



## Inspections, Compliance, Enforcement, and Criminal Investigations

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### Enforcement Actions

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### Tennessee Scientific, Inc./Scientific Formulations LLC 2/1/11



Department of Health and Human Services

Public Health Service  
Food and Drug Administration  
New Orleans District  
404 BNA Drive  
Suite 500 Building 200  
Nashville, TN 37217  
Telephone: 615-366-7801  
FAX: 615-366-7802

February 1, 2011

#### WARNING LETTER NO. 2011-NOL-08

#### UNITED PARCEL SERVICE Delivery Signature Requested

Jerry T. Thomthwaite, Ph.D.  
www.theformulation.com  
www.scientificformulations.com  
Tennessee Scientific, Inc./Scientific Formulations LLC  
1322 White Avenue  
Henderson, Tennessee 38340

Dear Dr. Thomthwaite:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your websites at the internet address, [www.theformulation.com](http://www.theformulation.com) and [www.scientificformulations.com](http://www.scientificformulations.com), in September 2010. FDA has determined the products NAC Supplement, Antioxidant Supplement, Anti-Angiogenesis Supplement, and Immune Enhancement Supplement are promoted for conditions which cause the products to be drugs under Section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)(B)]. The therapeutic claims on these websites establish the products are drugs because they are intended for use in the cure, mitigation, treatment, or prevention of disease. The marketing of the products with these claims violates the Act. You may find the Act and FDA's regulations through links on FDA's Internet home page at <http://www.fda.gov>.

In addition, it is unlawful under the FTC Act, 15 U.S.C. § 41 *et seq.*, to advertise that a product can prevent, treat, or cure human disease unless you possess competent and reliable scientific evidence, including, when appropriate, well-controlled human clinical studies, substantiating the claims are true at the time they are made. See *FTC v. Direct Mktg. Concepts*, 569 F. Supp. 2d 285, 300, 303 (D. Mass. 2008); *FTC v. Nat'l Urological Group, Inc.*, No. 1:04-CV-3294-CAP, 2008 U.S. Dist. LEXIS 44145, at \*43-44 (N.D. Ga. June 4, 2008); *FTC v. Natural Solution, Inc.*, No. CV 06-6112-JFW, 2007 U.S. Dist. LEXIS 60783, at \*11-12 (C.D. Cal. Aug. 7, 2007). More generally, to make or exaggerate such claims, whether directly or indirectly, through the use of a product name, website name, metatags, or other means, without rigorous scientific evidence sufficient to substantiate the claims, violates the FTC Act. See *In re Daniel Chapter One*, No. 9239, slip op. 18-20, 2009 WL 516000 (F.T.C.), 17-19 (Dec. 24, 2009) (<http://www.ftc.gov/os/adjpro/d9329/091224commissionopinion.pdf>).

Examples of some of the claims observed on the website [www.theformulation.com](http://www.theformulation.com) include the following:

#### From the webpage entitled "How The Formulation Works":

- "Antiangiogenesis, the inhibition of rapid blood vessel growth associated with cancer..."

#### NAC Supplement

- "A trace mineral with anti-tumor properties, selenium [ingredient in product] was recently examined by FDA scientists who found evidence of anti-tumor benefits for certain forms of cancer..."

#### Antioxidant Supplement

- "Research has shown that high doses of antioxidants can have anti-cancer benefits."
- "Resvida [an ingredient in your product], very high potency Resveratrol (antioxidant)... In vitro Resveratrol has been shown to have positive effects on the cells of breast, skin, gastric, colon, esophageal, prostate, and pancreatic cancer, and leukemia."

#### Anti-angiogenesis Supplement

- "Scientific Formulation's Anti-Angiogenesis... anti-tumor supplement ..."
- "Research shows that both of these primary active ingredients, curcumin and genistein, have these anti-tumor biomechanisms."
- "Genistein's [an ingredient in your product] antioxidant and tumor suppression properties, particularly for breast and prostate cancer, have been well researched."

#### Immune Enhancement Supplement

- "The Immune Enhancement Supplement ... destroy[s] mutated cells, including cancer."

Your [www.theformulation.com](http://www.theformulation.com) website also contains disease claims in the form of personal testimonials, including:

- "I was diagnosed with rectal cancer three years ago with metastases to the liver.... The Formulation was my only option, which I believe contributed to my liver tumors disappearing and my general well-being."
- "After I completed surgeries, chemotherapy, and radiation for Stage III breast cancer, my oncologist couldn't assure me that my cancer wouldn't return... I... started taking many of the supplements in the Immune Formulation... Within 30 days of starting on my high potency regimen of supplements, my tumor marker tests have been in the normal range."
- "[M]y wife had four recurrences since being diagnosed in 1996 with Stage III Melanoma... She was put on the Formulation components with tetrathiomolybdate for antiangiogenesis and has not had a recurrence in the past eight years."
- "[T]he doctor discovered a tumor on the outer fold of my stomach.... When we found 'The Formulation' ...we made the decision to get it. When the tumor was removed we learned that it had shrunk by 50%, and that was in just 90 days.... My husband and I are so thankful to have found such a successful treatment. We... recommend The Formulation to everyone we know who is battling cancer."

