

# Enforcement Report - Week of October 6, 2021

## Class I Drugs Event

**Event ID:**

88288

**Product Type:**

Drugs

**Status:**

Ongoing

**Date Terminated:****Recall Initiation Date:**

07/14/2021

**Voluntary / Mandated:**

Voluntary: Firm initiated

**Center Classification Date:**

09/24/2021

**Initial Firm Notification of Consignee or Public:**

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

**Recalling Firm:**Johnson & Johnson Consumer, Inc.  
199 Grandview Rd  
Skillman NJ United States**Distribution Pattern:**

Nationwide in US

## Associated Products

**Product Description:**

Neutrogena Beach Defense water+sun protection sunscreen spray BROAD SPECTRUM SPF 50, Avobenzone (3%), Homosalate (10%), Octisalate (5%), Octocrylene (10%), NET WT. 6.5 OZ. (184 g) aerosol can, Distributed by: JOHNSON &amp; JOHNSON CONSUMER, INC. Skillman, NJ 08858, UPC 0 86800 11254 9

**Product Quantity:**

1,437,804 cans

**Reason for Recall:**

Chemical Contamination: product contains benzene levels above the maximum daily exposure limits

**Recall Number:**

D-0844-2021

**Code Information:**

16621E01, exp 5/2024

**Product Description:**

Neutrogena Beach Defense water+sun protection sunscreen spray BROAD SPECTRUM SPF 60+, Avobenzone (3%), Homosalate (10%), Octisalate (5%), Octocrylene (10%) NET WT. 8.5 OZ. (240 g) aerosol can, Distributed by: JOHNSON &amp; JOHNSON CONSUMER, INC. Skillman, NJ 08858, UPC 0 86800 11255 6

**Product Quantity:**

387,648 cans

**Reason for Recall:**

Chemical Contamination: product contains benzene levels above the maximum daily exposure limits

**Recall Number:**

D-0845-2021

**Code Information:**

06320E26, exp 1/2023

## Class II Drugs Event

**Product Description:**

Aveeno Protect + Refresh sunscreen weightless spray with oat SPF 60, Avobenzone (3%), Homosalate (10%), Octisalate (5%), Octocrylene (10%), NET WT. 5.0 (OZ) (141 g) aerosol can, Distributed by: Johnson &amp; Johnson Consumer Inc., Skillman, NJ 08558 UPC 3 8137-119462 9

**Product Quantity:**

134,280 cans

**Reason for Recall:**

cGMP Deviations

**Recall Number:**

D-0831-2021

**Code Information:**

All lots within expiry.

**Product Description:**

Neutrogena COOLDRY SPORT sunscreen spray SPF 30, Avobenzone (3%), Homosalate (8%), Octisalate (5%), Octocrylene (8%), a) Net Wt 5.0 oz (141g) (UPC 0 86800 10035 5) and b) Net Wt. 8 oz. (226 g) UPC 0 86800 10031 7 aerosol can, Distributed by: JOHNSON & JOHNSON CONSUMER INC., Skillman, NJ 08858,

**Product Quantity:**

a) 223,884; b) 245,880 cans

**Reason for Recall:**

cGMP Deviations

**Recall Number:**

D-0832-2021

**Code Information:**

All lots within expiry.

**Product Description:**

Neutrogena Beach Defense water + sun protection sunscreen spray BROAD SPECTRUM SPF 30, Avobenzone (3%), Homosalate (8%), Octisalate (5%), Octocrylene (8%), a) NET WT. 6.5 OZ (184 g) (UPC 0 86800 87273 3) and b) NET WT. 8.5 oz (240 g) (UPC 0 86800 10032 4) aerosol can, Distributed by JOHNSON & JOHNSON CONSUMER, INC. Skillman, NJ 08858

**Product Quantity:**

a) 1,265,724 b) 1,052,544cans

**Reason for Recall:**

cGMP Deviations

**Recall Number:**

D-0833-2021

**Code Information:**

All lots within expiry.

**Product Description:**

Neutrogena COOLDRY SPORT sunscreen spray BROAD SPECTRUM SPF 50, Avobenzone (3%), Homosalate (10%), Octisalate (5%), Octocrylene (10%), NET WT 5.0 OZ (141 g) aerosol can, Distributed by: JOHNSON & JOHNSON CONSUMER, INC. Skillman, NJ 08858, UPC 0 86800 10036 2

**Product Quantity:**

867,816 cans

**Reason for Recall:**

cGMP Deviations

**Recall Number:**

D-0834-2021

**Code Information:**

All lots within expiry.

**Product Description:**

Neutrogena COOLDRY SPORT sunscreen spray BROAD SPECTRUM SPF 70, Avobenzone (3%), Homosalate (15%), Octisalate (5%), Octocrylene (10%), NET WT. 5.0 OZ (141 g) aerosol can, Distributed by: JOHNSON & JOHNSON CONSUMER, INC. Skillman, NY 08858, UPC 0 86800 10037 9

**Product Quantity:**

678,384 cans

**Reason for Recall:**

cGMP Deviations

**Recall Number:**

D-0835-2021

**Code Information:**

All lots within expiry.

**Product Description:**

Neutrogena Ultra Sheer body mist sunscreen BROAD SPECTRUM SPF 30, Avobenzone (3%), Homosalate (8%), Octisalate (5%), Octocrylene (8%), Net Wt. 5.0 OZ (141 g) aerosol can, Distributed by: JOHNSON & JOHNSON CONSUMER, INC. Skillman, NY 08858 UPC 0 86800 10038 6

**Product Quantity:**

1,611,180 cans

**Reason for Recall:**

cGMP Deviations

**Recall Number:**

D-0836-2021

**Code Information:**

All lots within expiry

**Product Description:**

Neutrogena Ultra Sheer body mist sunscreen BROAD SPECTRUM SPF 45, Avobenzone (3%), Homosalate (10%), Octisalate (5%), Octocrylene (10%), a) Net Wt. 5 OZ (141 g) (UPC 0 86800 10039 3) and b) Net Wt. 8.0 oz. (226 g) (UPC 0 86800 11134 4) aerosol can, Distributed by: JOHNSON & JOHNSON CONSUMER, INC. Skillman, NJ, 08858,

**Product Quantity:**

a) 5oz-1,282,488; b) 8oz-475,476 cans

**Reason for Recall:**

cGMP Deviations

**Recall Number:**

D-0837-2021

**Code Information:**

All lots within expiry.

**Product Description:**

Neutrogena Ultra Sheer body mist sunscreen BROAD SPECTRUM SPF 70, Avobenzone (3%), Homosalate (15%), Octisalate (5%), Octocrylene (10%), NET WT. 5.0 OZ (141 g) aerosol can, Distributed by: JOHNSON & JOHNSON CONSUMER, INC. Skillman, NJ 08858, UPC 0 86800 10040 9

**Product Quantity:**

2,724,480 cans

**Reason for Recall:**

cGMP Deviations

**Recall Number:**

D-0838-2021

**Code Information:**

All lots within expiry.

