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**P U R E - G A R**<sup>®</sup>  
A SUBSIDIARY OF BASIC VEGETABLE PRODUCTS

April 30, 1996

Elizabeth Yetley, Ph.D.  
Food & Drug Administration  
Office of Special Nutritionals  
200 C Street S.W.  
Washington, D.C. 20204

Dear Dr. Yetley:

Pursuant to Section 6 of the Dietary Supplement Health & Education Act of 1994, Pure-Gar wishes to notify the Food & Drug Administration that it is planning to market dietary supplements which bear the following statements of nutritional support.

- The dietary supplement for which the statements are made is Kava Herb. The statements of nutritional support read as follows:

"... as an effective herbal relaxant and for uterine cramp relief."

"Numerous scientific studies have confirmed the safe, natural relaxant properties of Kava Herb."

- The dietary supplement for which the statement is made is Neem Herb. The statement of nutritional support reads as follows:

"... for promoting general health and well being."

These statements are accompanied by the required disclaimer which is prominently displayed in bold-faced type.

These statements of nutritional support are based on a large body of data which, in our judgment, renders these statements substantiated, truthful and non-misleading.

Sincerely,

*William L. Spencer, Jr.*

William L. Spencer, Jr.  
President

WLS:lf

Attachments: Kava Herb and Neem Herb labels

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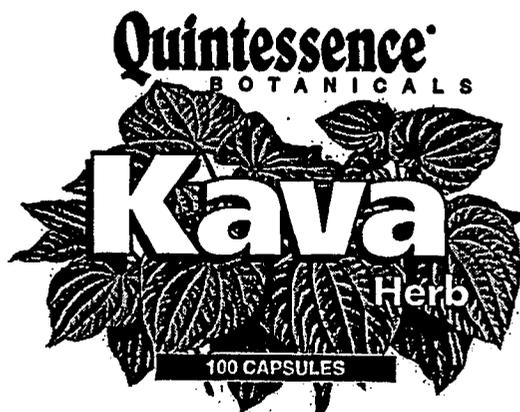
Kava Herb (*Piper methysticum*) has been used for centuries by the indigenous peoples of the Pacific Islands, as an effective herbal relaxant and for uterine cramp relief.\* Numerous scientific studies have confirmed the safe, natural relaxant properties of Kava Herb. The safe relaxant compounds are more highly concentrated in the Kava leaves and stem than in the root. Quintessence Kava Herb is made only from the leaf and stem; no root is used. Kava Herb is grown sustainably, and is an environmentally friendly crop.

Each capsule contains 500 mg. of Pure-Gar® Kava Herb Powder. Disintegration time: 15 minutes or less in the stomach. Yeast free.

**WARNING:** Keep out of reach of children. Please store in a cool, dry place with the cap on tight.

DISTRIBUTED BY: PURE-GAR, © 1996  
P.O. BOX 98812, TACOMA, WA 98498

\*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.



### Nutrition Facts

SERVING SIZE 1 CAPSULE

AMOUNT PER SERVING	
CALORIES 0	CALORIES FROM FAT 0
% DAILY VALUE*	
TOTAL FAT 0 g	0%
SODIUM 0 g	0%
TOTAL CARBOHYDRATE 0 g	0%
PROTEIN 0 g	0%

NOT A SIGNIFICANT SOURCE OF OTHER NUTRIENTS.

\*PERCENT DAILY VALUES ARE BASED ON A 2,000 CALORIE DIET.

INGREDIENTS: 100% PURE-GAR® KAVA HERB POWDER IN A GELATIN CAPSULE MADE OF GELATIN AND WATER.

RECOMMENDED 1 OR 2 CAPSULES, 2 TO 4 TIMES A DAY, DEPENDING ON NEED.

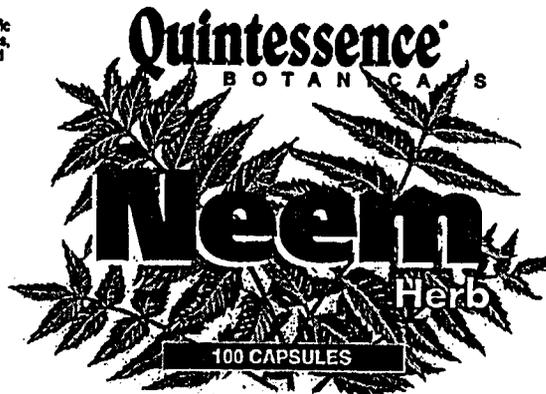
For centuries, the Neem tree (*Azadirachta indica*) has been esteemed by millions on the Indian Subcontinent, where it is known as "the village pharmacy." An extensive body of scientific research has confirmed the wisdom of these indigenous peoples, who have used the Neem leaf for promoting general health and well being.\* Neem Herb is grown sustainably, and is an environmentally friendly crop.

Each capsule contains 500 mg. of Pure-Gar® Neem Herb Powder. Disintegration time: 15 minutes or less in the stomach. Yeast free.

**WARNING:** Keep out of reach of children. Please store in a cool, dry place with the cap on tight.

DISTRIBUTED BY: PURE-GAR, © 1996  
P.O. BOX 96813, TACOMA, WA 98496

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### Nutrition Facts

SERVING SIZE 1 CAPSULE

AMOUNT PER SERVING	
CALORIES 0	CALORIES FROM FAT 0
% DAILY VALUE*	
TOTAL FAT 0 g	0%
SODIUM 0 g	0%
TOTAL CARBOHYDRATE 0 g	0%
PROTEIN 0 g	0%

NOT A SIGNIFICANT SOURCE OF OTHER NUTRIENTS.

\*PERCENT DAILY VALUES ARE BASED ON A 2,000 CALORIE DIET.

INGREDIENTS: 100% PURE-GAR® NEEM LEAF POWDER IN A GELATIN CAPSULE MADE OF GELATIN AND WATER.

RECOMMENDED 1 CAPSULE, 2 TO 4 TIMES A DAY.