

# Enforcement Report - Week of August 2, 2017

## Class II Drugs Event

<b>Event ID:</b> 77770	<b>Product Type:</b> Drugs	<b>Status:</b> Ongoing	<b>Date Terminated:</b>
<b>Recall Initiation Date:</b> 07/14/2017	<b>Voluntary / Mandated:</b> Voluntary: Firm Initiated	<b>Center Classification Date:</b> 07/26/2017	<b>Initial Firm Notification of Consignee or Public:</b> Letter
<b>Recalling Firm:</b> SCA Pharmaceuticals 8821 Knoedl Ct Little Rock AR United States		<b>Distribution Pattern:</b> Nationwide	

## Associated Products

<p><b>Product Description:</b> BUPIVacaine HCl 0.1% PF (From 0.75%) in 0.9% Sodium Chloride, 250 mL Bag, Preservative Free (Waste From 250 mL Bag), Rx only, SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205 --- NDC# 70004-0060-40</p> <p><b>Reason for Recall:</b> Lack of Assurance of Sterility; product has the potential to leak.</p> <p><b>Code Information:</b> Lots: 20170429@33 BUD: 7/28/2017, 20170503@23 BUD: 8/1/2017</p>	<p><b>Product Quantity:</b></p> <p><b>Recall Number:</b> D-1005-2017</p>
<p><b>Product Description:</b> BUPIVacaine HCl 0.125% In 250 mL 0.9% Sodium Chloride Bag, Preservative Free (Total Dose Bupivacaine 312.5 mg per 250 mL), Rx only, SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205 --- NDC# 70004-0062-40</p> <p><b>Reason for Recall:</b> Lack of Assurance of Sterility; product has the potential to leak.</p> <p><b>Code Information:</b> Lot: 20170502@32 BUD: 7/31/2017</p>	<p><b>Product Quantity:</b></p> <p><b>Recall Number:</b> D-1006-2017</p>
<p><b>Product Description:</b> BUPIVacaine HCl 0.2% IN 0.9% Sodium Chloride 250 mL Bag Preservative Free (Total Dose Bupivacaine 500 mg per 250 mL), Rx only, SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205 --- NDC# 70004-0066-40</p> <p><b>Reason for Recall:</b> Lack of Assurance of Sterility; product has the potential to leak.</p> <p><b>Code Information:</b> Lot: 20170501@69 BUD: 7/30/2017</p>	<p><b>Product Quantity:</b></p> <p><b>Recall Number:</b> D-1007-2017</p>
<p><b>Product Description:</b> fentaNYL (as citrate) 5 mcg/mL In 250 mL 0.9% Sodium Chloride Injection Bag (Total fentaNYL Dose 1250 mcg/ 250 mL), Preservative Free, Rx only, SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205 --- NDC# 70004-0201-40</p> <p><b>Reason for Recall:</b> Lack of Assurance of Sterility; product has the potential to leak.</p> <p><b>Code Information:</b> Lots: 20170428@57 BUD: 7/27/2017; 20170428@58 BUD: 7/27/2017; 20170511@24 BUD: 8/9/2017</p>	<p><b>Product Quantity:</b></p> <p><b>Recall Number:</b> D-1008-2017</p>
<p><b>Product Description:</b> fentaNYL (as citrate) 10 mcg per mL in 0.9% Sodium Chloride 250 mL Bag, Rx only, SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205 --- NDC# 70004-0202-40</p> <p><b>Reason for Recall:</b> Lack of Assurance of Sterility; product has the potential to leak.</p>	<p><b>Product Quantity:</b></p> <p><b>Recall Number:</b> D-1009-2017</p>

