Enforcement Report - Week of December 9, 2020

Class I Drugs Event

Event ID:
86717

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/28/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/30/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Lohxa LLC
600 Main St Ste 110
Worcester MA United States

Distribution Pattern:
Product was distributed to medical facilities in FL and NY.

Associated Products

Product Description:
Chlorhexidine Gluconate Oral Rinse USP, 0.12%, Alcohol Free, packaged in 15 mL unit does cups (barcode 7016602715), packaged in 50-count unit dose cups per carton, Rx only, Distributed by: Lohxa, Worcester, MA 01608, NDC 70166-027-15

Product Quantity:
329 cartons

Reason for Recall:
Microbial contamination of non-sterile products: Repackaged product was recalled by manufacturer because it was contaminated with the bacteria Burkholderia lata.

Recall Number:
D-0111-2021

Code Information:
Lot #: T09101A, Exp 01/2021; T08292A, T10011A, Exp 02/2021; T10223A, M10193A, Exp 03/2021

Class I Drugs Event

Event ID:
86767

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/17/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/07/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
MPM Medical LLC
1801 Big Town Blvd Ste 300
Mesquite TX United States

Distribution Pattern:
Distributed Nationwide in the USA

Associated Products

Product Description:
REGENECARE HA (Lidocaine HCL 2%) Topical Anesthetic Hydrogel, Net Wt. 3 oz. (85 g), Manufactured For: MPM Medical Mesquite, TX 75149. NDC 66977-107-03

Product Quantity:
7,637 tubes

Reason for Recall:
Microbial Contamination of Non-Sterile Drug Product. The product was found to be contaminated with the bacteria Burkholderia cepecia.

Recall Number:
D-0118-2021

Code Information:
Lot: 41262 Exp. 01/21

Class II Drugs Event

Event ID:
86786

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/17/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/30/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Golden State Medical Supply Inc.
5187 Camino Ruiz
Camarillo CA United States

Distribution Pattern:
Distributed Nationwide in the USA

Associated Products

Product Description:
ARIPIPRAZOLE TABLETS, 15 mg, 30-count. bottles, Rx Only, GSMS Incorporated, Manufactured by: Apotex Inc. Toronto, Ontario, Canada, Packaged by GSMS, Incorporated, Camarillo, CA 93012 USA, NDC #60429-449-30

Product Quantity:
11,922 bottles

Reason for Recall:
FAILED DISSOLUTION SPECIFICATIONS: Possibility of out-of-specification (OOS) dissolution limits for the remaining shelf life of the Aripiprazole Tablets

Recall Number:
D-0112-2021

Code Information:
Lot #: GS026353, GS027150, GS027653, GS028044, Exp. Date: 02/2021

Class II Drugs Event

Event ID:
86787

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/18/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/01/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
The Harvard Drug Group
17177 N Laurel Park Dr Ste 233
Livonia MI United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Aripiprazole Tablets, USP, 15 mg, 30 tablets per unit dose carton, Rx Only, Manufactured by: Apotex, Inc, Toronto, Ontario Canada M9L 1T9, Distributed by: Major Pharmaceuticals, 17177 N. Laurel Park Dr., Suite 233, Livonia, MI 48152 USA, NDC 0904-6512-04

Product Quantity:
841 cartons

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

Recall Number:
D-0114-2021

Code Information:
Lots: T02520, T02637, exp 02/2021

Class II Drugs Event

Event ID:
86868

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/19/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/01/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
US Pharmaceuticals Inc.
681 Main St Ste 27
Belleville NJ United States

Distribution Pattern:
Distributed in RI

Associated Products

Product Description:
CVS Health Hydrating Healing Ointment (Petrolatum 41%), Net Wt 3 OZ (85g), Distributed by CVS Pharmacy, Inc. One CVS Drive, Woonsocket, RI 02895 UPC 0 50428 53642 1

Product Quantity:
3312 units

Reason for Recall:
Lack Of CGMP:s Low weight fill tubes were identified in one lot of CVS Healing Ointment.

Recall Number:
D-0113-2021

Code Information:
Lot # 41C19 Exp 3/2021

Class III Drugs Event

Event ID:
86708

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/11/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/03/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
InvaTech Pharma Solutions, LLC
40c Cotters Ln Ste A
East Brunswick NJ United States

Distribution Pattern:
Distributed Nationwide in the USA

Associated Products

Product Description:
Levocetirizine Dihydrochloride Tablets, USP, 5 mg 30-count bottle, Rx Only, Distributed by: Marlex Pharmceuticals, Inc. New Castle, DE 19720. NDC 10135-0639-30

Product Quantity:

Reason for Recall:
Failed Impurities/Degradation Specifications: One lot of Levocetirizine dihydrochloride tablets 5 mg 30 count failed stability testing.

Recall Number:
D-0115-2021

Code Information:
Lot #: 051944A Exp. Date April - 2021; 1119124 Exp Date Oct - 2021; 062088 Exp Date June - 2022;

Class III Drugs Event

Event ID:
86714

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/05/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/08/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Teligent Pharma, Inc.
105 Lincoln Avenue
Buena NJ United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Clobetasol Propionate Ointment USP 0.05%, Net Wt. 50 grams, Rx Only, Teligent Pharma. Inc. Buena, NJ 08310 NDC 52565-039-60

Product Quantity:
20160 tubes

Reason for Recall:
Superpotent and Subpotent; low and high assay results

Recall Number:
D-0119-2021

Code Information:
Lot Number: 12597, exp. date 12/2020

Not Yet Classified Drugs Event

Event ID:
86859

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/24/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Ascend Laboratories LLC
339 Jefferson Rd Ste 101
Parsippany NJ United States

Distribution Pattern:
MI

Associated Products

Product Description:
Tizanidine Tablets, USP 4mg, Rx Only, 150 Tablets per Bottle, Manufactured by Alkem Laboratories Ltd, Mumbai - 400 013, INDIA, Distributed by: Ascend Laboratories, LLC Parsippany, NJ 07054, NDC: 67877-614-15.

Product Quantity:
9024 bottles

Reason for Recall:
Failed Dissolution Specifications; Out of Specification (low) results were obtained.

Recall Number:

Code Information:
Lot #19143017, Exp. 05/31/2021

Not Yet Classified Drugs Event

Event ID:
86878

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/25/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Torrent Pharma Inc
2091 Hartel Ave
Levittown PA United States

Distribution Pattern:
Nationwide USA and Puerto Rico

Associated Products

Product Description:
Anagrelide Capsules, USP 1 mg, 100 capsules, Rx only, Manufactured in India for: Torrent Pharma Inc., Basking Ridge, NJ 07920 NDC 13668-462-01

Product Quantity:
2496 Bottles

Reason for Recall:
Failed Dissolution Specifications

Recall Number:

Code Information:
Batch BFD1G001, exp 12/2021