



**UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION
OFFICE OF ADMINISTRATIVE LAW JUDGES**

In the Matter of

**GEMTRONICS, INC.,
a corporation, and**

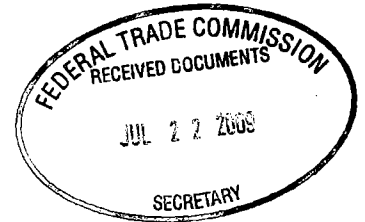
**WILLIAM H. ISELY,
individually and as the owner
of Gemtronics, Inc.**

PUBLIC

DOCKET NO. 9330

COMPLAINT COUNSEL'S POST TRIAL BRIEF

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Pursuant to the Court's Order on Post Trial Briefs dated July 1, 2009, Complaint Counsel hereby submits its Post Trial Brief, Proposed Findings of Fact, Conclusions of Law, and Exhibit and Witness Indices.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Barbara E. Bolton", written over a horizontal line.

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Dated: July 21, 2009

TABLE OF CONTENTS

Complaint Counsel’s Post Trial Brief..... TAB 1

Complaint Counsel’s Proposed Findings of Fact and Conclusions of Law.....TAB 2

Complaint Counsel’s Exhibit and Witness Indices.....TAB 3

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COMPLAINT COUNSEL'S POST-TRIAL BRIEF

I. INTRODUCTION

The evidence presented at trial demonstrated that Respondents Gemtronics, Inc. (“Gemtronics”), and William H. Isely (“Isely”) violated Sections 5(a) and 12 of the Federal Trade Commission Act (“FTC Act”) by making false and unsubstantiated claims for the herbal product, RAAX11, a food or drug within the meaning of Sections 12 and 15 of the FTC Act. Respondents offered for sale and sold RAAX11 to consumers through unsupported claims in Internet advertisements on the website www.agaricus.net that RAAX11 is effective in preventing, treating, or curing various types of cancer and that these claims are proven by reliable scientific evidence. The evidence presented also clearly demonstrated that scientific evidence does not support any cancer-related claims for RAAX11 and that Respondents did not possess adequate substantiation for their claims.

During the trial and throughout this proceeding, Respondents have not challenged either the content or interpretation of the advertising claims at issue in the Commission’s complaint. Instead, Respondents contend that they were not liable for these deceptive claims by denying

their association with the website www.agaricus.net. However, as demonstrated at trial, Respondents were willing participants in the challenged acts and practices. Respondents were part of a profitable scheme to sell RAAX11 by deceiving consumers that the product could treat their cancer. The evidence showed that Respondents were 1) identified as the party responsible for domain “agaricus.net” the website; 2) identified as part of the website’s cancer-related advertising claims; 3) the exclusive US sales outlet on the website for RAAX11; and 4) responsible for fulfilling orders for RAAX11 placed on the website. Moreover, Respondents participated in this scheme with full knowledge of the deceptive and unsubstantiated claims being made on the website.

Contrary to their assertions at trial, but as evidenced by their actions and statements, Respondents had the ability to control the website. For example, after Respondents Gemtronics and Isely received notices of potential law violations from the Federal Trade Commission and the Food and Drug Administration, Respondent Isely had little difficulty removing his name and address from the website’s domain registration. After doing so, the challenged cancer claims ceased and sales of RAAX11 from the website ceased in the United States

The injunctive relief set forth in the proposed order attached to the Commission’s complaint is the necessary and appropriate remedy in this matter. The proposed order enjoins Respondents from making or assisting others in making false, misleading, or unsupported claims in connection with the marketing of RAAX11 and other health-related products, and requires Respondents to notify their customers who purchased RAAX11 that scientific studies do not demonstrate that RAAX11, or its ingredients, are effective in the treatment of cancer.

II. STATEMENT OF FACTS¹

A. Respondents' Business Operations

Respondent Isely operated a business from his residence that advertised and sold dietary supplements to consumers nationwide through telephone, the internet and mail order. CCPF ¶¶ 1, 2, 3. Respondent Isely ran his dietary supplement business as a sole proprietor under the assumed name Gemtronics. CCPF ¶ 4.

