

# Enforcement Report - Week of February 26, 2020

## Class II Drugs Event

**Event ID:**

84990

**Product Type:**

Drugs

**Status:**

Ongoing

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

02/07/2020

**Voluntary / Mandated:**

Voluntary: Firm initiated

**Center Classification Date:**

02/18/2020

**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 USA

## Associated Products

**Product Description:**

Desmopressin Acetate Tablets, 0.1 mg, 30 tablets (3 x 10 unit dose blister cards), Rx Only, Packaged and distributed by: American Health Packaging, Columbus, Ohio 43217. NDC Carton: 68084-606-21; NDC Unit Dose 68084-606-11

**Product Quantity:**

1,879 cartons

**Reason for Recall:**

GMP Deviations: Product bottle may be absent of desiccant.

**Recall Number:**

D-0848-2020

**Code Information:**

Lot 181109, exp 4/30/2020

**Product Description:**

Desmopressin Acetate Tablets, 0.2 mg, 30 tablets (3 x 10 unit dose blister cards), Rx Only, Packaged and distributed by: American Health Packaging, Columbus, Ohio 43217. NDC Carton: 68084-604-21; NDC Unit Dose 68084-604-11

**Product Quantity:**

3,720 cartons

**Reason for Recall:**

GMP Deviations: Product bottle may be absent of desiccant.

**Recall Number:**

D-0849-2020

**Code Information:**

Lot 180510, exp 3/31/2020; Lot 181912, exp 4/30/2020

## Class II Drugs Event

**Event ID:**

84992

**Product Type:**

Drugs

**Status:**

Ongoing

**Date Terminated:**

**Recall Initiation Date:**

01/28/2020

**Voluntary / Mandated:**

Voluntary: Firm initiated

**Center Classification Date:**

02/18/2020

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

Letter

**Recalling Firm:**

NCS Healthcare of Kentucky Inc  
120 Carroll Knicely Dr  
Glasgow KY United States

**Distribution Pattern:**

Nationwide in the USA.

## Associated Products

**Product Description:**

Glycopyrrolate Tabs, USP, 1 mg, 30-count unit dose blister card, FOR INSTITUTIONAL USE ONLY, Rx Only, Packaged by Vanguard, Glasgow, KY 42141; NDC 0615-8170-39.

**Product Quantity:**

6929 blister cards

**Reason for Recall:**

Failed Impurities/Degradation Specification: High Out of Specification Results for Individual Unknown Impurity.

**Recall Number:**

D-0850-2020

**Code Information:**

Lot #: 8170-9004, Exp 01/2020

## Class III Drugs Event

**Event ID:**

84816

**Product Type:**

Drugs

**Status:**

Ongoing

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

01/28/2020

**Voluntary / Mandated:**

Voluntary: Firm initiated

**Center Classification Date:**

02/19/2020

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

Letter

**Recalling Firm:**

Teva Pharmaceuticals USA  
400 Interpace Pkwy  
Parsippany NJ United States

**Distribution Pattern:**

U.S.A. Nationwide

## Associated Products

**Product Description:**

Tramadol Hydrochloride Tablets USP CIV, 50 mg, packaged in a) 100-count bottles (NDC 0093-0058-01), b) 500-count bottles (NDC 0093-0058-05), RX only, Manufactured in Czech Republic for: Teva Pharmaceuticals USA, Inc., North Wales, PA 19545

**Product Quantity:**

2,044,497 bottles

**Reason for Recall:**

Labeling: Incorrect package insert - Patient leaflets for the specified lots of unscored tablets contain language relative to a 25 mg dosing titration that necessitates the use of a scored 50 mg tablet.

