

Enforcement Report - Week of November 24, 2021

Class I Drugs Event

Event ID:
88677

Status:
Ongoing

Recall Initiation Date:
10/01/2021

Center Classification Date:
11/18/2021

Recalling Firm:
Bayer Healthcare Pharmaceuticals Inc.
100 Bayer Blvd
Whippany NJ United States

Distribution Pattern:
Distributed Nationwide in the US, Puerto Rico, Canada and Mexico through a variety of retail channels.

Product Type:
Drugs

Date Terminated:

Voluntary / Mandated:
Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:
Press Release

Associated Products

Product Description:
LOTRIMIN AF (Miconazole nitrate 2%) Deodorant Powder Spray, NET WT 133g (4.6 OZ) can, Dist by: Bayer Healthcare LLC, Whippany, NJ 07981, Product of Spain, NDC 11523-1272-2 UPC 3 11017 41023 3

Product Quantity:
2,817,468 cans

Reason for Recall:
Chemical Contamination: presence of benzene

Recall Number:
D-0246-2022

Code Information:
Lot # TN008D3, TN009K7, Exp 5/31/2023.

Product Description:
LOTRIMIN AF, (Miconazole nitrate 2%), Jock Itch, Powder Spray, NET WT 133g (4.6 OZ) can, Dist by: Bayer Healthcare LLC, Whippany, NJ 07981, Product of Spain, NDC 11523-4140-2. UPC 3 11017 41031 8

Product Quantity:
4,546,152 cans

Reason for Recall:
Chemical Contamination: presence of benzene

Recall Number:
D-0247-2022

Code Information:
Lot # CV018TV, 11/30/2021; CV01A71, 1/31/2022; CV01CK4, 4/30/2022; TN0023G, 12/31/2022; TN006TC, 1/31/2023; TN007TG, 3/31/2023; TN008CZ, 4/30/2023; TN008CY, 4/30/2023.

Product Description:
LOTRIMIN AF, (Miconazole nitrate 2%), Powder Spray, NET WT 133g (4.6 OZ) can, Dist by: Bayer Healthcare LLC, Whippany, NJ 07981, Product of Spain, NDC 11523-0544-2 UPC 3 11017 41025 7

Product Quantity:
3,816,468 cans

Reason for Recall:
Chemical Contamination: presence of benzene

Recall Number:
D-0248-2022

Code Information:

Lot # CV01AP2, EXP 2/28/2022; TN006TD, EXP 3/31/2023; TN008CV, EXP 4/30/2023; TN008CW, EXP 5/31/2023;

Product Description:

Lotrimin AF (Tolnaftate 1%) Daily Prevention deodorant powder spray, NET WT 160g (5.6 OZ) can, Dist by: Bayer Healthcare LLC, Whippany, NJ 07981, Product of Finland, UPC 0 41100 58720 6, NDC 11523-0010-2.

Product Quantity:

579,456 cans

Reason for Recall:

Chemical Contamination: presence of benzene

Recall Number:

D-0249-2022

Code Information:

Lot # TN0023D, EXP 2/28/2022; TN004BX, EXP 6/30/2022;

Product Description:

Tinactin (Tolnaftate 1%) DEODORANT POWDER SPRAY NET WT 133g (4.6 OZ) can, Dist by: Bayer Healthcare LLC, Whippany, NJ 07981, UPC 3 11017 41000 4, NDC 11523-4162-1, Product of Finland 20006105

Product Quantity:

738,432 cans

Reason for Recall:

Chemical Contamination: presence of benzene

Recall Number:

D-0250-2022

Code Information:

Lot # TN0067A, EXP 2/28/2023; TN008CU, EXP 4/30/2023;

Product Description:

Tinactin (Tolnaftate 1%) LIQUID SPRAY NET WT150g (5.3 OZ) can, Labeled as (a) Product of Finland 20006101, (b) Product of Ireland 87022897, Dist by: Bayer Healthcare LLC, Whippany, NJ 07981, UPC 3 11017 41005 9, NDC 11523-0165-3.