In 2000, Respondent Isely began to purchase dietary supplements wholesale from a Brazilian manufacturer named Takesun do Brasil Ind. Com. e Exp. Ltda. ("Takesun") for resale to consumers. CCPF ¶ 5. The following year, in 2001, Respondent Isely established a business named Takesun USA ("Takesun USA") to import Takesun products into the United States from Brazil. CCPF ¶ 6. In 2003, he also registered his residence as an FDA approved warehouse to import and store Takesun products for resale. CCPF ¶ 7.

In 2004, Respondent Isely began to offer for sale and sell to consumers the Takesun product, RAAX11. CCPF ¶ 11. He imported RAAX11 from Takesun about every four months. CCPF ¶ 11. That year, 2004, Respondent Isely sold 19 bottles of RAAX11 at the price of \$400 per bottle. CCPF ¶ 12. Thereafter, from 2005 through 2008, Respondents sold approximately 1115 bottles of RAAX11 at the price of \$120 per bottle. CCPF ¶ 12. Respondents charged shipping and handling fees of \$15.00. CCPF ¶ 12.

In September 2006, Isely incorporated Gemtronics, Inc., a North Carolina corporation, whose principal place of business is located in Franklin, North Carolina, at Isely's residence.

¹ Pursuant to the Court's Scheduling Order, Complaint Counsel has submitted the accompanying Proposed Findings of Fact and Conclusions of Law ("CCPF") as a separate document.

CCPF ¶¶ 1, 6. Respondent Isely is the owner, registered agent, and general manager of Gemtronics CCPF ¶ 10. After incorporating Gemtronics, Isely continued his business advertising and selling dietary supplements. CCPF ¶ 9.

Since 2004, Respondent Isely and, since 2006, Respondent Gemtronics have advertised and sold the dietary supplement RAAX11 to consumers nationwide through the telephone, and Internet websites, including, *inter alia*, the website www.agaricus.net. CCPF ¶ 14. Since at least 2006, Respondent Isely's name, address and telephone number have been listed in the Internet domain registration for the domain "agaricus.net" as the domain's registrar and its administrative and technical contact. CCPF ¶ 13.

B. Deceptive Advertising Claims for RAAX11

Through the advertising claims found on www.agaricus.net, as well as other claims found elsewhere in the website, Respondents have made both express and implied representations that RAAX11 is effective and/or is scientifically proven to be effective in preventing, treating or curing various types of cancer. CCPF ¶ 15.

- 1. Claims that RAAX11 is scientifically proven effective as a treatment or cure of various types of cancer, including but not limited to leukemia, and cancers of the breast, brain, lung, bowel, larynx, and pancreas CCPF ¶ 16.**

Two webpages found on www.agaricus.net contain similar representations that RAAX11 has been proven effective as a treatment or cure of "human cancers," including, but not limited to leukemia, and cancers of the breast, brain, lung, bowel, larynx, and pancreas:

Has a cancer killer been discovered?

RAAX11 Extract . . .

Brazilian scientists have discovered a tropical plant substance that holds great promise in the fight against various types of cancer. . . .

Scientists report that during laboratory tests the substance destroyed cancer cells that had been resistant to treatment up to now. This is a rare occurrence. This substance is so promising it is being kept under wraps at present.

CCPF ¶ 17.

Even very resistant Leukemia cells die off

The successful lab tests were carried out on cells from breast- brain- lung- bowel- larynx- and pancreas tumors. “What has been most surprising to us, is the fact that besides these cancer cells, leukemia cells that are normally resistant to a lot of medicines and methods of treatment, were also killed” reported the scientists. It was initially questioned whether the substance, obtained from the Chrysobalanus Icacó plant was suited for the treatment of human cancers, but the results showed that it worked with 90% of the patients.

CCPF ¶ 18.

In addition to the representation regarding breast cancer, above, another webpage on the website contains the claim that RAAX11 has been scientifically proven effective in treating or curing breast cancer:

Breast Cancer Patients in remission (2006) 621 out of 749 People
in remission taking the RAAX11 protocol

* * *

RAAX11 Offers New Hope for an Alternative Breast Cancer Treatment

In a recent study, 91 women who were suffering from breast cancer at stage IIIb or IV took part in our RAAX11 protocol. By April 2004, 41 women had totally recovered, 23 women were in remission, 27 were stable, and only 9 had not survived, a survival rate of 91.27%.

