

Enforcement Report - Week of June 3, 2026

Class III Drugs Event

Event ID:

98972

Product Type:

Drugs

Status:

Ongoing

Date Terminated:

N/A

Recall Initiation Date:

05/14/2026

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

05/26/2026

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

AVEVA Drug Delivery Systems, Inc.
3250 Commerce Pkwy
Miramar, FL 33025-3907
United States

Distribution Pattern:

Nationwide within the U.S

Associated Products

Product Description:

Nicotine Transdermal System Patch, 14 mg, 14 patches per box, Aveva, Distributed by: RUGBY LABORATORIES, Indianapolis, IN 46268, www.majorpharmaceuticals.com, NDC 0536-5895-88.

Product Quantity:

59,808 pouches (4,272 Individual Folding Carton (IFC))

Reason for Recall:

Failed Impurities/Degradation Specifications: Elevated levels of oxidative-related impurities, exceeding shelf-life specifications during stability testing of individual units.

Recall Number:

D-0550-2026

Code Information:

Lot #: 56841, Expires: 03/2028

Class III Drugs Event

Event ID:

99008

Product Type:

Drugs

Status:

Ongoing

Date Terminated:

N/A

Recall Initiation Date:

05/18/2026

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

05/27/2026

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

AbbVie Inc.
1 N Waukegan Rd
North Chicago, IL 60064-1802
United States

Distribution Pattern:

US Nationwide.

Associated Products

Product Description:

PRED MILD, prednisolone acetate ophthalmic suspension, USP, 0.12%, 10 mL, Sterile, Rx only, Allergan, Inc., an AbbVie company, North Chicago, IL 60064, Product of France, NDC 11980-174-10.

Product Quantity:

2,736 bottles

Reason for Recall:

Failed Stability Specifications

Recall Number:

D-0551-2026

Code Information:

Lot # 402805, 407596, Exp Date: 08/2026.