Product Quantity:

4,990,860 cans

Reason for Recall:

Chemical Contamination: presence of benzene

Recall Number:

D-0251-2022

Code Information:

Lot # (a)TN006MX, EXP 10/31/2022; TN00BKV, TN008D1, TN008D2, EXP 3/31/2023; (b) CV0180B, EXP12/31/2021; TN003C5, EXP 1/31/2023

Product Description:

Tinactin (Tolnaftate 1%) JOCK ITCH POWDER SPRAY NET WT133g (4.6 oz) can, Dist by: Bayer Healthcare LLC, Whippany, NJ 07981, Product of Finland 20066104 UPC 3 11017 41007 3, NDC 11523-0072-5

Product Quantity:

592,416 cans

Reason for Recall:

Chemical Contamination: presence of benzene

Recall Number:

D-0252-2022

Code Information:

Lot # TN008M0, EXP 4/30/2023

Product Description:

Tinactin (Tolnaftate 1%) POWDER SPRAY NET WT 133g (4.6 oz) can, labeled as (a) Product of Ireland 86940418; (b)Product of Finland 20006106; Dist by: Bayer Healthcare LLC, Whippany, NJ 07981, Product of Finland, UPC 3 11017 41009 7, NDC 11523-0777-2.

Product Quantity:

2,841,012 cans

Reason for Recall:

Chemical Contamination: presence of benzene

Recall Number:

D-0253-2022

Code Information:

Lot # (a)CV015YS, EXP 9/30/2021 (b) TN008CT, TN007TJ, EXP 3/31/2023

Class II Drugs Event

Product Description:

LOTRIMIN AF (Miconazole nitrate 2%) Deodorant Powder Spray NET WT 133g (4.6 OZ) can, Dist by: Bayer Healthcare LLC, Whippany, NJ 07981, Product of Spain, NDC 11523-1272-2 UPC 3 11017 41023 3

Product Quantity:

2,817,468 cans

Reason for Recall:

cGMP Deviations: manufactured at the same facility where other lots were found to be contaminated with benzene.

Recall Number:

D-0236-2022

Code Information:

Lot # TN00082, Exp 9/30/2021;TN000TU, TN000TV, Exp. 10/31/2021; TN00236, Exp. 1/31/2022; TN003C8, Exp 2/28/2022; TN003C9, Exp 3/31/2022; TN003GS, Exp 4/30/2022; TN0041W, Exp 6/30/2022; TN006W8, Exp 8/31/2022; TN005P5, Exp 9/30/2022; TN006MZ, Exp 2/28/2023;

Product Description:

LOTRIMIN AF (Miconazole nitrate 2%) Jock Itch Powder Spray NET WT 133g (4.6 OZ) can, Dist by: Bayer Healthcare LLC, Whippany, NJ 07981, Product of Spain, NDC 11523-4140-2. UPC 3 11017 41031 8

Product Quantity:

4,546,152 cans

Reason for Recall:

cGMP Deviations: manufactured at the same facility where other lots were found to be contaminated with benzene.

Recall Number:

D-0237-2022

Code Information:

Lot #: CV01BEP, 3/31/2022; CV01D6W, 5/31/2022; CV01EV0, 7/31/2022; TN0004J, 9/30/2022; TN001AE, 11/30/2022; TN003C3, 1/31/2023; TN003C4, 2/28/2023; TN003HT, 3/31/2023; TN003CW, 4/30/2023; TN0045J, 6/30/2023; TN0040C, 7/31/2023; TN004BU, 8/31/2023; TN006MB, 9/30/2022;

Product Description:

LOTRIMIN AF (Miconazole nitrate 2%) Powder Spray NET WT 133g (4.6 OZ) can, packaged as (a) a single pack NDC 11523-0544-2 UPC 3 11017 41025 7; (b) 3 pack, NDC 11523-0544-2, UPC 0 41100 58594 3; Dist by: Bayer Healthcare LLC, Whippany, NJ 07981, Product of Spain,

Product Quantity:

3,816,468 cans

Reason for Recall:

cGMP Deviations: manufactured at the same facility where other lots were found to be contaminated with benzene.