**Product Description:**

Neutrogena Ultra Sheer body mist sunscreen BROAD SPECTRUM SPF 100+, Avobenzone (3%), Homosalate (15%), Octisalate (5%), Octocrylene (10%), Oxybenzone (15%), NET WT. 5.0 OZ (141 g) aerosol can, Distributed by: JOHNSON & JOHNSON CONSUMER INC. Skillman, NJ 08858, UPC 0 86800 10041 6

**Product Quantity:**

3,985,392 cans

**Reason for Recall:**

cGMP Deviations

**Recall Number:**

D-0839-2021

**Code Information:**

All lots within expiry.

**Product Description:**

Neutrogena COOLDRY SPORT sunscreen spray BROAD SPECTRUM SPF 100, Avobenzone (3%), Homosalate (15%), Octisalate (5%), Octocrylene (10%), Oxybenzone (6%) aerosol can, NET WT. 5.0 OZ (141 g) Distributed by: JOHNSON & JOHNSON CONSUMER, INC. Skillman, NJ 08858, UPC 0 86800 10143 7

**Product Quantity:**

405,264 cans

**Reason for Recall:**

cGMP Deviations

**Recall Number:**

D-0840-2021

**Code Information:**

All lots within expiry.

**Product Description:**

Neutrogena Beach Defense water+sun protection sunscreen spray BROAD SPECTRUM SPF 100, Avobenzone (3%), Homosalate (15%), Octisalate (5%), Octocrylene (10%), Oxybenzone (6%), NET WT. 6.5 OZ (184 g) aerosol can, Distributed by: JOHNSON & JOHNSON CONSUMER, INC. Skillman, NJ 08858, UPC 0 86800 10144 4

**Product Quantity:**

876,960 cans

**Reason for Recall:**

cGMP Deviations

**Recall Number:**

D-0841-2021

**Code Information:**

All lots within expiry.

**Product Description:**

Neutrogena COOLDRY SPORT WITH MICROMESH SUNSCREEN SPRAY Broad Spectrum SPF 50, Avobenzone 2.7%, Homosalate 5%, Octisalate 4.5%, Octocrylene 6%, Oxybenzone 4.5%. NET WT. 5.5 OZ. (155 g) aerosol can, Distributed by: JOHNSON & JOHNSON CONSUMER, INC. Skillman, NJ 08858, UPC 0 86800 11033 0

**Product Quantity:**

1,448,520 cans

**Reason for Recall:**

cGMP Deviations

**Recall Number:**

D-0842-2021

**Code Information:**

All lots within expiry.

**Product Description:**

Neutrogena Invisible Daily defense body spray sunscreen BROAD SPECTRUM SPF 60+, Avobenzone (3%), Homosalate (10%), Octisalate (5%), Octocrylene (10%), NET WT. 5.0 OZ. (141 g) aerosol can, Distributed by: JOHNSON & JOHNSON CONSUMER, INC. Skillman, NJ 08858, UPC 0 86800 11154 2

**Product Quantity:**

88,380 cans

**Reason for Recall:**

cGMP Deviations

**Recall Number:**

D-0843-2021

**Code Information:**

All lots within expiry.

**Product Description:**

Neutrogena Beach Defense water+sun protection sunscreen spray BROAD SPECTRUM SPF 70, Avobenzone (3%), Homosalate (15%), Octisalate (5%), Octocrylene (10%), a) NET WT. 6.5 OZ. (184 g) (UPC 0 86800 87274 0) and b) NET WT. 8.5 OZ. (240 g) (UPC 0 86800 10048 5) aerosol can, Distributed by: JOHNSON & JOHNSON CONSUMER, INC. Skillman, NJ 08858

**Product Quantity:**

a) 3,672,204; b) 11,180 cans

**Reason for Recall:**

cGMP Deviations

**Recall Number:**

D-0846-2021

**Code Information:**

All lots within expiry

**Product Description:**

Neutrogena Ultra Sheer body mist sunscreen BROAD SPECTRUM SPF 30, Avobenzone (3%), Homosalate (8%), Octisalate (5%), Octocrylene (8%), Net Wt. 8.0 oz. (226 g) aerosol can, Distributed by: JOHNSON & JOHNSON CONSUMER, INC. Skillman, NY 08858 UPC 0 86800 11133 7

**Product Quantity:**

196,380 cans

**Reason for Recall:**

cGMP Deviations

**Recall Number:**

D-0847-2021

**Code Information:**

All lots within expiry

**Product Description:**

Neutrogena Beach Defense water+sun protection sunscreen spray BROAD SPECTRUM SPF 70, Avobenzone (3%), Homosalate (15%), Octisalate (5%), Octocrylene (10%), NET WT. 8.5 OZ. (240 g) aerosol can, Distributed by: JOHNSON & JOHNSON CONSUMER, INC. Skillman, NJ 08858 UPC 0 86800 10048 5

**Product Quantity:**

411,180 cans

**Reason for Recall:**

cGMP Deviations

**Recall Number:**

D-0848-2021

**Code Information:**

All lots within expiry

**Product Description:**

Neutrogena Beach Defense water+sun protection sunscreen spray BROAD SPECTRUM SPF 50, Avobenzone (3%), Homosalate (10%), Octisalate (5%), Octocrylene (10%), NET WT. 6.5 OZ. (184 g) aerosol can, Distributed by: JOHNSON & JOHNSON CONSUMER, INC. Skillman, NJ 08858, UPC 0 86800 11254 9

**Product Quantity:****Reason for Recall:**

cGMP Deviations

**Recall Number:**

D-0849-2021

**Code Information:**

All lots within expiry

**Product Description:**

Neutrogena Beach Defense water+sun protection sunscreen spray BROAD SPECTRUM SPF 60+, Avobenzone (3%), Homosalate (10%), Octisalate (5%), Octocrylene (10%) NET WT. 8.5 OZ. (240 g) aerosol can, Distributed by: JOHNSON & JOHNSON CONSUMER, INC. Skillman, NJ 08858, UPC 0 86800 11255 6

**Product Quantity:****Reason for Recall:**

cGMP Deviations

**Recall Number:**

D-0850-2021

**Code Information:**

All lots within expiry

## Class II Drugs Event

**Event ID:**

88528

**Status:**

Ongoing

**Recall Initiation Date:**

08/20/2021

**Product Type:**

Drugs

**Date Terminated:****Voluntary / Mandated:**

Voluntary: Firm initiated

**Center Classification Date:**

09/29/2021

**Initial Firm Notification of Consignee or Public:**

Letter

**Recalling Firm:**

Washington Homeopathic Products, Inc.  
260 J R Hawvermale Way  
Berkeley Springs WV United States

**Distribution Pattern:**

Distributed Nationwide in the USA

## Associated Products

**Product Description:**

Aconitum nap Fear\* 87% Alcohol HPUS: 5X, 7X, 18X, 30X, packaged in 30 mL containers, Aconitum nap Fear\* 87% Alcohol HPUS: 24X, packaged in 50 mL containers, WHP Homeopathic Medicine, Washington Homeopathic Products 260 JR Hawvermale Way, Berkeley Springs, WV 25411.

**Product Quantity:**

562 bottles

**Reason for Recall:**

Out-of-specification test results obtained for identification testing based on HPTLC analysis.