<b>Code Information:</b> Lots: 20170502@18 BUD: 7/31/2017; 20170502@39 BUD: 7/31/2017; 20170502@62 BUD: 7/31/2017; 20170503@22 BUD: 8/1/2017; 20170503@4 BUD: 8/1/2017; 20170503@54 BUD: 8/1/2017; 20170504@10 BUD: 8/2/2017; 20170505@15 BUD: 8/3/2017; 20170506@23 BUD: 8/4/2017	
<b>Product Description:</b> fentaNYL as citrate 5 mcg/mL in 0.9% Sodium Chloride 1 mL in Single Dose syringe, Rx only, SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205 --- NDC# 70004-0225-24	<b>Product Quantity:</b>
<b>Reason for Recall:</b> Lack of Assurance of Sterility; product has the potential to leak.	<b>Recall Number:</b> D-1010-2017
<b>Code Information:</b> Lot: 20170510@40 BUD: 8/8/2017	
<b>Product Description:</b> fentaNYL 2 mcg/mL+Bupivacaine 0.0625% PF in 0.9% Sodium Chloride 250 mL, Rx only, SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205 ---- NDC# 70004-0226-40	<b>Product Quantity:</b>
<b>Reason for Recall:</b> Lack of Assurance of Sterility; product has the potential to leak.	<b>Recall Number:</b> D-1011-2017
<b>Code Information:</b> Lots: 20170429@29 BUD: 7/28/2017; 20170512@24 BUD: 8/10/2017	
<b>Product Description:</b> fentaNYL 10 mcg/mL PF in NS 1 mL Fill in 3 mL syringe, Rx only, SCA Pharmaceuticals, 8821 Knoedl Ct Little Rock, AR 72205 --- NDC# 70004-0229-05	<b>Product Quantity:</b>
<b>Reason for Recall:</b> Lack of Assurance of Sterility; product has the potential to leak.	<b>Recall Number:</b> D-1012-2017
<b>Code Information:</b> Lot: 20170512@19 BUD: 8/10/2017	
<b>Product Description:</b> fentaNYL 10 mcg/mL PF in Sodium Chloride 250 mL (Total Dose=2500 mcg), Rx only, SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205 --- NDC# 70004-0229-40	<b>Product Quantity:</b>
<b>Reason for Recall:</b> Lack of Assurance of Sterility; product has the potential to leak.	<b>Recall Number:</b> D-1013-2017
<b>Code Information:</b> Lots: 20170509@20 BUD: 8/7/2017; 20170509@21 BUD: 8/7/2017; 20170509@46 BUD: 8/7/2017; 20170511@33 BUD: 8/9/2017	
<b>Product Description:</b> fentaNYL 2 mcg/mL + BUPIvacaine 0.1% PF in 0.9% NS 250 mL, Rx only, SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205 --- NDC# 70004-0230-40	<b>Product Quantity:</b>
<b>Reason for Recall:</b> Lack of Assurance of Sterility; product has the potential to leak.	<b>Recall Number:</b> D-1014-2017
<b>Code Information:</b> Lots: 20170502@47 BUD: 7/31/2017; 20170502@56 BUD: 7/31/2017; 20170505@26 BUD: 8/3/2017; 20170506@25 BUD: 8/4/2017	
<b>Product Description:</b> fentaNYL 2 mcg/mL + BUPIvacaine 0.125% PF in 0.9% Sodium Chloride 250 mL, Rx only, SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205 --- NDC# 70004-0254-40	<b>Product Quantity:</b>
<b>Reason for Recall:</b> Lack of Assurance of Sterility; product has the potential to leak.	<b>Recall Number:</b> D-1015-2017
<b>Code Information:</b> Lots: 20170503@75 BUD: 8/1/2017; 20170511@21 BUD: 8/9/2017	
<b>Product Description:</b> fentaNYL 3 mcg/mL + BUPIvacaine 0.1% in 0.9% Sodium Chloride 250 mL, Rx only, SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205 --- NDC# 70004-0290-40	<b>Product Quantity:</b>
<b>Reason for Recall:</b> Lack of Assurance of Sterility; product has the potential to leak.	<b>Recall Number:</b> D-1016-2017
<b>Code Information:</b> Lot: 20170506@27 BUD: 8/4/2017	

