Class III Drugs Event

**Event ID:**

83526

**Status:**

Ongoing

**Recall Initiation Date:**

08/07/2019

**Center Classification Date:**

08/15/2019

**Product Type:**

Drugs

**Date Terminated:****Voluntary / Mandated:**

Voluntary: Firm initiated

**Initial Firm Notification of Consignee or Public:**

Letter

**Recalling Firm:**

Glenmark Pharmaceuticals Inc., USA  
750 Corporate Dr  
Mahwah NJ United States

**Distribution Pattern:**

Nationwide with the United States

**Associated Products****Product Description:**

Clotrimazole and Betamethasone Dipropionate Cream USP, 1%/0.05%, 15 gram tubes, Rx only, Manufactured by: Glenmark Pharmaceuticals Ltd. Village: Kishanpura, Baddi Nalagarh Road, District: Solan, Himachal Pradesh-173205, India. Manufactured for: Glenmark Pharmaceuticals Inc., USA Mahwah, NJ 07430, NDC 68462-298-17

**Product Quantity:**

31,224 tubes

**Reason for Recall:**

Temperature Abuse: Complaints received of liquidy texture.

**Recall Number:**

D-1743-2019

**Code Information:**

Lot #: 05180734, Exp. 03/2020

**Not Yet Classified Drugs Event****Event ID:**

83414

**Status:**

Ongoing

**Recall Initiation Date:**

07/17/2019

**Center Classification Date:****Recalling Firm:**

Macleods Pharma Usa Inc  
666 Plainsboro Rd Bldg 200 Ste 230  
Plainsboro NJ United States

**Distribution Pattern:**

Nationwide

**Product Type:**

Drugs

**Date Terminated:****Voluntary / Mandated:**

Voluntary: Firm initiated

**Initial Firm Notification of Consignee or Public:**

Letter

**Associated Products****Product Description:**

Tamsulosin Hydrochloride Capsules, USP 0.4 mg Rx only a) 100 count (NDC 33342-159-11), b) 500 count (NDC 33342-159-15) and c) 1000 count (NDC 33342-159-44) bottles, Manufactured : Macleods Pharma USA, Inc Plainsboro, NJ Manufactured by: Macleods Pharmaceuticals Ltd Baddi, Himchal Pradesh, INDIA

**Product Quantity:**

a) 5448 bottles b) 972 bottles c) 158 bottles

**Reason for Recall:**

Failed Dissolution Specifications

**Recall Number:****Code Information:**

a) BTP803A, exp 08/2020; b) BTP802A, exp 07/2020, BTP901A, exp 12/2020; c) BTP802B, exp 07/2020