

# Enforcement Report - Week of September 16, 2020

## Class II Drugs Event

**Event ID:**  
86063

**Status:**  
Ongoing

**Recall Initiation Date:**  
07/09/2020

**Center Classification Date:**  
09/10/2020

**Recalling Firm:**  
Maquiladora Miniara Sa De Cv  
Crt. Teoloyucan Huehuetoca Km. 22 Coyotepec  
Coyotepec Mexico

**Distribution Pattern:**  
Distributed Nationwide in the USA

**Product Type:**  
Drugs

**Date Terminated:**

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

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

## Associated Products

**Product Description:**

Shine & Clean Hand Sanitizer gel, (Ethyl Alcohol 70%), 33.81 fl oz (1L) bottle, Made in Mexico By: Maquiladora Miniara S.A. de C.V. Carrerera Teoloyucan Huehuetoca km: 22 S/N La Planada Mexico C.P.: 54665 NDC 76753-001-01

**Product Quantity:**  
245,500 bottles

**Reason for Recall:**  
CGMP Deviations: Products manufactured at the same site were FDA testing found below the label claim for ethanol content and the presence of undeclared methanol.

**Recall Number:**  
D-1565-2020

**Code Information:**  
Lots: F200829088, F200829095, F200829107, D202728743, D202528742, D202428733, D202728743, D2028753, D202528742, D202428733, D202028689, D201828660, D202428734, E200128784, E200418795, D202428734, D202828689, D201828660, E201628912, E201628913, E201628911, E201528902, E201528903, E201628910, E201628918, E201628914, E201628915, E201628916, E201628917, E202328969, E202428975, E202528981, E202128947, E201728918, E201728919, E201428876, E201828894, E201828920, E201428876, E201128850, E201328859, E200628817, E200828826, E200928840, D202128699, D202428700.

## Class II Drugs Event

**Event ID:**  
86251

**Status:**  
Ongoing

**Recall Initiation Date:**  
08/07/2020

**Center Classification Date:**  
09/09/2020

**Recalling Firm:**  
Open Book Extracts  
317 Lucy Garrett Rd  
Roxboro NC United States

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

**Product Type:**  
Drugs

**Date Terminated:**

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

**Initial Firm Notification of Consignee or Public:**  
E-Mail

## Associated Products

**Product Description:**

Always Be Clean Hand Sanitizer (73% Alcohol) 0.04 FL OZ (1.2 mL) packaged in a) Single snaps (NDC 75091-2020-1 UPC 375091202016); b) 100-count boxes (NDC 75091-2020-2 UPC 375091202023); c) 25-count boxes (NDC 75091-2020-3 UPC 375091202030)

**Product Quantity:**

340,000 packs

**Reason for Recall:**

Labeling Not Elsewhere Classified: Product labeled to contain methanol

**Recall Number:**

D-1563-2020

**Code Information:**

ES8-200514

**Product Description:**

Just Hand Sanitizer (Ethyl Alcohol 73%) Single Use-Packs 100-count NDC 78065-2020-2 UPC 703123998598 (Single packs NDC 78065-2020-1 UPC 703123998659) Distributed by: Just Hand Sanitizer

**Product Quantity:**

2880 boxes

**Reason for Recall:**

Labeling Not Elsewhere Classified: Product labeled to contain methanol

**Recall Number:**

D-1564-2020

**Code Information:**

Lot: ES9-200610

## Class II Drugs Event

**Event ID:**

86285

**Product Type:**

Drugs

**Status:**

Ongoing

**Date Terminated:****Recall Initiation Date:**

08/24/2020

**Voluntary / Mandated:**

Voluntary: Firm initiated

**Center Classification Date:**

09/10/2020

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

Letter

**Recalling Firm:**

Teva Pharmaceuticals USA  
400 Interpace Pkwy  
Parsippany NJ United States

**Distribution Pattern:**

Nationwide in the U.S. and Puerto Rico.

## Associated Products

**Product Description:**

Cephalexin for Oral Suspension, USP 250 mg per 5 mL, For Reconstitution, For Oral Use Only, Rx Only, 100 mL bottle when mixed, Teva Pharmaceuticals USA, Inc., North Wales, PA 19454, NDC 0093-4177-73.

**Product Quantity:**

38,487 bottles

**Reason for Recall:**

Sub-Potent Drug: Out of specification test results for potency (below specification).

**Recall Number:**

D-1566-2020

**Code Information:**

Lot #: 30310638A, Exp. 01/2022

## Class II Drugs Event

**Event ID:**

86324

**Status:**

Ongoing

**Recall Initiation Date:**

07/02/2020

**Center Classification Date:**

09/07/2020

**Recalling Firm:**

Edge Pharma, LLC

856 Hercules Dr

Colchester VT United States

**Distribution Pattern:**

WI

**Product Type:**

Drugs

**Date Terminated:****Voluntary / Mandated:**

Voluntary: Firm initiated

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

Letter

## Associated Products

**Product Description:**

Vancomycin HCL 1.5 mg Edge Pharma, LLC 856 Hercules Dr. Colchester, VT 05446 NDC 05446-1458-01

**Product Quantity:**

5 IV bags

**Reason for Recall:**

Labeling: Label Error on Declared Strength

**Recall Number:**

D-1562-2020

**Code Information:**

Lot # 06-2020-04@2 BUD 09-16-2020