

Company Announcement

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

Silver Star Brands, Inc. Issues Voluntary Nationwide Recall of Human and Animal Drug Products Due to Microbial Contamination

For Immediate Release

October 3, 2018

Contact

Consumers



Nativeremedies@silverstarbrands.com

☎ 1-888- 736-6389

Announcement

Silver Star Brands, Inc., is initiating a voluntary recall of six products for humans (including four Native Remedies® and two Healthful Naturals™) and two PetAlive® products for pets for a total of eight products with lot numbers, see table below, to the consumer level. The products have been tested and found to contain microbial contamination.

Administration of use of drug products with microbial contamination could potentially result in increased infections that may require medical intervention and could result in infections that could be life threatening to certain individuals and animals. To date, Silver Star Brands, Inc. has not received any reports of adverse events related to this recall.

These products can be identified by the main label on the bottle and the lot number that is printed on the label. Each product recalled is an individual 2 oz. oral spray in amber bottle (see table below), manufactured at the King Bio, Inc. facility in Asheville, NC. Product was distributed nationwide via wholesale, retail and online sales. Native Remedies®, PetAlive® and Healthful Naturals™ package images for products affected are attached (below).

HUMAN PRODUCTS

PRODUCT	INDICATION	NDC	UPC	LOT	EXPIRATION DATE
Native Remedies VertiFree oral spray	Temporary relief for dizziness and nausea	68703-253-02	818837012260	K061417B	6/20
Native Remedies VaricoGo oral spray	Relieves discomfort associated with varicose veins	68703-105-59	818837010419	K111717A	11/20
Native Remedies HypoSlim oral spray	Assists with healthy weight management and metabolism	68703-275-02	818837013724	K051818A	05/21
Native Remedies EyeClear Pro oral spray	Relieves symptoms of mineral buildup and eye irritation	68703-151-59	818837011652	K022317A, K022317B	02/20
Healthful Naturals DizziFree oral spray	Temporarily relieves dizziness and nausea	68703-204-02	840853166535	K022616D	N/A
Healthful Naturals Leg Cramp Support	Temporary relief from cramps and spasms while resting	68703-206-02	840853166559	K022216C	N/A

PET PRODUCTS

PRODUCT	INDICATION	NDC	UPC	LOT	EXPIRATION DATE
PetAlive Plump-Up Pet oral spray	Improves appetite in underweight dogs and cats	68703-290-02	818837013908	K011617E	01/20
PetAlive Allergy Itch Ease oral spray	Relieves skin itch	68703-135-59	818837011102	K111617B	11/20

Silver Star Brands, Inc. is notifying its distributors and customers by letter and is arranging for return and replacement (or refund) of the recalled products.

Consumers/distributors/retailers that have this product which is being recalled should discontinue use/distribution and contact Silver Star Brands, Inc. at **Nativeremedies@silverstarbrands.com** to make arrangements to return the product. These products were distributed to retailers (doctor offices, pharmacies, health food stores) and consumers (direct sales and website).

Consumers with questions regarding this recall can contact Silver Star Brands, Inc. at 1-888- 736-6389 Monday – Friday 8:00 am – 5:00 pm CST or email **Nativeremedies@silverstarbrands.com**. Consumers should contact their physician or healthcare provider if they believe they have experienced any problems that may be related to using this product.

Adverse reactions or quality problems associated with the use of this product may be reported to FDA's MedWatch Adverse Event Reporting program either by phone, on line, by regular mail or by fax.

- Complete and submit the report Online: **www.fda.gov/medwatch/report.htm**
(**http://www.fda.gov/medwatch/report.htm**)
- Regular Mail or Fax: Download form **www.fda.gov/MedWatch/getforms.htm**
(**http://www.fda.gov/MedWatch/getforms.htm**) or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

The Center for Veterinary Medicine recommends calling the drug company to report adverse drug experiences or product defects for FDA-approved animal products. The drug company responsible for the approved product is required to submit these reports to FDA. Call 1-888-736- 6389.

- If you prefer to report directly to the FDA, you can submit Form FDA 1932a by following the link to the form found at **https://www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/ucm055305.htm** and following the instructions for emailing the completed form to FDA.
- If you have a question about ADE reporting or need a paper copy of the form, contact CVM by email at **AskCVM@fda.hhs.gov** or by phone at 1-888-FDA-VETS (1-888-332-8387).

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The letters NPUS indicate that the components in this product are officially monographed in the Homeopathic Pharmacopoeia of the United States.

All Native Remedies health products are especially formulated by experts in the field of natural health and are manufactured according to the highest pharmaceutical standards for maximum safety and effectiveness. For more information, visit us at www.native Remedies.com.

Contains no artificial flavors or colors. No gluten added.