CCPF ¶ 19.

A fourth webpage on www.agaricus.net contains a representation that RAAX11 is effective in treating leukemia:

B-Cell Chronic Lymphocytic Leukemia

Patient, m, 54, in remission taking the RAAX11 protocol.
CCPF ¶ 20.

2. Claim that RAAX11 is scientifically proven effective in preventing cancer, including but not limited, to uterine cancer CCPF ¶ 21.

Beneath the webpage representations, noted above, that “scientists have discovered a tropical plant substance” found to be effective in “during laboratory tests,” the claim is made in that “ABM” (*agaricus blazei murill* mushrooms), one of the two ingredients in RAAX11, has been proven effective in the prevention of cancer, particularly uterine cancer:

Anti cancer effect: ABM contains natural steroids, known for it’s anti cancer effect. . . . It is particularly effective in prevention of uteran cancer.
CCPF ¶ 21.

III. NO SCIENTIFIC EVIDENCE SUPPORTS THE RAAX11 CANCER CLAIMS

Complaint Counsel has presented the expert report of Dr. Omer Kucuk, the FTC’s expert in this case. CCPF ¶ 22. Dr. Kucuk is an expert in the fields of cancer research and treatment, and in the use of botanical compounds on cancer patients. CCPF ¶ 23. Dr. Kucuk is Board Certified in Medical Oncology with the American Board of Internal Medicine. CCPF ¶ 24. Dr. Kucuk has been practicing in the field of medical oncology for over 27 years. CCPF ¶ 24. His areas of expertise include cancer prevention, nutrition and cancer, chemoprevention, chemotherapy, medical oncology and clinical trials. CCPF ¶ 24. Dr. Kucuk conducts clinical research treating cancers of the prostate, bladder, kidney and testis. CCPF ¶ 25. He has authored or co-authored approximately 125 articles published in peer-reviewed scientific journals and more than 20 published book chapters and reviews. CCPF ¶ 26.

Dr. Kucuk’s expert report states that cancer is not a single disease but many different diseases, and there is no known treatment that is generally accepted as effective for all forms of cancer. CCPF ¶ 27. According to Dr. Kucuk, to support cancer treatment claims for a product,

qualified experts in the field of oncology would require such claims to be supported by well-conducted, placebo-controlled, randomized, double-blind, clinical trials demonstrating the product's efficacy for the specific type(s) of cancer for which the claims are made. CCPF ¶ 28.

Dr. Kucuk's expert report includes a review of the RAAX11 product label, the documents submitted by Respondents as substantiation for the RAXX11 product claims, and his own independent search of the existing scientific literature. CCPF ¶ 29. It is Dr. Kucuk's expert opinion that the existing body of scientific literature does not provide competent and reliable evidence that RAAX11, or either of its ingredients *Chrysobalanus icaco* ("icaco") and *Agaricus blazei murill* ("agaricus"), alone or in combination, has been scientifically proven to, or effectively can prevent, treat or cure any form of cancer. CCPF ¶ 30.

A. No Scientific Evidence on RAAX11 or Its Ingredients on Cancer Patients

Dr. Kucuk reported that he found no published scientific literature evaluating either RAAX11 or evaluating the combination of *icaco* and *agaricus* as a cancer treatment. CCPF ¶ 31. Specifically, Dr. Kucuk found no published scientific literature evaluating the efficacy of RAAX11 or any clinical trial data with RAAX11. CCPF ¶ 32. Further, Dr. Kucuk's search of the published scientific literature revealed no articles about the efficacy of taking the combination of *icaco* and *agaricus* as a cancer treatment, or even looking at potential mechanisms of anticancer activity. CCPF ¶ 33. In examining the ingredients in RAAX11 separately, Dr. Kucuk found no published studies that evaluate *icaco* extract as a cancer treatment nor did he find a single human or animal study of *icaco*. CCPF ¶ 34. While Dr. Kucuk found eight publications reporting the results of clinical or human studies using *agaricus*, he found no reports of properly conducted clinical trials regarding the efficacy of *agaricus* extract in patients with cancer. CCPF ¶ 35.

