Enforcement Report - Week of March 4, 2026

Class II Drugs Event

Event ID:
98011

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
10/28/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/25/2026

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Agebox
108 W 13th St
Wilmington, DE 19801-1145
United States

Distribution Pattern:
The product was distributed nationwide in the U.S. Agebox sells its U.S. products through Agebox.com (using Shopify) and Amazon.com. All orders are shipped to customers by Agebox itself; other parties are not involved in the distribution of the physical product.

Associated Products

Product Description:
Agebox iKids-Growth (Day Formula) capsules, 60-count bottles, Manufactured Exclusively For: AGEBOX Inc., Wilmington, DE 19801 USA, UPC 8 50065 59701 0

Product Quantity:
665 bottles

Reason for Recall:
Marketed Without an Approved NDA/ANDA: presence of undeclared ibutamoren

Recall Number:
D-0344-2026

Code Information:
Lot # 23101201 exp 09/2026, 24080801 exp 07/2027, and 25020701 exp 01/2028

Product Description:
Agebox iKids-Growth (Night Formula), 60-count bottles, Manufactured Exclusively For: AGEBOX Inc., Wilmington, DE 19801 USA, UPC 850065597027

Product Quantity:
N/A

Reason for Recall:
Marketed Without an Approved NDA/ANDA: presence of undeclared ibutamoren

Recall Number:
D-0345-2026

Code Information:
Lot # 23101202 exp 09/2026, 24080802 exp 07/2027, and 25020702 exp 01/2028

Class II Drugs Event

Event ID:
98253

Product Type:
Drugs

Status:

Date Terminated:

Ongoing

N/A

Recall Initiation Date:
12/31/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/25/2026

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Wizcure Pharmaa Private Limited
H - 881
Bhiwadi
India

Distribution Pattern:
Distributed Nationwide in the USA

Associated Products

Product Description:
Vista Tears Polyethylene Glycol 400 0.4% w/v, Propylene Glycol 0.3% w/v Eye Drops, Dry Eye Relief, Lubricant Drops, Sterile 10 ml (1/3 fl. oz.), Manufactured by: RA/Drugs/ MFG/2019/196283, Omni Lens Pvt. Ltd. 5, Samrudhhi, Opposite:Sakar-III, Navrangpura, Ahmedabad-380014, INDIA. Manufactured for and distributed by hi-health, 15207 N. 75th Street, Suite #104, Scottsdale, AZ, 85260. NDC 77790-001-10.

Product Quantity:
5,760 cartons

Reason for Recall:
Lack of Assurance of Sterility: Products have not been manufactured in conformance with current good manufacturing practices.

Recall Number:
D-0346-2026

Code Information:
All lots

Product Description:
Vista Gel Hypromellose USP 0.3% w/v, Eye Drops Dry Eye Relief Lubricating Gel, 10 ml. (1/3 fl. oz), Wizcure Pharmaa PVT. LTD, H-881, Phase-3, RIICO Industrial Area, Bhiwadi-301019, India, Manufactured for and distributed by: hi-health, 15207 N. 75th Street, Suite #104, Scottsdale, AZ, 85260, NDC 77790-002-10.

Product Quantity:
17,280 cartons

Reason for Recall:
Lack of Assurance of Sterility: Products have not been manufactured in conformance with current good manufacturing practices.

Recall Number:
D-0347-2026

Code Information:
All lots

Product Description:
Vista Meibo Tears Propylene Glycol 0.6% w/v Eye Drops Advanced Dry Eye Relief Revitalizing Formula, 10 ml (1/3 fl.oz.), Wizcure Pharmaa PVT. LTD., H-881, Phase 3, RIICO Industrial Area, Bhiwadi-301019, India, Manufactured for and distributed by: hi-health, 15207 N. 75th Street, Suite #104, Scottsdale, AZ 85260, NDC 77790-003-10.

Product Quantity:
11,520 cartons

Reason for Recall:
Lack of Assurance of Sterility: Products have not been manufactured in conformance with current good manufacturing practices.

Recall Number:
D-0348-2026

Code Information:
All lots

Product Description:
Vista Gonio Eye Lubricant, Hypromellose Ophthalmic Solution USP (Sterile Drops. Dry Eye Relief, 15 ml. (1/2 fl. oz.), Wizcure Pharmaa Pvt. Ltd., H-881, Phase-3, RIICO Industrial Area, Bhiwadi-901019, INDIA, Manufactured for and distributed by: hi-health, 15207 N. 75th Street, Suite #104, Scottsdale, AZ, 85260, NDC 77790-022-15.

Product Quantity:
139,104 cartons

Reason for Recall:
Lack of Assurance of Sterility: Products have not been manufactured in conformance with current good manufacturing practices.