**Recall Number:**

D-0857-2021

**Code Information:**

Lot # 26198

**Product Description:**

ZTE-105 Formula Gentle Detoxing. Contents 1000 mL, RX Only, REMEDY: Bryoni Alba 10X, Chelidonium Majus 10X, Carduus Marianus 10X, Dolichos Pruriens 10X, Solidago Vigaurea 10X, Alfalfa 10X, Boldo 10X, Cynara Scolymus 10X, Zincum Muriaticum 13X, Chromium Sulphuricum 10X, Manganum Metallicum 10X, Dilution Alcohol 20%. WHP Homeopathic Medicine. For Manufacturing Use Only, Manufactured for Optimal Health Dimensi. Manufactured By: Washington Homeopathic Products, 260 JR Hawvermale Way, Berkeley Springs, WV, 25411.

**Product Quantity:**

3/1 Liter bottles

**Reason for Recall:**

Out-of-specification test results obtained for identification testing based on HPTLC analysis.

**Recall Number:**

D-0858-2021

**Code Information:**

Lot # 25950, 26933, Exp 8/17/2026

**Product Description:**

Ocular Allergy Blend 87% Alcohol; In Equal Parts of Apis Mellifica 7x Allium Cepa 7x Euphrasia Officinalis 7X Sabadilla 7X, WHP Homeopathic Medicine For Manufacturing Only, 500 ml. Manufactured by Washington Homeopathic Products 260JR Hawvermale Way, Berkeley Springs WV 25411

**Product Quantity:**

2/500 mL bottles

**Reason for Recall:**

Out-of-specification test results obtained for identification testing based on HPTLC analysis.

**Recall Number:**

D-0859-2021

**Code Information:**

Lot # 30148

**Product Description:**

Yeast Guard Blend, Calcareia Carbonica 6X, Collinsonia Canadensis 3X, Kali Muriaicum 3X, WHP Homeopathic Medicine, For Manufacturing Use Only. 1.957 kg Lactose, Manufactured by Wasington Homeopathic Products 260 JR Hawvermale Way, Berkeley Springs WV 25411.

**Product Quantity:**

1.957 kg.

**Reason for Recall:**

Out-of-specification test results obtained for identification testing based on HPTLC analysis.

**Recall Number:**

D-0860-2021

**Code Information:**

Lot # 29782

**Product Description:**

Haloderm Homeopathic Blend, For Manufacturing Use Only, 1,000 ml 20% Alcohol, Contains: Dulcamara 10x, Nitricum Acidum 12x, Thuja Occidentalis 10x, Antimonium Crudum 12x, Calcareo Carbonica 12x, Silicea 12x, WHP Homeopathic Medicine, For Manufacturing Use Only. 1.957 kg Lactose Manufactured by Washington Homeopathic Products 260 JR Hawvermale Way, Berkeley Springs WV 25411. Marketed by: Health Specialty

**Product Quantity:**

3 Liter bottles

**Reason for Recall:**

Out-of-specification test results obtained for identification testing based on HPTLC analysis.

**Recall Number:**

D-0861-2021

**Code Information:**

Lot # 30308

**Product Description:**

Cedar Fever Drops, 20% USP ALCOHOL, 30 mL, homeopathic drug for symptoms of cedar allergies, Manufactured for Peoples RX, 3801 S Lamar, Austin, TX 78704. UPC 7 40640 64166 8

**Product Quantity:**

1,931 bottles

**Reason for Recall:**

Out-of-specification test results obtained for identification testing based on HPTLC analysis.

**Recall Number:**

D-0862-2021

**Code Information:**

Lot # 25586, 27410

**Product Description:**

Althaea Officinalis 4X, Irritable Bladder\* packaged as Sucrose/Lactose Pills, 4 Dram, WHP Homeopathic Medicine, Washington Homeopathic Products, 260 JR Hawvermale Way, Berkeley Springs, WV 25411.

**Product Quantity:**

10 bottles

**Reason for Recall:**

Out-of-specification test results obtained for identification testing based on HPTLC analysis.

**Recall Number:**

D-0863-2021

**Code Information:**

Lot # 29377, Exp 8/17/2026

**Product Description:**

Cinnamomum 6X, Flatulence\* Sucrose/Lactose Pills, Packaged as a) 4 Dram, b) 1 oz, and Cinnamomum 30X, Flatulence\* Sucrose/Lactose Pills, Packaged as 4 Dram, WHP Homeopathic Medicine, Washington Homeopathic Products 260 JR Hawvermale Way, Berkeley Springs WV 25411

**Product Quantity:**

6 bottles

**Reason for Recall:**

Out-of-specification test results obtained for identification testing based on HPTLC analysis.

**Recall Number:**

D-0864-2021

**Code Information:**

Lot # 28626, Exp 8/17/2026

**Product Description:**

Cistus Canadensis 6X, 10X, 15X, 30X, Coldness\* Sucrose/Lactose Pills, 6X Packaged as a) 1 OZ, UPC 7 40640 28177 2, b) 4 dr, UPC 7 40640 28173 4; 10X Packaged as c) 4 dr; 15X Packaged as d) 1 OZ; 30X Packaged as e) 2 Dram, UPC 7 40640 28171 0, f) 4 dr, UPC 7 40640 28175 8; WHP Homeopathic Medicine, Washington Homeopathic Products 260 JR Hawvermale Way, Berkeley Springs WV 25411

**Product Quantity:**

17 bottles

**Reason for Recall:**

Out-of-specification test results obtained for identification testing based on HPTLC analysis.

**Recall Number:**

D-0865-2021

**Code Information:**

Lot # 28638, EXP 08/17/2026

**Product Description:**

Humulus 6X, 15X, Sucrose/Lactose Pills, 6X Packaged as a) 4dr, UPC 7 40640 33969 5; 15X Packaged as b) 4 dr; WHP Homeopathic Medicine. Washington Homeopathic Products, 260 JR Hawvermale Way, Berkeley Springs, WV 25411.

**Product Quantity:**

2 bottles

**Reason for Recall:**

Out-of-specification test results obtained for identification testing based on HPTLC analysis.

**Recall Number:**

D-0866-2021

**Code Information:**

Lot # 29298, Exp 8/17/2026

**Product Description:**

Quebracho 4C, 5C, 6C, 12C, 30C, Fever\*, Sucrose/Lactose Pills, 5C Packaged as a) 4dr; 6C Packaged as b) 4 Dram UPC 7 40640 44092 6; c) 2 oz UPC 7 40640 44100 8; 12C Packaged as d) 4 Dram; e) 2 oz; 30C Packaged as f) 2 dr UPC 7 40640 44090 2; g) 4 Dram, UPC 7 40640 44094 0; h) 1 oz, UPC 7 40640 44098 8; i) 2 oz, UPC 7 40640 44102 2; WHP Homeopathic Medicine, Washington Homeopathic Products, 260 JR Hawvermale Way, Berkeley Springs, WV 25411.

**Product Quantity:**

61 bottles

**Reason for Recall:**

Out-of-specification test results obtained for identification testing based on HPTLC analysis.

**Recall Number:**

D-0867-2021

**Code Information:**

Lot # 28930, Exp 8/17/2026

**Product Description:**

Verbena Officinalis 6X, Nervousness\* Sucrose/Lactose Pills, Packaged 2 Dram, WHP Homeopathic Medicine, Washington Hoemopathis Prodcus, 260 JR Hawvermale Way, Berkeley Springs, WV 25411.

