Enforcement Report - Week of June 7, 2017

Class II Drugs Event

Event ID:
77314
Product Type:
Drugs
Status:
Ongoing
Date Terminated:
Recall Initiation Date:
05/18/2017
Voluntary / Mandated:
Voluntary: Firm Initiated
Center Classification Date:
05/31/2017
Initial Firm Notification of Consignee or Public:
Letter
Recalling Firm:
SCA Pharmaceuticals
8821 Knoedl Ct
Little Rock AR United States
Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
morphine sulfate in 0.9% Sodium Chloride injectable, 1 mg per mL, Total Volume 100 mL, Single Dose Container bag, (Total morphine Dose 100 mg/ 100mL), Preservative Free (Contains Sulfites), Rx only, SCA Pharmaceuticals, 8821 Knoedl Ct, Little Rock, AR 72205, NDC 70004-0100-32.
Product Quantity:
80 bags
Reason for Recall:
Lack of assurance of sterility: Product bags leaking at seam.
Recall Number:
D-0870-2017
Code Information:
LOT # 20170508@57, Use By: 08/06/17

Product Description:
morphine sulfate in 0.9% Sodium Chloride injectable, 1 mg per mL, Total Volume 100 mL, Single Dose Container bag, (Total morphine Dose 100 mg/ 100 mL), Preservative Free (Contains Sulfites), Rx only, SCA Pharmaceuticals, 8821 Knoedl Ct, Little Rock, AR 72205, NDC 70004-0100-55
Product Quantity:
56 bags
Reason for Recall:
Lack of assurance of sterility: Product bags leaking at seam.
Recall Number:
D-0871-2017

Code Information:
LOT # 20170508@48, Use By: 08/06/17; 20170505@19, Use By: 08/03/17

Product Description:
fentaNYL (as citrate) in 0.9% Sodium Chloride injectable,10 mcg per mL, Total Volume 100 mL, Single Dose Container bag, (Total fentanyl Dose 1,000 mcg/100 mL) Preservative Free, Rx Only, SCA Pharmaceuticals, 8821 Knoedl Ct. Little Rock, AR 72205, NDC 70004-0229-32
Product Quantity:
118 bags
Reason for Recall:
Lack of assurance of sterility: Product bags leaking at seam.
Recall Number:
D-0872-2017
Code Information:
LOT # 20170505@14, Use By: 08/03/17; 20170510@2, Use By: 08/08/17

Product Description:
fentaNYL (as citrate) in 0.9% Sodium Chloride injectable,10 mcg per mL, Total Volume 100 mL, Single Dose Container bag, (Total fentanyl Dose 1,000 mcg/100 mL) Preservative Free, Rx Only, SCA Pharmaceuticals, 8821 Knoedl Ct. Little Rock, AR 72205, NDC 70004-0202-32
Product Quantity:
370 bags
Reason for Recall:
Lack of assurance of sterility: Product bags leaking at seam.
Recall Number:
D-0873-2017
Code Information:
LOT # 20170506@14, Use By: 08/04/17

Product Description:
fentaNYL (as citrate) in 100mL 0.9% Sodium Chloride injectable,20 mcg per mL, Single Dose Container bag, (Total fentanyl Dose 2,000 mcg/100 mL) Preservative Free, Rx Only, SCA Pharmaceuticals, 8821 Knoedl Ct. Little Rock, AR 72205, NDC 70004-203-32
Product Quantity:
100 bags
Reason for Recall:
Lack of assurance of sterility: Product bags leaking at seam.
Recall Number:
D-0874-2017
Code Information:
LOT # 20170508@59, Use By: 08/06/17

Product Description:
HYDROmorphone HCL in 0.9% Sodium Chloride injectable, 0.2 mg per ml, Total Volume 100mL, Single Dose Container bag, (Total HYDROmorphone Dose 20 mg per 100 mL) Preservative Free, Rx Only, SCA Pharmaceuticals, 8821 Knoedl Ct. Little Rock, AR 72205, NDC 70004-0300-55
Product Quantity:
87 bags
Reason for Recall:
Lack of assurance of sterility: Product bags leaking at seam.

Recall Number:
D-0875-2017
Code Information:
LOT # 20170505@23, 20170505@28, Use By: 08/03/17

Product Description:
ceFAZolin sodium added to 100 mL 0.9% Sodium Chloride injectable, 2g, Total Approximate Volume 100 mL, Single Dose Container bag, Preservative Free, Rx Only, SCA Pharmaceuticals, 8821 Knoedl Ct. Little Rock, AR 72205, NDC 70004-0522-32
Product Quantity:
240 bags
Reason for Recall:
Lack of assurance of sterility: Product bags leaking at seam.
Recall Number:
D-0876-2017
Code Information:
LOT # 20170510@12, Use By: 06-24-17

Product Description:
ceFAZolin sodium added to 100 mL 0.9% Sodium Chloride injectable, 3g, Total Approximate Volume 115 mL, Single Dose Container bag, Preservative Free, Rx Only, SCA Pharmaceuticals, 8821 Knoedl Ct. Little Rock, AR 72205, NDC 70004-0524-32
Product Quantity:
70 bags
Reason for Recall:
Lack of assurance of sterility: Product bags leaking at seam.
Recall Number:
D-0877-2017
Code Information:
LOT # 20170508@15, Use By: 06/22/17