**Recall Number:**

D-0851-2020

**Code Information:**

Lot#: a) 100005876, Exp 02/2020; 100008310, 100008311, Exp 07/2020; 100008638, 100008639, Exp 09/2020; 100011763, 02/2021; b) 100005418, 100005419, 100005420, 100005421, 100005877, 100005878, Exp 01/2020; 100005879, 100005880, 100005881, 100005882, 100005883, 100005884, 100005885, 100005886, 100005887, 100005888, 100005889, 100005890, 100005891, 100005892, 100005893, 100005894, 100005895, 100005896, 100005897, 100005898, 100005899, 100005900, 100005901, 100005902, 100005903, 100006588, 100006718, 100006719, 100006720, 100006721, Exp 02/2020; 100006722, 100006724, 100006725, 100006726, 100006727, 100006728, 100006729, 100006730, 100006731, 100006732, 100006733, 100006734, 100006735, 100006736, 100006737, 100006738, 100007005, 100007006, 100007007, 100007008, 100007009, 100007010, Exp 03/2020; 100007011, 100007012, 100007013, 100007014, 100007015, 100007016, 100007017, 100007018, 100007019, 100007020, 100007021, 100007022, 100007023, 100007024, 100007025, 100007026, 100007027, 100007028, 100007029, 100007030, 100007031, 100007032, Exp 04/2020; 100007519, 100007520, 100007521, 100007522, 100007523, 100007524, 100007526, 100007527, 100007528, 100007529, 100007530, 100007531, 100007532, 100007533, 100007534, 100007535, 100007536, 100007537, 100007538, 100007539, 100007540, 100007541, Exp 05/2020; 100007849, 100007850, 100007852, 100007853, 100007855, 100007856, 100007858, 100007859, 100007860, 100007861, 100007862, 100007863, Exp 06/2020; 100008296, 100008297, 100008298, 100008299, 100008300, 100008302, 100008303, Exp 07/2020; 100008640, 100008641, 100008643, 100008644, 100008645, 100008646, 100008647, 100008648, 100008649, 100008653, 100008654, 100008655, 100008656, 100008657, 100008658, 100008659, 100008660, 100008661, 100008662, 100008663, 100008664, 100008665, 100008666, 100008667, Exp 08/2020; 100008668, 100008669, 100008670, 100008671, 100009232, 100009233, Exp 09/2020; 100009999, 100010000, 100010001, 100010002, 100010003, 100010004, 100010005, 100010006, 100010007, 100010671, 100010672, 100010673, 100010674, 100010675, 100010676, Exp 12/2020; 100010677, Exp 01/2021; 100010805, 100010806, 100010807, 100010808, 100010809, 100010810, 100010811, 100011709, 100011710, 100011711, 100011712, 100011713, 100011714, 100011715, 100011716, 100011896, Exp 02/2021; 100011897, 100011898, 100011899, 100011900, 100011901, Exp 03/2021; 100011902, 100011903, 100011904, 100011905, 100011906, 100011907, 100011908, 100011909, 100011910, 100011911, 100011912, 100011913, 100011914, 100011918, Exp 04/2021

**Class III Drugs Event****Event ID:**

84927

**Product Type:**

Drugs

**Status:**

Ongoing

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

02/07/2020

**Voluntary / Mandated:**

Voluntary: Firm initiated

**Center Classification Date:**

02/20/2020

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

Letter

**Recalling Firm:**

AuroMedics Pharma LLC  
279 Princeton Hightstown Rd  
East Windsor NJ United States

**Distribution Pattern:**

Ohio, Louisiana, Mississippi

**Associated Products****Product Description:**

Glycopyrrolate Injection, USP 4 mg per 20 mL (0.2 mg/mL), 20 mL Multiple Dose Vial, Rx Only, For Intramuscular or Intravenous Use, Not for Use in Newborns, Contains Benzyl Alcohol, Distributed by: AuroMedics Pharma LLC, 279 Princeton-Hightstown Rd., E. Windsor, NJ, 08520, Made in India, NDC 55150-295-20.

**Product Quantity:**

4600 Vials

**Reason for Recall:**

Failed Impurities/Degradation Specifications: elevated levels of Benzaldehyde impurity was found in investigative samples (retain samples).

**Recall Number:**

D-0853-2020

**Code Information:**

Lot #CGP190001-A, Exp. 07/31/2020

**Class III Drugs Event**

**Event ID:**  
84955

**Product Type:**  
Drugs

**Status:**  
Ongoing

**Date Terminated:**

**Recall Initiation Date:**  
12/13/2019

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

**Center Classification Date:**  
02/14/2020

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

**Recalling Firm:**  
The Harvard Drug Group  
17177 N Laurel Park Dr Ste 233  
Livonia MI United States

**Distribution Pattern:**  
U.S.A. Nationwide

### Associated Products

<p><b>Product Description:</b> Memantine Hydrochloride Extended-release Capsules, 28mg, packaged in 100-count Unit Dose Cartons , Rx only, Manufactured for: Lupin Pharmaceuticals, Inc., Baltimore, Maryland 21202 United States; Distributed by: Major Pharmaceuticals, 17177 N Laurel Park Dr., Suite 233, Livonia, MI 48152 USA, NDC 0904-6735-61</p> <p><b>Product Quantity:</b> 246 Cartons</p> <p><b>Reason for Recall:</b> Failed Dissolution Specifications: High out of specification result observed at stability studies.</p> <p><b>Recall Number:</b> D-0844-2020</p> <p><b>Code Information:</b> Lot# M02465D</p>
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