

# Enforcement Report - Week of June 28, 2023

## Class III Drugs Event

**Event ID:**

92379

**Status:**

Ongoing

**Recall Initiation Date:**

05/18/2023

**Product Type:**

Drugs

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

06/20/2023

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

Aurolife Pharma, LLC  
2400 US Highway 130  
Dayton NJ United States

**Distribution Pattern:**

Nationwide within the United States

## Associated Products

**Product Description:**

Glycopyrrolate Tablets, USP, 1 mg, 100-count bottles, Rx Only, Distributed by: Aurobindo Pharma USA, Inc., East Windsor, NJ 08520, NDC 13107-014-01

**Product Quantity:****Reason for Recall:**

Failed Impurities/Degradation Specifications

**Recall Number:**

D-0877-2023

**Code Information:**

Lot #: 01421038A1, Exp. Date 05/2023

## Not Yet Classified Drugs Event

**Event ID:**

92463

**Status:**

Ongoing

**Recall Initiation Date:**

06/05/2023

**Center Classification Date:****Product Type:**

Drugs

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

Voluntary: Firm initiated

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

Letter

**Recalling Firm:**

The Harvard Drug Group  
341 Mason Rd  
La Vergne TN United States

**Distribution Pattern:**

Nationwide in the USA

## Associated Products

**Product Description:**

Dronabinol Capsules, USP 2.5 mg, Unit Dose Carton 100 Capsules, Rx Only, Manufactured by: Patheon Softgels Inc. High Point, NC 27265  
Distributed by: Ascend Laboratories, LLC. Parsippany, NJ 07054 Distributed by: Major Pharmaceuticals Livonia, MI 48152 USA, NDC 0904-7144-61

**Product Quantity:**

1,152 cartons

**Reason for Recall:**

Labeling: Label Mix-up: Unit Dose cartons labeled as Ziprasidone Hydrochloride Capsules, 20 mg were found to contain blister packages labeled as and containing Dronabinol Capsules, USP, 2.5 mg

**Recall Number:****Code Information:**

Lot: T04769 Exp. 2024/12

**Product Description:**

Ziprasidone Hydrochloride Capsules 20 mg\* Unit Dose Carton 40 Capsules, Rx only, Mfd. By: Dr. Reddy's Laboratories Limited Bachupally-500 090 India, Distributed by: Major Pharmaceuticals Livonia, MI 48152 USA, NDC 0904-6269-08

**Product Quantity:**

unknown

**Reason for Recall:**

Labeling: Label Mix-up: Unit Dose cartons labeled as Ziprasidone Hydrochloride Capsules, 20 mg were found to contain blister packages labeled as and containing Dronabinol Capsules, USP, 2.5 mg

**Recall Number:****Code Information:**

Lot: T04769 Exp. 2024/12