**Product Quantity:**

3 bottles

**Reason for Recall:**

Out-of-specification test results obtained for identification testing based on HPTLC analysis.

**Recall Number:**

D-0868-2021

**Code Information:**

Lot # 29060, Exp 8/17/2026

**Product Description:**

Viola Odorata 4X, 10X, 12X, Bee Stings\*, Sucrose/Lactose Pills, 4X Packaged in a) 2 Dram; 10X Packaged in b) 2 Dram; 12X Packaged in c) 2 Dram; d) 4 Dram; WHP Homeopathic Medicine, Washington Homeopathic Products, 260 JR Hawvermale Way, Berkeley Springs, WV, 25411.

**Product Quantity:**

12 bottles

**Reason for Recall:**

Out-of-specification test results obtained for identification testing based on HPTLC analysis.

**Recall Number:**

D-0869-2021

**Code Information:**

Lot # 29057, Exp 8/17/2026



**Product Description:**

La Core LCL-2-0191 Blend, 149,980ml 20% Alcohol, WHP Homeopathic Medicine, For Manufacturing Only, Liter LCL-2-0191-Bend: 12% Lycopodium Clavatum 10X, 12% Carbo Vegetabilis 16X, 12% Natrum Muriaticum 9X, 12% Calcarea Carbonica 12X, 10% Hypothalamus 30X, 6% Pituitarum Posterium 12X, 6% Pituitarum Posterium 30C, 3% Natrum Phosphoricum 12X, 3% Graphites 30X, 3# Agnus Castus 6X, 3% Thiosinaminum 8X, 3% Phytolacca Decandra 12X, 3% Magnesia Phosphorica 10X, 3% Ornithogalum Umbellatum 6X, 3% Chelidonium Majus 6X, 3% Quercus Robur 14X, 3% Nux Vomica 30X, Manufactured by Washington Homeopathic Products 260 JR Hawvermale Way, Berkeley Springs, WV, 25411.

**Product Quantity:**

2/149,980 mL bottles

**Reason for Recall:**

Out-of-specification test results obtained for identification testing based on HPTLC analysis.

**Recall Number:**

D-0870-2021

**Code Information:**

Lot # 27861, Exp 8/17/2026

**Product Description:**

Kali Sulphuricum 3X, 960ml 20% Alcohol, WHP Homeopathic Medicine, For Manufacturing Use Only. Manufactured by Washington Homeopathic Products 260JR hawvermale Way Berkeley Springs WV 25411.

**Product Quantity:**

12/960 mL bottles

**Reason for Recall:**

Out-of-specification test results obtained for identification testing based on HPTLC analysis.

**Recall Number:**

D-0871-2021

**Code Information:**

Lot # 29475, Exp 8/17/2026

**Product Description:**

Althaea Officinalis 6X, Irritable Bladder\* Sucrose/Lactose Pills, packaged as 4 Dram, WHP Homeopathic Medicine, Washington Homeopathic Products, 260 JR Hawvermale Way, Berkeley Springs, WV 25411.

**Product Quantity:**

10 bottles

**Reason for Recall:**

Out-of-specification test results obtained for identification testing based on HPTLC analysis.

**Recall Number:**

D-0872-2021

**Code Information:**

Lot # 29377, Exp 8/17/2026

**Product Description:**

Althaea 6X, Irritable Bladder\* Sucrose/Lactose Pills, packaged as 1 OZ, WHP Homeopathic Medicine, Washington Homeopathic Products, 260 JR Hawvermale Way, Berkeley Springs, WV 25411.

**Product Quantity:**

10 bottles

**Reason for Recall:**

Out-of-specification test results obtained for identification testing based on HPTLC analysis.

**Recall Number:**

D-0873-2021

**Code Information:**

Lot # 29377, Exp 8/17/2026

**Product Description:**

Althaea 6X, Irritable Bladder\* 20% Alcohol, Drops, packaged as 15 ml, WHP Homeopathic Medicine, Washington Homeopathic Products, 260 JR Hawvermale Way, Berkeley Springs, WV 25411.

**Product Quantity:**

10 bottles

**Reason for Recall:**

Out-of-specification test results obtained for identification testing based on HPTLC analysis.

**Recall Number:**

D-0874-2021

**Code Information:**

Lot # 29377, Exp 8/17/2026

**Product Description:**

Althaea 30X, Irritable Bladder\* Sucrose/Lactose Pills, packaged as 4 Dram, WHP Homeopathic Medicine, Washington Homeopathic Products, 260 JR Hawvermale Way, Berkeley Springs, WV 25411.

**Product Quantity:**

10 bottles

**Reason for Recall:**

Out-of-specification test results obtained for identification testing based on HPTLC analysis.

**Recall Number:**

D-0875-2021

**Code Information:**

Lot # 29377, Exp 8/17/2026

**Product Description:**

Cistus Canadensis 5X Coldness\* 20% Alcohol drops, Packaged in a) 15ml; b) 50 ml; WHP Homeopathic Medicine, Washington Homeopathic Products 260 JR Hawvermale Way, Berkeley Springs WV 25411

**Product Quantity:****Reason for Recall:**

Out-of-specification test results obtained for identification testing based on HPTLC analysis.

**Recall Number:**

D-0876-2021

**Code Information:**

Lot # 28638, Exp 8/17/2026

**Product Description:**

Quebracho 4C, Fever\*, 20% Alcohol, Packaged as 100ml, WHP Homeopathic Medicine, Washington Homeopathic Products, 260 JR Hawvermale Way, Berkeley Springs, WV 25411.

**Product Quantity:****Reason for Recall:**

Out-of-specification test results obtained for identification testing based on HPTLC analysis.

**Recall Number:**

D-0877-2021

**Code Information:**

Lot # 28930, Exp 8/17/2026

**Product Description:**

Viola od 6X, 30X, Bee Stings\*, Sucrose/Lactose Pills, 6X Packaged in a) 4 Dram, UPC 7 40640 50139 9; 30X Packaged in b) 4 dr, UPC 7 40640 50141 2; c) 2 oz, UPC 7 40640 50149 8; WHP Homeopathic Medicine, Washington Homeopathic Products, 260 JR Hawvermale Way, Berkeley Springs, WV, 25411.

**Product Quantity:****Reason for Recall:**

Out-of-specification test results obtained for identification testing based on HPTLC analysis.

**Recall Number:**

D-0878-2021

**Code Information:**

Lot # 29057, Exp 8/17/2026

**Product Description:**

Z-103 GU DETOXING. Contents 1000ml 20% Alcohol. WHP Homeopathic Medicine. For Manufacturing Use Only, REMEDY: Agrimonia Eupatoria 24X, Alfalfa 24X, Althaea Officinalis 24X, Avena Sativa 24X, Boldo 24X, Carduus Marianus 24X, Chioanathus Virginica 24X, Cynara Scolymus 24X, Iria Versicolor 24X, Millefolium 24X, Rumex Crispus 24X, Selenium Metallicum 12X, Selenium Metallicum 60X, Solidago Virgaurea 12X, Solidago Virgaurea 24X, Solidago Virgaurea 60X, Spiraea Ulmaira 24X, Taraxacum Officinale 24X, Urtica Dioica 24X, Uva-Ursi 24X, Zincum Muriaticum 13X, Zincum Mruiatricum 30X, Dilution Alcohol 20%. Manufactured for Optimal Health Dimensi. RX Only, Manufactured by Washington Homeopathic Products, 260 JR Hawvermale Way, Berkeley Springs, WV, 25411.