<p><b>Product Description:</b> Hydromorphone 0.5 mg/mL in 0.9% Sodium Chloride 1 mL Fill in 3 mL BD syringe, Rx only, SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205 --- NDC# 70004-0302-05</p> <p><b>Reason for Recall:</b> Lack of Assurance of Sterility; product has the potential to leak.</p> <p><b>Code Information:</b> Lot: 20170508@75 BUD: 8/6/2017</p>	<p><b>Product Quantity:</b></p> <p><b>Recall Number:</b> D-1017-2017</p>
<p><b>Product Description:</b> ePHEDrine Sulfate 5 mg/mL in NS 5 mL Fill in 12 mL Syringe (25 mg), Rx only, SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205 --- NDC# 70004-0600-11</p> <p><b>Reason for Recall:</b> Lack of Assurance of Sterility; product has the potential to leak.</p> <p><b>Code Information:</b> Lots: 20170503@28 BUD: 7/17/2017; 20170508@60 BUD: 7/22/2017</p>	<p><b>Product Quantity:</b></p> <p><b>Recall Number:</b> D-1018-2017</p>
<p><b>Product Description:</b> EPINEPHrine HCl 4 mg in 0.9% Sodium Chloride 250 mL, Rx only, SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205 --- NDC# 70004-0613-40</p> <p><b>Reason for Recall:</b> Lack of Assurance of Sterility; product has the potential to leak.</p> <p><b>Code Information:</b> Lots: 20170508@51 BUD: 9/10/2017; 20170503@17 BUD: 9/5/2017</p>	<p><b>Product Quantity:</b></p> <p><b>Recall Number:</b> D-1019-2017</p>
<p><b>Product Description:</b> NORepinephrine 4 mg in 0.9% Sodium Chloride 250 mL from Stock, Rx only, SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205 --- NDC# 70004-0771-40</p> <p><b>Reason for Recall:</b> Lack of Assurance of Sterility; product has the potential to leak.</p> <p><b>Code Information:</b> Lots: 20170502@36 BUD: 7/31/2017; 20170512@1 BUD: 8/10/2017; 20170504@13 BUD: 8/2/2017; 20170504@18 BUD: 8/2/2017</p>	<p><b>Product Quantity:</b></p> <p><b>Recall Number:</b> D-1020-2017</p>
<p><b>Product Description:</b> NORepinephrine Bitartrate 8 mg in 0.9% Sodium Chloride 250 mL, Rx only, SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205 --- NDC# 70004-0774-40</p> <p><b>Reason for Recall:</b> Lack of Assurance of Sterility; product has the potential to leak.</p> <p><b>Code Information:</b> Lots: 20170502@31 BUD: 7/16/2017; 20170508@34 BUD: 7/22/2017; 20170508@70 BUD: 7/22/2017; 20170512@15 BUD: 7/26/2017</p>	<p><b>Product Quantity:</b></p> <p><b>Recall Number:</b> D-1021-2017</p>
<p><b>Product Description:</b> NORepinephrine Bitartrate 16 mg in 0.9% Sodium Chloride 250 mL from Stock, Rx only, SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205 --- NDC# 70004-0775-40</p> <p><b>Reason for Recall:</b> Lack of Assurance of Sterility; product has the potential to leak.</p> <p><b>Code Information:</b> Lots: 20170512@8 BUD: 8/10/2017; 20170506@18 BUD: 8/4/2017</p>	<p><b>Product Quantity:</b></p> <p><b>Recall Number:</b> D-1022-2017</p>
<p><b>Product Description:</b> PHENYLephine HCl 60 mg in 0.9% Sodium Chloride 250 mL, Rx only, SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205 --- NDC# 70004-0809-40</p> <p><b>Reason for Recall:</b> Lack of Assurance of Sterility; product has the potential to leak.</p> <p><b>Code Information:</b> Lots: 20170502@53 BUD: 7/31/2017; 20170505@16 BUD: 8/3/2017</p>	<p><b>Product Quantity:</b></p> <p><b>Recall Number:</b> D-1023-2017</p>
<p><b>Product Description:</b> PHENYLephine HCl 25 mg in 0.9% Sodium Chloride 250 mL, Rx only, SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205 --- NDC# 70004-0810-40</p>	<p><b>Product Quantity:</b></p>

