

Enforcement Report - Week of May 20, 2026

Class II Drugs Event

Event ID:

98610

Status:

Ongoing

Recall Initiation Date:

03/13/2026

Center Classification Date:

05/11/2026

Recalling Firm:

ENDO USA, Inc.
870 Parkdale Rd
Rochester, MI 48307-1740
United States

Distribution Pattern:

USA Nationwide

Product Type:

Drugs

Date Terminated:

N/A

Voluntary / Mandated:

Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:

Letter

Associated Products

Product Description:

Buprenorphine Hydrochloride, Injection, 0.3mg/mL, 5x1 mL Single Dose Vials, Rx only, Manufactured for: Endo USA, Malvern, PA 19855, NDC 42023-179-05.

Product Quantity:

34,293 vials

Reason for Recall:

Presence of particulate matter: identified as Buprenorphine free base

Recall Number:

D-0527-2026

Code Information:

Lot #: 84132, Exp 02/28/2027; 87693, Exp 03/31/2027

Class II Drugs Event

Event ID:

98821

Status:

Ongoing

Recall Initiation Date:

04/27/2026

Center Classification Date:

05/20/2026

Recalling Firm:

Ascend Laboratories, LLC
135 Us Highway 202 206 Ste 15
Bedminster, NJ 07921-2608
United States

Distribution Pattern:

U.S. Nationwide

Product Type:

Drugs

Date Terminated:

N/A

Voluntary / Mandated:

Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:

Letter

Associated Products

Product Description:

Ascend Laboratories, LLC, Metoprolol Succinate Extended-Release Tablets, USP, 25 mg* Rx Only, Manufactured by: Alkem Laboratories Ltd., India, Distributed by: Ascend Laboratories, LLC, Parsippany, NJ 07054, NDC 67877-590-01.

Product Quantity:

17,304 100-count bottles

Reason for Recall:

Failed Dissolution Specifications

Recall Number:

D-0547-2026

Code Information:

Lot # 25140859; Exp. Date: Jan 2027

Class II Drugs Event

Event ID:

98897

Status:

Ongoing

Recall Initiation Date:

04/27/2026

Center Classification Date:

05/08/2026

Recalling Firm:

Oasis Medical, Inc.
510 S Vermont Ave # 528
Glendora, CA 91741-6205
United States

Distribution Pattern:

Nationwide within the United States

Product Type:

Drugs

Date Terminated:

N/A

Voluntary / Mandated:

Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:

Letter

Associated Products

Product Description:

Oasis Tears PF, Preservative-Free Lubricant Eye Drops, 10mL/0.34 Fl OZ Bottle, Sterile, Manufactured for: OASIS Medical, Inc., 514 S. Vermont Ave., Glendora, CA 91741, USA, Made in France, NDC 42126-6400-1.

Product Quantity:

N/A

Reason for Recall:

Lack of Assurance of Sterility: The recall is being initiated out of an abundance of caution following FDA observations noted during a recent inspection of Excelvision.

Recall Number:

D-0525-2026

Code Information:

Lot # 1V59, Exp Date: 05/31/26; Lot # 3V12, 3V69, Exp Date: 08/31/26.