Enforcement Report - Week of December 25, 2024

Class II Drugs Event

Event ID:
95772

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
11/22/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/16/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Provepharm Inc.
100 Springhouse Dr Ste 105
Collegeville, PA 19426-4709
United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Dihydroergotamine Mesylate Injection, solution for injection, USP, 1 mg/mL Ampules, Rx Only, Distributed by: Provepharm Inc. 100 Springhouse Drive Suite 105, Collegeville, PA 19426, NDC 81284-411-05

Product Quantity:
2160 packs/5 ampules per pack = 10,800 ampules

Reason for Recall:
Discoloration

Recall Number:
D-0150-2025

Code Information:
Lot #: F9026F01, F9026F02, Exp. Date 12/2025

Class II Drugs Event

Event ID:
95824

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
11/22/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/17/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Apothecus Pharmaceutical Corp.
485 S Broadway Ste 27
Hicksville, NY 11801-5071
United States

Distribution Pattern:
Nationwide in the USA and 2 Distributors in Hong Kong

Associated Products

Product Description:
VCF, Vaginal Contraceptive Gel, Birth Control, 10 Pre-filled Applicators, Net Wt. 0.09 oz (2.55g) Each, Distributed By: Apothecus Pharmaceutical Corp., Ronkonkoma, NY 11779, NDC 52925-512-10

Product Quantity:
33,659 retail boxes in US

Reason for Recall:
CGMP deviations: out of specifications for assay

Recall Number:
D-0151-2025

Code Information:
Lot: 3A001/3A001A, Exp: 07/25

Class II Drugs Event

Event ID:
95838

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
11/25/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/19/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Macleods Pharmaceuticals Ltd
304 Atlanta Arcade Church Road
Mumbai
India

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Olanzapine Tablets, USP 2.5 mg, 30-count bottle, Rx Only, Manufactured for: Macleods Pharma USA, Inc. Princeton, NJ 08540, Manufactured for: Macleods Pharma USA Inc. Princeton, NJ,08540: Manufactured by: Macleods Pharmaceuticals, Ltd. Baddi Himachal Pradesh, INDIA, NDC 33342-067-07.

Product Quantity:
15,744 30-count bottles

Reason for Recall:
Failed Impurities/Degradation Specifications

Recall Number:
D-0154-2025

Code Information:
Lot# BOB12318A Exp 07/31/2027

Class II Drugs Event

Event ID:
95854

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
11/14/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/13/2024

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Keystone Industries
480 S Democrat Rd
Gibbstown, NJ 08027-1239
United States

Distribution Pattern:
Nationwide in the USA and Canada, Dominican Republic, El Salvador, Honduras, and Qatar.

Associated Products

Product Description:
Gelato, Benzocaine 20% Topical Gel Anesthetic Gel, Net Wt. 1 oz. (30ml), Manufactured by Keystone Industries 480 S. Democrat Rd., Gibbstown, NJ 08027, NDC# 68400-352-30.

Product Quantity:
N/A

Reason for Recall:
CGMP deviations: the bulk product was rejected by the Quality Unit after routine inspection of the mixing vessel showed scratches on the sides and bottom of the mixing vessel. Product was to be rejected but was inadvertently released and shipped to customers.

Recall Number:
D-0137-2025

Code Information:
Lot: BNZ-001646, Exp Date: 11/26/2026, Keystone item No. 03-02319

Product Description:
M&S Dental Supply Co LLC., Topical Anesthetic Gel, Benzocaine 20%, Net Wt. 1 oz. (30ml), Manufactured for: M&S Dental Supply Co LL, 105-30 101 Avenue, Ozone Park, NY 11416.

Product Quantity:
N/A

Reason for Recall:
CGMP deviations: the bulk product was rejected by the Quality Unit after routine inspection of the mixing vessel showed scratches on the sides and bottom of the mixing vessel. Product was to be rejected but was inadvertently released and shipped to customers.

Recall Number:
D-0138-2025

Code Information:
Lot: BNZ-001646, Exp Date: 11/26/2026, Keystone Item No: 03-09619

Product Description:
Primo, Topical Anesthetic gel, Benzocaine 20%, Net Content: 1 oz. (30g), Gluten Free, Manufactured for: Primo Dental Products, 845 Third Avenue, 6th Floor, New York, NY 10022.

Product Quantity:
N/A

Reason for Recall:
CGMP deviations: the bulk product was rejected by the Quality Unit after routine inspection of the mixing vessel showed scratches on the sides and bottom of the mixing vessel. Product was to be rejected but was inadvertently released and shipped to customers.

