



NIKKEN

December 2, 2003

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Office of Special Nutrition Products, Labeling and Dietary Supplements (HFS-810)
Center of Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

Re: Notification of Product Claims

Dear Sir or Madam:

This letter serves as thirty day notification, pursuant to 21 U.S.C. 343 (r) (6) (section 403 (r) (6) of the Federal Food, Drug and Cosmetic Act), of the nutritional support label statement being made by Nikken, Inc., located at 52 Discovery, Irvine CA 92618, in connection with the marketing of its Jade GreenZymes, Kenzen Wellness Dannsei Men and Kenzen Wellness Josei Women formulas. A list of the product ingredients and nutritional support statements are set forth in the attached Exhibit "A."

The undersigned certifies that the information contained in this notice is complete and accurate and that the company maintains documentation to substantiate that its product claims are truthful and not misleading.

If you have any questions, please feel free to contact the undersigned.

Sincerely,

Kendall Cho, President
Nikken, Inc.

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EXHIBIT "A"

1. **Product: Jade GreenZymes**

A dietary supplement containing vitamin A, vitamin C, thiamin, riboflavin, chlorophyll, galactomannan (as guar gum, cyamopsis, tetragonolobus), kombu extract and pearl barley seed extract.

Statements of Nutritional Support:

- Dr. Hagiwara has devoted his life's work to finding a natural substance that would promote health with ingredients that help support the body's nutritional needs
- [Barley Grass] has a natural alkalinity that offsets the acid quality of much of the foods we eat.
- Scientists have studied the relationship between barley grass juice ingredients and the immune system, oxidation, enzymes, and more. Barley grass juice has properties that promote wellness.
- Whole-body conditioning.
- The water soluble fiber helps maintain regularity and adheres to toxins, helping remove them.
- Support for nutritional needs.
- Jade GreenZymes supports the body's immune system – aids in detoxifying, acid balance, weight control.

2. **Product: Kenzen Wellness: Dannsei Men**

A dietary supplement containing all vitamins and minerals for which an RDI has been established except iron, phosphorus, molybdenum, chloride, sodium and potassium. The formula also contains beet root, broccoli plant, cabbage plant, carrot root, celery seed, parsley leaf, spinach leaf, tomato fruit, apple pectin, papaya leaf, digestive enzymes, (as amylase, protease, lipase and cellulase), green tea leaf extract, saw palmetto berry extract, alpha lipoic acid, taurine, glycine, grape seed extract, glutamine, pygeum bark extract, turmeric root, glutathione (reduced), marine fish oil, high lignan flax seed oil, borage seed oil, choline, bromelain, n-acetyl-cysteine, alpha lipoic acid, lycopene and lutein.

Statements of Nutritional Support:

- It offers the vitamins and minerals necessary to help maintain good health.
- It promotes overall wellness in a way that compliments a man's lifestyle.
- It includes ingredients that have been identified as important in supporting men's health and wellness, including prostate health, heart and cardiovascular function, eye health, antioxidant protection, energy levels, and brain function.

3. **Product: Kenzen Wellness: Josei Women**

A dietary supplement containing all vitamins and minerals for which an RDI has been established except iron, phosphorus, molybdenum, chloride, sodium and potassium. The formula also contains beet root, broccoli plant, cabbage plant, carrot root, celery seed, parsley leaf, spinach leaf, tomato fruit, apple pectin, papaya leaf, digestive enzymes, (as amylase, protease, lipase and cellulase), green tea leaf extract, cranberry, fenugreek seed, doug quai root, n-acetylcysteine, soy isoflavens, red clover extract, alpha lipoic acid, grape seed extract, glutathione (reduced), marine fish oil, high lignan, flax seed oil, borage seed oil, choline, bromeline, alpha lipoic acid, lycopene and lutein.

Statements of Nutritional Support:

- It offers the vitamins and minerals necessary to help women maintain good health.
- It promotes overall wellness in a way that compliments a women's lifestyle.
- It includes ingredients that have been identified as important in supporting women's heart health, eye health, energy levels, PMS and menopause symptoms, and brain function.