

COMPANY ANNOUNCEMENT

Gaia Ethnobotanical, LLC., Voluntarily Recalls Kratom Products Due to Potential Salmonella Contamination

This recall has been completed and FDA has terminated this recall.

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:

June 21, 2018

FDA Publish Date:

June 21, 2018

Product Type:

Dietary Supplements

Drugs

Nutritional Supplement

Generic Drugs

Reason for Announcement:

Salmonella

Company Name:

Gaia Ethnobotanical, LLC

Brand Name:

Gaia Ethnobotanical

Product Description:

Kratom Products

Company Announcement

Gaia Ethnobotanical, LLC., is voluntarily recalling all kratom (*mitragyna speciosa*) powder products, with Lot No.: 0102031800 (tel:0102031800) it manufactured, processed, packed, and/or held, between March 18, 2018 to March 30, 2018 to the consumer level. The products have been found by the U.S. Food and Drug Administration ("FDA") via sample testing and finding to have salmonella contamination. In lieu of such FDA findings the company has implemented standard operating procedures and sterilization processes in accordance to FDA guidelines.

These products have the potential to be contaminated with *Salmonella*, an organism which can cause serious and sometimes fatal infections in young children, frail or elderly people, and others with weakened immune systems. Healthy persons infected with *Salmonella* often experience fever, diarrhea (which may be bloody), nausea, vomiting and abdominal pain. In rare circumstances, infection with *Salmonella* can result in the organism getting into the bloodstream and producing more severe illnesses such as arterial infections (i.e., infected aneurysms), endocarditis and arthritis.


The affected products (listed below) can be identified by Lot No.: 0102031800 (tel:0102031800) and Batch No.: 031800. Specifically, the products were distributed to AK, AZ, CA, CO, CT, FL, GA, HI, IA, ID, IL, KS, KY, LA, MA, MD, ME, MI, MN, MO, MS, MT, NC, ND, NE, NJ, NM NV, NY, OH, OK, OR, PA, PR, SC, SD, TX, VA, WA, WY via the internet.

| <u>Label</u> | <u>Size</u> | <u>Packaging</u> |
|--------------|-------------|------------------|
|--------------|-------------|------------------|

| | | |
|---|----------------|-------------|
| Gaia Ethnobotanical Bali Gold | 1oz, 250g, 1kg | Plastic Bag |
| Gaia Ethnobotanical Elephant | 1oz, 250g, 1kg | Plastic Bag |
| Gaia Ethnobotanical Ganesh MD | 1oz, 250g, 1kg | Plastic Bag |
| Gaia Ethnobotanical Green Dragon | 1oz, 250g, 1kg | Plastic Bag |
| Gaia Ethnobotanical Green Horn | 1oz, 250g, 1kg | Plastic Bag |
| Gaia Ethnobotanical Green Kapuas Hulu | 1oz, 250g, 1kg | Plastic Bag |
| Gaia Ethnobotanical Green Malay | 1oz, 250g, 1kg | Plastic Bag |
| Gaia Ethnobotanical Green MD | 1oz, 250g, 1kg | Plastic Bag |
| Gaia Ethnobotanical Green Thai | 1oz, 250g, 1kg | Plastic Bag |
| Gaia Ethnobotanical Plantation Green MD | 1oz, 250g, 1kg | Plastic Bag |
| Gaia Ethnobotanical Plantation Red MD | 1oz, 250g, 1kg | Plastic Bag |
| Gaia Ethnobotanical Plantation White MD | 1oz, 250g, 1kg | Plastic Bag |
| Gaia Ethnobotanical Purple 8-1 | 1oz, 250g, 1kg | Plastic Bag |
| Gaia Ethnobotanical Red Bali | 1oz, 250g, 1kg | Plastic Bag |
| Gaia Ethnobotanical Red Borneo | 1oz, 250g, 1kg | Plastic Bag |
| Gaia Ethnobotanical Red Dragon | 1oz, 250g, 1kg | Plastic Bag |
| Gaia Ethnobotanical Red Horn | 1oz, 250g, 1kg | Plastic Bag |
| Gaia Ethnobotanical Red Kapuas Hulu | 1oz, 250g, 1kg | Plastic Bag |
| Gaia Ethnobotanical Red MD | 1oz, 250g, 1kg | Plastic Bag |
| Gaia Ethnobotanical Red Thai | 1oz, 250g, 1kg | Plastic Bag |
| Gaia Ethnobotanical Super Green Malay | 1oz, 250g, 1kg | Plastic Bag |
| Gaia Ethnobotanical White Borneo | 1oz, 250g, 1kg | Plastic Bag |
| Gaia Ethnobotanical White Horn | 1oz, 250g, 1kg | Plastic Bag |

| | | |
|------------------------------------|----------------|-------------|
| Gaia Ethnobotanical White MD | 1oz, 250g, 1kg | Plastic Bag |
| Gaia Ethnobotanical White Thai | 1oz, 250g, 1kg | Plastic Bag |
| Gaia Ethnobotanical Yellow Thai | 1oz, 250g, 1kg | Plastic Bag |
| Gaia Ethnobotanical Yellow Vietnam | 1oz, 250g, 1kg | Plastic Bag |


Gaia is notifying its customers by e-mail and/or telephone and are urged to return the recalled products to us or immediately discard them.

Consumers with questions regarding this recall can contact the company at fdarecall@gaiaethnobotanical.com (mailto:fdarecall@gaiaethnobotanical.com) or call 24/7 at [702-996-8523](tel:702-996-8523) (tel:702-996-8523). .

Company Contact Information

Consumers:

Gaia Ethnobotanical, LLC

 [702-996-8523](tel:702-996-8523) (tel:702-996-8523).

 fdarecall@gaiaethnobotanical.com (mailto:fdarecall@gaiaethnobotanical.com).

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