Further, specifically evaluating the scientific literature in light of the allegations contained in the Commission's Complaint, Dr. Kucuk reported that there is no scientific support for the claims that: (1) reliable scientific evidence demonstrates that RAAX11 is effective in the prevention, treatment, and cure of cancer; (2) RAAX11 is effective in the treatment and cure of various types of cancer, including, but not limited to leukemia and cancers of the breast, brain, lung, larynx, pancreas, and bowel; and (3) RAAX11 is effective in the prevention of cancer, including, but not limited to uterine cancer. CCPF ¶ 36.

B. Respondents Provided No Competent and Reliable Evidence to Support the Claims for RAAX11

Respondents submitted three articles downloaded from the Memorial Sloan Kettering database regarding agaricus which were analyzed by Dr. Kucuk. CCPF ¶ 37. After reviewing these materials, Dr. Kucuk concluded that the materials do not provide any data from randomized, placebo-controlled clinical trials with cancer patients and therefore, they do not provide any additional relevant clinical data to substantiate or otherwise support the cancer claims challenged in the Commission's Complaint for RAAX11. CCPF ¶ 37.

IV. RESPONDENTS HAVE VIOLATED SECTION 5 AND 12 OF THE FTC ACT

A. Respondents' Advertising Claims are Facially Clear and Material

Respondents' advertising claims for RAAX11 clearly misrepresent that the product is effective in preventing, treating and curing cancer. The *prima facie* evidence of what representations an advertisement conveys to reasonable consumers is the advertisement itself. *FTC Policy Statement on Deception*, 103 F.T.C. 174, 176 (1984) (*Deception Statement*); *see, e.g., Telebrands Corp.*, 140 F.T.C. 279, 290 (2005); *Novartis Corp.*, 127 F.T.C. 580, 680 (1999), *aff'd*, 223 F.3d 783 (D.C. Cir. 2000); *Stouffer Foods Corp.*, 118 F.T.C. 746, 798 (1994); *Kraft*,

Inc., 114 F.T.C. 40, 121 (1991), *aff'd*, 970 F.2d 311 (7th Cir. 1992), *cert. denied*, 507 U.S. 909 (1993). When the language of an advertisement is clear enough to permit the Commission to conclude with confidence that the ad can reasonably be read to contain a particular claim, a facial analysis, alone, will permit the Commission to conclude that the ad contains the claim. *Stouffer*, 188 F.T.C. at 798, *citing Kraft, Inc.*, 114 F.T.C. at 121 and *In re Thompson Medical Co.*, 104 F.T.C. 648, 789 (1984), *aff'd*, 791 F.2d 189 (D.C. Cir. 1986), *cert. denied*, 479 U.S. 1086 (1987). Thus, where the language in the challenged advertisement is clear, the Commission may rely on the ad itself and need not resort to extrinsic evidence to determine if the claim is conveyed to reasonable consumers. *Novartis*, 127 F.T.C. at 680; *see Stouffer*, 118 F.T.C. at 798; *Deception Statement*, 103 F.T.C. at 176.

Respondents' advertising claims are material, not only because they are express, but also because they relate to the purpose, safety, and/or efficacy of RAAX11, a product advertised specifically as a cancer prevention, treatment and cure. An advertisement is deceptive if it contains a representation or omission of fact that is likely to mislead consumers acting reasonably under the circumstances, and that representation or omission is material to consumers' purchasing decisions. *Deception Statement*, 103 F.T.C. at 175; *see, e.g., Telebrands*, 140 F.T.C. at 290; *Novartis*, 127 F.T.C. at 679; *Stouffer*, 118 F.T.C. at 798; *Kraft*, 114 F.T.C. at 120. Advertising claims are also presumed to be material if they are express or if they pertain to the purpose, safety, or efficacy of the product. *Deception Statement*, 103 F.T.C. at 182, *see, e.g., Telebrands Corp.*, 140 F.T.C. 379, 450 (Initial Decision 2004).

