



Wellness International Network, Ltd.

5800 Democracy Drive • Plano, Texas 75024 • www.win1td.com

January 6, 2003

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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 BIOLEAN Free®.

A. BIOLEAN Free® Dietary Supplement

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

- Statement 1: BIOLEAN Free is an unprecedented nutritional supplement dedicated to good health.
- Statement 2: By utilizing different ingredients to achieve the same end results as Biolean, this ephedra-free herbal and amino acid product may also be used to help discourage progress plateaus commonly experienced during weight loss.
- Statement 3: This exclusive ephedra-free formula increases the body's ability to convert substances such as proteins, fats and carbohydrates into heat energy.
- Statement 4: BIOLEAN Free helps you to restore lost energy and establish a healthy weight loss regimen.
- Statement 5: WIN offers BIOLEAN Free as an alternative for those who would rather not take Ma Huang.
- Statement 6: BIOLEAN Free utilizes many compounds which act at various locations in this pathway to ensure the maximum efficiency of the thermogenic process. This helps stimulate metabolism and energy levels naturally.

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- Statement 7: Satisfies the appetite
- Statement 8: Accelerates your nutrition and exercise program
- Statement 9: Extremely effective in promoting the healthy loss of excess body fat while helping to maintain lean body mass and potent energy levels.
- Statement 10: BIOLEAN Free activates the natural fat-burning process.
- Statement 11: Controls the appetite and cravings.
- Statement 12: Curbs the cravings.
- Statement 13: Enhances food processing metabolism
- Statement 14: Promotes energy.
- Statement 15: Raises body temperature in order to more effectively metabolize fat.
- Statement 16: A strategic blend of herbs, spices, vitamins, minerals and amino acids specifically formulated to enhance fat utilization and energy production through various metabolic pathways.
- Statement 17: Shown to reduce body fat through its thermogenic effects and to enhance both physical and mental performance.

Quebracho (ingredient in BIOLEAN Free® Dietary Supplement):

- Statement 18: Quebracho is a South American plant which contains quebrachine, aspidospermine, and other alkaloids that possess the ability to block alpha-2 adrenergic receptors in the body.
- Statement 19: This produces an enhanced sympathetic nervous system effect which, in turn, increases lipolysis (fat breakdown) within fat cells. The fatty acids released by this process can then be transported into the mitochondria to be used as a fuel.

Ginger, Cinnamon, Horseradish, Turmeric, Cayenne and Mustard (ingredients in BIOLEAN Free® Dietary Supplement):

- Statement 20: Ginger, cinnamon, horseradish, turmeric, cayenne, and mustard are spices that stimulate thermogenesis in different ways.
- Statement 21: Some stimulate lipid mobilization in adipose tissue; others raise the resting metabolic rate; and some increase cAMP levels by inducing more beta receptors on fat cells and by increasing the concentration of adenylate cyclase.
- Statement 22: cAMP increases the breakdown of triglycerides to free fatty acids which are later used as fuel by the mitochondria in the cell.

Green Tea (ingredient in BIOLEAN Free® Dietary Supplement):

- Statement 23: Methylxanthines (such as those found in green tea and yerba mate) also increase cAMP levels, but do this by inhibiting the enzyme phosphodiesterase.
- Statement 24: These compounds have been noted to increase mental alertness, improve vitality, satisfy the appetite, and increase energy.
- Statement 25: Green tea has been shown to possess strong antioxidant properties.

Yerba Mate (ingredient in BIOLEAN Free® Dietary Supplement):

- Statement 23: Methylxanthines (such as those found in green tea and yerba mate) also increase cAMP levels, but do this by inhibiting the enzyme phosphodiesterase.
- Statement 24: These compounds have been noted to increase mental alertness, improve vitality, satisfy the appetite, and increase energy.
- Statement 26: Yerba mate is a plant that has been show to produce the positive effects above without causing the insomnia seen with other methylxanthine-containing plants (such as coffee and kola nut.)

Vitamin B3, Vitamin B6, Chromium, Vanadium (ingredients in BIOLEAN Free® Dietary Supplement):

- Statement 27: Vitamins B-3, B6, chromium and vanadium aid in the proper metabolism of fats, proteins, and carbohydrates.

L-Tyrosine (ingredient in BIOLEAN Free® Dietary Supplement):

- Statement 28: L-tyrosine aids in metabolism and promotes satiety through hypothalamic release of CCK.

Methionine, L-carnitine (ingredients in BIOLEAN Free® Dietary Supplement):

- Statement 29: Methionine is a precursor to L-carnitine, which aids in the transport of fatty acids into the mitochondria for thermogenesis.

Ginseng (ingredient in BIOLEAN Free® Dietary Supplement):

- Statement 30: Ginseng and Ho Shou Wu possess adaptogenic properties.
- Statement 31: Adaptogens help the body adapt to physiological and environmental stresses.
- Statement 32: Ginseng accomplishes through its stabilizing effect on the hypothalamic-pituitary-adrenal-sympathetic nervous system.

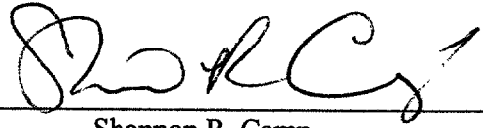
Ho Shou Wu (ingredient in BIOLEAN Free® Dietary Supplement):

- Statement 30: Ginseng and Ho Shou Wu possess adaptogenic properties.

- Statement 31: Adaptogens help the body adapt to physiological and environmental stresses.

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: 1/6/2003

By: 
Shannon R. Camp
Director of Communications