

# Enforcement Report - Week of November 15, 2017

## Class II Drugs Event

<b>Event ID:</b> 78229	<b>Product Type:</b> Drugs	<b>Status:</b> Ongoing	<b>Date Terminated:</b>
<b>Recall Initiation Date:</b> 10/05/2017	<b>Voluntary / Mandated:</b> Voluntary: Firm Initiated	<b>Center Classification Date:</b> 11/03/2017	<b>Initial Firm Notification of Consignee or Public:</b> Letter
<b>Recalling Firm:</b> Purdue Pharma, LP 1 Stamford Forum Stamford CT United States		<b>Distribution Pattern:</b> Nationwide in the USA	

## Associated Products

<b>Product Description:</b> Betadine Solution Swabstick Povidone-Iodine Solution USP, 10% Dist.by: Purdue Products LP. Stamford, CT 06901-3431 NDC 67618-153-01	<b>Product Quantity:</b> 3997 swabsticks
<b>Reason for Recall:</b> Subpotent Drug: The laminate used to make the pouches was reversed such that the aluminum layer was in contact with the product causing an exothermic reaction between the free iodine and the aluminum.	<b>Recall Number:</b> D-0070-2018
<b>Code Information:</b> Lots: 62823 Exp. 12/31/18; 64304 Exp. 05/31/2019; 64711 Exp. 08/31/2019; 65915 Exp. 12/31/2019	

## Class II Drugs Event

<b>Event ID:</b> 78376	<b>Product Type:</b> Drugs	<b>Status:</b> Ongoing	<b>Date Terminated:</b>
<b>Recall Initiation Date:</b> 10/24/2017	<b>Voluntary / Mandated:</b> Voluntary: Firm Initiated	<b>Center Classification Date:</b> 11/07/2017	<b>Initial Firm Notification of Consignee or Public:</b> Letter
<b>Recalling Firm:</b> Ace Surgical Supply Co., Inc. 1034 Pearl St Brockton MA United States		<b>Distribution Pattern:</b> Product was distributed throughout the United States.	

## Associated Products

<b>Product Description:</b> Succinylcholine 20 MG/ML INJ (QUELICIN), 10 ML Vials, Rx only, Distributed by: ACE Surgical Co., Inc., Brockton, MA	<b>Product Quantity:</b> 200 vials (25 mislabeled vials)
<b>Reason for Recall:</b> Labeling: Incorrect or Missing Lot and/or Exp Date; incorrect expiration date on the labeling of the outer poly bag	<b>Recall Number:</b> D-0071-2018
<b>Code Information:</b> Lot # 64340EV, exp 07/2018 ACE ITEM # 1671018	

## Class III Drugs Event

**Event ID:**  
78404

**Product Type:**  
Drugs

**Status:**  
Ongoing

**Date Terminated:**

**Recall Initiation Date:**  
10/30/2017

**Voluntary / Mandated:**  
Voluntary: Firm Initiated

**Center Classification Date:**  
11/07/2017

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

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

**Distribution Pattern:**  
Nationwide

## Associated Products

<b>Product Description:</b> Doan's Pain Relieving Cream with 4% Lidocaine Plus Menthol, (lidocaine 4%, menthol 1%), Net Wt. 2.75 oz. (77.3 g) Tube, Distributed by: Ducere Pharma, LLC New Hope, PA 18938 USA --- UPC 849648000023	<b>Product Quantity:</b> 23402 cases
<b>Reason for Recall:</b> Labeling: Incorrect or Missing Lot and/or Exp Date; lot number on the secondary packaging doesn't match the lot number printed on the bottle	<b>Recall Number:</b> D-0072-2018
<b>Code Information:</b> lots #2462100R, Exp 11/2018; 2583800R, Exp 09/2018	