Enforcement Report - Week of January 19, 2022

Class I Drugs Event

Event ID:
89241

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/15/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/18/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Taro Pharmaceuticals U.S.A., Inc.
3 Skyline Dr
Hawthorne NY United States

Distribution Pattern:
Two distributors in UT and LA who could have further distributed to the retail level nationwide in the USA.

Associated Products

Product Description:
Clobetasol Propionate Ointment USP, 0.05%, 60g tubes, Rx only, Mfd. by: Taro Pharmaceutical Industries Ltd., Haifa Bay, Israel 2624761, Dist. by: Taro Pharmaceuticals U.S.A., Inc., Hawthorne, NY 10532. NDC 51672-1259-3

Product Quantity:
96 tubes

Reason for Recall:
Microbial Contamination of Non-Sterile Products: presence of R. Pickettii bacteria

Recall Number:
D-0375-2022

Code Information:
Lot# AC13786, exp. date DEC 2022

Class II Drugs Event

Event ID:
89146

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/02/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/11/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Torrent Pharma Inc.
150 Allen Rd Ste 102
Basking Ridge NJ United States

Distribution Pattern:
Nationwide USA

Associated Products

Product Description:
Carbamazepine Tablets, USP 200 mg 100 Tablets Rx only NDC 13668-268-01 Manufactured by: Torrent Pharmaceuticals Ltd. Bharuch-

392130, India Manufactured for: Torrent Pharma Inc., Basking Ridge, NJ 07920.

Product Quantity:
15,336 Bottles

Reason for Recall:
Failed Dissolution Specifications

Recall Number:
D-0365-2022

Code Information:
Batch: 4J11G002 Exp. 08/2024

Class II Drugs Event

Event ID:
89289

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/28/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/10/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Revive Personal Products Company
2 Myrtle Ave
Allendale NJ United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
The Natural Dentist Healthy Balance Peppermint Sage, Menthol 0.12%, 16.9 FL OZ (500 mL) bottles, Manufactured for Revive Personal Products Company, Madison, NJ 07940, UPC 7 14132 00071 4

Product Quantity:
258 bottles

Reason for Recall:
Labeling; Label mix-up and Wrong Bar Code; back label incorrectly states active ingredient as Menthol with UPC 7 14132 00071 4 instead of Peppermint Oil and Sage Oil with UPC 7 14132 00073 8

Recall Number:
D-0364-2022

Code Information:
Lot 2091A, exp 7/2023

Class II Drugs Event

Event ID:
89310

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/27/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/13/2022

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

Recalling Firm:
Padagis US LLC
3940 Quebec Ave N
Minneapolis MN United States

Distribution Pattern:
Nationwide USA

Associated Products

Product Description:
Nitroglycerin Lingual Spray, 400 mcg per spray, 200 metered sprays, 12 g bottles, Rx only, Manufactured by Perrigo, Yeruham, Israel; Distributed by Perrigo, Allegan, MI 49010, NDC 45802-210-02

Product Quantity:
11,868 bottles

Reason for Recall:
Defective Delivery System

Recall Number:
D-0372-2022

Code Information:
Lot, expiry: Lot 150892, exp Oct 2022; Lot 153199, exp Feb 2023; Lot 156041, exp Apr 2023

Class II Drugs Event

Event ID:
89311

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/31/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/07/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Rubicon Research Private Limited
4 & K 30 5 Plot No K 30
Ambernath India

Distribution Pattern:
Product was distributed to one distributor who may have distributed the product further nationwide.

Associated Products

Product Description:
Metoprolol Tartrate Tablets, USP 25 mg, 1000 - count bottle, Rx Only, Distributed by: TruPharma, LLC. Tampa, FL 33609; Manufactured by: Rubicon Research Prvate Limited Ambernath, Dist. Thane, 421506 India. NDC 52817-360-00

Product Quantity:
3,684 1000-count bottles

Reason for Recall:
Complaint received of foreign matter (metal) embedded in tablet.

Recall Number:
D-0362-2022

Code Information:
Batch # 210211H1, Exp. date FEB 2024

Class II Drugs Event

Event ID:
89326

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/31/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/13/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Teva Pharmaceuticals USA
400 Interpace Pkwy
Parsippany NJ United States

Distribution Pattern:
Methylprednisolone, TN Norepinephrine BItartrate - MS, OH

Associated Products

Product Description:
MethylPREDNISolone Acetate Injectable Suspension USP 400 mg/10mL (40mg/mL), 10 mL Multiple-Dose Vial, Rx Only, Manufactured for: Northstar Rx LLC, Memphis, TN 38141, Manufactured By: Teva Pharmaceuticals USA, Inc., Parsippany, NJ 07054, NDC 16714-090-01, packaged in cartons.

Product Quantity:
7,400 cartons

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0370-2022

Code Information:
Lot # 100022393, exp 09/2022

Product Description:
Norepinephrine Bitartrate Injection USP 4 mg/4 mL (1 mg/mL), 4 mL Single-Dose Vials, 10 vials per carton, Rx Only, Manufactured By: Teva Pharmaceuticals USA, Inc., Parsippany, NJ 07054, NDC 0703-1153-03.

Product Quantity:
11,450 vials

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0371-2022

Code Information:
Lot # 100020800, exp 07/2022

Class II Drugs Event

Event ID:
89331

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/30/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/11/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
RemedyRepack Inc.
625 Kolter Dr Ste 4

Indiana PA United States

Distribution Pattern:
Product was distributed to one direct account in PA.

Associated Products

Product Description:
Metformin 750 mg Extended Release NDC # 70518-2920-00

Product Quantity:
56 Blister Cards

Reason for Recall:
CGMP Deviations: Detection of N-Nitrosodimethylamine (NDMA) levels in excess of the Acceptable Daily Intake Limit.

Recall Number:
D-0366-2022

Code Information:
Lot # J0511265-021121, exp. date 02/28/2022 J0499451-122220, exp. date 01/31/2022 J0496563-120820, exp. date 12/31/2021 J0495111-120120, exp. date 12/31/2021

Class II Drugs Event

Event ID:
89402

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/11/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/13/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Exela Pharma Sciences LLC
1245 Blowing Rock Blvd
Lenoir NC United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
8.4% Sodium Bicarbonate Injection, USP 50 mEq/50 mL (1 mEq/mL), 50 mL vials, Rx Only, Manufactured and Distributed by: Exela Pharma Sciences, LLC., Lenoir, NC 28645, NDC 51754-5001-1

Product Quantity:
18,960 vials

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0369-2022

Code Information:
Lot #: C0001088/P0001317, Exp. Date 08/2023

Class III Drugs Event

Event ID:
89142

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/03/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/13/2022

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 USA

Associated Products

Product Description:
Morphine Sulfate Oral Solution 100 mg per 5 mL (20 mg/mL) 30 mL bottles, Rx only, Hi-Tech Pharmacal Co., Inc., Amityville, NY 11701 -- NDC 50383-965-30

Product Quantity:
10,836 bottles

Reason for Recall:
Labeling: Missing Label

Recall Number:
D-0367-2022

Code Information:
Lot: 375153 Exp. 10/31/2022

Product Description:
Oxycodone Hydrochloride Oral Solution, USP 5 mg per 5 mL (1 mg/mL), 500 mL bottle, Rx only, Manufactured by: Hi-Tech Pharmacal Co., Inc., Amityville, NY 11701 --- NDC 50383-961-34

Product Quantity:
8184 bottles

Reason for Recall:
Labeling: Missing Label

Recall Number:
D-0368-2022

Code Information:
Lots: 377186 Exp. 2/28/2023; 377188 Exp. 3/31/2023