

# Enforcement Report - Week of April 26, 2023

## Class II Drugs Event

**Event ID:**

91918

**Status:**

Ongoing

**Recall Initiation Date:**

03/17/2023

**Center Classification Date:**

04/19/2023

**Recalling Firm:**

Ascend Laboratories, LLC  
339 Jefferson Rd Ste 101  
Parsippany NJ United States

**Distribution Pattern:**

Nationwide in the USA

**Product Type:**

Drugs

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

Voluntary: Firm initiated

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

Letter

## Associated Products

**Product Description:**

Aripiprazole Tablets, USP, 20 mg, Rx Only, Packaged in 500-count bottle Manufactured by: Alkem Laboratories Ltd., INDIA Distributed by: Ascend Laboratories, LLC Parsippany, NJ 07054, NDC#: 67877-434-05

**Product Quantity:**

135 bottles

**Reason for Recall:**

Out of specification (OOS) for Spectroscopic Identification test by IR.

**Recall Number:**

D-0539-2023

**Code Information:**

Lot #22143120, Exp. Date: June 2024

## Class II Drugs Event

**Event ID:**

91956

**Status:**

Ongoing

**Recall Initiation Date:**

03/16/2023

**Center Classification Date:**

04/14/2023

**Recalling Firm:**

Amerisource Health Services LLC  
2550 John Glenn Ave Ste A  
Columbus OH United States

**Distribution Pattern:**

Nationwide in the USA

**Product Type:**

Drugs

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

Voluntary: Firm initiated

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

Telephone

## Associated Products

**Product Description:**

Verapamil Hydrochloride Extended-Release Tablets, USP, 180 mg, 100 Tablets (10 x 10) per carton, Rx only, Distributed by: American Health Packaging, Columbus, Ohio 43217. NDC Carton: 60687-504-01; NDC Unit Dose: 60687-504-11, barcode (01) 003 60687 504 11 7.

**Product Quantity:**

695 cartons

**Reason for Recall:**

Failed Dissolution Specifications: Out of specification dissolution results above specified values.

**Recall Number:**

D-0536-2023

**Code Information:**

Lots: 1008622, 1010026, Exp 2/29/24

## Class II Drugs Event

**Event ID:**

92080

**Product Type:**

Drugs

**Status:**

Ongoing

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

04/06/2023

**Voluntary / Mandated:**

Voluntary: Firm initiated

**Center Classification Date:**

04/14/2023

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

Letter

**Recalling Firm:**

Pharma Nobis LLC  
7400 Alumax Rd  
Texarkana TX United States

**Distribution Pattern:**

Nationwide in the USA

## Associated Products

**Product Description:**

Fast Acting Earwax Removal System (carbamide peroxide), 6.5%, 0.5 FL OZ (15 mL) Drops per bottle, OTC, Distributed by: CVS Pharmacy, Inc., One CVS Drive, Woonsocket, RI 02895, CVS Product # 999532, UPC 0 50428 36475 8.

**Product Quantity:**

69,615 bottles

**Reason for Recall:**

CGMP Deviations: active ingredient may be subpotent before the labeled expiry due to degradation.

**Recall Number:**

D-0537-2023

**Code Information:**

Lots: A70293, A70294, A70295, Exp. 12/2023; A70746, A70747, A70748, A70749, Exp. 01/2024; A73051, A73052, Exp. 05/2024

## Class II Drugs Event

**Event ID:**

92121

**Product Type:**

Drugs

**Status:**

Ongoing

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

04/13/2023

**Voluntary / Mandated:**

Voluntary: Firm initiated

**Center Classification Date:**  
04/19/2023

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

**Recalling Firm:**  
Pharmacy Plus, Inc. dba Vital Care Compounder  
115 S 40th Ave  
Hattiesburg MS United States

**Distribution Pattern:**  
MS only

### Associated Products

<p><b>Product Description:</b> C-Semaglutide 5mg/mL injection, 0.5mL vials, Rx only, Vital Care Compounder 115 South 40th Ave, Suite A Hattiesburg, MS 39402</p> <p><b>Product Quantity:</b> 45 vials</p> <p><b>Reason for Recall:</b> Lack of assurance of sterility.</p> <p><b>Recall Number:</b> D-0538-2023</p> <p><b>Code Information:</b> Lot #: 73810, Exp. Date 5/1/2023</p>
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