

Enforcement Report - Week of December 27, 2023

Class I Drugs Event

Event ID:

89055

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

11/17/2021

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

12/21/2023

Initial Firm Notification of Consignee or Public:

Two or more of the following: Email, Fax, Letter, Press Release, Telephone, Visit

Recalling Firm:

Blistex Inc
1800 Swift Dr
Oak Brook IL United States

Distribution Pattern:

Nationwide with the USA, Canada and Korea

Associated Products

Product Description:

Odor-Eaters Spray Powder, Tolnaftate 1% Antifungal, packaged in a) 4 oz. aerosol cans (UPC 0 41388 0041 2, NDC 10157-4645-1) and b) 5.3 oz. aerosol cans (UPC 0 41388 00411 2, NDC 10157-4645-2) Blistex P.O. Box 5392, Oak Brook, IL 60522-5392.

Product Quantity:

243,386 cases (7 6-pack cases; 36 12-pack cases; 2,678,430 cans total)

Reason for Recall:

Chemical contamination: Presence of benzene

Recall Number:

D-0159-2024

Code Information:

a) Lot #: D19K22, D19K23, Exp. Date 10/21; D19M24, D19M25, D19M26, D19M27, Exp. Date 12/21; D20C01, D20C02, D20C03, D20C04, Exp. Date 3/22; D20F08, D20F09, Exp. Date 6/22; LD20H10, D20H11, Exp. Date 8/22; D20K13, D20K14, Exp. Date 10/22 D21B01, Exp. Date 2/23; D21D03, Exp. Date 4/23; D21E04, D21F04, Exp. Date 5/23; D21F05, Exp. Date 6/23; D21G01, D21G02, Exp. Date 7/23; D21H03, D21H04, D21H05, Exp. Date 8/23. b) Lot #: D19M27, D19M28, D19M29, D19M30, Exp. Date 12/21; D20E05, D20E06, D20E07, Exp. Date 5/22; D20M15, D20M16, Exp. Date 12/22; D21B02, Exp. Date 2/23

Class I Drugs Event

Event ID:

93224

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

10/23/2023

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

12/20/2023

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

The Harvard Drug Group LLC dba Major Pharmaceuticals and Rugby Laboratories
341 Mason Rd
La Vergne TN United States

Distribution Pattern:

Nationwide in the USA

Associated Products**Product Description:**

Phenytoin Oral Suspension, USP, 100 mg/4 mL, packaged in packaged in 4 mL unit dose cups (NDC 0904-7079-24), 50 per case (NDC 0904-7079-57), Rx only, Major Pharmaceuticals Livonia, MI 48152

Product Quantity:

3718 saleable units

Reason for Recall:

Failed Content Uniformity Specifications

Recall Number:

D-0153-2024

Code Information:

Lot# C00099, C00115 Exp. date: 07/31/2024; C00079 Exp. date: 12/31/2023

Class I Drugs Event**Event ID:**

93231

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

10/16/2023

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

12/21/2023

Initial Firm Notification of Consignee or Public:

Telephone

Recalling Firm:Noah's Wholesale LLC
4720 Nw 165th St
Miami Lakes FL United States**Distribution Pattern:**

Florida, Bahamas, Turks & Caicos Islands

Associated Products**Product Description:**

THE ROCK, Male Sexual Performance Enhancement Capsules, 1200 mg, 1 count blister card, Distributed by Steele Productions: Hallandale, FL 33008 UPC 6 61799 95052 7

Product Quantity:

173 capsules

Reason for Recall:

Marketed Without an Approved NDA/ANDA: FDA analysis found the product to be tainted with Sildenafil an ingredient found in an FDA approved product for the treatment of male sexual enhancement, making this an unapproved drug.