Recall Number:
D-0139-2025

Code Information:
Lot: BNZ-001646, Exp Date: 11/26/2026, Keystone Item No. 03-13119

Product Description:
Dental City, Topical Anesthetic Gel, Benzocaine 20%, Net Content: 1 oz. (30 ml), Gluten Free, Manufactured for: Dental City, Green Bay, WI 54311,

dentalcity.com.

Product Quantity:
N/A

Reason for Recall:
CGMP deviations: the bulk product was rejected by the Quality Unit after routine inspection of the mixing vessel showed scratches on the sides and bottom of the mixing vessel. Product was to be rejected but was inadvertently released and shipped to customers.

Recall Number:
D-0140-2025

Code Information:
Lot: BNZ-001646, Exp Date: 11/26/2026, Keystone Item No. 03-25119

Product Description:
Patterson Dental, Patterson Topical Anesthetic Gel, Benzocaiine, 1 oz. (30 ml), Manufactured for (Fabrique pour): Patterson Dental Supply, Inc. 1031 Mendota Heights Road, Saint Paul, MN 55120, NDC 50227-1002-3.

Product Quantity:
N/A

Reason for Recall:
CGMP deviations: the bulk product was rejected by the Quality Unit after routine inspection of the mixing vessel showed scratches on the sides and bottom of the mixing vessel. Product was to be rejected but was inadvertently released and shipped to customers.

Recall Number:
D-0141-2025

Code Information:
Lot: BNZ-001646, Exp Date: 11/26/2026, Keystone Item No. 03-27119

Product Description:
Health-Tec, Topical Anesthetic Gel, Benzocaine 20%, Made in USA, 1 FL. OZ (29.6 ml), NDC 69634-021-30.

Product Quantity:
N/A

Reason for Recall:
CGMP deviations: the bulk product was rejected by the Quality Unit after routine inspection of the mixing vessel showed scratches on the sides and bottom of the mixing vessel. Product was to be rejected but was inadvertently released and shipped to customers.

Recall Number:
D-0142-2025

Code Information:
Lot: BNZ-001646, Exp Date: 11/26/2026, Keystone Item No. 03-28119

Product Description:
Burkhart, Topical Anesthetic Gel, Benzocaine 20%, Gluten Free, 1 FL. OZ (30 ml), Manufactured for Burkhart Dental Supply, Tacoma, Washington 98409.

Product Quantity:
N/A

Reason for Recall:
CGMP deviations: the bulk product was rejected by the Quality Unit after routine inspection of the mixing vessel showed scratches on the sides and bottom of the mixing vessel. Product was to be rejected but was inadvertently released and shipped to customers.

Recall Number:
D-0143-2025

Code Information:
Lot: BNZ-001646, Exp Date: 11/26/2026, Keystone Item No. 03-29119

Product Description:
Pearson Quality, Topical Anesthetic Gel, 20% Benzocaine, For Professional Use Only, Net Contents: 1 oz (30 g), Manufactured for Pearson Dental Supply Inc., Sylmar, CA 91342 USA.

Product Quantity:
N/A

Reason for Recall:
CGMP deviations: the bulk product was rejected by the Quality Unit after routine inspection of the mixing vessel showed scratches on the sides and bottom of the mixing vessel. Product was to be rejected but was inadvertently released and shipped to customers.

Recall Number:
D-0144-2025

Code Information:
Lot: BNZ-001646, Exp Date: 11/26/2026, Keystone Item No. 03-30619

Product Description:
safco, SensiCaine Ultra, Topical Anesthetic Gel, Contains 20% Benzocaine, 1 oz (29.6 mL), Cherry, NDC 67239-0219-1, Gluten Free, Distributed by: Safco Dental Supply Co., Buffalo Grove, IL 60089, Made in USA, For Professional Use Only.

Product Quantity:
N/A

Reason for Recall:
CGMP deviations: the bulk product was rejected by the Quality Unit after routine inspection of the mixing vessel showed scratches on the sides and bottom of the mixing vessel. Product was to be rejected but was inadvertently released and shipped to customers.

Recall Number:
D-0145-2025

Code Information:
Lot: BNZ-001646, Exp Date: 11/26/2026, Keystone Item No. 03-64119

Product Description:
Quala Dental Products, Topical Anesthetic Gel, Contains 20% Benzocaine, Net Contents: 1 oz (30g), Gluten Free, Quala Dental Products, Made in USA for: NDC, Inc, 407 New Sanford Road, La Vergne, TN 37086, www.quala.com

Product Quantity:
N/A

Reason for Recall:
CGMP deviations: the bulk product was rejected by the Quality Unit after routine inspection of the mixing vessel showed scratches on the sides and bottom of the mixing vessel. Product was to be rejected but was inadvertently released and shipped to customers.

