Enforcement Report - Week of April 1, 2026

Class II Drugs Event

Event ID:
98510

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
02/26/2026

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/24/2026

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
MACLEODS PHARMA USA, INC
103 College Rd E Fl 2
Princeton, NJ 08540-6611
United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Levothyroxine Sodium Tablets USP 150 mcg, 1000 Tablets bottle, Rx Only, Manufactured for: Macleods Pharma USA, Inc., Princeton, NJ, Manufactured by: Macleods Pharmaceuticals Ltd., Sarigam, Valsad, Guajarat, INDIA NDC 33342-401-44

Product Quantity:
1315 bottles

Reason for Recall:
Subpotent Drug

Recall Number:
D-0403-2026

Code Information:
Lot 16240062A, exp date 3/2026

Class II Drugs Event

Event ID:
98526

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
03/16/2026

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/31/2026

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Amerisource Health Services LLC
2550 John Glenn Ave Ste A
Columbus, OH 43217-1188
United States

Distribution Pattern:
U.S. Nationwide

Associated Products

Product Description:
Meclizine Hydrochloride Tablets, USP 12.5 mg, (a) 50 Tablets [5 x 10] (NDC 60687-775-65) (b) 12.5 mg Individual Dose (NDC 60687-775-11), Rx Only, Distributed by: American Health Packaging, Columbus, Ohio, 43217.

Product Quantity:
697 cartons

Reason for Recall:
Failed tablet specifications.

Recall Number:
D-0418-2026

Code Information:
Lot #1024852; Exp 9/30/2026

Class II Drugs Event

Event ID:
98593

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
03/17/2026

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/20/2026

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Chiesi USA, Inc.
175 Regency Woods Pl Ste 600
Cary, NC 27518-6007
United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
CUROSURF (poractant alfa), 240 mg, Intratracheal Suspension, 3L Single-dose-Vial, Rx only, Chiesi USA, Inc, Cary, NC 27518, NDC 10122-510-03.

Product Quantity:
7,235 vials

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0402-2026

Code Information:
Lot #: 1213748, Exp. Date 09/2026; 1215076, 1215077, Exp. Date 10/26.

Class II Drugs Event

Event ID:
98609

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
03/17/2026

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/27/2026

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Teva Pharmaceuticals USA, Inc
400 Interpace Pkwy Bldg A
Parsippany, NJ 07054-1120
United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Octreotide Acetate for Injectable Suspension, for gluteal intramuscular use, 10 mg, Single-dose 8 mL vial, Rx only, Manufactured in Greece BY: Pharmathen International S.A, Rodopi, 693 00 Greece, Manufactured For: TEVA Pharmaceuticals, Parsippany, NJ 07054, NDC 0480-9257-08.

Product Quantity:
1,897 Cartons

Reason for Recall:
Lack of Assurance of Sterility: Quality system deficiencies identified during a routine U.S Food and Drug Administration (FDA) inspection at the contract manufacturer.

Recall Number:
D-0404-2026

Code Information:
Lot: 4401619, Exp.: 09/30/2026; 4501005, 03/31/2027.

Product Description:
Octreotide Acetate for Injectable Suspension, for gluteal intramuscular use, 20 mg, Single-dose 8 mL vial, Rx only, Manufactured in Greece BY: Pharmathen International S.A, Rodopi, 693 00 Greece, Manufactured For: TEVA Pharmaceuticals, Parsippany, NJ 07054, NDC 0480-9259-08.

Product Quantity:
19,869 Cartons

Reason for Recall:
Lack of Assurance of Sterility: Quality system deficiencies identified during a routine U.S Food and Drug Administration (FDA) inspection at the contract manufacturer.

Recall Number:
D-0405-2026

Code Information:
Lot: 4401491, 4401600, 4401603, 4401629, Exp.: 9/31/2026; 4500594, 4500786, 4500920, 4501007, 4501462, Exp.: 3/31/2027.

Product Description:
Octreotide Acetate for Injectable Suspension, for gluteal intramuscular use, 30 mg, Single-dose 8 mL vial, Rx only, Manufactured in Greece BY: Pharmathen International S.A, Rodopi, 693 00 Greece, Manufactured For: TEVA Pharmaceuticals, Parsippany, NJ 07054, NDC 0480-9262-08.

Product Quantity:
21,930 Cartons

Reason for Recall:
Lack of Assurance of Sterility: Quality system deficiencies identified during a routine U.S Food and Drug Administration (FDA) inspection at the contract manufacturer.

Recall Number:
D-0406-2026

Code Information:
Lot:4400401, Exp.: 6/30/2026; 4401393, 4401494, 4401604, Exp.: 9/31/2026; 4500564, 4500601, 4500707, 4500796, 4500859, 4500918, 4500919, 4501006, Exp.: 3/31/2027.

Class III Drugs Event

Event ID:
98492

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
02/19/2026

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/20/2026

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Radnostix
4137 Commerce Cir
Idaho Falls, ID 83401-1205
United States

Distribution Pattern:
Nationwide in the US, including Puerto Rico

Associated Products

Product Description:
Gelatin Capsule Pack for use with the Sodium Iodide I-131 Kit (containing 5 empty capsules and 5 Dibasic Sodium Phosphate Capsules 300 mg, International Isotopes Inc., Idaho Falls, ID 83401. NDC: 69208-003-15; 69208-003-25; 69208-003-35

Product Quantity:
2,699 blister cartons

Reason for Recall:
Failed Tablet/Capsule Specifications

Recall Number:
D-0401-2026

Code Information:
Lot, expiry: Lot 3666245, exp: 02/28/2026; Lot 4546213, exp: 02/28/2026 and Lot 4951280, exp 09/30/2027