B. Respondents' Claims are False and Unsubstantiated

The Commission has consistently held that objective claims made without a reasonable basis constitute a deceptive practice in violation of Section 5. *FTC Policy Statement Regarding*

Advertising Substantiation, 104 F.T.C. 839 (1984) (*Substantiation Statement*); *see, e.g., Automotive Breakthrough Sciences, Inc.*, 126 F.T.C. 229, 293 & 293 n.20 (1998); *Jay Norris, Inc.*, 91 F.T.C. 751, 854 (1978), *aff'd as modified*, 598 F.2d 1244 (2d Cir. 1979), *cert. denied*, 444 U.S. 980 (1979). What constitutes a reasonable basis is an objective standard: advertisers must possess at least the level of substantiation expressly or impliedly claimed in the advertisement. *See Honeywell, Inc.*, 126 F.T.C. 202, 204-05 (1998); *FTC v. Natural Solution, Inc.*, No. CV 06-6112-JFW, 2007 U.S. Dist. LEXIS 60783, at *10 (C.D. Cal. Aug. 7, 2007) (citing *FTC v. U.S. Sales Corp.*, 785 F. Supp. 737, 748 (N.D. Ill. 1992)).

For health and safety claims, advertisers must possess competent and reliable scientific evidence substantiating their claims in order to have a reasonable basis for such claims. *See FTC v. National Urological Group, Inc.*, No. 1:04-CV-3294-CAP, 2008 U.S. Dist. LEXIS 44145, at *77 (N.D. Ga. June 4, 2008) (granting FTC's summary judgment motion, court finds safety and efficacy claims for dietary supplements must be substantiated by competent and reliable scientific evidence); *Natural Solution*, 2007 U.S. Dist. LEXIS 60783, at *11-13 (granting FTC's summary judgment motion, court requires competent and reliable scientific evidence for cancer prevention and treatment claims for product); *FTC v. QT, Inc.*, 448 F. Supp. 2d 908, 961 (N.D. Ill. 2006) *aff'd*, 512 F.3d 858 (competent and reliable scientific standard applied for evidence that bracelet relieves pain). Competent and reliable scientific evidence is typically defined as tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results. *See, e.g., Brake Guard Products, Inc.*, 125 F.T.C. 138 (1998); *ABS Tech Sciences, Inc.*, 126 F.T.C. 229 (1998).

To provide adequate substantiation to support the truthfulness of health-related efficacy claims, courts have consistently required double-blind, placebo-controlled studies. *See, e.g., FTC v. SlimAmerica, Inc.*, 77 F. Supp. 2d 1263, 1274 (S.D. Fla. 1999) (double-blind study of the combination of product's ingredients required to support product claims); *FTC v. Sabal*, 32 F. Supp. 2d 1004, 1008-09 (N.D. Ill. 1998) (study found not valid as substantiation, in part, because neither blinded nor placebo controlled); *FTC v. QT, Inc.*, 448 F. Supp. 2d at 962 (medical claims for bracelet required a well-conducted, placebo-controlled, randomized, double-blind study).

The product, RAAX11, is dietary supplement that is advertised and sold as a clinically proven treatment, prevention and cure for cancer. CCPF ¶ 15-21. These representations relate to health and safety and, thus, require substantiation consisting of competent and reliable scientific evidence. Complaint Counsel's expert, Dr. Kucuk, concludes that to support cancer treatment claims for a product, such as RAAX11, qualified experts in the field of oncology require randomized, well-controlled, and double-blinded clinical trials demonstrating a product's efficacy for the specific type(s) of cancer for which the claims are made. CCPF ¶ 28. After examining the substantiation submitted by Respondents, as well as examining the current state of peer-reviewed scientific literature regarding RAAX11 and its ingredients, it is Dr. Kucuk's expert opinion that there is no competent and reliable scientific evidence that RAAX11 effectively can, or is scientifically proven to, prevent, treat, and cure cancer. CCPF ¶¶ 30, 36, 37. Respondents, therefore, lacked a reasonable basis for their advertising claims for RAAX11, and accordingly, have violated Sections 5 and 12 of the FTC Act.