Recall Number:

D-0238-2022

Code Information:

Lot # (a) CV017D9, EXP 10/31/2021; CV01940, EXP 11/30/2021; CV01CD9, EXP 4/30/2022; CV01D9T, CV01DZ3, EXP 6/30/2022; CV01EPP, EXP 7/31/2022; TN000TT, EXP 10/31/2022; TN003CG, EXP 1/31/2023; TN003CH, TN00407, EXP 3/31/2023; TN0041V, EXP 6/30/2023; TN0056W, EXP 7/31/2022; TN005P4, EXP 8/31/2022; TN006MJ, EXP 9/30/2022; (b) CV01940, CV01940A, EXP 11/30/2021; CV01AP2, EXP 02/28/2022; CV01D9T, CV01D9TA, CV01DZ3, EXP 06/30/2022; CV01EPP, EXP 07/31/2022; TN005P4, EXP 08/31/2022; TN000TT, TN000TTA, EXP 10/31/2022; TN003CG, EXP 01/31/2023; TN003CH, TN003CHA, TN00407, TN006TD, TN006TDB, TN00407A, EXP 03/31/2023; TN0041V, EXP 06/30/2023

Product Description:

LOTRIMIN AF (Tolnaftate 1%) DAILY PREVENTION deodorant powder spray NET WT 133g (4.6 OZ) can, Dist by: Bayer Healthcare LLC, Whippany, NJ 07981, Product of Finland, UPC 0 41100 59036 7, NDC 11523-0010-1.

Product Quantity:

77,076 cans

Reason for Recall:

cGMP Deviations: manufactured at the same facility where other lots were found to be contaminated with benzene.

Recall Number:

D-0239-2022

Code Information:

Lot # TN005K4, EXP 4/30/2022; TN005K8, EXP 6/30/2022

Product Description:

LOTRIMIN AF (Tolnaftate 1%) DAILY PREVENTION deodorant powder spray, NET WT 160g (5.6 OZ) can, packaged as (a) single pack, UPC 0 41100 58720 6, NDC 11523-0010-2; (b) 3-pack, UPC 0 41100 58961 3; Dist by: Bayer Healthcare LLC, Whippany, NJ 07981, Product of Finland,

Product Quantity:

579,456 cans

Reason for Recall:

cGMP Deviations: manufactured at the same facility where other lots were found to be contaminated with benzene.

Recall Number:

D-0240-2022

Code Information:

Lot # (a)TN0023C, EXP 1/31/2022; TN003C7, EXP 4/30/2022; TN00570, EXP 7/31/2022; TN0056Z, TN005KJ, EXP 8/31/2022; (b)TN0023C, EXP 01/31/2022; TN003C7, EXP 04/30/2022; TN0023DV, TN0023DAV, TN0023DBV, TN0023DC, EXP 02/28/2022; TN005KJ, TN005KJA, TN005KJB, EXP 08/31/2022;

Product Description:

Lotrimin AF (Miconazole nitrate 2%) Liquid Spray NET WT 133g (4.6 oz) can, Packaged as (a) single pack, UPC 0 41100 40788 7, NDC 11523-4327-1; (b) 3-pack UPC 0 41100 58593 6; Dist by: Bayer Healthcare LLC, Whippany, NJ 07981, Product of Spain

Product Quantity:

1,801,332 cans

Reason for Recall:

cGMP Deviations: manufactured at the same facility where other lots were found to be contaminated with benzene.

Recall Number:

D-0241-2022

Code Information:

Lot # (a) TN000TR, EXP 10/31/2021; TN0011B, EXP 11/30/2021; TN003CC, TN003CD, EXP 02/28/2022; TN0040B, EXP 05/31/2022; TN0041U, EXP 06/30/2022; TN004BK, EXP 08/31/2022; TN005P3, EXP 10/31/2022; TN006AP, TN006MC, EXP 01/31/2023; TN006TB, EXP 04/30/2023; (b) TN000TR, EXP 10/31/2021; TN0011B, TN0011BA, EXP 11/30/2021; TN003CD, TN003CDA, TN003CDB, EXP 02/28/2022; TN0040BA, TN0040BV, EXP 05/31/2022; TN0041U, EXP 06/30/2022; TN004BK, EXP 08/31/2022; TN006MC, EXP 01/31/2023;

Product Description:

Tinactin (Tolnaftate 1%) DEODORANT POWDER SPRAY NET WT 133g (4.6 OZ) can, labeled as (a) UPC 3 11017-410-00 4, NDC 11523-4162-1, Product of Finland 86568411; (b) UPC 3 11017 41000 4, NDC 11523-4162-1, Product of Finland 20006105; Dist by: Bayer Healthcare LLC, Whippany, NJ 07981

Product Quantity:

738,432 cans

Reason for Recall:

cGMP Deviations: manufactured at the same facility where other lots were found to be contaminated with benzene.

