Enforcement Report - Week of February 27, 2019

Class II Drugs Event

Event ID:
81838

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/20/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
02/15/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Torrent Pharma Inc.
1803 Whites Rd Ste 1
Kalamazoo MI United States

Distribution Pattern:
Nationwide USA and Puerto Rico

Associated Products

Product Description:
LOSARTAN POTASSIUM TABLETS, USP, 100 mg, a) 30-count (NDC: 13668-115-30), b) 90-count (NDC: 13668-115-90), c) 1000-count (NDC: 13668-115-10) per bottle, Rx only, Manufactured by: Torrent Pharmaceuticals LTD, Indrad-382 721, Dist. Mehsana Inda

Product Quantity:
83,016 bottles

Reason for Recall:
CGMP Deviations: FDA lab confirmed presence an impurity, N-nitrosodimethylamine (NDEA) contained in the API used to manufacture the product above the interim acceptable daily intake level of 0.083 parts per million.

Recall Number:
D-0501-2019

Code Information:
Count, lots, expiry: [30-count bottle] Lot BO31C016, exp 04/2019; [90-count bottle] Lot BO31C016, exp 04/2019; [1000-count bottle] Lots 4DK3C004, 4DK3C005, exp 04/2019; Lots 4DU3C040, exp 10/2019; Lots 4DU3E049, 4DU3E050, exp 05/2021

Product Description:
LOSARTAN POTASSIUM TABLETS, USP, 50 mg, a) 30-count bottle (NDC: 13668-409-30), b) 90-count bottle (NDC: 13668-409-90), c) 1000-count bottle (NDC: 13668-409-10), Rx only, Manufactured by: Torrent Pharmaceuticals LTD, Indrad-382 721, Dist. Mehsana Inda

Product Quantity:
65,832 bottles

Reason for Recall:
CGMP Deviations: FDA lab confirmed presence an impurity, N-nitrosodimethylamine (NDEA) contained in the API used to manufacture the product above the interim acceptable daily intake level of 0.083 parts per million.

Recall Number:
D-0502-2019

Code Information:
Count, lots, expiry: [30-count bottle] Lot 4L67C035, exp 10/2019; [90-count bottle] Lot 4L67C035, 4L67C036 exp 10/2019; [1000-count bottle] Lot 4O50C005, exp 11/2019

Product Description:
LOSARTAN POTASSIUM TABLETS, USP, 25 mg, 90-count bottle (NDC: 13668-113-90), Rx only, Manufactured by: Torrent Pharmaceuticals LTD, Indrad-382 721, Dist. Mehsana Inda

Product Quantity:
43,416 bottles

Reason for Recall:
CGMP Deviations: FDA lab confirmed presence an impurity, N-nitrosodimethylamine (NDEA) contained in the API used to manufacture the product above the interim acceptable daily intake level of 0.083 parts per million.

Recall Number:
D-0503-2019

Code Information:
Count, lots, expiry: [90-count bottle] Lot 4O49C013, exp 09/2019

Product Description:
LOSARTAN POTASSIUM and HYDROCHLOROTHIAZIDE TABLETS, USP, 100 mg/12.5 mg, a) 90-count bottle (NDC: 13668-117-90), b) 1000-count bottle (NDC: 13668-117-10), Rx only, Manufactured by: Torrent Pharmaceuticals LTD, Indrad-382 721, Dist. Mehsana Inda

Product Quantity:
18,852 bottles

Reason for Recall:
CGMP Deviations: FDA lab confirmed presence an impurity, N-nitrosodimethylamine (NDEA) contained in the API used to manufacture the product above the interim acceptable daily intake level of 0.083 parts per million.