Distributed by:
Silver Star Brands
Oshkosh, WI 54906
Phone: +1.877.289.1235
International: +1.920.232.3275

Homeopathic Formula

NDC 68703-251-02



NativeRemedies®
THE NATURAL CHOICE

VertiFree™ ORAL SPRAY

Temporarily relieves
dizziness & nausea

2 fl oz (59 mL)

Drug Facts
NPUS Active Ingredients: Equal volumes of each ingredient in a 30C potency: Bryonia, Cocculus, Gelsemium, Lobelia inf.
Use: Homeopathic remedy for the temporary symptom relief of dizziness and nausea.
Warnings: If symptoms persist or worsen, consult a healthcare professional. If pregnant or breastfeeding, ask a healthcare professional before use. **Keep this and all medication out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.
Directions: Initially, depress pump until primed. Hold close to mouth and spray directly into mouth. Use 3 times daily. Use additionally as needed. Adults and children 13+: 1 pump spray. Children 2-12: 2 pump sprays.
Inactive Ingredients: Carya ovata bark extract (hickory), citrus extract, Lonicera japonica (honeysuckle), polyethylene natural ferment, purified water, stanol glycosides (stevia).

*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.



Temper resistant for your protection. Use only if safety seal is intact.

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Homeopathic Formula

NDC 68703-105-59



NativeRemedies®
THE NATURAL CHOICE

VaricoGo™ ORAL SPRAY

Relieves discomfort
associated with varicose veins

2 fl oz (59 mL)

Made in USA

Drug Facts
NPUS Active Ingredients: Equal volumes of each ingredient in 10X, 30X, 12M potencies: Anacardium, Arnica, Calc. Fluor., Carbo veg., Carduus mar. Collinsii, Echinacea purp., Hamamelis, Lachesis, Pulsatilla, Secale Cere. For temporary relief of discomfort associated with varicose veins: cramping in lower extremities, aching or soreness in limbs, enlarged veins, congested veins, and tenderness in legs.
Warnings: If symptoms persist or worsen, consult a healthcare professional. If pregnant or breastfeeding, ask a healthcare professional before use. **Keep this and all medication out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.
Directions: Initially, depress pump until primed. Hold close to mouth and spray directly into mouth. Use 3 times daily. Use additionally as needed. Adults and children 13+: 3 pump sprays. Children 2-12: 2 pump sprays.
Inactive Ingredients: Carya ovata bark extract (hickory), citrus extract, Lonicera japonica (honeysuckle), polyethylene natural ferment, purified water, stanol glycosides (stevia).

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Homeopathic Formula

NDC 68703-275-02



NativeRemedies®
THE NATURAL CHOICE

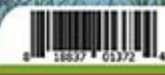
HypoSlim™ ORAL SPRAY

Assists with healthy weight
management & metabolism

2 fl oz (59 mL)

Drug Facts
NPUS Active Ingredients: Equal volumes of each ingredient in a 30C potency: Calc. carb., Ferrum met., Graphites, Lycopodium, Spongia.
Use: Assists with healthy weight management and metabolism when used along with a healthy diet and exercise.
Warnings: If symptoms persist or worsen, consult a healthcare professional. If pregnant or breastfeeding, ask a healthcare professional before use. **Keep this and all medication out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.
Directions: Initially, depress pump until primed. Hold close to mouth and spray directly into mouth. Use 5 times daily for the first 2 days and 2 times daily thereafter. Adults: 3 pump sprays.
Inactive Ingredients: Carya ovata bark extract (hickory), citrus extract, Lonicera japonica (honeysuckle), polyethylene natural ferment, purified water, stanol glycosides (stevia).

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Homeopathic Formula

NDC 68703-151-59



NativeRemedies®
THE NATURAL CHOICE

EyeClear Pro™ ORAL SPRAY

Relieves symptoms of
mineral buildup & eye irritation

2 fl oz (59 mL)

Drug Facts
NPUS Active Ingredients: Equal volumes of each ingredient in 10X, 30X, 12M potencies: Calc. carb., Calc. Fluor., Causticum, Chenaria, Euphrasia, Nigella arvensis, Nat. mur., Thuja, Quercia. Serrata.
Use: For temporary relief of symptoms of common eye irritations: mineral accumulations, tearing, light sensitivity, eye fatigue, redness, itching.
Warnings: If symptoms persist or worsen, consult a healthcare professional. If pregnant or breastfeeding, ask a healthcare professional before use. **Keep this and all medication out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.
Directions: Initially, depress pump until primed. Hold close to mouth and spray directly into mouth. Use 3 times daily and additionally as needed. Adults: 1 pump spray. Children 2-12: 2 pump sprays.
Inactive Ingredients: Carya ovata bark extract (hickory), citrus extract, Lonicera japonica (honeysuckle), polyethylene natural ferment, purified water, stanol glycosides (stevia).

*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.



Temper resistant for your protection. Use only if safety seal is intact.

Contains no artificial flavors or artificial colors. No gluten added.
The letters NPUS indicate that the components in this product are officially monographed in the Homeopathic Pharmacopoeia of the United States.
Temper resistant for your protection.
Use only if safety seal is intact.