Recall Number:

D-0242-2022

Code Information:

Lot # (a) TN004BW, EXP 7/31/2022, (b) TN00678, EXP 8/31/2022; TN00679, EXP 9/30/2022;

Product Description:

Tinactin (Tolnaftate 1%) LIQUID SPRAY NET WT150g (5.3 OZ) can, labeled as (a) Product of Finland 20006101, (b) Product of Ireland 87022897, (c) Product of Ireland 87022897, with an instant redeemable coupon (IRC) tag attached to the can; Dist by: Bayer Healthcare LLC, Whippany, NJ 07981, UPC 3 11017 41005 9, NDC 11523-0165-3 Tinactin (Tolnaftate 1%) LIQUID SPRAY NET WT150g (5.3 OZ) can, Labeled as (a) Product of Finland 20006101, (b) Product of Ireland 87022897, Dist by: Bayer Healthcare LLC, Whippany, NJ 07981, UPC 3 11017 41005 9, NDC 11523-0165-3.

Product Quantity:

4,990,860 cans

Reason for Recall:

cGMP Deviations: manufactured at the same facility where other lots were found to be contaminated with benzene.

Recall Number:

D-0243-2022

Code Information:

Lot # (a)TN0060U, TN0060V, TN0060W, EXP 7/31/2022; TN0060X, TN0060Y, TN0060Z, TN006CJ, TN006CK, TN006CM, TN00610, EXP 9/30/2022; TN006YW, EXP 10/31/2022; TN006MY, TN006YX, TN006YY, EXP 12/31/2022; TN007EN, TN007EP, TN007ER, EXP 2/28/2023; (b)CV016TH, CV016TJ, CV017D8, CV017D7, EXP 10/31/2021; CV017XS, EXP 11/30/2021; CV01980, CV019DS, EXP 12/31/2021; CV01A72, CV01A73, CV01AE6, EXP 1/31/2022; CV01AUA, CV01B1E, EXP 2/28/2022; CV01BNE, EXP 3/31/2022; CV01BVU, EXP 3/31/2022; CV01CT6, CV01CY1, EXP 4/30/2022; CV01D2G, EXP 5/31/2022; CV01DRX, CV01DRY, CV01E2T, EXP 6/30/2022; CV01E2W, CV01E2X, EXP 7/31/2022; CV01E2U, EXP 7/31/2022; CV01E2V, EXP 8/31/2022; TN001V6, EXP 11/30/2022; TN00243, EXP 12/31/2022; TN0024B, TN0024C, TN0024D, TN0024E, TN003C6, EXP 1/31/2023; TN00408, TN00409, TN0047J, TN0047K, TN0040A, EXP 4/30/2022, (c) CV01DRX, CV01DRY, CV01E2T, EXP 6/30/2022

Product Description:

Tinactin (Tolnaftate 1%) JOCK ITCH POWDER SPRAY NET WT133g (4.6 oz) can, Dist by: Bayer Healthcare LLC, Whippany, NJ 07981, Product of Ireland 86951967, UPC 3 11017 41007 3, NDC 11523-0072-5

Product Quantity:

592,416 cans

Reason for Recall:

cGMP Deviations: manufactured at the same facility where other lots were found to be contaminated with benzene.

Recall Number:

D-0244-2022

Code Information:

Lot # TN00086, CV015YU, EXP 10/31/2022; TN00273, EXP 12/31/2022; TN005RW, Exp 5/31/2023;

Product Description:

Tinactin (Tolnaftate 1%) POWDER SPRAY NET WT 133g (4.6 oz) can, Labeled as (a) Product of Ireland 86940418, (b)Product of Finland 20006106, (c) Product of Ireland with Instant redeemable coupon (IRC); Dist by: Bayer Healthcare LLC, Whippany, NJ 07981, Product of Finland, UPC 3 11017 41009 7, NDC 11523-0777-2.

