



**Indiana State Department of Health**  
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Michael R. Pence  
Governor

William C. VanNess II, MD  
State Health Commissioner

**DATE:** March 17, 2014

**TO:** All Local Health Departments  
Attn: Chief Food Inspection Officer

**FROM:** *A. Scott Gilliam*  
A. Scott Gilliam, MBA, CP-FS  
Director, Food Protection Program

**SUBJECT:** SNI National – RECALL [Drug]

**AFFECTED PRODUCT:** Kratom; a botanical that qualifies as a dietary ingredient.

**SUMMARY:** Unclassified Recall; The recall is due to the discovery that the product was distributed as a dietary supplement when, in fact, the primary ingredient did not fall under the Federal Food, Drug, and Cosmetic Act as having all the information necessary to deem it as a safe ingredient. Undeclared drug Ingredients.

All Kratom products, including Kratom XL 4 Pack, Maeng Da Kratom 10 Pack, Max Kratom 20 Pack, and Bali Kratom 40 Pack. The products are packaged in clamshell, zip sealed packets and green pill bottles, 4, 10, 20, and 40 count. The products can be identified by their bright green packaging and label which states that it contains Kratom.

The products were sold to wholesale distributors in the following nearby states: Illinois, Kentucky, and Ohio. The products were further distributed by those entities. SNI National has completely terminated distribution.

**SUGGESTED ACTION:** For consumer inquiry only. Consumers with questions regarding this recall can contact SNI National at (1-801-388-4690) or [-Kratomrecall@gmail.com](mailto:-Kratomrecall@gmail.com) Monday-Friday 10:00 am to 2:00 pm Mountain Standard Time.

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**Recall -- Firm Press Release**

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.



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To promote and provide essential public health services.

## **SNI National is Voluntarily recalling Kratom XL 4 Pack, Maeng Da Kratom 10 Pack, Max Kratom 20 Pack, and Bali Kratom 40 pack Due to Undeclared Drug Ingredients**

**Contact:**

Consumer:

1-801-388-4690

[Kratomrecall@gmail.com](mailto:Kratomrecall@gmail.com)

Media:

1-801-388-4690

**FOR IMMEDIATE RELEASE** - March 14, 2014 - SNI National is voluntarily recalling all Kratom products, including Kratom XL 4 Pack, Maeng Da Kratom 10 Pack, Max Kratom 20 Pack, and Bali Kratom 40 Pack, from distributors and retail locations. These products contain Kratom (*Mitragyna Speciosa*).

Kratom is a botanical that qualifies as a dietary ingredient under section 201(ff)(1) of the Federal Food, Drug, and Cosmetic Act. When marketed as a dietary ingredient, FDA considers kratom to be a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury. Furthermore, scientific literature discloses serious concerns regarding the toxicity of Kratom in multiple organ systems. Consumption of Kratom can lead to a number of health impacts, including respiratory depression, nervousness, agitation, aggression, sleeplessness, hallucinations, delusions, tremors, loss of libido, constipation, skin hyperpigmentation, nausea, vomiting, and severe withdrawal signs and symptoms.

The recall was initiated after the US Food and Drug Administration discovered that the product was distributed as a dietary supplement when, in fact, the primary ingredient did not fall under the Federal Food, Drug, and Cosmetic Act as having all the information necessary to deem it as a safe ingredient.

SNI National has to date not received any complaints or been made aware of any illness or adverse effects stemming from the sale of these products.

SNI National did not manufacture the products in question, but did re-package and re-label it for sale to wholesalers and distributors who further distributed the products.

The products are packaged in clamshell, zip sealed packets and green pill bottles, 4, 10, 20, and 40 count. The products can be identified by their bright green packaging and label which states that it contains Kratom. The products were sold to wholesale distributors in the following states: Alabama, California, Illinois, Missouri, Kentucky, Florida, Oklahoma, Idaho, Colorado, Wisconsin, Massachusetts, and Ohio. The products were further distributed by those entities. SNI National has completely terminated distribution.