Recall Number:
D-0146-2025

Code Information:
Lot No.: BNZ-001646, Exp Date: 11/26/2026, Keystone Item No. 03-64419

Product Description:
Ipana, 20% Benzocaine Topical Gel, 28g, Maxill Inc., St Thomas ON Canada.

Product Quantity:
N/A

Reason for Recall:
CGMP deviations: the bulk product was rejected by the Quality Unit after routine inspection of the mixing vessel showed scratches on the sides and bottom of the mixing vessel. Product was to be rejected but was inadvertently released and shipped to customers.

Recall Number:
D-0147-2025

Code Information:
Lot No.: BNZ-001646, Exp Date: 11/26/2026, Keystone Item No. 03-35119

Product Description:
Henry Schein, Benzo-Jel, Topical Anesthetic Gel, 20% Benzocaine, 1 fl. oz. (29.6 mL), Distributed by Henry Schein, Melville, NY 11747, For Professional Use Only,

Product Quantity:
N/A

Reason for Recall:
CGMP deviations: the bulk product was rejected by the Quality Unit after routine inspection of the mixing vessel showed scratches on the sides and bottom of the mixing vessel. Product was to be rejected but was inadvertently released and shipped to customers.

Recall Number:
D-0148-2025

Code Information:
Lot: BNZ-001646, Exp Date: 11/26/2026, Keystone Item No. 03-43619

Class II Drugs Event

Event ID:
95912

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
12/10/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/17/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Regenerative Processing Plant, LLC
34176 Us Highway 19 N
Palm Harbor, FL 34684-2144
United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
LITE Regener-Eyes, Ophthalmic Solution (glycerin 0.4%), 3mL bottles, Distributed by: Regener-Eyes, Tampa, FL; Manufactured by: Regenerative Processing Plant, LLC, 34176 US HWY 19N, FL, NDC 82305-006-01

Product Quantity:
170812 bottles

Reason for Recall:
Lack of Sterility Assurance

Recall Number:
D-0152-2025

Code Information:
Lot #: P121322A, P121322B, Exp. Date 12/13/2024; P121422A, Exp. Date 12/14/2024; P121922A, P121922B, Exp. Date 12/19/2024; P122022A, Exp. Date 12/20/2024; P122122A, P122122B, Exp. Date 12/21/2024; P122622A, P122622B, Exp. Date 12/26/2024; P122722A, P122722B, Exp. Date 12/27/2024; P122822A, P122822B, Exp. Date 12/28/2024. P010223A, Exp. Date 1/2/2025; P010323LV1, Exp. Date 1/3/2025; P010523A, P010523B, Exp. Date 1/5/2025; P010923A, Exp. Date 1/9/2025; P011023LV2, Exp. Date 1/10/2025, P011223A, P011223B, Exp. Date 1/12/2025; P011623A; Exp. Date 1/16/2025, P011723LV3, Exp. Date 1/17/2025; P011923A, P011923B, Exp. Date 1/19/2025; P012323A, P012323B, Exp. Date 1/23/2025; P012523A, Exp. Date 1/25/2025; P013123A, Exp. Date 1/31/2025; P020223A, Exp. Date 2/2/2025; P020623A, Exp. Date 2/6/2025,P020823A, Exp. Date 2/8/2025, P020923A, Exp. Date 2/9/2025, P021323A, Exp. Date 2/13/2025; P021523A, P021523B, Exp. Date 2/15/2025, P021623A, Exp. Date 2/16/2025, P022023A, Exp. Date 2/20/2025, P022123A, Exp. Date 2/21/2025, P022323A, Exp. Date 2/23/2025, P022723A, Exp. Date 2/27/2025, P030123A, Exp. Date 3/1/2025, P030223A, Exp. Date 3/2/2025, P030623A, Exp. Date 3/6/2025; P030723A, Exp. Date 3/7/2025; P030823A, Exp. Date 3/8/2025; P030923A Exp. Date 3/9/2025, P031423A, Exp. Date 3/14/2025, P032023A, Exp. Date 3/20/2025, P032123A, Exp. Date 3/21/2025; P032223A, Exp. Date 3/22/2025; P032723A, Exp. Date 3/27/2025; P040423A, Exp. Date 4/4/2025; P040523A, Exp. Date 4/5/2025; P040623A, Exp. Date 4/6/2025; P041023A, Exp. Date 4/10/2025;P041123A, Exp. Date 4/11/2025; P041223A, Exp. Date 4/12/2025; P041323A, Exp. Date 4/13/2025; P041723A, Exp. Date 4/17/2025; P041823A, Exp. Date 4/18/2025;P041923A, Exp. Date 4/19/2025; P042023A, Exp. Date 4/20/2025; P042423A, Exp. Date 4/24/2025; P042523A, Exp. Date 4/25/2025;P042623A, Exp. Date 4/26/2025; P050323A, Exp. Date 5/3/2025; P050823A, Exp. Date 5/8/2025;P050923A, Exp. Date 5/9/2025;P051023A, Exp. Date 5/10/2025;P051123A, Exp. Date 5/11/2025;P051523A, Exp. Date 5/15/2025; P051623A, Exp. Date 5/16/2025; P051723A, Exp. Date 5/17/2025; P052223A, Exp.: 5/22/2025; P052323A, Exp.: 5/23/2025; P052423A, Exp. Date 5/24/2025; P052523A, Exp.: 5/25/2025; P053023A, Exp. Date 5/30/2025; P053123A, Exp. Date 5/31/2025; P060123A, Exp. Date 6/1/2025; P060223A, Exp. Date 6/2/2025; P060523A, Exp. Date 6/5/2025; P060623A, Exp. Date 6/6/2025; P060723A, Exp. Date 6/7/2025; P060823A, Exp. Date 6/8/2025; P061223A, Exp. Date 6/12/2025; P061323A, Exp. Date 6/13/2025; P061423A, Exp. Date 6/14/2025