V. THE WEBSITE IDENTIFIED GEMTRONICS AND ISELY AS THE EXCLUSIVE SOURCE FOR RAAX11 IN THE UNITED STATES

In numerous instances, the Internet website www.agaricus.net advertised Respondents as

the only source for products in the United States . CCPF ¶ 38. As detailed below, the website instructed consumers to call Respondent Isely personally and/or telephone numbers belonging to Respondent Isely for product ordering or information about RAAX11. CCPF ¶ 38. The website also indicated that credit card payments for orders on the website would be made directly to Gemtronics or to Takesun USA. CCPF ¶ 39.

A “Shopping Cart for USA only” webpage from www.agaricus.net, dated April 2, 2004, advertises that consumers can purchase products from an “FDA registered Warehouse in NC/USA” by telephoning Respondents directly: “Retail prices valid only for USA. Phone 1 828 369 7590 (other countries contact the national agent).” CCPF ¶ 41. This webpage further indicates that consumers can purchase from Respondents by credit card by authorizing “Takesun USA to charge my credit card . . .” and notes “[b]y pressing the ORDER confirmations button below, I agree to pay Takesun do Brasil (GEMTRONICS) For any question call 1 828-369-7590.” CCPF ¶ 42.

Beginning in 2004 and continuing on into 2008, the website www.agaricus.net advertised and offered for sale RAAX11 in the United States by making cancer-related claims for the product. CCPF ¶ 43. Here, again, the website advertised Respondents as the websites sole source for ordering RAAX11 in the United States. CCPF ¶ 44. One of these webpages, dated May 9, 2004, advertised that RAAX11 can be ordered from an “FDA registered Warehouse in USA.” CCPF ¶ 45. Another webpage, dated February 10, 2005, advertises the sale of RAAX11 exclusively through Respondents either by credit card authorizing “Takesun USA to charge my credit card” and agreeing to pay “GEMTRONICS” or by calling Respondent Isely’s telephone number “[f]or any question call 1 828-369-7590.” CCPF ¶ 46.

A home webpage advertising RAAX11 from www.agaricus.net dated January 7, 2006,

contains a box with the title: "Prostate Cancer Patient - now cancer free" and directs consumers to call "Bill at 828-369-7590." CCPF ¶ 47. Another home webpage advertising RAAX11, dated August 15, 2007, provides an additional telephone number belonging to Respondent Isely as the only number to call to order: "Chemo and Radiation not working. This could be the alternative treatment. Call now 1 866 944 7359 for US information" and "USA only Order Information call 866 944 7359." CCPF ¶ 48. Similarly, two webpages from www.agaricus.net, dated August 15, 2007, and January 3, 2008, show only Respondent Isely's telephone number, 828-369-7590, for consumers to call in the United States for information about RAAX11. CCPF ¶ 49. In fact, this webpage directs American consumers to call Respondent Isely: "if you are living in the US, just call Mr. Isely and he will explain how it works." CCPF ¶ 49.

A more recent www.agaricus.net webpage advertising RAAX11 from January 3, 2008, specifically instructs consumers:

Contact:
Intl. Tel.xx1 828-369-7590
US Tel. (Free) 866-944-7359
FAX. 828-369-5861

CCPF ¶ 50.

Each of the three telephone numbers belongs to Respondent Isely. CCPF ¶ 50. This webpage goes on to describe a clinical study using RAAX11 for treating breast cancer and again directs American consumers to call Respondent Isely: "If you would like to find out how you too can participate in our ongoing study in the USA, call 828-369-7590." CCPF ¶ 51.

VI. RESPONDENTS ARE LIABLE FOR FTC ACT VIOLATIONS

A. Liability of Respondent Gemtronics

The corporate Respondent Gemtronics, by and through its owner, William Isely, violated Sections 5 and 12 of the FTC Act. Gemtronics fulfilled orders for RAAX11 made on the website

www.agaricus.net. CCPF ¶¶ 52, 56. On January 3, 2008, and again on January 28, 2008, an FTC Investigator purchased RAAX11 from the website www.agaricus.net. CCPF ¶ 53. A confirmation webpage from the purchase stated: “Your Credit Card is charged using a SSL secured server. On your statement will appear “GEMTRONICS SECURE PAYMENTS.” CCPF ¶ 54. The two packages of RAAX11 received by the FTC were sent by Gemtronics and included Gemtronics invoices indicating that payment had been made to the company, one of which stated that Gemtronics was responsible for retail sales. CCPF ¶ 55. The promotional literature in one package included a Gemtronics brochure stating “for more information . . . go to www.agaricus.net” and “click on USA sales” and providing telephone and email contact information for Gemtronics. CCPF ¶ 57.

