



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

JUN 12 2007

17 AUG 21 P5:12

Mr. Michael Matthews
Wellness International Network, Ltd.
5800 Democracy Drive
Plano, Texas 75024

Dear Mr. Matthews:

This is in response to your letter of May 10, 2007 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your notice states that Wellness International Network, Ltd. is making the claim "Support healthy levels of...cholesterol."

In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1018), FDA stated that claims about the maintenance of normal cholesterol levels did not necessarily constitute implied disease claims. We stated, however, that because "many people think of cholesterol solely in terms of the negative role of elevated cholesterol in heart disease," in order to avoid implying that the product prevents or treats heart disease, a cholesterol maintenance claim would have to clarify that the product is only for maintenance of cholesterol levels that are already within the normal range. Because the claim you are making for this product represents that the product is intended to affect blood cholesterol but does not also include a statement about it being intended to affect blood cholesterol that is already in the normal range, it is an implied disease claim.

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to treat, prevent, or mitigate disease. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20855.

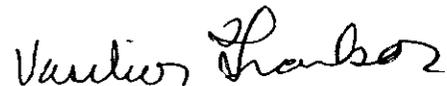
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Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Vasilios Frankos". The signature is written in a cursive, flowing style.

Vasilios H. Frankos, Ph.D.
Director
Division of Dietary Supplement Programs
Office of Nutrition, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, Dallas District Office, Office of Compliance, HFR-SW140



Wellness International Network, Ltd.

May 10, 2007

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

MAY 30 2007

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 Tranquility™.

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

(Statement 1): Support healthy levels of triglycerides and cholesterol.

(Statement 2): Help manage stress and regulate the sleep cycle.

(Statement 3): Aid in relaxation.

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>
1.	myo-inositol
2.	valerian root
3.	inositol

1917

07-3789



Wellness International Network, Ltd.

I, Michael Matthews, am authorized to certify this Notification on behalf of WIN. 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: 5/10/07

By: 
Michael Matthews
Director of Regulatory Affairs