**Product Quantity:**

2/1 Liter bottles

**Reason for Recall:**

Out-of-specification test results obtained for identification testing based on HPTLC analysis.

**Recall Number:**

D-0879-2021

**Code Information:**

Lot # 26364, Exp 8/17/2026

**Product Description:**

Z-107 Formula Soft Tissue Healing. Contents 1000ml. For Manufacturing Use Only, REMEDY: Amygdalus Persica 10X, Arnica Montana 10X, Bellis Perennis 10X, Chromium Sulphuricum 10X, Citrus Vulgaris 10X, Derris Pinnata 13X, Franciscea Uniflora 13X, Hamamelis Virginiana 10X, Manganum Metallicum 10X, Ruta Graveolens 10X, Sarsaparilla 10X, Zincum Muriaticum 13X, Dilution Alcohol 20%. Manufactured for Optimal Health Dimensi. RX Only, Manufactured by Washington Homeopathic Products, Inc. 260 JR Hawvermale Way, Berkeley Springs, WV, 25411.

**Product Quantity:**

2 1/liter bottle

**Reason for Recall:**

Out-of-specification test results obtained for identification testing based on HPTLC analysis.

**Recall Number:**

D-0880-2021

**Code Information:**

Lot # 27668, Exp 8/17/2026

**Product Description:**

ZTE-1020 Formula. Contents 1000ml. WHP Homeopathic Medicine, For Manufacturing Use Only, REMEDY: Aurum Metallicum 10X, Crataegus Oxyacantha 10X, Baryta Carbonica 10X, Digitalis Purpurea 10X, Zincum Muriaticum 13X, Chromium Sulphuricum 10X, Manganum Metallicum 10X, Dilution Alcohol 20%. Manufactured for Optimal Health Dimensions. RX Only, Manufactured by Washington Homeopathic Products, Inc. 260 JR Hawvermale Way, Berkeley Springs, WV, 25411.

**Product Quantity:**

1 1/Liter bottle

**Reason for Recall:**

Out-of-specification test results obtained for identification testing based on HPTLC analysis.

**Recall Number:**

D-0881-2021

**Code Information:**

Lot # 25740, Exp 8/17/2026

**Product Description:**

Z-1020 Formula. Contents 1000ml 20% Alcohol. WHP Homeopathic Medicine, For Manufacturing Use Only, REMEDY: Aurum Metallicum 10X, Baryta Carbonica 10X, Chromium Sulphuricum 10X, Crataegus Oxyacantha 10X, Digitalis Purpurea 10X, Manganum Metallicum 10X, Zincum Muriaticum 13X, Dilution Alcohol 20%. Manufactured for Optimal Health Dimensions. Manufactured by Washington Homeopathic Products, Inc. 260 JR Hawvermale Way, Berkeley Springs, WV, 25411.

**Product Quantity:**

2 1/liter bottle

**Reason for Recall:**

Out-of-specification test results obtained for identification testing based on HPTLC analysis.

**Recall Number:**

D-0882-2021

**Code Information:**

Lot # 26529, Exp 8/17/2026

**Product Description:**

Z-1050 Formula Hepatodetox. Contents 1000ml. WHP Homeopathic Medicine, For Manufacturing Use Only, REMEDY: Cholesterinum 10X, Avena Sativa 12X, Cynara Scolymos 12X, Phosphorus 12X, Oroticum Acidum 13X, Aesculus Hippocastanum 24X, Carduus Marianus 24X, Chelidonium Majus 24X, Cimicifuga Racemosa 24X, Cinchona Officinalis 24X, Colocynthis 24X, Histaminum Hydrochloricum 24X, Lycopodium Clavatum 24X, Sulphur 24X, Tataxacum Officinale 24X, Veratrum Album 24X, Sepia 30X, Strontium Carbonicum 30X, Dilution Alcohol 20%. Manufactured for Optimal Health Dimensions. RX Only. anufactured by Washington Homeopathic Products, Inc. 260 JR Hawvermale Way, Berkeley Springs, WV, 25411.

**Product Quantity:**

3/1 Liter bottles

**Reason for Recall:**

Out-of-specification test results obtained for identification testing based on HPTLC analysis.

**Recall Number:**

D-0883-2021

**Code Information:**

Lot # 26071, 28180, Exp 8/17/2026

**Product Description:**

Z-1070 Formula Anxioheal. Contents 1000ml 20% Alcohol. WHP Homeopathic Medicine, For Manufacturing Use Only, REMEDY:Causticum 30X, Conium Maculatum 8X, Conium Maculatum 12X, Crataegus Oxyacantha 12X, Crataegus Oxyacantha 30X, Ignatia Amara 24X, Lycopus Virginicus 12X, Phosphoricum Acidum 12X, Phosphoricum Acidum 24X, Rhus Toxicodendron 24X, Secale Cornutum 24X, Secale Cornutum 30X, Sepia 6X, Sepia 24X, Solanum Nigrum 30X, Zincum Valerianicum 8X, Zincum Valerianicum 12X, Dilution Alcohol 20%. Manufactured for Optimal Health Dimensions. RX Only. anufactured by Washington Homeopathic Products, Inc. 260 JR Hawvermale Way, Berkeley Springs, WV, 25411.

**Product Quantity:**

2/1 Liter bottle

**Reason for Recall:**

Out-of-specification test results obtained for identification testing based on HPTLC analysis.

**Recall Number:**

D-0884-2021

**Code Information:**

Lot # 26007, Exp 8/17/2026

**Product Description:**

ZTE-1034 Formula Antimicrobial Bowel. Contents 1000ml. WHP Homeopathic Medicine, For Manufacturing Use Only, REMEDY: Arsenicum Album 10X, Baptisia Tinctoria 10X, Pulsatilla 10X, Lachesis Mutus 11X, Rhus Toxicodendron 10X, Belladonna 7X, Colchicum Autumnale 5X, Aconitum Napellus 8X, Astragalus Menziesli 8X, Carbo Vegetabilis 8X, Chamomilla 3X, Hydrastis Canadensis 3X, Echinacea Angustifolia 12X, Pulsatilla 11X, Anas Barariae, Hepatis ET 60C, Anas Barariae, Hepatis ET 100C, Anas Barariae, Hepatis ET 200C, Carduus Marianus 6X, Taraxacum Officinale 4X, Berberis Aquifolium 8X, Zingiber Officinal 8X, Allium Sativum 4X, Dilution Alcohol 20%. Causticum 30X, Conium Maculatum 8X, Conium Maculatum 12X, Crataegus Oxyacantha 12X, Crataegus Oxyacantha 30X, Ignatia Amara 24X, Lycopus Virginicus 12X, Phosphoricum Acidum 12X, Phosphoricum Acidum 24X, Rhus Toxicodendron 24X, Secale Cornutum 24X, Secale Cornutum 30X, Sepia 6X, Sepia 24X, Solanum Nigrum 30X, Zincum Valerianicum 8X, Zincum Valerianicum 12X, Dilution Alcohol 20%. Manufactured for Optimal Health Dimensions. RX Only. anufactured by Washington Homeopathic Products, Inc. 260 JR Hawvermale Way, Berkeley Springs, WV, 25411.

