

Enforcement Report - Week of December 22, 2021

Class I Drugs Event

Event ID:

88850

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

10/12/2021

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

12/13/2021

Initial Firm Notification of Consignee or Public:

Press Release

Recalling Firm:

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

Distribution Pattern:

Nationwide within the United States

Associated Products

Product Description:

Lidocaine Hydrochloride Topical Solution USP 4% (40 mg/mL), 50 mL glass bottles, Rx Only, Teligent Pharma Inc., Buena, NJ 08310, NDC 52565-009-50

Product Quantity:

52,104 glass bottles

Reason for Recall:

Superpotent Drug

Recall Number:

D-0280-2022

Code Information:

Lot #: 13262, Exp. 03/2022; 14217, Exp. 08/2022

Class II Drugs Event

Product Description:

Lidocaine Hydrochloride Topical Solution USP 4% (40 mg/mL), 50 mL glass bottles, Rx Only, Manufactured by: Teligent Pharma Inc., Buena, NJ 06310, Distributed by: McKesson Corporation dba Sky Packaging, 497 Southridge Blvd, Suite 101, Memphis, TN 36141, NDC 63739-997-64.

Product Quantity:

7,008 glass bottles

Reason for Recall:

CGMP Deviations: Lots recalled because they were manufactured at the same facility using the same components as the products that had cracked seals in caps that were found to be superpotent.

Recall Number:

D-0279-2022

Code Information:

Lot #: 16306, Exp. Date 01/2024.

Product Description:

Lidocaine Hydrochloride Topical Solution USP 4% (40 mg/mL), 50 mL glass bottles, Rx Only, Teligent Pharma Inc., Buena, NJ 08310, NDC 52565-009-50

Product Quantity:

14,664 glass bottles

Reason for Recall:

CGMP Deviations: Lots recalled because they were manufactured at the same facility using the same components as the products that had cracked seals in caps that were found to be superpotent.

Recall Number:

D-0281-2022

Code Information:

Lot #: 13058, Exp. date 02/2022 and 13768, Exp. date 05/2022

Class II Drugs Event

Event ID:

88910

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

11/08/2021

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

12/14/2021

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

TOLMAR, Inc.
1201 Cornerstone Dr
Windsor CO United States

Distribution Pattern:

Nationwide within the United States

Associated Products

Product Description:

Clindamycin and Benzoyl Peroxide Gel, 1%/5% 25 g jars, Rx only, Mfg by TOLMAR Inc. Fort collins, CO 80526, NDC 0781-7263-68

Product Quantity:**Reason for Recall:**

Superpotent Drug

Recall Number:

D-0282-2022

Code Information:

Lot #: 11557C1, Exp. Date: Feb 2022; 11552B1, Exp. Date Apr 2022; 12206A1, Exp. Date: Nov 2022

Class II Drugs Event

Event ID:

89143

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

11/29/2021

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

12/13/2021

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Preferred Pharmaceuticals, Inc.
1250 N Lakeview Ave Ste O
Anaheim CA United States

Distribution Pattern:

Distributed to 5 physician consignees located in the following states: CT, FL, and KS.

Associated Products

Product Description:

Diclofenac Sodium Topical Solution, 1.5% w/w, packaged in 150 mL bottles, Rx only, Mfg: SOLA Pharmaceuticals Preferred Pharmaceuticals, Inc., NDC 68788-7707-01

Product Quantity:

72 bottles

Reason for Recall:

Defective container: Out of specification for container integrity leading to bottles leaking.

Recall Number:

D-0278-2022

Code Information:

Lot #: E1220B

Class II Drugs Event

Event ID:

89209

Product Type:

Drugs

Status:

Completed

Date Terminated:**Recall Initiation Date:**

12/03/2021

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

12/15/2021

Initial Firm Notification of Consignee or Public:

Telephone

Recalling Firm:

Valgene Incorporated dba Cape Drugs
1384 Cape St Claire Rd
Annapolis MD United States

Distribution Pattern:

Maryland Only

Associated Products

Product Description:

Methylcobalamin 12mg/ml injection, 1 mL vials, Rx only, Cape Drugs 1384 Cape St. Claire Road Annapolis, MD 21409

Product Quantity:

27 vials

Reason for Recall:

Lack of Processing Controls

Recall Number:

D-0283-2022

Code Information:

Lot #: 188008, BUD 03/19/2022

Product Description:

B-Complex, injection, 1 mL vials, Rx only, Cape Drugs 1384 Cape St. Claire Road Annapolis, MD 21409

Product Quantity:

12 vials

Reason for Recall:

Lack of Processing Controls

Recall Number:

D-0284-2022

Code Information:

Lot# 190036, BUD 12/27/2021

Class III Drugs Event

Event ID:

89141

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

12/01/2021

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

12/16/2021

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:

Telmisartan and Hydrochlorothiazide Tablets, USP, 40 mg/12.5 mg, 30 count bottles, Rx only, Manufactured by: Torrent Pharmaceuticals LTD., Indrad-382 721, India. Manufactured for: Torrent Pharma Inc., Basking Ridge, NJ 07920. NDC: 13668-159-30

Product Quantity:

27,312 Bottles

Reason for Recall:

Superpotent; Hydrochlorothiazide

Recall Number:

D-0285-2022

Code Information:

Batch: BZ74G001 Exp. 12/2021.