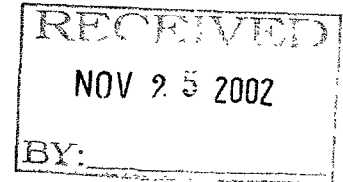




Wellness International Network, Ltd.

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

November 7, 2002



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

Dear Sir/Madam:

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®.

A. BIOLEAN® Dietary Supplement

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

- Statement 1: Accelerates your nutrition and exercise program.
- Statement 2: Acts as a positive stimulator to immune functions involved in protection from normal, daily build-up of environmental and dietary toxins.
- Statement 3: Designed to help improve overall health.
- Statement 4: Extremely effective in promoting the healthy loss of excess body fat while helping to maintain lean body mass and potent energy levels.
- Statement 5: Satisfies the appetite.
- Statement 6: BIOLEAN® activates the natural fat-burning process.
- Statement 7: BIOLEAN® is a unique, synergistic blend of herbs, amino acids and nutrients designed to elevate your metabolism, stimulating thermogenesis, which helps your body burn excess calories from your everyday caloric intake and fat reserves while maintaining lean body mass.

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- Statement 8: Controls the appetite and cravings.
- Statement 9: Curbs the cravings.
- Statement 10: Enhances food processing metabolism.
- Statement 11: Helps the body rid itself of accumulated toxins, which retard the healthy operation of internal organs, and directly stimulates them as well, especially those involved in the metabolism of food.
- Statement 12: In order to get the maximum results from BIOLEAN®, it is best to utilize it throughout the active part of the day. This is the period when your body is at its maximum rate of food metabolism, energy use, and replacement of energy stores.
- Statement 13: Overall individual health and wellness is constantly and substantially boosted with BIOLEAN® regardless of the speed at which the results are perceived.
- Statement 14: Promotes energy.
- Statement 15: Raises body temperature in order to more effectively metabolize fat.
- Statement 16: Shown to stimulate immune function in individuals with blunted sympathetic nervous systems.
- Statement 17: Thermogenic effect naturally suppresses your appetite and speeds up your metabolism, so you can burn excess calories and fat reserves while maintaining lean body mass.
- Statement 18: Thermogenic fat burner, time-tested and advanced herbal formula.
- Statement 19: BIOLEAN® is an extremely complex formula utilizing efficacious amounts of all listed ingredients
- Statement 20: Unique herbal/amino acid blend in conjunction with the thermogenic elements in BIOLEAN® cause a shift in the way the body stores and generates energy, so that lean mass is retained while fat stores are released and decreased.

B. Green Tea (ingredient in BIOLEAN® Dietary Supplement):

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

- Statement 1: Green Tea is a superior antioxidant.
- Statement 2: Increases mental awareness
- Statement 3: Fights fatigue

- Statement 4: Helps diminish appetite.
- Statement 5: Promotes weight loss.
- Statement 6: Green tea can promote the burning of fat and maintain a healthy blood sugar balance.
- Statement 7: Beneficial for the cardiovascular system and maintaining cholesterol levels that are already in then normal range.
- Statement 8: Catechins are a flavanol-type of plant substance belonging to a larger group called polyphenols. It is the catechins which have proven to be a highly diverse weapon against certain human health problems. Catechins, of which six types have been identified in green tea, compose approximately 30% of the dry leaf weight and 80-85% of the total polyphenols. Most of the total catechin mass is composed of the four "epi" forms: epicatechin, epigallocatechin, epicatechin gallate and epigallocatechin gallate. Of these, the gallate forms, ECG and EGCG, have been found to be the active constituents to which researchers attribute most of the beneficial effects of green tea. Thus far, EGCG has been found to be substantially more powerful than ECG in most applications. EGCG is also naturally plentiful in tea leaf, accounting for almost 50% of the total catechins
- Statement 9: Green tea catechins, especially the gallo catechins and catechin gallates, have been found to be superior to even ascorbic acid (Vitamin C) and tocopherol (Vitamin E) with respect to the active oxygen free radicals; and slightly less pronounced than Vitamin C, yet 3 times that of Vitamin E with hydroxyl radicals.
- Statement 10: Several studies have shown the anti-oxidant properties of tea catechins, especially KGCG.
- Statement 11: Studies have shown the ability of tea catechins and especially EGCG to maintain healthy cholesterol that is already in the normal range.
- Statement 12: In one study, prior oral administration of tea catechins showed an inhibitory effect on amylase or sucrase, enzymes responsible for the absorption of starches and sucrose (sugar), creating a beneficial digestive blocking result.

C. L-carnitine (ingredient in BIOLEAN® Dietary Supplement):

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

- Statement 1: L-carnitine is needed to release energy from fat.
- Statement 2: It transports fatty acids into mitochondria, the powerhouses of cells.

- Statement 3: L-carnitine's actions appear to be particularly important in heart health.
- Statement 4: Research shows that people who supplement with L-carnitine while engaging in an exercise regimen are less likely to experience muscle soreness, common after a workout.
- Statement 5: L-carnitine stabilizes red blood cells.

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:

11/7/02

By:



Shannon R. Camp
Director of Communications