SNI National is notifying its distributors and customers by Phone Call or Email, and is arranging for immediate return of all recalled products. Consumers, Distributors and retailers that have purchased or are selling these products should discontinue use or distributing them and return them to place of purchase, or discard them.

Consumers with questions regarding this recall can contact SNI National at (1-801-388-4690) or - [Kratomrecall@gmail.com](mailto:Kratomrecall@gmail.com) Monday-Friday 10:00 am to 2:00 pm Mountain Standard Time.

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

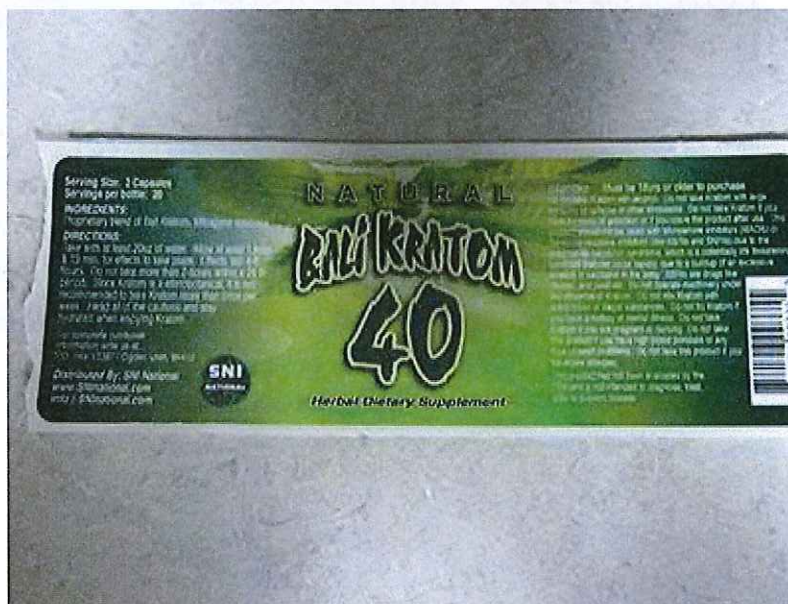
- Complete and submit the report **Online:** [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm)
- **Regular Mail or Fax:** Download form [www.fda.gov/MedWatch/getforms.htm](http://www.fda.gov/MedWatch/getforms.htm) or call 1-800-332-1088 to request a reporting form, then complete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

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

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**SNI National is Voluntarily recalling Kratom XL 4 Pack, Maeng Da Kratom 10 Pack, Max Kratom 20 Pack, and Bali Kratom 40 pack Due to Undeclared Drug Ingredients**  
**Photos**



**INGREDIENTS:**

Proprietary blend of Maeng Da Kratom

**DIRECTIONS:**

Take with at least 8oz of water. Allow at least 1 hour & 15 min. for effects to take place. Effects last 4-6 hours. Do not take more than 2 doses within a 24 hr period. Since Kratom is a psychoactive, it is not recommended to take Kratom more than once per week. Read all of the cautions below and stay hydrated when enjoying Kratom.

**CAUTIONS:**

Do not take Kratom with alcohol. Do not take Kratom with large amounts of caffeine or other stimulants. Do not take Kratom if you have a history of addiction or if you crave the product after use. Persons who take mood altering drugs such as SSRIs / MAOI inhibitors should not take Kratom. Do not operate machinery under the influence of Kratom. Do not mix Kratom with prescription or illegal substances. Do not try Kratom if you have a history of mental illness. Do not take Kratom if you are pregnant or nursing.

The product claims made about this specific product have not been evaluated by the FDA (United States Food & Drug Administration). This product is not approved to diagnose, treat, cure or prevent disease.

For complete nutritional information write us at...

P.O. Box 12297

Ogden, Utah, 84412

Must be 18yrs or older to purchase



Distributed By: SNI National  
www.SNInational.com  
info@SNInational.com