Recall Number:
D-0349-2026

Code Information:
All lots

Product Description:
CHNaO Fluorescein Sodium Ophthalmic Strips, USP 1mg, packaged as a) 100-count box, NDC 83851-100-10; b) 300-count box, NDC 83851-100-30. Manufactured by Wizcure Pharmaa PVT. LTD, H-681, Phase 3, RIICO Industrial Area, Bhiwadi- 301019 INDIA, Vistamerica USA, 20 Perkins Dr. Prescott, AZ 86301, Vistamerica USA, Made in India,

Product Quantity:
10,080 boxes

Reason for Recall:
Lack of Assurance of Sterility: Products have not been manufactured in conformance with current good manufacturing practices.

Recall Number:
D-0350-2026

Code Information:
All lots

Product Description:
Bio Glo Fluorescein Sodium Ophthalmic Strips USP, 300 diagnostic strips, Manufactured Omni Lens Pvt Ltd 5 - Samruddhi, Opp. Sakar - III, Navrangpura, Ahmedabad - 380014, India, Email:info@omnilens.in, Manufactured for & distributed by: HUB Pharmaceuticals, LLC, 8767 E Via de Ventura #175, Scottsdale, AZ, 85258, NDC 17238-900-30.

Product Quantity:
50,400 Boxes

Reason for Recall:
Lack of Assurance of Sterility: Products have not been manufactured in conformance with current good manufacturing practices.

Recall Number:
D-0351-2026

Code Information:
All lots

Product Description:
BioGlo Fluorescein Sodium Ophthalmic Strips USP, 100 diagnostic strips, Manufactured by Omni Lens PVT. Ltd., 5 - Samrudhhi, Opp. Sakar-III, Navrangpura, Ahmedabad, Gujarat, India - 380014, Email:info@omnilens.in, Manufactured for & disibruted by: HUB Pharmaceuticals, LLC, 8767 E Via de Ventura #175, Scottsdale, AZ, 85258, NDC 17238-900-11.

Product Quantity:
184,320 containers

Reason for Recall:
Lack of Assurance of Sterility: Products have not been manufactured in conformance with current good manufacturing practices.

Recall Number:
D-0352-2026

Code Information:
All lots

Class II Drugs Event

Event ID:
98401

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
02/10/2026

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/23/2026

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
LEO PHARMA INC
7 Giralda Farms
Madison, NJ 07940-1051
United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Adbry, (tralokinumab-ldrm) injection, 300 mg/2mL, Packaged as a) 1 x Single dose Autoinjector, SAMPLE NOT FOR SALE, NDC 50222-350-91; b) 2 x Single dose Autoinjectors, NDC 50222-350-02; Rx only, Manufactured by: LEO Pharma A/S. Industriparken 55, DK-2750 Ballerup, Denmark, Distributed by: LEO Pharma Inc., Madison, NJ 07940, USA,

Product Quantity:
11,407 units

Reason for Recall:
Lack of Assurance of Sterility: due to the presence of particulate matter in one unit from the lot, which lab tests have identified as wool fiber.

Recall Number:
D-0339-2026

Code Information:
Lot: a) 003E24C, Exp 04/30/2027; b) 003E24A, Exp 04/30/2027.

Class II Drugs Event

Event ID:
98449

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
02/13/2026

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/23/2026

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
AvKARE
615 N 1st St
Pulaski, TN 38478-2403
United States

Distribution Pattern:
Nationwide in the USA.

Associated Products

Product Description:
Amantadine HCl, Capsules, UPS, 100 mg, 50 Capsules (5 x 10) unit dose, Rx Only, Manufactured for: AvKARE, Pulaski, TN 38478, www.avkare.com, NDC 50268-069-15.

Product Quantity:
N/A

Reason for Recall:
Failed Dissolution Specifications: This recall has been initiated due to an Out of Specification finding in dissolution.

Recall Number:
D-0341-2026

Code Information:
Lot # 49261, Exp: 04/30/27

Class III Drugs Event

Event ID:
98416

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
02/12/2026

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/23/2026

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Slate Run Pharmaceuticals
277 W Nationwide Blvd Ste 260
Columbus, OH 43215-0169
United States

Distribution Pattern:
Nationwide within the USA.

Associated Products

Product Description:
Eptifibatide Injection, 75 mg/100 mL vial for weight-adjusted bolus dosing, 1x100 mL Single-dose Vial, For Intravenous Use Only, Rx Only, Manufactured by: Hainan Poly Pharm. Co., Ltd., Guilinyang Economic Development Area, Haikou, Hainan Province, China 571127; Distributed by: Slate Run Pharmaceuticals, LLC, Columbus, Ohio 43215. NDC Slate Run Carton Label: 70436-027-80; NDC ProRx Carton Label: 70436-163-80

Product Quantity:
N/A

Reason for Recall:
Labeling: Not Elsewhere Classified. The carton for Eptifibatide Injection 75 mg/100 mL states 75 mg/100 mL vial for weight-adjusted bolus dosing. The approved statement is 75 mg/100 mL vial for weight-adjusted infusion.

Recall Number:
D-0343-2026

Code Information:
All lots within expiry