



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

4558 7

Food and Drug Administration
Reg. Part 312.5013
20740

AUG 13 2007

Lee A. Surkin, M.D.
Cardiac Wellness Supplements
796-B Moye Boulevard
Greenville, North Carolina 27834

Dear Dr. Surkin:

This is in response to your letter received by the Food and Drug Administration (FDA) on August 8, 2007 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 Cardiac Wellness Supplements is making the claim "Supports Healthy cholesterol levels...." for the product Wellcor Energize Supreme Green Tea.

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.

You also are making the claim "May reduce the extent of cardiac cell damage following a heart attack" for the product Wellcor Control Alpha Lipoic Acid/L-Carnitine.

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 statements that you are making for these products suggest that they are intended to treat, prevent, or mitigate diseases. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are 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.

19975-0163

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Page 2 - Dr. Lee A. Surkin

Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in cursive script that reads "Vasilios Frankos".

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, Atlanta District Office, Office of Compliance, HFR-SE140



CARDIAC WELLNESS
SUPPLEMENTS

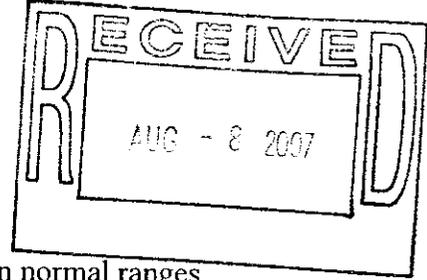
LEE A. SURKIN, M.D.
F.A.C.C., I.C.C.P.

Dear Sir/Madam:

Notice is hereby given pursuant to the requirements of Section 403 (6) (21 U.S.C. 343 (6) of the Federal Food, Drug, and Cosmetic Act) and in accordance with the requirements of 21 CFR 101.93, that Cardiac Wellness Supplements within the past 30 days commenced marketing a nutritional supplement bearing the following statement(s) on the label and/or in the labeling:

TEXT OF CLAIM(S):

- Provides Antioxidant & Glucose Metabolism Support
- Supports healthy blood vessel function
- Supports glucose metabolism
- Helps protect against free radical damage
- Helps maintain good cholesterol and triglycerides levels within normal ranges
- May reduce the extent of cardiac cell damage following a heart attack



NAME OF INGREDIENT(S) THAT IS SUBJECT TO CLAIM

Alpha Lipoic Acid
L-Carnitine

NAME OF SUPPLEMENT (INCLUDING BRAND NAME)

Wellcor™ Control Alpha Lipoic Acid/L-Carnitine

The undersigned certifies that the information contained in this notice is complete and accurate and that Cardiac Wellness Supplements has substantiation that the statements are truthful and not misleading.

Sincerely,

Lee A. Surkin MD

2007-5594

WELLCOR DEFENSE • WELLCOR ENERGIZE • WELLCOR GUARD • WELLCOR STRENGTH • WELLCOR CONTROL

Nutritional supplements formulated by Dr. Surkin for people who want to enhance their cardiac wellness

www.cardiacwellness.com

796-B Moye Boulevard

Greenville

North Carolina 27834

888.5WELLCOR

(888.593.5526) toll free

252.757.3973 facsimile

932



CARDIACWELLNESS
SUPPLEMENTS

LEE A. SURKIN, M.D.
F.A.C.C., F.C.C.R.

Dear Sir/Madam:

Notice is hereby given pursuant to the requirements of Section 403 (6) (21 U.S.C. 343 (6) of the Federal Food, Drug, and Cosmetic Act) and in accordance with the requirements of 21 CFR 101.93, that Cardiac Wellness Supplements within the past 30 days commenced marketing a nutritional supplement bearing the following statement(s) on the label and/or in the labeling:

TEXT OF CLAIM(S):

Supports Healthy Cholesterol Levels & Metabolism
Contains EGCG, a potent antioxidant, that supports a healthy cardiovascular system
Supports thermogenesis for optimal cardiovascular function
As an antioxidant, EGCG is 100 times more effective than vitamin C and 25 times better than vitamin E

AUG - 8 2007

NAME OF INGREDIENT(S) THAT IS SUBJECT TO CLAIM

Green Tea (Epigallo-catechin-3-gallate)

NAME OF SUPPLEMENT (INCLUDING BRAND NAME)

Wellcor™ Energize Supreme Green Tea

The undersigned certifies that the information contained in this notice is complete and accurate and that Cardiac Wellness Supplements has substantiation that the statements are truthful and not misleading.

Sincerely,

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