

# Enforcement Report - Week of June 9, 2021

## Class II Drugs Event

**Event ID:**

87856

**Product Type:**

Drugs

**Status:**

Ongoing

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

05/04/2021

**Voluntary / Mandated:**

Voluntary: Firm initiated

**Center Classification Date:**

05/28/2021

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

Letter

**Recalling Firm:**

Boehringer Ingelheim Pharmaceuticals, Inc.  
900 Ridgebury Rd  
Ridgefield CT United States

**Distribution Pattern:**

AR, CO, CT, LA, NC, ND, NH, NJ, OH, PA and PR

## Associated Products

**Product Description:**

Micardis Tablets, (telmisartan Tablets) 80 mg, 30 ct. per folding cartons, Rx only, NDC 0597-0041-37), Distributed by: Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT 06877

**Product Quantity:**

15,198 bottles (30 tablets per bottle)

**Reason for Recall:**

Subpotent Drug

**Recall Number:**

D-0600-2021

**Code Information:**

Lot #860412; SEPT 2022

## Class II Drugs Event

**Event ID:**

87873

**Product Type:**

Drugs

**Status:**

Ongoing

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

05/05/2021

**Voluntary / Mandated:**

Voluntary: Firm initiated

**Center Classification Date:**

06/02/2021

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

Letter

**Recalling Firm:**

Oxford Pharmaceuticals, LLC  
301 Leaf Lake Pkwy  
Birmingham AL United States

**Distribution Pattern:**

USA Nationwide.

## Associated Products

**Product Description:**

BusPIRone Hydrochloride Tablets, USP, 15 mg, 100-count bottle, Rx only, Manufactured By: Oxford Pharmaceuticals, LLC Birmingham, Alabama 35211, NDC 69584-093-10

**Product Quantity:**

6,864 bottles

**Reason for Recall:**

Presence of Foreign Tablets/Capsules

**Recall Number:**

D-0602-2021

**Code Information:**

Lot #: C21021A, Exp. 03/2023

## Class III Drugs Event

**Event ID:**

87803

**Status:**

Ongoing

**Recall Initiation Date:**

05/03/2021

**Center Classification Date:**

06/01/2021

**Recalling Firm:**Mylan Institutional LLC  
4901 Hiawatha Dr  
Rockford IL 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:**

Thiamine HCl Injection, USP 200 mg/2 mL (100mg/mL), 2 mL vials, packaged in 25 (2 mL multi-dose vial) per carton, Rx only, Manufactured for: Mylan Institutional LLC, Rockford, IL 61103 USA; Manufactured by: Mylan Institutional, Galway, Ireland. NDC: 67457-196-02

**Product Quantity:**

2,131 cartons

**Reason for Recall:**

Labeling: Incorrect or Missing Lot and/or Exp Date: Cartons with the correct lot number 200906 contain vials labeled with the incorrect lot number 200901.

**Recall Number:**

D-0601-2021

**Code Information:**

Lot #: 200906, Exp. Date February 2022

## Not Yet Classified Drugs Event

**Event ID:**

87837

**Status:**

Ongoing

**Recall Initiation Date:**

05/03/2021

**Center Classification Date:****Recalling Firm:**PFIZER, INC  
275 N Field Dr Bldg H3-3N  
Lake Forest IL United States**Product Type:**

Drugs

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

Voluntary: Firm initiated

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

Letter

**Distribution Pattern:**

Nationwide USA, Puerto Rico, Guam

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

0.5% Bupivacaine Hydrochloride Injection, USP, 150 mg/30 mL (5 mg/mL), 30 mL Single-dose Teartop Vials, 25 per carton, Rx only, Distributed by Hospira, Inc., Lake Forest, IL 60045 USA. NDC Vial: 0409-1162-19; NDC Carton: 0406-1162-02

**Product Quantity:**

163,957 vials

**Reason for Recall:**

Label Mix up: some vials labeled to contain 0.5% Bupivacaine Hydrochloride Injection, USP may contain 1% Lidocaine HCl Injection, USP and some vials labeled to contain 1% Lidocaine HCl Injection, USP may contain 0.5% Bupivacaine Hydrochloride Injection, USP

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

Lot EG6023, 07/01/2022

**Product Description:**

1% Lidocaine HCl Injection, USP, 300 mg/30 mL (10 mg/mL), 30 mL Single-dose vials per carton, Rx only, Distributed by Hospira, Inc., Lake Forest, IL 60045 USA. NDC Vial: 0409-4279-16; NDC Carton: 0409-4279-02

**Product Quantity:**

139,050 vials

**Reason for Recall:**

Label Mix up: some vials labeled to contain 0.5% Bupivacaine Hydrochloride Injection, USP may contain 1% Lidocaine HCl Injection, USP and some vials labeled to contain 1% Lidocaine HCl Injection, USP may contain 0.5% Bupivacaine Hydrochloride Injection, USP

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

Lot EG8933, 08/01/2022