

# Enforcement Report - Week of December 7, 2022

## Class II Drugs Event

**Event ID:**

91161

**Status:**

Ongoing

**Recall Initiation Date:**

11/16/2022

**Center Classification Date:**

11/28/2022

**Recalling Firm:**

Noven Pharmaceuticals Inc  
11960 Sw 144th St  
Miami FL 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:**

Daytrana (methylphenidate transdermal system), Delivers 15 mg over 9 hours, (1.6 mg/hr), 30 patches per box, Rx only, Manufactured for Noven Therapeutics, LLC, Miami, FL 33186; By Noven Pharmaceuticals, Inc., Miami, FL 33186, NDC 68968-5553-3.

**Product Quantity:**

3977 boxes

**Reason for Recall:**

Defective Delivery System: Recalled lot was found to be out of specification for shear. Shear is an attribute related to the adhesive properties of the transdermal patches.

**Recall Number:**

D-0071-2023

**Code Information:**

Lot: 91316 Exp. 02/2023

## Class II Drugs Event

**Event ID:**

91171

**Status:**

Ongoing

**Recall Initiation Date:**

11/23/2022

**Center Classification Date:**

11/29/2022

**Recalling Firm:**

Heritage Pharmaceuticals Inc  
1 Tower Center Blvd Ste 1700  
East Brunswick NJ 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:**

Letter

## Associated Products

**Product Description:**

Desmopressin Acetate Tablets 0.2mg, 100-count bottles, RX Only, Distributed by: Avet Pharmaceuticals Inc. East Brunswick, NJ 08816, NDC 23155-490-01

**Product Quantity:**

13805 Bottles each containing 100 tablets

**Reason for Recall:**

Subpotent Drug

**Recall Number:**

D-0072-2023

**Code Information:**

Lot #: 220440A, Exp. Date 05/2024

## Class III Drugs Event

**Event ID:**

91150

**Product Type:**

Drugs

**Status:**

Ongoing

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

11/14/2022

**Voluntary / Mandated:**

Voluntary: Firm initiated

**Center Classification Date:**

12/01/2022

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

Letter

**Recalling Firm:**

Acella Pharmaceuticals, LLC  
1880 Mcfarland Pkwy Ste 110  
Alpharetta GA United States

**Distribution Pattern:**

USA Nationwide

## Associated Products

**Product Description:**

Sodium Sulfacetamide 10% Sulfur 4% Cleansing Pads, Net weight 3.7g (60 cleansing pads Net weight 3.7 g each per carton,) Rx Only, Manufactured For: Acella Pharmaceuticals, LLC Alpharetta, GA 300025, NDC 42192-113-60

**Product Quantity:**

528 cartons

**Reason for Recall:**

Subpotent drug: Out of specification for assay at the end-of-shelf-life 24-month period.

**Recall Number:**

D-0074-2023

**Code Information:**

Lot#: 21084, 21085, Exp 06/30/2023

## Class III Drugs Event

**Event ID:**

91190

**Product Type:**

Drugs

**Status:**

Ongoing

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

11/21/2022

**Voluntary / Mandated:****Center Classification Date:**

11/30/2022

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

Letter

**Recalling Firm:**

Dr. Reddy's Laboratories, Inc.  
107 College Rd E  
Princeton NJ United States

**Distribution Pattern:**

Nationwide in the USA

## Associated Products

**Product Description:**

Allergy Relief D, Fexofenadine HCL 60mg/Antihistamine, Pseudoephedrine HCL 120mg/Nasal Decongestant, Extended-Release Tablets USP, packaged as (a) 20 count carton NDC 49032-273-20; (b) 30 count carton, NDC49032-273-30; Distributed by: Walmart Inc., Bentonville, AR 72716, Product of India

**Product Quantity:**

25,176, 30-count; 22,968 20-count

**Reason for Recall:**

Failed dissolution specifications

**Recall Number:**

D-0073-2023

**Code Information:**

Lot# (a) AC2203133B, EXP 01/2024; (b) AC2203133A, EXP 01/2024.