# Enforcement Report - Week of December 1, 2021

## Class II Drugs Event

**Event ID:**
88884

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**

**Recall Initiation Date:**
10/19/2021

**Voluntary / Mandated:**
Voluntary: Firm initiated

**Center Classification Date:**
11/23/2021

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

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

**Distribution Pattern:**
Nationwide within the United States

## Associated Products

**Product Description:**
Diclofenac Sodium Topical Solution USP, 1.5 w/w, 5 fl oz (150 mL) plastic bottles, Rx only, Teligent Pharma, Inc., Buena, New Jersey, 08310, NDC 52665-002-05

**Product Quantity:**
2664 bottles

**Reason for Recall:**
Defective Container

**Recall Number:**
D-0258-2022

**Code Information:**
Lot #: 15188, Exp 2/2023

**Product Description:**
Diclofenac Sodium Topical Solution USP, 1.5 w/w, 5 fl oz (150 mL) plastic bottles, Rx only, Teligent Pharma, Inc., Buena, New Jersey, 08310, NDC 52665-025-05.

**Product Quantity:**
5400 units

**Reason for Recall:**
Defective Container

**Recall Number:**
D-0259-2022

**Code Information:**
Lot #: 15028, Exp 1/2023; 15379, Exp 3/2023.

## Class III Drugs Event

**Event ID:**
88847

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**

**Recall Initiation Date:**
09/28/2021

**Voluntary / Mandated:**
Voluntary: Firm initiated

**Center Classification Date:**
11/23/2021

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

**Recalling Firm:**
Bryant Ranch Prepack, Inc. dba BRP Pharmaceuticals
1919 N Victory Pl
Burbank CA United States

**Distribution Pattern:**
Nationwide in the USA

## Associated Products

**Product Description:**
Butalbital, APAP, Caf 50/325/40 Tablets, packaged in a) 12-count bottles, NDC: 63629-8392-09, barcode 083929152151; b) 60-count bottles, NDC: 63629-8392-03, barcode 083923152614; c) 90-count bottles, NDC:63629-8392-04, barcode 083924152614, Lannett Company Inc; Rx only, Packaged by Bryant Ranch Prepack, Burbank, CA 91504.

**Product Quantity:**
119 Bottles

**Reason for Recall:**
Labeling: Not Elsewhere Classified: the controlled substance classification "CIII" is missing on the label

**Recall Number:**
D-0256-2022

**Code Information:**
a) Lots: 152838, 152156, 152151, 151708, 151693, 151375, 151131, 151114, Exp: 7/31/2022, b) Lots: 152245, 151822, 151708, 151160, 151131, Exp: 7/31/2022, c) Lot #: 152614, Exp: 7/31/2022.

**Product Description:**
Butalbital, APAP, Caf 50/325/40 Tablet, packaged in a) 12-count bottles, NDC: 71335-1767-09, barcode 083929164865; b) 20-count bottles, NDC: 71335-1767-01, barcode 083921157837; c) 30-count bottles, NDC: 71335-1767-02, barcode 083922165687, d) 60-count bottles, NDC: 71335-1767-03, barcode 083923153776, e) 90-count bottles, NDC: 71335-1767-04, barcode 083924152889, f) 120-count bottles, NDC: 71335-1767-07, barcode 083927153735. Westminster Pharmaceuticals LLC, Rx only, Packaged by Bryant Ranch Prepack, Burbank, CA 91504 USA

**Product Quantity:**
574 Bottles

**Reason for Recall:**
Labeling: Not Elsewhere Classified: the controlled substance classification "CIII" is missing on the label

**Recall Number:**
D-0257-2022

**Code Information:**
a) Lots: 164865, Exp: 2/28/2021; 162113, Exp: 8/31/2022; 160419, Exp: 2/28/2023; 160004, 155752, 154380, 153776, 152889, Exp: 8/31/2022, b) Lots: 157837, 154997, Exp: 8/31/2022, c) Lots: 165687, 160419, 160330, Exp: 2/28/2023; 159973, 159943, 159352, 159345, 158841, 155752, 152347, Exp: 8/31/2022; 152245, 152156, 152197, 151338, 151160, Exp: 7/31/2022, d) Lots: 162641, Exp: 2/28/2023; 154380, 153776, 152889, Exp: 8/31/2022, e)Lots: 158841, 152889, Exp: 8/31/2022, f) Lots: 153776, 153735, 152347, Exp: 8/31/2022

## Class III Drugs Event

**Event ID:**
88891

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**

**Recall Initiation Date:**
10/25/2021

**Voluntary / Mandated:**
Voluntary: Firm initiated

**Center Classification Date:**
11/19/2021

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

**Recalling Firm:**
UNICHEM PHARMACEUTICALS USA INC
1 Tower Center Blvd Ste 2200
East Brunswick NJ United States

**Distribution Pattern:**
Nationwide within the United States

## Associated Products

**Product Description:**
Topiramate Tablets, USP 50 mg, 500-count bottles, Rx Only, Manufactured by: Unichem Laboratories LTD, Ind. Area. Meerut Road, Ghaziabad -201 003, India. Manufactured for: Unichem Pharmaceuticals (USA), Inc., East Brunswick, NJ 06815, NDC 29300-116-05.

**Product Quantity:**
1284 bottles

**Reason for Recall:**
Discoloration

**Recall Number:**
D-0255-2022

**Code Information:**
Lot #: ZTPM20044, Exp. Date 09/30/2022