

# Enforcement Report - Week of October 25, 2017

## Class II Drugs Event

<b>Event ID:</b> 78162	<b>Product Type:</b> Drugs	<b>Status:</b> Ongoing	<b>Date Terminated:</b>
<b>Recall Initiation Date:</b> 09/26/2017	<b>Voluntary / Mandated:</b> Voluntary: Firm Initiated	<b>Center Classification Date:</b> 10/19/2017	<b>Initial Firm Notification of Consignee or Public:</b> Letter
<b>Recalling Firm:</b> The Harvard Drug Group 17177 N Laurel Park Dr Ste 233 Livonia MI United States		<b>Distribution Pattern:</b> Nationwide in the USA	

## Associated Products

<b>Product Description:</b> Alprazolam Tablets, USP, 0.25 mg, 100-count Unit Dose tablets per carton, Rx Only, Manufactured by: Watson Pharma Private Limited, Verna, Salcette Goa 403 722 INDIA; Distributed by: Actavis Pharma, Inc., Parsippany, NJ 07054; Distributed by: Major Pharmaceuticals, 17177 N. Laurel Park Dr., Suite 233, Livonia, MI 48152, NDC 0904-5858-61.	<b>Product Quantity:</b> 3,935 cartons
<b>Reason for Recall:</b> Failed Impurities/Degradation Specifications: Out-of-specification result for an unknown impurity.	<b>Recall Number:</b> D-0013-2018
<b>Code Information:</b> Lot 1274C151A, Exp 10/17	

## Class II Drugs Event

<b>Event ID:</b> 78174	<b>Product Type:</b> Drugs	<b>Status:</b> Ongoing	<b>Date Terminated:</b>
<b>Recall Initiation Date:</b> 09/20/2017	<b>Voluntary / Mandated:</b> Voluntary: Firm Initiated	<b>Center Classification Date:</b> 10/18/2017	<b>Initial Firm Notification of Consignee or Public:</b> Letter
<b>Recalling Firm:</b> Deserving Health International Corp 13160 Vanier Pl Unit 110 Richmond Canada		<b>Distribution Pattern:</b> Product was distributed throughout the United States.	

## Associated Products

<b>Product Description:</b> Symbio Muc Eye, 0.17 fl.oz. 5mL bottles, Manufactured for and distributed in the US b: Biological Health Group Corp. Bremerton, WA 98337. NDC 69711-125-61	<b>Product Quantity:</b> 623 dropper bottles
<b>Reason for Recall:</b> Lack of Assurance of Sterility	<b>Recall Number:</b> D-0011-2018
<b>Code Information:</b> Lot #: DM17B12, Exp 03/2020; DM16L44, Exp 12/2019; DM16L07, Exp12/2019	

## Class II Drugs Event

<b>Event ID:</b> 78175	<b>Product Type:</b> Drugs	<b>Status:</b> Ongoing	<b>Date Terminated:</b>
<b>Recall Initiation Date:</b> 09/25/2017	<b>Voluntary / Mandated:</b> Voluntary: Firm Initiated	<b>Center Classification Date:</b> 10/18/2017	<b>Initial Firm Notification of Consignee or Public:</b> Telephone
<b>Recalling Firm:</b> RXQ Compounding LLC 340 W State St Unit 9 Athens OH United States		<b>Distribution Pattern:</b> TX, LA, PA, MA, FL, and OH	

### Associated Products

<b>Product Description:</b> methylPREDNisolone ACETATE, 40 MG/ML INJECTION SUSPENSION, 10 ML Vial, RXQ Compounding, Athens, OH --- NDC: 70731-0936-10	<b>Product Quantity:</b> 945 vials
<b>Reason for Recall:</b> Lack of Assurance of Sterility; autoclave parameters were not correct for one of two autoclaves used to sterilize the product.	<b>Recall Number:</b> D-0012-2018
<b>Code Information:</b> Lot: 04252017@1, exp 5/9/2018	

## Class II Drugs Event

<b>Event ID:</b> 78218	<b>Product Type:</b> Drugs	<b>Status:</b> Ongoing	<b>Date Terminated:</b>
<b>Recall Initiation Date:</b> 10/02/2017	<b>Voluntary / Mandated:</b> Voluntary: Firm Initiated	<b>Center Classification Date:</b> 10/18/2017	<b>Initial Firm Notification of Consignee or Public:</b> Letter
<b>Recalling Firm:</b> Unichem Pharmaceuticals Usa Inc 777 Terrace Ave Suite 102 Hasbrouck Heights NJ United States		<b>Distribution Pattern:</b> Product was distributed nationwide	

### Associated Products

<b>Product Description:</b> Bisoprolol Fumarate tablets, 5 mg, 30-count bottles, Rx only, Manufactured by: UNICHEM LABORATORIES, LTD. Pilerne Ind. Estate, Pilerne, Bardez, Goa, 403 511, India, Marketed by: UNICHEM PHARMACEUTICALS, (USA), INC. Hasbrouck Heights, NJ 07604, NDC 29300-126-13.	<b>Product Quantity:</b> 96,876 bottles
<b>Reason for Recall:</b> Failed Impurities/Degradation Specifications: Out of Specification for an unknown impurity was observed during the 18 month stability testing.	<b>Recall Number:</b> D-0010-2018
<b>Code Information:</b> Lot #: GBOL16001, GBOL16002, Exp 12/31/2017; GBOL16015, Exp 03/31/2018.	