**Product Quantity:**

2/1 Liter bottles

**Reason for Recall:**

Out-of-specification test results obtained for identification testing based on HPTLC analysis.

**Recall Number:**

D-0885-2021

**Code Information:**

Lot # 25887, Exp 8/17/2026

**Product Description:**

ZTE-1035 Formula, Antimicrobial Combination, Contents 1006 ml, REMEDY: Arsenicum Album 10X, Baptista Tinctoria 10X, Phosphorus 10X, Arnica Montana 10X, Bryonia Alba 10X, Antimonium Crudum 10X, Iodium 10X, Lycopodium Clavatum 10X, Pulsatilla 10X, Berberis Vulgaris 10X, Glycyrrhiza Clabra 10X, Condurango 10X, Gincio Biloba 10X, Zincum Muriaticum 13X, Chromium Sulphuricum 10X, Manganum Metallicum 10X, Alfalfa 3X, Dilution Alcohol 20%, Manufactured by: Washington Homeopathic Products 260 JR Hawvermale Way, Berkeley Springs, WV, 225411, Manufactured for Optimal Health Dimensions, Washington Homeopathic Products, Inc. 260 JR Hawvermale Way, Berkeley Springs, WV, 25411,

**Product Quantity:**

2 1/liter

**Reason for Recall:**

Out-of-specification test results obtained for identification testing based on HPTLC analysis.

**Recall Number:**

D-0886-2021

**Code Information:**

Lot # 25697, no expiry date

**Product Description:**

ZTE 1013 Formula Antimicrobial - F&M , Contents 1000 ml, REMEDY: Bryonia Alba 10X, Antimonium Crudum 10X, Iodium 10X, Lycopodium Clavatum 10X, Pulsatilla 10X, Berberus Vulgaris 10X, Glycyrrhiza Clabra 10X, Condurango 10X, Gincio Biloba 10X, Chromium Sulphuricum 10X, Manganum Metallicum 10X, Zincum Muriaticum 13X, Dilution Alcohol 20%, WHP Homeopathic Medicine, For Manufacturing Use Only;

Manufactured for Optimal Health Dimensions, Manufactured by: Washington Homeopathic Products 260 JR Hawvermale Way, Berkeley Springs, WV, 25411,

**Product Quantity:**

1 1/liter

**Reason for Recall:**

Out-of-specification test results obtained for identification testing based on HPTLC analysis.

**Recall Number:**

D-0887-2021

**Code Information:**

Lot # 25738, no expiry date

**Product Description:**

ZTE 1015 Formula, Contents 1000 ml, For Manufacturing Use only, REMEDY: Argentum Nitricum 10X, Rhus Toxicodendron 10X, Aurum Metallicum 10X, Iris Versicolor 10X, Lycopodium Clavatum 10X, Zincum Muriaticum 13X, Chromium Sulphuricum 10X, Manganum Metallicum 10X, Dilution Alcohol 20%, Manufactured for Optimal Health Dimensions, Manufactured by: Washington Homeopathic Products 260 JR Hawvermale Way, Berkeley Springs, WV, 25411,

**Product Quantity:**

1 1/liter

**Reason for Recall:**

Out-of-specification test results obtained for identification testing based on HPTLC analysis.

**Recall Number:**

D-0888-2021

**Code Information:**

Lot # 25739, no expiry date

**Product Description:**

Strophanthus hisp 30X, Hives\*, 20% Alcohol, Packaged in (a) 15 mL, UPC 7 40640 47553 9; (b) 30mL UPC 7 40640 47557 7; (c) 100mL, UPC 7 40640 47565 2; WHP Homeopathic Medicine, 260 JR Hawvermale Way, Berkeley Springs, WV 25411

**Product Quantity:**

91 bottles

**Reason for Recall:**

Out-of-specification test results obtained for identification testing based on HPTLC analysis.

**Recall Number:**

D-0889-2021

**Code Information:**

Lot # 29061

**Product Description:**

Strophanthus hisp 30X, Hives\*, Sucrose/Lactose Pills , Packaged in (a) 2 dr, UPC 7 40640 47533 1; (b) 4 dr UPC 7 40640 47537 9; (c) 1 oz, UPC 7 40640 47541 6; (d) 2 oz, UPC 7 40640 47545 4; WHP Homeopathic Medicine, 260 JR Hawvermale Way, Berkeley Springs, WV 25411

**Product Quantity:**

91 bottles

**Reason for Recall:**

Out-of-specification test results obtained for identification testing based on HPTLC analysis.

**Recall Number:**

D-0890-2021

**Code Information:**

Lot # 29061

**Product Description:**

Aconitum Napellus Fear\* 20% Alcohol HPUS: 5X, 6X, 26X, 30X, packaged in 15mL containers, Aconitum Napellus Fear\* 20% Alcohol HPUS: 6X, 10X, packaged in 30mL containers Aconitum Napellus Fear\* 20% Alcohol HPUS: 5X, 10X, 12X, 30X, packaged in 50mL containers Aconitum Napellus Fear\* 20% Alcohol HPUS: 5X, packaged in 100mL containers WHP Homeopathic Medicine, Washington Homeopathic Products 260 JR Hawvermale Way, Berkeley Springs, WV 25411.

**Product Quantity:**

562 bottles

**Reason for Recall:**

Out-of-specification test results obtained for identification testing based on HPTLC analysis.

**Recall Number:**

D-0891-2021

**Code Information:**

Lot # 26198

**Product Description:**

Aconitum nap Fear\* Sucrose/Lactose Pills HPUS: 4X, 5X, 6X, 15X, packaged in 1 oz containers, Aconitum nap Fear\* Sucrose/Lactose Pills HPUS: 4X, 7X, 12X, packaged in 2 dr containers, Aconitum nap Fear\* Sucrose/Lactose Pills HPUS: 4X, 12X, 20X, packaged in 2 oz containers, Aconitum nap Fear\* Sucrose/Lactose Pills HPUS: 4X, 5X, 9X, 11X, 24X, packaged in 4 dr containers, Aconitum nap Fear\* Sucrose/Lactose Pills HPUS: 6X, 30X, packaged in 4 oz containers, WHP Homeopathic Medicine, Washington Homeopathic Products 260 JR Hawvermale Way, Berkeley Springs, WV 25411.

**Product Quantity:**

562 bottles

**Reason for Recall:**

Out-of-specification test results obtained for identification testing based on HPTLC analysis.

**Recall Number:**

D-0892-2021

**Code Information:**

Lot # 26198

**Product Description:**

Aconitum Napellus Fear\* Sucrose/Lactose Pills HPUS: 8X, 9X, 12X, 30X, packaged in 1 oz containers, Aconitum Napellus Fear\* Sucrose/Lactose Pills HPUS: 6X, 10X, 15X, 24X, 30X, packaged in 2 dr containers, Aconitum Napellus Fear\* Sucrose/Lactose Pills HPUS: 6X, 30X, packaged in 2 oz containers, Aconitum Napellus Fear\* Sucrose/Lactose Pills HPUS: 6X, 7X, 8X, 10X, 12X, 15X, 16X, 18X, 30X, packaged in 4 dram containers, WHP Homeopathic Medicine, Washington Homeopathic Products 260 JR Hawvermale Way, Berkeley Springs, WV 25411.