<b>Reason for Recall:</b> Lack of Assurance of Sterility; product has the potential to leak.	<b>Recall Number:</b> D-1024-2017
<b>Code Information:</b> Lots: 20170512@20 BUD: 8/10/2017; 20170504@61 BUD: 8/2/2017	
<b>Product Description:</b> PHENYLephrine HCl 10 mg in 0.9% Sodium Chloride 250 mL Bag, Preservative Free, Rx only, SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205 --- NDC# 70004-0811-40	<b>Product Quantity:</b>
<b>Reason for Recall:</b> Lack of Assurance of Sterility; product has the potential to leak.	<b>Recall Number:</b> D-1025-2017
<b>Code Information:</b> Lots: 20170503@26 BUD: 8/1/2017; 20170510@48 BUD: 8/8/2017	
<b>Product Description:</b> PHENYLephrine 10 mg in 0.9% Sodium Chloride 250 mL bag, Rx only, SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205 ---- NDC# 70004-0811-59	<b>Product Quantity:</b>
<b>Reason for Recall:</b> Lack of Assurance of Sterility; product has the potential to leak.	<b>Recall Number:</b> D-1026-2017
<b>Code Information:</b> Lots: 20170503@29 BUD: 8/1/2017; 20170512@22 BUD: 8/10/2017; 20170509@64 BUD: 8/7/2017	
<b>Product Description:</b> PHENYLephrine 40 mg in 0.9% Sodium Chloride 250 mL, Rx only, SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205 --- NDC# 70004-0812-40	<b>Product Quantity:</b>
<b>Reason for Recall:</b> Lack of Assurance of Sterility; product has the potential to leak.	<b>Recall Number:</b> D-1027-2017
<b>Code Information:</b> Lots: 20170429@28 BUD: 7/28/2017; BUD: 20170509@65 BUD: 8/7/2017	
<b>Product Description:</b> PHENYLephrine 100 mg in 0.9% Sodium Chloride 250 mL Bag, Rx only, SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205 --- NDC# 70004-0813-40	<b>Product Quantity:</b>
<b>Reason for Recall:</b> Lack of Assurance of Sterility; product has the potential to leak.	<b>Recall Number:</b> D-1028-2017
<b>Code Information:</b> Lot: 20170503@16 BUD: 8/1/2017	
<b>Product Description:</b> PHENYLephrine 200 mg in 0.9% Sodium Chloride 250 mL, Rx only, SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205 --- NDC# 70004-0815-40	<b>Product Quantity:</b>
<b>Reason for Recall:</b> Lack of Assurance of Sterility; product has the potential to leak.	<b>Recall Number:</b> D-1029-2017
<b>Code Information:</b> Lot: 20170511@51 BUD: 8/9/2017	
<b>Product Description:</b> PHENYLephrine 20 mg in 0.9% Sodium Chloride 250 mL Bag, Rx only, SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205 --- NDC# 70004-0816-40	<b>Product Quantity:</b>
<b>Reason for Recall:</b> Lack of Assurance of Sterility; product has the potential to leak.	<b>Recall Number:</b> D-1030-2017
<b>Code Information:</b> Lot: 20170503@19 BUD: 8/1/2017	
<b>Product Description:</b> PHENYLephrine 50 mg in 0.9% Sodium Chloride 250 mL, Rx only, SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205 --- NDC# 70004-0820-40	<b>Product Quantity:</b>
<b>Reason for Recall:</b> Lack of Assurance of Sterility; product has the potential to leak.	<b>Recall Number:</b> D-1031-2017

<b>Code Information:</b> Lots: 20170512@6 BUD: 8/10/2017; 20170511@56 BUD: 8/9/2017	
<b>Product Description:</b> Potassium Chloride 20 meq Added to Sodium Chloride 0.9% 250 mL, Rx only, SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205 --- NDC# 70004-0832-40	<b>Product Quantity:</b>
<b>Reason for Recall:</b> Lack of Assurance of Sterility; product has the potential to leak.	<b>Recall Number:</b> D-1032-2017
<b>Code Information:</b> Lots: 20170501@66 BUD: 7/15/2017	
<b>Product Description:</b> Potassium Chloride 40 meq Added to Sodium Chloride 0.9% 250 mL, Rx only, SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205 ---- NDC# 70004-0833-40	<b>Product Quantity:</b>
<b>Reason for Recall:</b> Lack of Assurance of Sterility; product has the potential to leak.	<b>Recall Number:</b> D-1033-2017
<b>Code Information:</b> Lots: 20170509@10 BUD: 7/23/2017	
<b>Product Description:</b> fentaNYL 2 mcg/mL + Ropivacaine 0.2% PF in NS 250 mL, Rx only, SCA Pharmaceuticals 8821 Knoedl Ct Little Rock, AR 72205 --- NDC# 70004-0260-40	<b>Product Quantity:</b>
<b>Reason for Recall:</b> Lack of Assurance of Sterility; product has the potential to leak.	<b>Recall Number:</b> D-1034-2017
<b>Code Information:</b> Lots: 20170509@17 BUD: 8/7/2017	

### Class II Drugs Event

<b>Event ID:</b> 77777	<b>Product Type:</b> Drugs	<b>Status:</b> Ongoing	<b>Date Terminated:</b>
<b>Recall Initiation Date:</b> 07/14/2017	<b>Voluntary / Mandated:</b> Voluntary: Firm Initiated	<b>Center Classification Date:</b> 07/25/2017	<b>Initial Firm Notification of Consignee or Public:</b> Letter
<b>Recalling Firm:</b> SCA Pharmaceuticals 8821 Knoedl Ct Little Rock AR United States		<b>Distribution Pattern:</b> Nationwide in the USA	

