# Enforcement Report - Week of March 21, 2018

## Class I Drugs Event

**Event ID:**
79114

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**

**Recall Initiation Date:**
02/07/2018

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

**Center Classification Date:**
03/14/2018

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

**Recalling Firm:**
Pfizer Inc.
235 E 42nd St
New York NY United States

**Distribution Pattern:**
Nationwide in the USA

## Associated Products

**Product Description:**
Hydromorphone, Hydrochloride, Injection, USP CII, 10 mg/mL, Rx Only, 1 mL Single-dose Vial, High Potency Formulation. Mfd For: Teva Parenteral Medicines, Inc., Irvine, CA 92618. NDC: 0703-0110-01

**Product Quantity:**
53600 vials

**Reason for Recall:**
Non-Sterility: Confirmed customer complaints of glass product container vials that may be empty or cracked.

**Recall Number:**
D-0596-2018

**Code Information:**
Lots # 691853F, EXP. 9/1/2018; 700753F, EXP. 10/1/2018.

**Product Description:**
Hydromorphone, Hydrochloride, Injection, USP CII, 10 mg/mL, Rx Only, 1 mL Single-dose Vial, High Potency Formulation. Hospira, Inc., Lake forest, IL 60045 USA. NDC: 0409-2634-01

**Product Quantity:**
29, 680 vials

**Reason for Recall:**
Non-Sterility: Confirmed customer complaints of glass product container vials that may be empty or cracked.

**Recall Number:**
D-0597-2018

**Code Information:**
Lot 71330DD EXP. 11/1/2018.

## Class II Drugs Event

**Event ID:**
79142

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**

**Recall Initiation Date:**
02/13/2018

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

**Center Classification Date:**
03/16/2018

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

**Recalling Firm:**
Hetero Labs Limited Unit V
Unit V (SEZ Unit I in APIIC SEZ) Surv. No. 439-441, 458, Polepally Vill.
Jadcherla Mandal, Mahaboob Nagar India

**Distribution Pattern:**
NJ and then distributed Nationwide in the USA

## Associated Products

**Product Description:**
Valganciclovir Tablets, USP, 450 mg, 60-count bottle, Rx Only, Manufactured for Camber Pharmaceuticals, Inc. Piscataway, NJ 08854, By: Hetero Hetero Labs Limit Unit V Pollypally Jadcherla Mahaboob Nagar - 509 301 India. NDC # 31722-832-60

**Product Quantity:**
1764 60-count bottles

**Reason for Recall:**
Temperature Abuse: Valganciclovir Tablets USP 450 mg and Valacyclovir Tablets USP 1 gram were exposed to higher temperature at airport or cargo and in the same consignment of Famciclovir complaint batch (D-0415-2018).

**Recall Number:**
D-0601-2018

**Code Information:**
Lot #s VGC17040 & VGC17041, EXP 07/2019

**Product Description:**
Valacyclovir Tablets USP 1 gram, 30-count bottle, Rx Only, Manufactured for Camber Pharmaceuticals, Inc. Piscataway, NJ 08854 By: Hetero Hetero Labs Limit Unit V Pollypally Jadcherla Mahaboob Nagar - 509 301 India NDC # 31722-705-30

**Product Quantity:**
48132 60-count bottles

**Reason for Recall:**
Temperature Abuse: Valganciclovir Tablets USP 450 mg and Valacyclovir Tablets USP 1 gram were exposed to higher temperature at airport or cargo and in the same consignment of Famciclovir complaint batch (D-0415-2018).

**Recall Number:**
D-0602-2018

**Code Information:**
Lot # VLC17027 Exp 07-2019

## Class II Drugs Event

**Event ID:**
79419

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**

**Recall Initiation Date:**
03/05/2018

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

**Center Classification Date:**
03/12/2018

**Initial Firm Notification of Consignee or Public:**
Two or more of the following: Email, Fax, Letter, Press Release, Telephone, Visit

**Recalling Firm:**
Sagent Pharmaceuticals Inc
1901 N Roselle Rd Ste 700
Schaumburg IL United States

**Distribution Pattern:**
Nationwide in the USA.

## Associated Products

**Product Description:**
methylPREDNISolone Sodium Succinate for Injection, USP, 40 mg* per vial, Single-Dose Vial, Rx only, Mfd. for: Sagent Pharmaceuticals, Schaumburg, IL 60195 (USA), Made in India. NDC 25021-807-05.

**Product Quantity:**
205,370 vials

**Reason for Recall:**
Failed Impurities/Degradation Specifications: High out of specification results for an impurity.

**Recall Number:**
D-0586-2018

**Code Information:**
Lot #: AJM601, Exp. Jul-2018; AJM701, AJM702, Exp. Dec-2018

**Product Description:**
methylPREDNISolone Sodium Succinate for Injection, USP, 125 mg* per vial, Single-Dose Vial, Rx only, Mfd. for: Sagent Pharmaceuticals, Schaumburg, IL 60195 (USA), Made in India. NDC 25021-808-10.

**Product Quantity:**
176,410 vials

**Reason for Recall:**
Failed Impurities/Degradation Specifications: High out of specification results for an impurity.

**Recall Number:**
D-0587-2018

**Code Information:**
Lot #: AJN601, Exp. Jun-2018; AJN701, AJN702, Exp. Dec-2018

**Product Description:**
methylPREDNISolone Sodium Succinate for Injection, USP, 1 gram* per vial, Single-Dose Vial, Rx only, Mfd. for: Sagent Pharmaceuticals, Schaumburg, IL 60195 (USA), Made in India. NDC 25021-810-30.

