Enforcement Report - Week of March 22, 2023

Class II Drugs Event

Event ID:
91757

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/23/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/20/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Teva Pharmaceuticals USA Inc
400 Interpace Pkwy Bldg A
Parsippany NJ United States

Distribution Pattern:
Nationwide in the U.S.A.

Associated Products

Product Description:
Clear Eyes, Once Daily, Eye Allergy Itch Relief, olopatadine hydrochloride ophthalmic solution, USP, 0.2%, Antihistamine, 2.5 mL (0.085 fl oz) bottle, Sterile, Distributed by Medtech Products Inc. Tarrytown, NY 10591, A Prestige Consumer Healthcare company, Made in Israel, UPC 678112000708; NDC 67172-504-01.

Product Quantity:
715,632 bottles

Reason for Recall:
Failed Impurities Specification: Out-of-specification (OOS) stability test result was obtained for unspecified impurity.

Recall Number:
D-0469-2023

Code Information:
Lot #114349, Exp. 05/2023; 117396, Exp. 09/2023; 120128, Exp. 11/2023; 114371, Exp. 06/2023; 123781, Exp. 02/2024.

Class III Drugs Event

Event ID:
91712

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/15/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/14/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
AVEVA Drug Delivery Systems, Inc.
3250 Commerce Pkwy
Miramar FL United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Buprenorphine Transdermal System, CIII 10 mcg/hour, 4 Transdermal Systems One package of 4 disposal units, Rx Only, Manufactured by: Aveva Drug Delivery Systems Inc. Miramar, FL. 33025, Manufactured for: Apotex Corp Weston, FL. 33326, NDC 60505-7077-05

Product Quantity:
11,520 cartons

Reason for Recall:
Failed Impurities/Degradation Specifications: Out of specification for related substance 10-hydroxy buprenorphine N-Oxide results generated at the 18-month stability timepoint.

Recall Number:
D-0465-2023

Code Information:
Lot#: 51835 Exp: 06/2023

Product Description:
Buprenorphine Transdermal System, CIII 20 mcg/hour, 4 Transdermal Systems One package of 4 disposal units, Rx Only, Manufactured by: Aveva Drug Delivery Systems Inc. Miramar, FL. 33025, Manufactured for: Apotex Corp Weston, FL. 33326, NDC 60505-7079-05

Product Quantity:
5,208 cartons

Reason for Recall:
Failed Impurities/Degradation Specifications: Out of specification for related substance 10-hydroxy buprenorphine N-Oxide results generated at the 18-month stability timepoint.

Recall Number:
D-0466-2023

Code Information:
Lot#: 51836 Exp: 07/2023

Class III Drugs Event

Event ID:
91770

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/24/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/14/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Zydus Pharmaceuticals (USA) Inc
73 Route 31 N
Pennington NJ United States

Distribution Pattern:
AZ, OH, MS.

Associated Products

Product Description:
Colchicine Tablets, USP 0.6 mg, Rx Only, a) 30 tablets per bottle, NDC 16714-0039-01, b) 100 tablets per bottle, NDC 16714-0039-02, Manufactured for: NorthStar Rx LLC., Memphis, TN 38141, Manufactured by: Zydus Lifesciences Ltd., Ahmedabad, India, c) 100 tablets per bottle, NDC 70710-1351-01, Manufactured by: Cadila Healthcare Ltd., Ahmedabad, India, Distributed by: Zydus Pharmaceuticals (USA) Inc., Pennington, NJ 08534.

Product Quantity:
21,936/30 count bottles and 33,096/100 count bottles

Reason for Recall:
Failed Impurities/Degradation Specifications: An out-of-specification (OOS) result was observed during release testing of one lot for a related

substance, i.e. Beta-lumicolchicine.

Recall Number:
D-0467-2023

Code Information:
Lot #s: a) E203821, Exp. 05/2024; b) E203822, Exp. 05/2024, E206186, Exp. 10/2024; c) E203820, Exp. 05/2024.

Class III Drugs Event

Event ID:
91771

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/21/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/10/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Padagis US LLC
3940 Quebec Ave N
Minneapolis MN United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Evamist (estradiol transdermal spray), 1.53 mg of estradiol per spray, 0.27 fl oz (8.1 mL) per metered-dose pump, Rx Only, Manufactured by DPT Laboratories, Ltd San Antonio, TX 78215, Manufactured for: Perrigo, Allegan, Minnapolis, MN 55427, NDC: 0574-2067-27

Product Quantity:
43,238 cartons

Reason for Recall:
Failed Content Uniformity Specifications: The Spray Content Uniformity (SCU) requirement for Standard Deviation did not meet the requirement at the 18-month stability time point.

Recall Number:
D-0464-2023

Code Information:
Lot# SCDR, Exp 02/2024