Product Quantity:

2,841,012 cans

Reason for Recall:

cGMP Deviations: manufactured at the same facility where other lots were found to be contaminated with benzene.

Recall Number:

D-0245-2022

Code Information:

Lot # (a) CV015YT, EXP 10/31/2021; CV01AE7, EXP 2/28/2022; CV01CY2, EXP 4/30/2022; CV01E6P, EXP 8/31/2022; TN00085, TN001EK, EXP 10/31/2022; TN001ZV, TN00274, EXP 12/31/2022; TN003CU, EXP 1/31/2023; TN003CV, EXP 3/31/2023; TN0047H, EXP 4/30/2023; TN0047R, EXP 5/31/2023; (b)TN0067B, EXP 9/30/2022; TN006AT, EXP 12/31/2022; TN006TA, EXP 2/28/2023; (c) CV01E6PV, CV01E6PD, CV01E6PC, CV01E6PBV, CV01E6PAV, EXP 8/31/2022

Product Description:

LOTRIMIN AF (Tolnaftate 1%) DAILY PREVENTION deodorant powder spray, NET WT 160g (5.6 OZ) can, UPC 0 41100 58720 6, NDC 11523-0010-2; Dist by: Bayer Healthcare LLC, Whippany, NJ 07981, Product of Finland, Packaged with LOTRIMIN ULTRA (butenafine hydrochloride 1%) cream, UPC 0 11017 40823 9, Dist by: Bayer Healthcare LLC, Whippany, NJ 07981, Product of Japan, ECOM PK UPC 00041100590756 NDC 11523-0010-2

Product Quantity:

579,456 units

Reason for Recall:

cGMP Deviations: LOTRIMIN AF (Tolnaftate 1%) manufactured at the same facility where other lots were found to be contaminated with benzene.

Recall Number:

D-0254-2022

Code Information:

Lot # NAA8997, EXP 01/31/2022; NAA8EK8, EXP 02/28/2022; NAA9E18, NAA9LFP, NAA9T53, NAA5RW, EXP 08/31/2022;

Class II Drugs Event

Event ID:

88997

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

11/04/2021

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

11/16/2021

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Amneal Pharmaceuticals of New York, LLC
50 Horseblock Rd
Brookhaven NY United States

Distribution Pattern:

Product was distributed nationwide within the United States

Associated Products

Product Description:

Floclonolone Acetonide 0.01% Topical Oil, Body Oil, Rx, packaged in 4 oz. bottle, Distributed by: Amneal Pharmaceuticals Bridgewater, NJ 08807, NDC 65162-704-86

Product Quantity:

7,766 bottles

Reason for Recall:

Subpotent Drug: Out-of-specification assay result was obtained for Fluocinolone Acetonide.

Recall Number:

D-0233-2022

Code Information:

Lot #: 07040001A, exp. date 02/2022

Product Description:

Floclonolone Acetonide 0.01% Topical Oil, Scalp Oil, Rx, packaged in 4 oz. bottle, Distributed by: Amneal Pharmaceuticals Bridgewater, NJ 08807, NDC 65162-703-86

Product Quantity:

15,88 bottles

Reason for Recall:

Subpotent Drug: Out-of-specification assay result was obtained for Fluocinolone Acetonide.

Recall Number:

D-0234-2022

Code Information:

Lot #: 07030002A, exp. date 02/2022

Class III Drugs Event

Event ID:

88938

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

10/28/2021

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

11/16/2021

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Teva Pharmaceuticals USA

Distribution Pattern:
Nationwide and Puerto Rico

Associated Products

<p>Product Description: Clonidine Transdermal System, USP 0.1 mg/day, 4 patches per carton, Rx only, Manufactured by: Actavis Laboratories, UT Inc., Salt Lake City, UT, Distributed by: Actavis Pharma, Inc., Parsippany, NJ NDC 0591-3508-04</p> <p>Product Quantity: 64,978 patches</p> <p>Reason for Recall: Failed Impurities/Degradation Specifications</p> <p>Recall Number: D-0235-2022</p> <p>Code Information: Lot# 1369117B, exp. date 11/2021</p>
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