Recall Number:
D-0504-2019

Code Information:
Count, lots, expiry: [90-count bottle] Lot BX35C020, exp 05/2019, Lot BX35C049, exp 08/2019; [1000-count bottle] Lots BX35C022, BX35C023, exp 05/2019

Product Description:
LOSARTAN POTASSIUM and HYDROCHLOROTHIAZIDE TABLETS, USP 50 mg/12.5 mg, a) 90-count bottle (NDC: 13668-116-90), b) 1000-count bottle (NDC: 13668-116-10), Rx only, Manufactured by: Torrent Pharmaceuticals LTD, Indrad-382 721, Dist. Mehsana Inda

Product Quantity:
18,780 bottles

Reason for Recall:
CGMP Deviations: FDA lab confirmed presence an impurity, N-nitrosodimethylamine (NDEA) contained in the API used to manufacture the product above the interim acceptable daily intake level of 0.083 parts per million.

Recall Number:
D-0505-2019

Code Information:
Count, lots, expiry: [90-count bottle] Lot BP02C008, exp 03/2019; [1000-count bottle] Lots BEF7D006, exp 03/2020

Class II Drugs Event

Event ID:
82012

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/29/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
02/15/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
US Compounding Inc
1270 Dons Ln
Conway AR United States

Distribution Pattern:
U.S.A. Nationwide

Associated Products

Product Description:
Ephedrine Sulfate, 50 mg/10 mL, 10 mL Single Use Syringe, Rx only, US Compounding Pharmacy 1270 Don's Lane Conway, AR 800-718-3588, Barcode: 62295308407

Product Quantity:
1686 syringes

Reason for Recall:
Lack of assurance of sterility.

Recall Number:
D-0508-2019

Code Information:
Lot: 20181812@2 BUD: 06/16/2019

Class II Drugs Event

Event ID:
82048

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/04/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
02/19/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
ICU Medical Inc
600 N FIELD DRIVE
LAKE FOREST IL United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
0.9% Sodium Chloride Injection, USP 1000 mL flexible container, Rx only, Hospira, Inc., Lake Forest, IL 60045 USA, NDC 0409-7983-09

Product Quantity:
475320 bags

Reason for Recall:
CGMP Deviations

Recall Number:
D-0509-2019

Code Information:
Lot #: 91-016-JT, Exp. July 01, 2020

Class II Drugs Event

Event ID:
82085

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/31/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
02/15/2019

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:
U.S.A. Nationwide

Associated Products

Product Description:
Divalproex Sodium Extended-release Tablets, USP 250 mg, 100-count bottle, Rx only, Mfd.By: Dr. Reddy's Laboratories Limited Bachupally - 500 090 India NDC 55111-533-01

Product Quantity:
10,656 bottles

Reason for Recall:
Failed Dissolution Specifications: Out of specification results observed for high dissolution.

Recall Number:
D-0507-2019

Code Information:
Lot #: C802676, Exp 03/20

Class II Drugs Event

Event ID:
82112

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/12/2015

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
02/19/2019

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Mariposa Labs LLC
270 E 50th St
Boise ID United States

Distribution Pattern:
Distributed in California

Associated Products

Product Description:
tubby todd Bath Co, 100% NATURAL DREAM CREAM, Shea Butter and Mint, 3.5 FL OZ 99G, Distributed by: Tubby Todd Bath Co. Vista, CA 920, (619) 894-6560.

Product Quantity:
1654 jars

Reason for Recall:
Microbial Contamination of Non-Sterile Products: Consumer complaint and subsequent testing found lot to be out of specification for mold.

Recall Number:
D-0510-2019

Code Information:
Lot#: 5589, Exp. 08/2017

Class II Drugs Event

Event ID:
82130

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/06/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
02/15/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Advanced Pharma Inc.
9265 Kirby Dr
Houston TX United States

Distribution Pattern:
PA

Associated Products

Product Description:
Fentanyl in 0.9% Sodium Chloride QS 0.5 mL, 5 mcg/0.5 mL with up to 0.1 mL of overfill Injectable Solution, Sterile single use syringe, Rx only, Avella of Houston 9265 Kirby Dr., Houston, TX 77054 (877) 794-0404, NDC 42852-210-72

Product Quantity:
100 syringes

Reason for Recall:
Labeling: Incorrect expiration date.

