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AUG 11 2005

Mr. Ira L. Goldberg
President
Source Naturals
23 Janis Way
Scotts Valley, California 95066

Dear Mr. Goldberg:

This is in response to your letter of June 29, 2005 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)).

The product **Renewal Antioxidants™** is using the claim "Some scientific evidence suggests that consumption of antioxidant vitamins may reduce the risk of certain forms of cancer. However, FDA has determined that this evidence is limited and not conclusive." This statement is not a claim subject to 21 U.S.C. 343(r)(6), but a claim subject to 21 U.S.C. 343(r)(1)(B) because it implies that the product will prevent a disease (i.e., cancer). In a April 1, 2003 letter in response to the court decision directing the FDA to consider qualified health claims for dietary supplement labeling (*Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999)) when the evidence in support of the claim does not meet the significant scientific agreement standard, we stated that FDA would exercise its enforcement discretion for a qualified claim with respect to antioxidant vitamin dietary supplements containing vitamin E and/or vitamin C when: (1) one of the disclaimers cited in the letter is placed immediately adjacent to and directly beneath the antioxidant vitamin claim, with no intervening material, in the same size, typeface, and contrast as the claim itself; and (2) the supplement does not recommend or suggest in its labeling, or under ordinary conditions of use, a daily intake exceeding the Tolerable Upper Intake Level established by the Institute of Medicine (IOM) of 2000 mg per day for vitamin C and 1000 mg per day for vitamin E (see May 4, 2001, letter at 4-6 and references cited therein).

A dietary supplement bearing a claim that is not eligible to use the claim (for example, it does not contain the antioxidant vitamins which the qualified claim is the subject of) or that is not properly qualified or consistent with the weight of the evidence is subject to regulatory action as a misbranded food under section 403(r)(1)(B) of the Act, a misbranded drug under section 502(f)(1), and as an unapproved new drug under section 505(a).

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Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to be 'S. Walker', with a long horizontal flourish extending to the right.

Susan J. Walker, M.D.
Director
Division of Dietary Supplement Programs
Office of Nutritional Products, 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, Los Angeles District Office, Office of Compliance, HFR-PA240

Source Naturals®
23 Janis Way
Scotts Valley, CA 95066

June 29, 2005

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C St. SW., Washington, D.C. 20204

JUL 1 1 05

RE: Notification of Nutritional Support Statements

To whom it may concern:

I hereby notify the Food and Drug Administration (FDA) of the use of statements of nutritional support in the labeling of Renewal Antioxidants™, a dietary supplement. Source Naturals® is the manufacturer of Renewal Antioxidants™.

Statements being made in the labeling of Renewal Antioxidants™

- 1) Free radicals cause oxidative stress, a major cause of accelerated aging.
- 2) Some scientific evidence suggests that consumption of antioxidant vitamins may reduce the risk of certain forms of cancer.
- 3) However, the FDA has determined that this evidence is limited and not conclusive.
- 4) Renewal Antioxidants is a Bio Aligned™ formula which, unlike other products, provides a very broad range of free radical protection critical for various tissues and cells.
- 5) With both lipid and water soluble antioxidants that target specific body systems, Renewal Antioxidants helps defend against an extremely wide spectrum of destructive free radicals including peroxy, hydroxy, and superoxide radicals, as well as singlet oxygen.

To the best of my knowledge and belief, and based upon information available at the time of the execution of this notice, I certify that the above information is accurate and complete. Source Naturals® possesses substantiation that the statements are truthful and not misleading.



Ira L. Goldberg
President, Source Naturals®

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