**Product Quantity:**

562 bottles

**Reason for Recall:**

Out-of-specification test results obtained for identification testing based on HPTLC analysis.

**Recall Number:**

D-0893-2021

**Code Information:**

Lot # 26198

**Product Description:**

Aconitum nap Fear\* 20% Alcohol HPUS: 6X, packaged in 50mL & 8 oz containers Aconitum nap Fear\* 20% Alcohol HPUS: 7X, 12X, packaged in 15mL containers WHP Homeopathic Medicine, Washington Homeopathic Products 260 JR Hawvermale Way, Berkeley Springs, WV 25411.

**Product Quantity:**

562 bottles

**Reason for Recall:**

Out-of-specification test results obtained for identification testing based on HPTLC analysis.

**Recall Number:**

D-0894-2021

**Code Information:**

Lot # 26198

**Product Description:**

Aconitum Napellus 12X Fear\* 87% Alcohol HPUS: packaged in 30 mL containers; WHP Homeopathic Medicine, Washington Homeopathic Products 260 JR Hawvermale Way, Berkeley Springs, WV 25411.

**Product Quantity:**

562 bottles

**Reason for Recall:**

Out-of-specification test results obtained for identification testing based on HPTLC analysis.

**Recall Number:**

D-0895-2021

**Code Information:**

Lot # 26198

## Class II Drugs Event

**Event ID:**

88542

**Status:**

Ongoing

**Recall Initiation Date:**

08/23/2021

**Center Classification Date:**

09/24/2021

**Recalling Firm:**

Viatis

781 Chestnut Ridge Rd

Morgantown WV United States

**Distribution Pattern:**

Nationwide within the United States

**Product Type:**

Drugs

**Date Terminated:****Voluntary / Mandated:**

Voluntary: Firm initiated

**Initial Firm Notification of Consignee or Public:**

Letter

## Associated Products

**Product Description:**

Lyrica CR (pregabalin) extended release tablets, 330 mg, 30-count bottles, Rx only, Distributed by Parke-Davis Division of Pfizer Inc., NY, NY 10017, NDC 0071-1029-01

**Product Quantity:**

9,515 bottles

**Reason for Recall:**

Failed Dissolution Specifications

**Recall Number:**

D-0851-2021

**Code Information:**

Lot #: DN5396, EP9726, EK2417, Exp. Date August 2022

## Class II Drugs Event

**Event ID:**

88696

**Status:**

Ongoing

**Recall Initiation Date:**

09/15/2021

**Center Classification Date:**

09/24/2021

**Recalling Firm:**

American Health Packaging

2550 John Glenn Ave Ste A

Columbus OH United States

**Distribution Pattern:**

Nationwide USA

**Product Type:**

Drugs

**Date Terminated:****Voluntary / Mandated:**

Voluntary: Firm initiated

**Initial Firm Notification of Consignee or Public:**

Letter

## Associated Products

**Product Description:**

Valproic Acid Oral Solution, USP, 500 mg/10 mL, 100 10 mL unit dose cups per case, Rx Only, Packaged and Distributed by: American Health Packaging, Columbus, Ohio 43217 Case NDC#: 60687-262-56; Individual Dose NDC: 60687-262-42

**Product Quantity:**

548 ccases

**Reason for Recall:**

CGMP Deviations: Potential concern with products manufactured using liquid sugar batches contaminated with microbial organisms.

<b>Recall Number:</b> D-0854-2021
<b>Code Information:</b> Lot 1000082; Exp 06/30/2022

Class II Drugs Event

<b>Event ID:</b> 88698	<b>Product Type:</b> Drugs
<b>Status:</b> Ongoing	<b>Date Terminated:</b>
<b>Recall Initiation Date:</b> 09/17/2021	<b>Voluntary / Mandated:</b> Voluntary: Firm initiated
<b>Center Classification Date:</b> 09/27/2021	<b>Initial Firm Notification of Consignee or Public:</b> Letter
<b>Recalling Firm:</b> Fresenius Kabi USA LLC 2020 N Ruby St Melrose Park IL United States	
<b>Distribution Pattern:</b> U.S.A. Nationwide	

Associated Products

<b>Product Description:</b> Morphine Sulfate Injection, USP, 2 mg per mL, 1 mL single dose vial, Rx only, Fresenius Kabi, Lake Zurich, IL 60047, NDC 63323-452-01. 25 vials per tray packaged 18 trays per shipper
<b>Product Quantity:</b> 963000 vials
<b>Reason for Recall:</b> Defective container: Cracked vials leading to lack of sterility assurance
<b>Recall Number:</b> D-0856-2021
<b>Code Information:</b> Lot # 6023731, 6023732, Exp 03/2023; 6024172, 6024260, Exp 06/2023

Class II Drugs Event

<b>Event ID:</b> 88731	<b>Product Type:</b> Drugs
<b>Status:</b> Ongoing	<b>Date Terminated:</b>
<b>Recall Initiation Date:</b> 09/17/2021	<b>Voluntary / Mandated:</b> Voluntary: Firm initiated
<b>Center Classification Date:</b> 09/30/2021	<b>Initial Firm Notification of Consignee or Public:</b> Telephone
<b>Recalling Firm:</b> IntegraDose Compounding Services LLC 719 Kasota Ave Se Minneapolis MN United States	
<b>Distribution Pattern:</b> NH, MA, MN	

Associated Products

<b>Product Description:</b> ceFAZolin, 2 G/20 mL in Sterile Water, 20 mL Sterile Syringe for Injection, IntegraDose Compounding Services, LLC, 719 Kasota Ave SE, Minneapolis, MN. NDC 71139-7087-1
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**Product Quantity:**

2,614 syringes

**Reason for Recall:**

Lack of sterility assurance.

**Recall Number:**

D-0896-2021

**Code Information:**

Lot, expiry: Lot 20210803CEF-1, exp 09/17/2021; Lot 20210805CEF-3, 09/19/2021; Lots 20210806CEF-1, 20210806CEF-2, exp 09/20/2021; Lots 20210809CEF-1, 20210809CEF-2, exp 09/23/2021; Lot 20210810CEF-1, exp 09/24/2021; Lot 20210811CEF-1, exp 09/25/2021; Lot 20210812CEF-1, exp 09/26/2021

**Product Description:**

ceFAZolin 3 G in 0.9% Sodium Chloride, 115 mL Bag for Injection, Sterile Product, IntegraDose Compounding Services, LLC, 719 Kasota Ave SE, Minneapolis, MN. NDC: 71139-7153-1

**Product Quantity:**

589 bags

**Reason for Recall:**

Lack of sterility assurance.

