

Enforcement Report - Week of March 16, 2022

Class II Drugs Event

Event ID:

89670

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

02/22/2022

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

03/11/2022

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

American Health Packaging
2550 John Glenn Ave Ste A
Columbus OH United States

Distribution Pattern:

Nationwide in the USA

Associated Products

Product Description:

Oxycodone Hydrochloride Oral Solution, USP (C-II), 5 mg/5 mL, Delivers 5 mL per Cup, 1 Tray of 10 Cups, Rx Only, For Institutional Use Only, American Health Packaging, Columbus, OH 43217. UPC (01) 003 60687 406 40 4; Case NDC#: 60687-406-77, Unit Dose NDC#: 60687-406-40

Product Quantity:

89,880 unit-dose cups

Reason for Recall:

Impurity failure at 0-time of the repackaged lot.

Recall Number:

D-0652-2022

Code Information:

Lot# 1004276, Exp 11/30/2022

Class II Drugs Event

Event ID:

89681

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

02/28/2022

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

03/09/2022

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

The Harvard Drug Group
17187 N Laurel Park Dr Ste 300
Livonia MI United States

Distribution Pattern:

Nationwide within the United States

Associated Products

Product Description:

PALIPERIDONE EXTENDED-RELEASE TABLETS, 9 mg, 100 Tablets per carton (10 x 10 blister packs), Rx only, Manufactured by: Sun Pharmaceutical Industries Ltd., Survey No. 259/15, Dadra-396 191, India. Distributed by: MAJOR PHARMACEUTICALS, 17177 N. Laurel Park Dr., Suite 233, Livonia, MI 48152. NDC: 0904-6937-61

Product Quantity:

174 cartons

Reason for Recall:

Failed Dissolution Specifications

Recall Number:

D-0649-2022

Code Information:

Lot #: N00522, Exp. Date 09/2022; N00618, Exp. Date 11/2022

Class II Drugs Event

Event ID:

89749

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

03/04/2022

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

03/10/2022

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Direct Rx
94 Worldwide Dr
Dawsonville GA United States

Distribution Pattern:

FL, GA, LA

Associated Products

Product Description:

Alprazolam C-IV 1 mg 60-count bottles, Rx Only, Dist. By: Par Pharmaceutical Chestnut Ridge, NY 10977 Packaged and Distributed By: Direct Rx Dawsonville, GA 30534, NDC 61919-836-60

Product Quantity:

16 bottles

Reason for Recall:

CGMP Deviations: The Recall is due to the potential cross-contamination at the contract manufacturer (Ultra Tab Laboratories Inc.)

Recall Number:

D-0650-2022

Code Information:

Lot #: 19AU1910 Exp. 5/31/22

Product Description:

Alprazolam C-IV 2 mg, 60-count bottles, Rx Only, Dist. By: Par Pharmaceutical Chestnut Ridge, NY 10977 Packaged and Distributed By: Direct Rx Dawsonville, GA 30534, NDC 72189-0058-60

Product Quantity:

8 bottles

Reason for Recall:

CGMP Deviations: The Recall is due to the potential cross-contamination at the contract manufacturer (Ultra Tab Laboratories Inc.)

Recall Number:

D-0651-2022

Code Information:

Lot #: 07NO1901 Exp. 5/31/22