



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
College Park, MD 20740

JUL 21 2003

Mr. Shannon R. Camp  
Director of Communications  
Wellness International Network, Ltd.  
5800 Democracy Drive  
Plano, Texas 75024

Dear Mr. Camp:

This is in response to your letter to the Food and Drug Administration (FDA) dated June 18, 2003. Your letter was submitted pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Wellness International Network, Ltd. is making the following claims, among others, for the product **Winrgy Dietary Supplement** which it intends to market as a dietary supplement:

“A delicious, vitamin C-enriched beverage...to offer a nutritional alternative to coffees and colas”

“...a delicious, nutritional alternative to coffee and cola”

“A nutritional alternative to caffeinated beverages”

21 U.S.C. 321(ff) defines the term “dietary supplement.” As defined by the Act, dietary supplements do not include products represented for use as conventional foods. 21 U.S.C. 321(ff)(2)(B). In your submission, you state that the intended use of this product is, in part, as a substitute and alternative to other beverages. Beverages are conventional foods. Given this representation for the product’s intended use, Winrgy Dietary Supplement is not a dietary supplement within the meaning of 21 U.S.C. 321(ff) and claims made for it are not subject to 21 U.S.C. 343(r)(6).

Instead, Winrgy Dietary Supplement is a beverage and, therefore, a conventional food and it must meet the regulatory requirements that apply to conventional foods rather than those requirements that apply to dietary supplements. Briefly, Winrgy Dietary Supplement must bear nutrition labeling in accordance with 21 CFR 101.9 and claims may be made for the product in its labeling if they are claims defined by 21 U.S.C. 403(r)(1) or 21 U.S.C. 321(g)(1)(C) that may be made for conventional foods. Additionally, under the Act, any ingredient intentionally added to a conventional food must be used in accordance with a food additive regulation unless it is generally recognized as safe (GRAS) among qualified experts for its intended use in food. A food ingredient that is not GRAS or an approved food additive

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causes a food to be adulterated under 21 U.S.C. 342(a)(2)(C) and cannot be legally marketed in the U.S. If you intend to market Winrgy Dietary Supplement as a beverage and you have any questions about the status of its ingredients, you should direct them to FDA's Office of Food Additive Safety (HFS-200), 200 C St., SW, Washington, DC 20204.

Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'S. Walker', with a long horizontal stroke extending to the right.

Susan J. Walker, M.D.  
Acting Director  
Division of Dietary Supplement Programs  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

**Copies:**

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

FDA, Dallas District Office, Office of Compliance, HFR-SW140



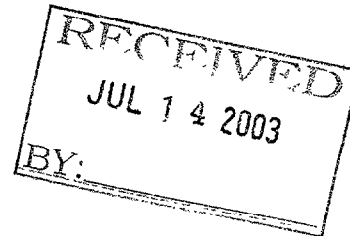
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# Wellness International Network, Ltd.

5800 Democracy Drive • Plano, Texas 75024 • www.winltd.com

June 18, 2003

Office of Special Nutritional (HFS-450)  
Center for Food Safety and Applied Nutrition  
U.S. Food and Drug Administration  
200 C Street S.W.  
Washington D.C. 20204



Re: Notification for Statements on Dietary Supplement Labeling

This notification is being filed on behalf of Wellness International Network, Ltd., a distributor of dietary supplement products (hereinafter "WIN"). Its business address is: 5800 Democracy Drive, Plano, TX 75024. This notification is being made pursuant to Section 6 of DSHEA and 21 C.F.R. § 101.93. The dietary supplement product on whose label or labeling the statements appear is Winrgy.

## A. Winrgy Dietary Supplement

The text of each structure-function statement for which notification is now being given is:

- Statement 1: A delicious, vitamin C-enriched beverage, Winrgy was formulated with a special blend of nutrients designed to offer a nutritional alternative to coffees and colas
- Statement 2: For a long-lasting lift, mix Winrgy with 6 ounces of chilled water or your favorite fruit juice.
- Statement 3: Winrgy is an ideal energizer during stressful activities, while traveling long distances, or anytime peak performance is needed.
- Statement 4: Winrgy tastes great alone or, for added flavor and nutritional support, mix Winrgy and Food For Thought together.
- Statement 5: A unique blend of vitamins and minerals important to the creation of noradrenaline has been incorporated into Winrgy™, making it a delicious, nutritional alternative to coffee and cola
- Statement 6: Unlike the caffeine found in coffee, Winrgy offers the raw materials necessary to continue the production of noradrenaline and is ideal for any time performance is required.
- Statement 7: Promotes noradrenaline
- Statement 8: A nutritional alternative to caffeinated beverages, Winrgy is a wonderful way to start any day.
- Statement 9: Its pleasant citrus flavor and relatively gentle lift have made it a favorite of athletes, students, and hard-working executives who have to keep their minds functioning efficiently, even when the work week stretches beyond the norm.