Examples of some of the claims observed on the website [www.scientificformulations.com](http://www.scientificformulations.com) include the following:

#### On the webpage entitled "The Formulation Summary Statement":

- "However, the importance of the components of The Formulation, which also includes direct cancer cytotoxicity, may be considered for the prevention of cancer and as a first line treatment regardless of the anatomic site in the near future."

#### On the webpage entitled "Overview of the Formulation Components":

- "The 13 components listed above [ingredients in the product] are the result of extensive research to determine the optimum components that would support major pathways... including direct cytotoxicity against cancer and viral infected cells."

#### On the webpage regarding the component Alpha Lipoic Acid:

- "The antioxidant Alpha Lipoic Acid (ALA) ...has been shown to posses [sic] promising anti-cancer activity because of its ability to ...inhibit proliferation of cancer cells..."

#### On the webpage regarding the component Curcumin:

- "-Anti-inflammatory
- "-Antibacterial
- "-Antifungal...
- "-Cytotoxic to cancer"

#### On the webpage regarding the component N Acetyl Cysteine:

- "In addition, NAC has been found to be safe and < [sic] efficacious in the clinic for treating acute respiratory distress and inflammation, as well as being a useful antidote for acute drug intoxication, e.g. Tylenol (Betten, et al. 2007)."
- "Treats Tylenol Overdose"

#### On the webpage regarding the component Resveratrol:

- "Resveratrol is known to have potent anti-inflammatory and antioxidant effects and to inhibit... the growth of a variety of cancer cells."

#### On the webpage regarding the component Vitamin B6:

- "This vitamin prevents nervous and skin disorders, provides protection against a high cholesterol [sic] level, certain types of heart disease, and diabetes. It prevents tooth decay."
- "Vitamin B6 is now considered as a wonder treatment for a wide range of common ailments, such as diabetes, haemorrhoids, convulsions in infants and women... and insomnia..."

#### On the webpage regarding the component Vitamin E:

- "[Vitamin E] is important in the treatment of many cancers including throat, esophagus, stomach, colon, cervix, breast and the prostate gland."

Your products are not generally recognized as safe and effective for the above referenced uses and therefore, the products are "new drugs" under Section 201(P) of the Act [21 U.S.C. § 321(P)]. New drugs may not be legally marketed in the U.S. without prior approval from FDA as described in Section 505(a) of the Act [21 U.S.C. § 355(a)]. FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate the drug is safe and effective.

Furthermore, because your products are offered for conditions which are not amenable to self diagnosis and treatment by individuals who are not medical practitioners, adequate directions cannot be written so a layman can use the products safely for their intended uses. Thus, their labeling fails to bear adequate directions for their intended uses, causing them to be misbranded under Section 502(f)(1) of the Act, 21 U.S.C. § 352(f)(1). The introduction of a misbranded drug into interstate commerce is a violation of § 301(a) of the Act, 21 U.S.C. § 331(a).

The above violations are not meant to be an all-inclusive list of deficiencies in your products and their labeling. It is your responsibility to ensure all of your products are in compliance with the laws and regulations enforced by FDA. You should take prompt action to correct the violations. Failure to promptly correct these violations may result in regulatory actions without further notice, such as seizure and/or injunction.

Please notify FDA, in writing, within fifteen (15) working days of the receipt of this letter, as to the specific steps you have taken to correct the violations noted above and to ensure similar violations do not occur. Include any documentation necessary to show corrections have been achieved. If corrective actions cannot be completed within fifteen working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be directed to, Rebecca A. Asente, Compliance Officer, U.S. Food and Drug Administration. If you have any questions regarding any issues in this letter, please contact Ms. Asente at the address above or telephone 504-219-8818 extension 104.

In addition, FTC strongly urges you to review all claims for your products and ensure those claims are supported by competent and reliable scientific evidence. Violations of the FTC Act may result in legal action seeking a Federal District Court injunction or Administrative Cease and Desist Order. An order also may require you pay back money to consumers. Please notify FTC, via electronic mail at [healthproducts@ftc.gov](mailto:healthproducts@ftc.gov), within fifteen (15) working days of receipt of this letter of the specific actions you have taken to address FTC's concerns. If you have any questions regarding compliance with the FTC Act, please contact Richard Cleland at 202-326-3088.

Sincerely,

/s/  
Patricia K. Schafer  
Acting District Director  
New Orleans Districtcc: Henry Respass, CEO  
Scientific Formulations LLC  
705 West Hundred Road  
Chester, VA 23836

Page Last Updated: 02/04/2011

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

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