**Recall Number:**

D-0897-2021

**Code Information:**

Lot, expiry: 20210722CEF-2, exp 09/20/2021; 20210728CEF-1, exp 09/26/2021

## Class II Drugs Event

**Event ID:**

88733

**Status:**

Ongoing

**Recall Initiation Date:**

09/22/2021

**Center Classification Date:**

09/30/2021

**Recalling Firm:**

New Vitalis Pharmacy LLC dba New Vitalis Pharmacy  
4139 Cadillac Ct Ste 201  
Louisville KY United States

**Distribution Pattern:**

Nationwide within the United States

**Product Type:**

Drugs

**Date Terminated:****Voluntary / Mandated:**

Voluntary: Firm initiated

**Initial Firm Notification of Consignee or Public:**

Letter

## Associated Products

**Product Description:**

Testosterone Cypionate Testosterone Propionate, 180mg/mL, 20mg/mL, 1 mL vial, Rx only, New Vitalis Pharmacy 4139 Cadillac Ct # 201 Louisville, KY 40213

**Product Quantity:**

1,347 vials

**Reason for Recall:**

Lack of Assurance of Sterility

**Recall Number:**

D-0899-2021

**Code Information:**

Lot, expiry: Lot #AL07202021@901, Exp 9/18/21; Lot #AL07272021@901, Exp 9/25/21; Lot #AL08032021@901, Exp 10/2/21; Lot #AL08102021@901, Exp 10/9/21; Lot #AL08172021@901, Exp 10/16/21; Lot #AL08242021@901, Exp 10/23/21

## Class II Drugs Event

**Event ID:**  
88736

**Status:**  
Ongoing

**Recall Initiation Date:**  
09/21/2021

**Center Classification Date:**  
09/30/2021

**Recalling Firm:**  
SigmaPharm Laboratories LLC  
3375 Progress Dr  
Bensalem PA United States

**Distribution Pattern:**  
Nationwide

**Product Type:**  
Drugs

**Date Terminated:**

**Voluntary / Mandated:**  
Voluntary: Firm initiated

**Initial Firm Notification of Consignee or Public:**  
Letter

Associated Products

<b>Product Description:</b> Sodium Phenylbutyrate Powder, 250 Grams, Rx Only, packaged in 500 cc HDPE bottles and 53 mm CRC caps packed in a carton and then in case packs containing 2 bottles. Sigmapharm Laboratories, LLC, Bensalem, PA 19020, NDC 42794-086-14
<b>Product Quantity:</b> 1192 bottles
<b>Reason for Recall:</b> Failed Impurities/Degradation Specifications; Out of Specification impurity results obtained during routine testing.
<b>Recall Number:</b> D-0898-2021
<b>Code Information:</b> Lots 2005401, 2005501, 2005601, 2005701, Exp FEB 2023; Lots 2101401, 2101501, Exp FEB-2024

Class II Drugs Event

**Event ID:**  
88755

**Status:**  
Ongoing

**Recall Initiation Date:**  
09/23/2021

**Center Classification Date:**  
09/27/2021

**Recalling Firm:**  
Monarch PCM, LLC  
7333 Jack Newell Blvd N Ste 100  
Fort Worth TX United States

**Distribution Pattern:**  
TN

**Product Type:**  
Drugs

**Date Terminated:**

**Voluntary / Mandated:**  
Voluntary: Firm initiated

**Initial Firm Notification of Consignee or Public:**  
Letter

Associated Products

<b>Product Description:</b> Hydroquinone USP, 4% Skin Bleaching Cream, Rx only, Net Wt 1 oz (28.35g), Manufactured for: Westminster Pharmaceuticals, LLC Nashville, TN 37217 NDC 69367-174-01
<b>Product Quantity:</b> 11,419 tubes
<b>Reason for Recall:</b> Finished product specification did not meet USP specifications.
<b>Recall Number:</b> D-0855-2021

**Code Information:**

Lots: 21FP1743, 21FP1745 Exp. 05/2023

## Class III Drugs Event

**Event ID:**

88608

**Status:**

Ongoing

**Recall Initiation Date:**

09/02/2021

**Center Classification Date:**

09/24/2021

**Recalling Firm:**

New Vision Pharmaceuticals LLC  
10200 Nw 67th St  
Tamarac FL United States

**Distribution Pattern:**

AL, CA, FL, IN, MI, MO, NJ, NY, PA, RI, SC, TN, TX, VA

**Product Type:**

Drugs

**Date Terminated:****Voluntary / Mandated:**

Voluntary: Firm initiated

**Initial Firm Notification of Consignee or Public:**

Letter

## Associated Products

**Product Description:**

Daytime Severe Cold & Flu Relief 8 Pre-Measured Vials 0.51 FL OZ (15 mL) Each 4.06 FL OZ (120 mL) Total/Nighttime Severe Cold & Flu Relief 8 Pre-Measured Vials 1.01 FL OZ (30 mL) Each 8.12 FL OZ (240 mL) Total Single-Use Vials Mixed Berry Flavor NDC 69842-495-16  
UPC 0 50428 64057 9 Distributed by: CVS Pharmacy, Inc. One CVS Drive, Woonsocket, RI 02895

**Product Quantity:**

14,976 FG cartons

**Reason for Recall:**

Subpotent Drug

**Recall Number:**

D-0852-2021

**Code Information:**

Lot: 2021-10159 Exp. 06/08/2023

**Product Description:**

CVS Health Daytime Severe Cold & Flu Relief Single-Use Vials Mixed Berry Flavor 8 Pre-Measured Vials 0.51 FL OZ (15 mL) Each 4.06 FL OZ (120 mL) Total NDC 69842-499-08 UPC 0 50428 64130 9 Distributed by: CVS Pharmacy, Inc. One CVS Drive Woonsocket, RI 02895

**Product Quantity:**

18,864 FG cartons

**Reason for Recall:**

Subpotent Drug

**Recall Number:**

D-0853-2021

**Code Information:**

Lots: 2021-10154 Exp. 06/29/2023; 2021-10164 Exp. 06/11/2023

## Not Yet Classified Drugs Event

**Event ID:**

88647

**Status:**

Ongoing

**Recall Initiation Date:**

09/09/2021

**Center Classification Date:****Product Type:**

Drugs

**Date Terminated:****Voluntary / Mandated:**

Voluntary: Firm initiated

**Initial Firm Notification of Consignee or Public:**

Letter

**Recalling Firm:**

Jacobus Pharmaceutical Company Inc.  
Industrial Research Laboratory Building 31 Schalks Crossing Rd  
Plainsboro NJ United States

**Distribution Pattern:**

Product was distributed within the USA and Foreign. Control # 18038, was distributed to Canada only.

**Associated Products**

<p><b>Product Description:</b> Ruzurgi (amifampridine), 10 mg tablets, packaged in a 100-count bottle , Rx only, Manufactured by: Jacobus Pharmaceutical Company, Inc., P.O. Box 5290, Princeton, New Jersey 08540, NDC 49938-110-01</p> <p><b>Product Quantity:</b> 2,324 bottles</p> <p><b>Reason for Recall:</b> Microbial contamination of non-sterile products: Test results indicate affected control numbers exceeded the specification for Total Yeast and Mold Counts (TYMC).</p> <p><b>Recall Number:</b></p> <p><b>Code Information:</b> Lot #: 18038, 18039, Exp 03/2023; 18079, Exp 05/2023</p>
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