Recall Number:
D-0496-2019

Code Information:
Lot#: 12/31/18 0555 21072S, Exp 3/31/2019

Class II Drugs Event

Event ID:
82177

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/04/2019

Voluntary / Mandated:
Voluntary: FDA Requested

Center Classification Date:
02/19/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Akorn Inc
1925 W Field Ct Ste 300
Lake Forest IL United States

Distribution Pattern:
Nationwide in the USA.

Associated Products

Product Description:
Moisturizing Lubricant Eye Drops, 0.25% Sodium Carboxymethylcellulose, 0.5 Fl OZ (15mL) Distributed by: Walgreen Co, 200 Wilmont Rd Deerfield IL 60015 NDC 00363-9651-01.

Product Quantity:
78120 dropper bottles

Reason for Recall:
Failed Stability Specification: out of specification results for Sodium Perborate

Recall Number:
D-0511-2019

Code Information:
Lot # 8D31A, Exp: 03/20; 7H98A, Exp: 07/19; 7L80A, Exp: 10/19.

Class III Drugs Event

Event ID:
80878

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/07/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
02/20/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
ACP Nimble Buyer, Inc.
111 Coolidge St
South Plainfield NJ United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Mometasone Furoate Cream, 0.1%, 45 g tube, Rx Only, Manufactured by: G&W Laboratories, Inc. South Plainfield, NJ 07080, NDC 0713-0726-37

Product Quantity:
58,176 units

Reason for Recall:
Labeling: Not Elsewhere Classified. Mometasone Furoate Cream has an NDC typographical error.

Recall Number:
D-0514-2019

Code Information:
Lot #: 1009431, 1009507, Exp. 08/2020; 1009886, Exp. 09/2020

Class III Drugs Event

Event ID:
82086

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/13/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
02/15/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Mylan Pharmaceuticals Inc.
781 Chestnut Ridge Rd
Morgantown WV United States

Distribution Pattern:
Throughout the United States

Associated Products

Product Description:
Diltiazem HCl Extended-Release Capsules, USP 180mg, Packaged in a) 100-count bottles (NDC 0378-5280-01) , and b) 500-count bottles (NDC 0378-5280-05). Rx only, Manufactured by: Mylan Pharmaceuticals Inc. Morgantown, WV, 26505

Product Quantity:
8,159 bottles

Reason for Recall:
Failed Impurities/Degradation Specifications: High out of specification results obtained during routine stability testing

Recall Number:
D-0506-2019

Code Information:
Lot # a) and b) 3090167, Exp. October 2019

Class III Drugs Event

Event ID:
82089

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/06/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
02/15/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Advanced Pharma Inc.
9265 Kirby Dr
Houston TX United States

Distribution Pattern:
Nationwide in the USA.

Associated Products

Product Description:
Oxytocin 10 Units added to NS 1000 mL (oxytocin and 0.9% Sodium Chloride) Injectable Solution, Approximately 1001 mL Sterile single use bag, Rx only, Avella of Houston, 9265 Kirby Dr., Houston, TX 77054, NDC 42852-730-99.

Product Quantity:
12 bags

Reason for Recall:
Superpotent Drug: product may contain concentrations of oxytocin higher than what is represented on the label.

Recall Number:
D-0497-2019

Code Information:
Lot: 12/20/18 1056 73099P, BUD: 02/03/2019

Product Description:
Oxytocin 20 Units added to NS 1000 mL (oxytocin and 0.9% Sodium Chloride) Injectable Solution, Approximately 1002 mL Sterile single use bag, Rx only, Avella of Houston, 9265 Kirby Dr., Houston, TX 77054, NDC 42852-703-99.

Product Quantity:
672 bags

Reason for Recall:
Superpotent Drug: product may contain concentrations of oxytocin higher than what is represented on the label.

Recall Number:
D-0498-2019

Code Information:
Lots: 12/14/18 1482 70399P, BUD: 02/27/19; 12/14/18 1610 70399P, BUD: 02/27/19

Product Description:
Oxytocin 30 Units added to NS 500 mL (oxytocin and 0.9% Sodium Chloride) Injectable Solution, Approximately 503 mL Sterile single use bag, Rx only, Avella of Houston, 9265 Kirby Dr., Houston, TX 77054, NDC 42852-706-50.