Recall Number:

D-0158-2024

Code Information:

Lot# 03032021 Exp: 12/31/2027

Class I Drugs Event**Event ID:**

93449

Product Type:

Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/22/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/15/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Insight Pharmaceuticals Corporation
1170 Wheeler Way Ste 150
Langhorne PA United States

Distribution Pattern:
Nationwide and Puerto Rico

Associated Products

<p>Product Description: TING 2% Miconazole Nitrate Athlete's Foot Spray Antifungal Spray Powder, NET WT 4.5 oz (128 g) cans, Distributed by: Insight Pharmaceuticals LLC, a Prestige Consumer Healthcare company, Tarrytown, NY 10591, UPC 363736532611.</p> <p>Product Quantity: 117,336 cans</p> <p>Reason for Recall: Chemical Contamination; presence of benzene.</p> <p>Recall Number: D-0151-2024</p> <p>Code Information: Lot #s: 0H88645, Exp 07/31/2024; 0B88345, Exp 02/29/2024.</p>

Class II Drugs Event

Event ID:
93594

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/11/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
12/21/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Fagron, Inc
2400 Pilot Knob Rd
Saint Paul MN United States

Distribution Pattern:
Product was distributed to 1 distributor and may have further distributed the product to repacker/relabelers and pharmacies in the United States and Canada to be used for prescription compounding.

Associated Products

<p>Product Description: NYSTATIN 5BU, Activity (as is): 6482 Units/mg, bulk powder container, Rx Only, For Prescription Compounding, Fagron, Inc. - 2400 Pilot Knob Rd. St Paul, MN 55120. NDC 51552-0041-5 Bar code 3 51552 00415 3</p> <p>Product Quantity: 13 containers</p> <p>Reason for Recall:</p>
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Labeling: Label Error on Declared Strength: Assay value on the label is incorrect.

Recall Number:

D-0154-2024

Code Information:

Lot#: 230308-U46196, Exp. date 04/30/2025

Product Description:

NYSTATIN 500 MU, Activity (as is): 6482 Units/mg, bulk powder container, Rx Only, For Prescription Compounding, Fagron, Inc. - 2400 Pilot Knob Rd. St Paul, MN 55120. NDC 51552-0041-3, Bar code 3 51552 00413 9

Product Quantity:

46 containers

Reason for Recall:

Labeling: Label Error on Declared Strength: Assay value on the label is incorrect.

Recall Number:

D-0155-2024

Code Information:

Lot #: 230308-U46225, Exp. date 04/30/2025, 221031-U42110, Exp. date 04/30/2025

Product Description:

NYSTATIN 2 BU, Activity (as is): 6482 Units/mg, bulk powder container, Rx Only, For Prescription Compounding, Fagron, Inc. - 2400 Pilot Knob Rd. St Paul, MN 55120. NDC 51552-0041-4, Bar code 3 51552 00414 6

Product Quantity:

9 containers

Reason for Recall:

Labeling: Label Error on Declared Strength: Assay value on the label is incorrect.

Recall Number:

D-0156-2024

Code Information:

Lot #: 230308-U46224, Exp. date 04/30/2025, 221031-U42105, Exp. date 04/30/2025

Product Description:

NYSTATIN 150 MU, Activity (as is): 6482 Units/mg, bulk powder container, Rx Only, For Prescription Compounding, Fagron, Inc. - 2400 Pilot Knob Rd. St Paul, MN 55120. NDC 51552-0041-1, Bar code 3 51552 00411 5

Product Quantity:

52 containers

Reason for Recall:

Labeling: Label Error on Declared Strength: Assay value on the label is incorrect.

Recall Number:

D-0157-2024

Code Information:

Lot #: 221031-U42104, Exp. date 04/30/2025

Class II Drugs Event

Event ID:

93616

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

12/13/2023

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

12/19/2023

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Private Label Partners, Inc.
551 N Fairview St
Santa Ana CA United States

Distribution Pattern:

NJ

Associated Products

<p>Product Description: Selenium Sulfide 2.25% Shampoo, 180mL bottle, Rx Only, Manufactured for: Bi-Coastal Pharma Int. LLC, Shrewsbury, NJ 07702, NDC 42582-900-06.</p> <p>Product Quantity: 3,396 bottles</p> <p>Reason for Recall: CGMP Deviations: Stability data does not support expiry date.</p> <p>Recall Number: D-0152-2024</p> <p>Code Information: Lot #220551, Exp: 2/28/2025</p>