Product Description:
MAGNESIUM Sulfate added to 100 mL 0.9% Sodium Chloride injectable, 4g, Total Approximate Volume 108 mL (does not include mfg. overfill) Single Dose Container bag, Preservative Free, Rx Only, SCA Pharmaceuticals, 8821 Knoedl Ct. Little Rock, AR 72205, NDC: 70004-0737-32
Product Quantity:
40 bags
Reason for Recall:
Lack of assurance of sterility: Product bags leaking at seam.
Recall Number:
D-0878-2017
Code Information:
LOT # 20170509@29, Use By: 08/07/17

Product Description:
PHENYLephrine HCL in 0.9% Sodium Chloride injectable, 10 mg (Final Concentration = 0.1 mg per mL) Total Volume 100 mL, Single Dose Container bag, Preservative Free (Contains Sulfites), Rx Only, SCA Pharmaceuticals, 8821 Knoedl Ct. Little Rock, AR 72205, NDC: 70004-0810-32
Product Quantity:
30 bags

Reason for Recall:
Lack of assurance of sterility: Product bags leaking at seam.
Recall Number:
D-0879-2017
Code Information:
LOT # 20170511@17, Use By: 08/09/17

Class II Drugs Event

Event ID:
77315
Product Type:
Drugs
Status:
Ongoing
Date Terminated:
Recall Initiation Date:
05/18/2017
Voluntary / Mandated:
Voluntary: Firm Initiated
Center Classification Date:
05/31/2017
Initial Firm Notification of Consignee or Public:
Letter
Recalling Firm:
Forest Laboratories, LLC
Harborside Financial Center Plaza V- Suite 1900
Jersey City NJ United States
Distribution Pattern:
Nationwide

Associated Products

Product Description:
Saphris 10 mg (asenapine) sublingual tablets, 6x10 count blister packs, Rx only, Black Cherry Flavor, Manufactured by: Catalent UK Swindon, Zydis Ltd, Blagrove, Swindon, Wilshire SN5 BRU, UK Distributed by Forest Pharmaceuticals, Inc. subsidiary of Forest Laboratories, LLC, Cincinnati OH 45209 USA --- NDC 0456-2410-60; Shellpack containing 1 blister card --- NDC 0456-2410-06
Product Quantity:
40,621 blister packs
Reason for Recall:
Labeling; Label Mixup; blister lidding foil and shell-pack labeled as 10 mg but package actually contains 5 mg tablets
Recall Number:
D-0880-2017
Code Information:
Lots W00733 and W00946, exp Apr 2019

Class III Drugs Event

Event ID:
77117
Product Type:
Drugs
Status:
Ongoing
Date Terminated:
Recall Initiation Date:
04/26/2017
Voluntary / Mandated:
Voluntary: Firm Initiated
Center Classification Date:
05/26/2017
Initial Firm Notification of Consignee or Public:
Letter
Recalling Firm:
Sandoz Inc
100 College Rd W
Princeton NJ United States
Distribution Pattern:
NY, OH

Associated Products

Product Description:
Amoxicillin and Clavulanate Potassium Tablets, USP, 500 mg/125 mg, in 20 count bottles, Rx Only, Manufactured in Austria by Sandoz Gmbh for Sandoz Inc. Princeton NJ NDC 0781-1831-20
Product Quantity:
4,464 bottles
Reason for Recall:
Subpotent Drug; Clavulanic Acid
Recall Number:
D-0868-2017
Code Information:
Lot FP8735, 8/2017

Class III Drugs Event

Event ID:
77319
Product Type:
Drugs
Status:
Ongoing
Date Terminated:
Recall Initiation Date:
05/17/2017

Voluntary / Mandated:
Voluntary: Firm Initiated
Center Classification Date:
05/31/2017
Initial Firm Notification of Consignee or Public:
Letter
Recalling Firm:
VistaPharm, Inc.
7265 Ulmerton Rd
Largo FL United States
Distribution Pattern:
Nationwide in the US and Puerto Rico

Associated Products

Product Description:
Nystatin Oral Suspension, USP, 100,000 units/mL, packaged in a) 2 fl.oz. (60mL) bottles (NDC 66689-008-02), and 500,000 units/5mL individual unit dose cup (NDC 66689-037-01) packaged in b) 50 count unit dose cups/case (NDC 66689-037-50) and c) 100 count unit dose cups/case (NDC 66689-037-99) Rx only, Manufactured by: VistaPharm, Largo, FL 33771.
Product Quantity:
2,208,500 cups/18696 bottles
Reason for Recall:
Failed Impurities/Degradation Specifications: Presence of an impurity peak that exceeds approved specification.
Recall Number:
D-0869-2017
Code Information:
a) Lot #: 431300, Exp. 01/2018; b) Lot #: 434000, 432500, Exp. 07/2017;462200, Exp. 02/2018 c) Lot #: 443800, 445500, Exp. 09/2017; 460500, 461500, Exp. 01/2018.