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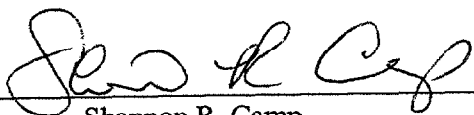
- Statement 10: Through nutrients in the diet, nerves are able to send signals throughout the body called neurotransmitters. One such neurotransmitter, noradrenaline, provides individuals with the necessary alertness and energy required in day-to-day activity.
- Statement 11: A unique blend of vitamins and minerals important to the creation of noradrenaline has been incorporated into Winrgy , making it a delicious, nutritional alternative to coffee and cola.
- Statement 12: Unlike caffeine, Winrgy offers the raw materials necessary to continue the production of noradrenaline and is ideal for anytime performance is required.
- Statement 13: Having trouble getting a jump start on your morning? Ready to kick the coffee and soda habit? It's easier than you think. Restore your energy the natural way with... Winrgy™.
- Statement 14: This high in Vitamin C beverage offers an alternative to coffees and sodas.
- Statement 15: You'll also enjoy the tangy citrus flavor, providing a special blend of nutrients designed to get you through the day with productivity and stamina.
- Statement 16: Get your morning boost with Winrgy.
- Statement 17: Experience the energetic difference of Winrgy, containing ingredients such as Vitamin B12 and Riboflavin that help release energy and combat fatigue.
- Statement 18: Phenylalanine helps to keep noradrenaline stores full so you don't experience the "caffeine crash" associated with coffee
- Statement 19: Winrgy contains the essential amino acid phenylalanine plus copper, vitamin B6 and several other nutrient cofactors which act as precursors to noradrenaline, the brain's energizing, mood-elevating transmitter.
- Statement 20: In addition to phenylalanine, it contains copper, folic acid, vitamin B-6, and several other nutrient cofactors designed to maximize the conversion to noradrenaline in the brain
- Statement 21: Vitamin B3 (niacin), works with both thiamin and riboflavin in the metabolism of carbohydrates and is essential for providing energy for cell tissue growth.
- Statement 22: Niacin has also proven to dilate blood vessels and thereby increase the blood flow to various organs of the body, sometimes resulting in a blush of the skin and a healthy sense of warmth.
- Statement 23: Studies reveal that vitamin B<sub>2</sub> helps the body release energy from protein, carbohydrates and fat
- Statement 24: Vitamin B12 is given to combat fatigue and alleviate neurological problems, including weakness and memory loss.
- Statement 25: The B vitamins, including B1, B2, B3, B6 and B12, which assist in the release of energy from foods
- Statement 26: Copper, potassium and zinc, essential trace minerals necessary for the production of energy in the mitochondria of cells.
- Statement 27: Caffeine, which helps to release noradrenaline while increasing the brain's sensitivity to its effect.

B. The following summary identifies the dietary ingredient(s) or supplement(s) for which a statement has been made:

<u>Statement Number</u>	<u>Identity of Dietary Ingredient(s) or Supplement that is the Subject of the Statement</u>
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11.	Winrgy
12.	Winrgy
13.	Winrgy
14.	Winrgy
15.	Winrgy
16.	Winrgy
17.	Vitamin B12 and Riboflavin
18.	Phenylalanine
19.	Phenylalanine, Copper, Vitamin B6
20.	Copper, Folic Acid, Vitamin B6
21.	Niacin
22.	Niacin
23.	Vitamin B2
24.	Vitamin B12
25.	Vitamins B1, B2, B3, B6, B12
26.	Copper, Potassium, Zinc
27.	Caffeine

I certify that the information presented and contained in this Notification is complete and accurate, and that WIN has substantiation that each structure-function statement is truthful and not misleading.

Date Signed: 6/18/2003

By:   
Shannon R. Camp  
Director of Communications

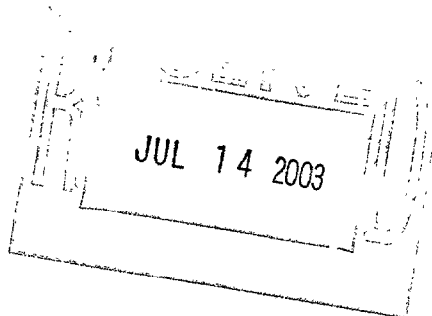


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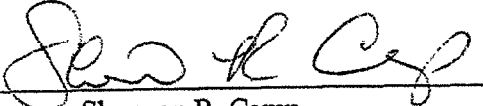
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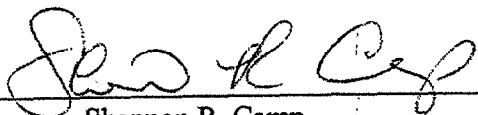
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