**Product Quantity:**
48,964 vials

**Reason for Recall:**
Failed Impurities/Degradation Specifications: High out of specification results for an impurity.

**Recall Number:**
D-0588-2018

**Code Information:**
Lot #: AJP701, AJP702, Exp. Dec-2018; AJP601, Exp. Jul-2018; AJP703, Exp. Aug-2019

## Class II Drugs Event

**Event ID:**
79420

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**

**Recall Initiation Date:**
03/07/2018

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

**Center Classification Date:**
03/12/2018

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

**Recalling Firm:**
American Pharmaceutical Ingredients LLC

6650 Highland Rd Ste 302
Waterford MI United States

**Distribution Pattern:**
Nationwide in the USA.

## Associated Products

**Product Description:**
Oxytocin USP, powder, 1g-bottle, API American Pharmaceutical Ingredients, NDC 58597-7042-3

**Product Quantity:**
21 g

**Reason for Recall:**
Stability Data Does Not Support Expiry: Stability data from manufacturer does not support expiration dates listed.

**Recall Number:**
D-0591-2018

**Code Information:**
Lot 012517-1R

**Product Description:**
Sermorelin Acetate, powder, a) 1 GM-bottle (NDC58597-8092-1) b) 5 GM-bottle (NDC 58597-8092-2) c) 10 GM-bottle (NDC 58597-8092-4) API American Pharmaceutical Ingredients

**Product Quantity:**
1460 GM

**Reason for Recall:**
Stability Data Does Not Support Expiry: Stability data from manufacturer does not support expiration dates listed.

**Recall Number:**
D-0592-2018

**Code Information:**
Lots: 071916-1, Exp. 07/08/2018; 080516-1, 080516-2, Exp. 07/22/2018; 101216-1, 011917C-1, Exp. 09/15/2018;

## Class III Drugs Event

**Event ID:**
79298

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**

**Recall Initiation Date:**
03/05/2018

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

**Center Classification Date:**
03/14/2018

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

**Recalling Firm:**
Novel Laboratories, Inc.
400 Campus Dr
Somerset NJ United States

**Distribution Pattern:**
Nationwide

## Associated Products

**Product Description:**
Lupin Hydrocodone Bitartrate and Homatropine Methylbromide Tablets, USP 5/1.5 mg Rx Only 30 Tablets Manufactured by: Novel Laboratories, Inc. Somerset, NJ 08873 Manufactured for: Lupin Pharmaceuticals, Inc. Baltimore, MD 21202 NDC 43386-118-03 UPC 343386118038

**Product Quantity:**
134,364 bottles (4,030,920 tablets)

**Reason for Recall:**
Failed Impurities/Degradation Specifications

**Recall Number:**
D-0599-2018

**Code Information:**
M16002A (02/2018); M16246A (04/2018); M16246B (04/2018); M16434A (07/2018); M16569A (10/2018); M17015A (01/2019); S700271 (04/2019);

## Class III Drugs Event

**Event ID:**
79450

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**

**Recall Initiation Date:**
03/09/2018

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

**Center Classification Date:**
03/12/2018

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

**Recalling Firm:**
Alva-Amco Pharmacal Companies., Inc.
7711 N Merrimac Ave
Niles IL United States

**Distribution Pattern:**
Nationwide in the USA; Italy; Sweden; Germany; New Zealand; Netherlands; Australia; Moldova; United Kingdom; Mexico; Brazil; Chile; Greece; Sp ain; Norway; Belgium; Bulgaria

## Associated Products

**Product Description:**
Psoriasin Daytime Relief Cream with Vitamin D & Oatmeal, (Coal Tar 1.25%), packagedin 57 g plastic tubes, Distributed by: ALVA-AMCO Pharmacal Cos., Inc., Niles, IL 60714, USA. NDC 52389-745-56, UPC 0 72959 01045 4.

**Product Quantity:**
206,513 tubes

**Reason for Recall:**
Subpotent Drug: The product has failed to maintain its label claim of coal tar throughout its labeled 24-month expiry period.

**Recall Number:**
D-0589-2018

**Code Information:**
Lot #: 61031, 61041, 61051, Exp. 4/30/2018; 61601, 61651, 61751, Exp. 6/30/2018; 61941, Exp. 7/31/2018; 62321, Exp. 8/31/2018; 62561, 62721, Exp. 9/30/2018; 62871, Exp. 10/31/2018; 63331, Exp. 11/30/2018; 72011, 72021, 72131, 72141, Exp. 7/31/2019; 72221, 72441, Exp. 8/31/2019; 72 921, Exp. 10/31/2019; 73351, Exp. 11/30/2019

## Class III Drugs Event

**Event ID:**
79472

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**

**Recall Initiation Date:**
03/08/2018

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

**Center Classification Date:**
03/14/2018

**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:**
Product was distributed Nationwide in the USA.

## Associated Products

**Product Description:**
Clocortolone Pivalate Cream, 0.1%, 90-gram tube, Rx only, Distributed by: Dr. Reddy's Laboratories, Inc. Princeton, NJ 08540, Manufactured by: DPT, Laboratories Ltd. San Antonio, TX 78215, NDC 43598-341-90

**Product Quantity:**
4,152 tubes

**Reason for Recall:**
Failed Stability Specifications:Out-of-specification results observed for viscosity during stability testing.

**Recall Number:**
D-0598-2018

**Code Information:**
Lot # MGEC