

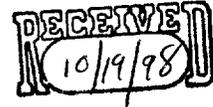
**Alden Botanica**

Alden Botanica LLC, P.O. Box 111, Moreno Valley, California 92556-0111  
kava@aldbot.com <http://www.aldbot.com>

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Office of Special Nutritionals  
(HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C St. SW  
Washington, D.C. 20204

32:3 98 OCT 27 P4:51



Re: Notification of Statement on A Dietary Supplement

Wednesday October 14, 1998

To Whom It May Concern,

With regard to 21 CFR Part 101 Docket No. 96N-0240, Page 49886, Alden Botanica LLC encloses herein the notification of statements on a dietary supplement product. The marketing of the product in question, Essence of Kava™, began on October 5, 1998, and this notification complies with the Final Rule to notify the FDA within 30 days of the first marketing of the product.

Also, please find enclosed the label that appears on the product. As is seen on the label the following statement appears:

**THESE STATEMENTS HAVE NOT BEEN EVALUATED BY THE FOOD AND DRUG ADMINISTRATION. THIS PRODUCT IS NOT INTENDED TO DIAGNOSE, PREVENT, TREAT, OR CURE ANY DISEASE.**

97S-0162

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LET 2354

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Name and Address of distributor:

Alden Botanica LLC  
PO Box 111  
Moreno Valley, CA 92556-0111

The Text of the Statement that is being made and which appears on the label:

Help maintain composure naturally

and, Promotes calm while under stress

The name of the dietary ingredient:

Standardized Kava Root Extract: *KAVIAR®*

The name of the dietary supplement:

Essence of Kava™

Sincerely yours,



John A. Pierce, Ph.D.  
President  
Alden Botanica LLC

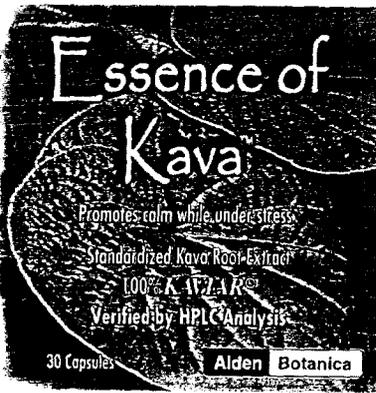
Help maintain composure naturally\* with  
**ESSENCE OF KAVA™**

The natives of Polynesia have understood the calming benefits of the kava root for almost 3,000 years. The rest of the world is just beginning to appreciate how kava can be used to help manage the stresses of modern life.

**ESSENCE OF KAVA™** is 100% pure **KAVIAR®**, a high potency standardized extract of the root of the kava plant (*Piper methysticum*) grown without the use of pesticides or herbicides in Vanuatu, Polynesia. The **KAVIAR®** extraction process does not use any toxic substances. **KAVIAR®** uniquely contains a very wide spectrum of the effective constituents in the kava root, in addition to being standardized to 30% kavalactones.

Each capsule contains 200 mg of **KAVIAR®**.

**ESSENCE OF KAVA™** is a 100% natural herbal supplement WITHOUT preservatives, artificial colors and flavors, sugar, salt, yeast, corn, wheat, milk, or soy.



**Directions for Adult Use:**  
 As an herbal dietary supplement, take 1 to 3 tablets daily as needed, preferably on an empty stomach.

**NOTE:** Do not exceed recommended dose except under the advice and supervision of a physician. Do not use with substances that cause drowsiness, including alcohol. Not for use by pregnant or nursing women. Use caution when driving a motor vehicle or operating machinery. Consult a physician if taking prescription medication. Store in a cool and dry place.

Keep out of the reach of children.  
 Manufactured for and distributed by:  
 Alden Botanica LLC, Moreno Valley, CA 92556 USA  
 Visit us on the Web at: <http://www.aldenbot.com>

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 ™ Licensed trademark of Alden Botanica LLC  
 KAVIAR® registered trademark of Cosmopolitan Trading, WA.

THESE STATEMENTS HAVE NOT BEEN EVALUATED BY THE FOOD AND DRUG ADMINISTRATION. THIS PRODUCT IS NOT INTENDED TO DIAGNOSE, PREVENT, TREAT, OR CURE ANY DISEASE.

LOT NO.:  
 EXP. DATE: