

Enforcement Report - Week of July 31, 2024

Class II Drugs Event

Event ID:

94850

Status:

Ongoing

Recall Initiation Date:

06/21/2024

Center Classification Date:

07/23/2024

Recalling Firm:

Zydus Pharmaceuticals (USA) Inc
73 Route 31 N
Pennington, NJ 08534-3601
United States

Distribution Pattern:

Nationwide within the United States

Product Type:

Drugs

Date Terminated:

N/A

Voluntary / Mandated:

Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:

Letter

Associated Products

Product Description:

Venlafaxine Hydrochloride Extended-Release Capsules, USP 37.5mg, packaged in a) 90-count bottles (NDC 68382-034-16) and b) 1000-count bottles (NDC 68382-034-10), Rx only, Mfg. by: Zydus Lifesciences Ltd, Ahmedabad, India; Dist. by: Zydus Pharmaceuticals (USA) Inc, Pennington, NJ 08534

Product Quantity:

a) 13,128 bottles; b) 252 bottles

Reason for Recall:

Failed Dissolution Specifications: Out-of-specification results observed for dissolution testing at the 8-hour and 12-hour pull intervals.

Recall Number:

D-0617-2024

Code Information:

Lot #: a) M213175, Exp. Date 09/2024; b) M213176, Exp. Date 09/2024

Class III Drugs Event

Event ID:

94838

Status:

Ongoing

Recall Initiation Date:

06/25/2024

Center Classification Date:

07/22/2024

Recalling Firm:

GLOBAL WIDGET LLC
8419 Sunstate St
Tampa, FL 33634-1306
United States

Distribution Pattern:

Nationwide within the United States

Product Type:

Drugs

Date Terminated:

N/A

Voluntary / Mandated:

Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:

Letter

Associated Products

Product Description:

Hemp Bombs CBD Pain Freeze (menthol 4%), 100mg, 1 oz bottles, Distributed by: Global Widget 8419 Sunstate St, Tampa FL 33634, NDC 73423-003-01; UPC Code: 8-40078-56493-2

Product Quantity:

18540 bottles

Reason for Recall:

Subpotent drug: The potency of the active (menthol) was less than the label claim of 4%.

Recall Number:

D-0613-2024

Code Information:

Lot #: 230189, Exp. date Apr 2025; 230335, Exp. date Jul 2025; 230351, Exp. date Aug 2025

Product Description:

Nature's Script CBD Cryotherapy Pain Relief Roll on (menthol 4%) 200mg, 1 oz bottles, Distributed by: Global Widget 8419 Sunstate St, Tampa FL 33634, UPC code: 8-40078-56731-5

Product Quantity:

2466 bottles

Reason for Recall:

Subpotent drug: The potency of the active (menthol) was less than the label claim of 4%.

Recall Number:

D-0614-2024

Code Information:

Lot #: 230346, Exp. date Aug 2025; 230090 Exp. date Feb 2025

Product Description:

Hemp Bombs CBD Pain Freeze (menthol 4%), 400mg, 4 oz bottles, Distributed by: Global Widget 8419 Sunstate St, Tampa FL 33634; UPC code: 8-40078-56497-0

Product Quantity:

11130 bottles

Reason for Recall:

Subpotent drug: The potency of the active (menthol) was less than the label claim of 4%.

Recall Number:

D-0615-2024

Code Information:

Lot #: 220364, Exp. date Oct 2024; 230424, Exp. date Sep 2025

Product Description:

Hemp Bombs CBD Pain Freeze (menthol 4%), 1000mg, 4 oz bottles, Distributed by: Global Widget 8419 Sunstate St, Tampa FL 33634; UPC Code: 8-40078-56612-7

Product Quantity:

2082 bottles

Reason for Recall:

Subpotent drug: The potency of the active (menthol) was less than the label claim of 4%.

Recall Number:

D-0616-2024

Code Information:

Lot #: 220365, Exp date Oct 2024 ; 230090, Exp. date Feb 2025

Class III Drugs Event

Event ID:
94975

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
05/31/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
07/25/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Washington Homeopathic Products, Inc.
260 J R Hawvermale Way
Berkeley Springs, WV 25411-6957
United States

Distribution Pattern:
Nationwide in the USA

Associated Products

<p>Product Description: Complete 30C/200C Homeopathic Kit, Contains: One hundred 1/2 dram vials of homeopathic medicines, Washington Homeopathic Products, Inc., Berkley Springs, WV 25411, UPC 7 40640 64300 6.</p> <p>Product Quantity: 11 kits</p> <p>Reason for Recall: Labeling: Label Mix-up: Some bottles of Ferrum Phosphoricum 200C were incorrectly labeled as Ferrum Metallicum 200C.</p> <p>Recall Number: D-0618-2024</p> <p>Code Information: lot #: 32093, Exp. 8/31/2028</p>