Distributed by Silver Star Brands
Oshkosh, WI 54906 | 1-800-308-1384



Homeopathic Formula

NDC # 68703-204-02



DizziFree

Temporarily relieves
dizziness & nausea

2 fl oz (59 mL)

MADE IN USA

Drug Facts
NPUS Active Ingredients: Each dose contains equal volumes of each ingredient in 30C potency: Bryonia, Cocculus, Gelsemium, Lobelia inf.
Use: Homeopathic remedy for the temporary symptom relief of dizziness and nausea.
Warnings: If symptoms persist or worsen, consult a healthcare professional. If pregnant or breastfeeding, ask a health professional before use. **Keep this and all medication out of reach of children.**
Directions: Before initial use, depress pump 4-5 times or until primed. Hold close to mouth and spray directly into mouth. Use 3 times daily as needed, or until symptoms improve. Adults: Take 3 sprays. Children 2-12: Take 2 sprays.
Inactive Ingredients: Citric acid, potassium sorbate, purified water.
*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

Contains no artificial flavors or artificial colors. No gluten added. The letters HPUS indicate that the components in this product are officially monographed in the Homeopathic Pharmacopoeia of the United States. Tamper resistant for your protection. Use only if safety seal is intact.

Homeopathic Formula
NDC# 68703-208-02

**Healthful™
Naturals**

Leg Cramp Support
Temporary relief from cramps & spasms while resting
2 fl oz (59 mL)
MADE IN USA

Drug Facts
HPUS Active Ingredients: Equal volumes of each ingredient in 10X, 20X, LM1 potencies. Calcarea carbonica, Cuprum metallicum, Graphitum polycephalum, Hystecyamus niger, Ispatis amara, Magnesia phosphorica, Nux vomica, Passiflora incanata, Platanus metallicum, Plumbum metallicum, Secale cornutum, Strychnium **Use*:** For temporary relief of symptoms such as: spasms in the legs, calves, feet, or hands that occur while resting at night, or from athletic overexertion.
Warnings: If symptoms persist or worsen, consult a healthcare professional. If pregnant or breastfeeding, ask a health professional before use. **Keep this and all medication out of reach of children.**
Directions: Before initial use, depress pump 4-5 times or until primed. Hold close to mouth and spray directly into mouth. Use 3 times daily, as needed, or until symptoms improve. Adults: take 3 sprays. Children 2-12: take 2 sprays.
Inactive Ingredients: Citric acid, potassium sorbate, purified water.
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Homeopathic Formula
NDC 68703-290-02

PetAlive™
BY NATIVE REMEDIES, NATURALLY

**Plump-Up Pet™
ORAL SPRAY**
Improves appetite in underweight dogs & cats
2 fl oz (59 mL)
MADE IN USA

Drug Facts
HPUS Active Ingredients: Equal volumes of each ingredient in a 30C potency: Mulsatum ac, Sulfurilla, Senecio az, Sulphurum ac, Uranium nitricum.
Use*: Homeopathic remedy for underweight dogs & cats with poor appetite.
Warnings: If symptoms persist or worsen, seek advice of a veterinarian. If pet is pregnant or nursing, give only on advice of a veterinarian. **Keep this and all medication out of reach of children.**
Directions: Initially, depress pump until primed. Hold close and spray directly into pet's mouth, or spray onto its food or water. Use 1 time daily. Cats and dogs under 20 lbs: 1-2 pump sprays. Dogs 20-50 lbs: 2-3 pump sprays. Dogs over 50 lbs: 4 pump sprays.
Inactive Ingredients: Carya ovata bark extract (Bakory), citrus extract, Lonicera japonica (honeysuckle), polylysine (natural ferment), purified water, steviol glycosides (stevia).
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International: +1.920.232.3275



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Homeopathic Formula
NDC 68703-135-59

PetAlive™
BY NATIVE REMEDIES, NATURALLY

**Allergy Itch Ease™
ORAL SPRAY**
Relieves skin itch
2 fl oz (59 mL)
MADE IN USA

Drug Facts
HPUS Active Ingredients: Equal volumes of each ingredient: Arum triph 6C, Chamomilla 12C, Cina 6C, Comocladia dentata 6C, Viola tri 6C.
Use*: Homeopathic remedy for the relief of itchy skin in pets.
Warnings: If symptoms persist or worsen, seek advice of a veterinarian. If pet is pregnant or nursing, give only on advice of a veterinarian. **Keep this and all medication out of reach of children.**
Directions: Initially, depress pump until primed. Hold close and spray directly into pet's mouth, or spray onto its food or water. Use 3 times daily. Cats and dogs under 20 lbs: 2 pump sprays. Dogs 20-50 lbs: 3 pump sprays. Dogs over 50 lbs: 4 pump sprays.
Inactive Ingredients: Carya ovata bark extract (Bakory), citrus extract, Lonicera japonica (honeysuckle), polylysine (natural ferment), purified water, steviol glycosides (stevia).
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