COMPANY ANNOUNCEMENT

Sunstone Organics Issues Voluntary Nationwide Recall of Select Kratom Products Due to Potential Contamination by Salmonella

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.

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Summary

Company Announcement Date:

February 28, 2019

FDA Publish Date:

March 01, 2019

Product Type:

Food & Beverages
Meal Replacements

Reason for Announcement:

Potential Contamination by Salmonella

Company Name:

Sunstone Organics

Brand Name:

Sunstone Organics

Product Description:

White Vein Kratom and Maeng Da Kratom

Company Announcement

Sunstone Organics is voluntarily recalling **two** lots of **Sunstone Organics Kratom**. These two lots include Sunstone Organics White Vein Kratom Lot 119 and Sunstone Organics Maeng Da Kratom Lot 124A in both capsules and powder form and in all sizes. The **products** have been found to potentially be contaminated with *salmonella*.

Risk Statement: The **product potentially could** result in **contracting *salmonella***. Symptoms of salmonella can include illness, vomiting, and some cases even death. This risk is higher for users a compromised or weak immune system, including elderly and young children. **Sunstone Organics** has not received any reports of adverse events to date related to this recall.

The product is used as a **tea or supplement** and is packaged in **kraft stand-up pouches in both capsule form and powder form, in 3 different size bags, for a total of 12 products.** The affected **Sunstone Organics Kratom** lots include the following **lot numbers: Sunstone Organics White Vein Lot 119 and Sunstone Organics Maeng Da Lot 124A in Powder form and package sizes 25 grams, 50 grams, and 100 grams, and in capsule form in sizes 20 count, 60 count, and 150 count. See table below for UPC codes:**

Sizes and Types	Sunstone Organics Maeng Da Kratom Lot 124A	Sunstone Organics White Vein Kratom Lot 119
20 count Capsules	00859667007149 (tel:00859667007149)	00859667007347 (tel:00859667007347)
60 count Capsules	00859667007156 (tel:00859667007156)	00859667007354 (tel:00859667007354)
150 count Capsules	00859667007163 (tel:00859667007163)	00859667007361 (tel:00859667007361)

25 gram Powder	00859667007118 (tel:00859667007118)	00859667007316 (tel:00859667007316)
50 gram Powder	00859667007125 (tel:00859667007125)	00859667007323 (tel:00859667007323)
100 gram Powder	00859667007132 (tel:00859667007132)	00859667007330 (tel:00859667007330)

All 6 sizes pertain to the same lot number (i.e. Maeng Da Kratom Lot 124A or White Vein Kratom Lot 119). These products do not have an expiration date.

The product can be identified by **the kraft packaging with Sunstone Organics Kratom round label on the front of the package along with the strain type (i.e. White Vein, Maeng Da). Lot number (i.e. lot 119 or lot 124A) is provided on the back of the package. These products** were distributed **to retail outlets in Oregon, Washington, California, and Nebraska.**

Sunstone Organics is notifying its distributors and customers by **visiting retail outlets on our distribution routes, phone calls to outlets we cannot visit, letters to all outlets, and a sign posted in all outlets notifying consumers,** and is arranging for **replacement** of all recalled products. **Consumers and retailers** that have **Sunstone Organics Kratom** which is being recalled should **stop using, discard or return to place of purchase.**

Consumers with questions regarding this recall can contact **Sunstone Organics** by phone at **541-972-3327 (tel:541-972-3327)** or by **e-mail at info@sunstoneorganics.com (mailto:info@sunstoneorganics.com). We are available by phone Monday-Friday from 8am to 6pm PST.** Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or 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 (tel: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 (tel:1-800-FDA-0178).

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

Company Contact Information

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Sunstone Organics

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