### Associated Products

<b>Product Description:</b> morphine sulfate 1 mg per mL in 0.9% Sodium Chloride, (Total morphine Dose 100 mg/100 mL), Total Volume 100 mL Single Dose Container bag, Rx Only, SCA Pharmaceuticals, 8821 Knoedl Ct, Little Rock, AR 72205, (877) 550-5059; labeled as a) NDC: 70004-0100-59; b) NDC: 70004-100-58.	<b>Product Quantity:</b> 220 bags
<b>Reason for Recall:</b> Lack of Assurance of Sterility: Product made with recalled 0.9% sodium chloride bags which have the potential to leak.	<b>Recall Number:</b> D-0999-2017
<b>Code Information:</b> Lots: a) 20170707@34, BUD:10/5/2017; 20170710@21, BUD: 10/8/2017; b) 20170706@44, BUD: 10/4/2017	
<b>Product Description:</b> fentaNYL (as citrate) 10 mcg per mL in 0.9% Sodium Chloride, (Total fentaNYL Dose 1,000 mcg/100 mL), Total Volume 100 mL Single Dose Container bag, Rx Only, SCA Pharmaceuticals, 8821 Knoedl Ct, Little Rock, AR 72205 (877) 550-5059; NDC: 70004-0202-32.	<b>Product Quantity:</b> 130 bags
<b>Reason for Recall:</b> Lack of Assurance of Sterility: Product made with recalled 0.9% sodium chloride bags which have the potential to leak.	<b>Recall Number:</b> D-1000-2017

<b>Code Information:</b> Lot: 20170707@27, BUD: 10/5/2017	
<b>Product Description:</b> ceFAZolin 3 g added to 100 mL 0.9% Sodium Chloride, Total Approximate Volume 115 mL Single Dose Container bag, Rx Only, SCA Pharmaceuticals, 8821 Knoedl Ct, Little Rock, AR 72205 (877) 550-5059; NDC: 70004-0524-32.	<b>Product Quantity:</b> 108 bags
<b>Reason for Recall:</b> Lack of Assurance of Sterility: Product made with recalled 0.9% sodium chloride bags which have the potential to leak.	<b>Recall Number:</b> D-1001-2017
<b>Code Information:</b> Lot: 20170707@26, BUD: 8/21/2017	
<b>Product Description:</b> Diltiazem 125 mg in 0.9% Sodium Chloride, 1 mg per mL, Total Volume 125 mL Single Dose Container bag, Rx Only, SCA Pharmaceuticals, 8821 Knoedl Ct, Little Rock, AR 72205 (877) 550-5059; NDC: 70004-0541-35.	<b>Product Quantity:</b> 120 bags
<b>Reason for Recall:</b> Lack of Assurance of Sterility: Product made with recalled 0.9% sodium chloride bags which have the potential to leak.	<b>Recall Number:</b> D-1002-2017
<b>Code Information:</b> Lot: 20170707@54, BUD: 10/4/2017	
<b>Product Description:</b> MAGNESIUM Sulfate 4 g added to 100 mL 0.9% Sodium Chloride, Total Approximate Volume 108 mL (does not include mfg. overfill) Single Dose Container bag, Rx Only, SCA Pharmaceuticals, 8821 Knoedl Ct, Little Rock, AR 72205 (877) 550-5059; NDC: 70004-0737-32.	<b>Product Quantity:</b> 40 bags
<b>Reason for Recall:</b> Lack of Assurance of Sterility: Product made with recalled 0.9% sodium chloride bags which have the potential to leak.	<b>Recall Number:</b> D-1003-2017
<b>Code Information:</b> Lot: 20170710@54, BUD: 10/8/2017	
<b>Product Description:</b> PHENYLephrine HCl 10 mg in 0.9% Sodium Chloride, (Final Concentration = 0.1 mg per mL), Total Volume 100 mL Single Dose Container bag, Rx Only, SCA Pharmaceuticals, 8821 Knoedl Ct, Little Rock, AR 72205 (877) 550-5059; NDC: 70004-0810-32.	<b>Product Quantity:</b> 2 bags
<b>Reason for Recall:</b> Lack of Assurance of Sterility: Product made with recalled 0.9% sodium chloride bags which have the potential to leak.	<b>Recall Number:</b> D-1004-2017
<b>Code Information:</b> Lot: 20170710@3, BUD: 10/8/2017	