



Wellness International Network, Ltd.

5800 Democracy Drive • Plano, Texas 75024 • www.winltd.com NOV 25 11 59

November 7, 2002

RECEIVED
NOV 19 2002
BY:

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 Essential.

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

- Statement 1: Promotes a healthy cardiovascular system
- Statement 2: Supports your entire cardiovascular system, including the heart, arteries and veins.
- Statement 3: Provides unparalleled support for the heart and circulatory system
- Statement 4: Assists your circulatory system in supporting all of the cells and organs in your body
- Statement 5: Helps promote cardiovascular health.
- Statement 6: Nutritionally supports the cardiovascular system of the body.
- Statement 7: Essential is a nutritional food supplement which contains specific tissue proteins supported by vitamins, minerals, herbs and amino acids that are proactive to cardiovascular and circulatory management.
- Statement 8: Essential is a nutritional food supplement containing specific tissue proteins supported by vitamins, minerals, herbs and amino acids, which have long been established as being important for the health of the heart and circulatory system.

975 0162 LET 11222

82587

Doc. 116779

- Statement 9: Essential, as part of an active lifestyle and a diet that is low in saturated fats, high in fruits, vegetables, fiber, protein, essential fats, and clean water, can help you be heart healthy for life.
- Statement 10: Essential provides Omega-3 fatty acids to promote a healthy blood lipid profile.
- Statement 11: Omega-3 fatty acids promote normal triglyceride levels and a healthy blood lipid profile.
- Statement 12: Studies show that d-alpha tocopherol may have very potent antioxidant properties that promote the health of the heart as well as the immune system.
- Statement 13: L-carnitine has been shown to support healthy heart activity.
- Statement 14: L-carnitine is necessary for the transport of long-chain fatty acids into the mitochondria, the metabolic furnace of the cells. These fatty acids prove a major source for the production of energy in the heart and skeletal muscles, structures that are particularly vulnerable to L-carnitine deficiency.

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.	Essential
2.	Essential
3.	Essential
4.	Essential
5.	Essential
6.	Essential
7.	Essential
8.	Essential
9.	Essential
10.	Omega 3 fatty acids
11.	Omega 3 fatty acids
12.	d-alpha tocopherol
13.	L-carnitine
14.	L-carnitine

C. The following identifies the brand name of each supplement for which a statement is made: (Complete this section only if the supplement(s) were not identified in Paragraph B.)

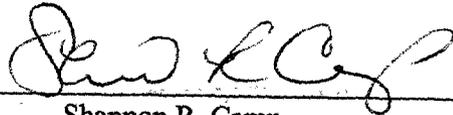
<u>Statement Number</u>	<u>Brand Name</u>
10.	Essential
11.	Essential

- 12.
- 13.

Essential
Essential

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