Product Description:
PROFESSIONAL Regener-Eyes, Ophthalmic Solution (glycerin 0.5%) , 3mL bottles, Distributed by: Regener-Eyes, Tampa, FL; Manufactured by: Regenerative Processing Plant, LLC, 34176 US HWY 19N, FL, NDC 82305-003-01

Product Quantity:
59275

Reason for Recall:
Lack of Sterility Assurance

Recall Number:
D-0153-2025

Code Information:
Lot #: P120522A, Exp. Date 12/5/2025, P120522B, Exp. Date 12/5/2024; P120822A, Exp. Date 12/8/2024; P1208228, Exp. Date 12/8/2024; P121222A, P1212228, Exp. Date 12/12/2024; P121922A, P121922B, Exp. Date 12/19/2024; P122222A, Exp. Date 12/22/2024; P122622A, P122622B, Exp. Date 12/26/2024; P010223A, Exp. Date 1/2/2025; P010423PV1, Exp. Date 1/4/2025; P010523A, P010523B, Exp. Date 1/5/2025; P010923A, Exp. Date 1/9/2025; P011123PV2, Exp. Date 1/11/2025; P011223A, P011223B, Exp. Date 1/12/2025; P011623A, Exp. Date 1/16/2025; P011823PV3, Exp. Date 1/18/2025; P011923A, P011923B, Exp. Date 1/19/2025; P012323A, P012323B, Exp. Date 1/23/2025; P012623A, Exp. Date 1/26/2025; P013023A, Exp. Date 1/30/2025; P020123A, Exp. Date 2/1 /2025; P020723A, Exp. Date 2/7/2025; P021423, Exp. Date 2/14/2025, P021623A, Exp. Date 2/16/2025; P022023A, Exp. Date 2/20/2025; P022223A, Exp. Date 2/22/2025; P022823A, Exp. Date 2/28/2025; P030123A, Exp. Date 3/1/2025; P050423A, Exp. Date 5/4/2025, P051823A, Exp. Date 5/18/2025, P052523A, Exp. Date 5/25/2025

Class II Drugs Event

Event ID:
95934

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
12/06/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/16/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Aurobindo Pharma USA Inc
279 Princeton Hightstown Rd
East Windsor, NJ 08520-1401
United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Nebivolol Tablets, 2.5. mg, 30-count bottles, Rx only, Distributed by: Aurobindo Pharma USA, Inc., 279 Princeton-Hightstown Road, East Windsor, NJ 08520. NDC: 59651-137-30

Product Quantity:
N/A

Reason for Recall:
CGMP Deviations: Presence of Nitrosamine Drug Substance Related Impurity (NDSRI), N-Nitroso Nebivolol above acceptable intake (AI) limit.

Recall Number:
D-0149-2025

Code Information:
Lot #: NB0224001A and NB0224001B, Exp. Date 04/2027