Product Quantity:
1460 bottles

Reason for Recall:
Superpotent Drug: product may contain concentrations of oxytocin higher than what is represented on the label.

Recall Number:
D-0499-2019

Code Information:
Lots: 11/27/18 3177 70650P, BUD: 02/10/2019; 11/27/18 6618 70650P, BUD: 02/10/2019; 11/28/18 7716 70650P, BUD: 02/12/19; 12/31/18 5698 70650P, BUD: 03/16/19

Class III Drugs Event

Event ID:
82092

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/25/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
02/20/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Akorn Inc
1925 W Field Ct Ste 300
Lake Forest IL United States

Distribution Pattern:
Nationwide, including Puerto Rico.

Associated Products

Product Description:
Clobetasol Propionate Emollient Cream 0.05%, a) 30 gram (NDC 50383-270-30) and b) 60 gram (NDC 50383-270-60) tubes, Rx only. Manufacturer: Akorn Inc. 369 Bayview Ave., Amityville, NY 117701.

Product Quantity:
a) 4896 tubes; b) 5064 tubes

Reason for Recall:
Failed Stability Specification; out of specification (OOS) results for a preservative at 9 month stability study.

Recall Number:
D-0515-2019

Code Information:
a) 357052, exp 4/19/19 b) 356892, exp 4/16/19 and 356927, exp 4/15/19

Class III Drugs Event

Event ID:
82126

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/13/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
02/20/2019

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:
Nationwide in the USA and Puerto Rico.

Associated Products

Product Description:
Lovastatin Tablets USP, 40 mg, packaged in a) 60-count (NDC 68180-469-07 and b) 100-count (NDC 68180-469-01) bottles, Rx only, Manufactured for: Lupin Pharmaceuticals, Inc., Baltimore, Maryland 21202; Manufactured by: Lupin Limited, Goa 403 722 INDIA.

Product Quantity:
44,640 bottles

Reason for Recall:
CGMP Deviations: Finished product made with lovastatin drug substance that was out of specification for individual impurity results.

Recall Number:
D-0513-2019

Code Information:
Lot #: a) G702755, Exp March 2020; b) G702756, Exp March 2020

Class III Drugs Event

Event ID:
82127

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/13/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
02/20/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Perrigo New York, Inc.
1700 Bathgate Ave
Bronx NY United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Ciclopirox shampoo 1%,120 mL bottle, Rx only, Manufactured By Perrigo Bronx, NY 10457 Distributed by Perrigo Allegan, MI 49010, 45802-401-09

Product Quantity:
12252 bottles

Reason for Recall:
Failed Degradation/Impurities Specifications: Out of specification related substance results during stability testing.

Recall Number:
D-0512-2019

Code Information:
Lot #: 7DT0280, 7ET0565, Exp. 02/19

Class III Drugs Event

Event ID:
82158

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/19/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
02/20/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Amerigen Pharmaceuticals Inc.
9 Polito Ave Ste 900
Lyndhurst NJ United States

Distribution Pattern:
Product was distributed to 4 wholesalers/distributors and 1 retail account who may have further distribute the product throughout the United States.

Associated Products

Product Description:
Temozolomide Capsules, 5 mg, packaged in a) 5-count bottle (NDC 43975-252-05) b) 14-count bottle (NDC 43975-252-14), Rx only, Mfd. by: Stason Pharmaceuticals, Inc., Irvine, CA 92618, Dist. By: Amerigen Pharmaceuticals, Lyndhurst, NJ 07071

Product Quantity:
a) 2,413 bottles b) 3,355 bottles

Reason for Recall:
Failed dissolution specifications

Recall Number:
D-0516-2019

Code Information:
Lot #: a) 18J043A, Exp 09/30/2020, b) 18J043B, Exp 09/30/2020