

Enforcement Report - Week of April 28, 2021

Class II Drugs Event

Event ID:
87694

Status:
Ongoing

Recall Initiation Date:
04/09/2021

Center Classification Date:
04/28/2021

Recalling Firm:
Teligent Pharma, Inc.
105 Lincoln Avenue
Buena NJ United States

Distribution Pattern:
Distributed Nationwide in the USA

Product Type:
Drugs

Date Terminated:

Voluntary / Mandated:
Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:
Letter

Associated Products

Product Description:

Flurandrenolide Ointment USP, 0.05%, Net Wt. 60 grams, Rx Only, Teligent Pharma, Inc. Buena, New Jersey 08310 NDC 52565-017-60

Product Quantity:

3432 tubes

Reason for Recall:

Failed Impurities/Degradation Specifications:

Recall Number:

D-0356-2021

Code Information:

Lot #13974 EXP 7/2021

Class II Drugs Event

Event ID:
87710

Status:
Ongoing

Recall Initiation Date:
04/12/2021

Center Classification Date:
04/19/2021

Recalling Firm:
Edge Pharma, LLC
856 Hercules Dr
Colchester VT United States

Distribution Pattern:
Nationwide in the US

Product Type:
Drugs

Date Terminated:

Voluntary / Mandated:
Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:
Letter

Associated Products

Product Description:

Betadine (Povidone-Iodine) 5%, 0.5mL per syringe Single Use Syringe Rx only, For Topical Ophthalmic Use (DO NOT INJECT) STERILE OPHTHALMIC SOLUTION, PRESERVATIVE FREE, Edge Pharma, LLC 856 Hercules Dr. Colchester, VT 05446 Customer Service (USA) 1-802-992-1178

Product Quantity:

5850 syringes

Reason for Recall:

Defective container; syringe content migrating past the seal of the plunger may cause a lack of assurance of sterility

Recall Number:

D-0335-2021

Code Information:

Lot 02-2021-16@4 BUD 5/31/2021

Class II Drugs Event

Event ID:

87741

Status:

Ongoing

Recall Initiation Date:

04/16/2021

Center Classification Date:

04/20/2021

Recalling Firm:Noven Pharmaceuticals Inc
11960 Sw 144th St
Miami FL 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:

Minivelle (estradiol transdermal system) Delivers 0.075 mg/day, 8 patches/box, Rx only, Mfd. by: Noven Pharmaceuticals, Inc. Miami, Florida 33186 Dist. by: Noven Therapeutics, LLC Miami, Florida 33186, NDC 68968-6675-8

Product Quantity:

12060 cartons

Reason for Recall:

Defective Delivery System: Out of specification for release rate testing and shear, an attribute related to the adhesive properties of the transdermal patches. As a result, patients could experience patches that do not stick well to the skin.

Recall Number:

D-0336-2021

Code Information:

Lot #: 88584 Exp. 03/2022

Product Description:

Estradiol Transdermal System Delivers 0.0375 mg/day, 8 Systems/box, Rx only, Mfd. by: Noven Pharmaceuticals, Inc. Miami, Florida 33186 Dist. by: Noven Therapeutics, LLC Miami, Florida 33186, NDC 68968-3437-8

Product Quantity:

10872 cartons

Reason for Recall:

Defective Delivery System: Out of specification for release rate testing and shear, an attribute related to the adhesive properties of the transdermal patches. As a result, patients could experience patches that do not stick well to the skin.

Recall Number:

D-0337-2021

Code Information:

Lot #: 88321 Exp. 02/2022