While admitting at trial that Gemtronics no longer conducts business, Respondent Isely testified that he has not dissolved the corporation. CCPF ¶ 58. Accordingly, Gemtronics, Inc., the Corporate Respondent, should be held liable for violations of the FTC Act.

B. Individual Liability of Respondent Isely

The Commission and the courts examine, separately or in combination, a number of factors when determining individual liability: the unlawful practices involved; the respondent’s involvement with the practices; the type of corporate entity; the respondent’s ownership interest; the corporate office (if any) held; and the influence he exercised over corporate affairs. *Telebrands Corp.*, 140 F.T.C. at 450; *National Housewares*, 90 F.T.C. 512, 598 (1977). The standard for determining whether an individual is subject to injunctive relief for the acts of the corporation is whether the individual participated directly in the acts or practices or had authority to control the company involved in the unlawful practices. *See FTC v. Cyberspace.com, LLC*, 453 F.3d 1196, 1202 (9th Cir. 2006); *FTC v. Publishing Clearing House, Inc.*, 104 F.3d 1168,

1170 (9th Cir. 1997); *FTC v. Amy Travel Serv., Inc.*, 875 F.2d 564, 573 (7th Cir. 1989); *FTC v. Gem Merchandising Group*, 87 F.3d 466, 470 (11th Cir. 1996) (citation omitted); *In re Nat'l Credit Mgmt.*, 21 F. Supp.2d at 461; *FTC v. Nat'l Invention Servs.*, 1997 U.S. Dist. LEXIS 16777, at *12-13. (D.N.J. Aug. 11,1997).

Gemtronics is a closely-held corporation and Respondent Isely is its owner and manager. CCPF ¶59. Both the courts and the Commission have held that it is appropriate to hold the owner of a closely-held corporation individually liable because his inclusion in the order would be necessary to make the order fully effective in preventing future violations of the law. *See, e.g., FTC v. Standard Education Society*, 302 U.S. 112, 119-20 (1937) (managers and sole stockholders held liable); *Fred Meyer, Inc. v. FTC*, 359 F.2d 351, 367-68 (9th Cir.), *cert. denied*, 308 U.S. 908 (1967) n.60.

Respondent Isely clearly is individually liable in this case because he was actively involved in and controlled every facet of Gemtronics' business, whether running the business as a sole proprietorship or as a corporation. Respondent Isely ran Gemtronics business from his home and controlled the business's bank account. CCPF ¶ 60. Further, Respondent Isely individually participated in the acts and practices at issue in this matter. CCPF ¶ 61. Isely acknowledged personally fulfilling the two orders for RAAX11 that were placed on the www.agaricus.net website by the FTC. CCPF ¶ 56. Isely was personally identified on the Gemtronics packages, invoices, and in the promotional literature received by the FTC. CCPF ¶ 62.

Respondent Isely also played an integral part in the website www.agaricus.net as the domain's registered contact and as website's "front man" for RAAX11. CCPF ¶ 13.

First, since at least 2006, Respondent Isely was identified as the registrant for the domain name “agaricus.net” on internet searches of WHOIS domain name registries. CCPF ¶ 13.

Specifically, his name, address and telephone number were listed on the “agaricus.net” domain name registration as the domain’s registrar and its administrative, technical, and zone contact.

CCPF ¶ 13. Respondent Isely received notice that the domain name “agaricus.net” as well as other domain names were registered to him at his home address by means of domain renewal notices and annual website search engine listings mailed to his home. CCPF ¶¶ 63, 64.

However, Respondent Isely admitted that he ignored or did not follow up on these notices.

CCPF ¶ 65. It was not until April 2008, when the FDA sent a “Warning Letter” to Respondents Gemtronics and Isely notifying them of potential law violations regarding, *inter alia*, their advertising claims for RAAX11 on their website www.agaricus.net, that Respondent decided to change the domain registration. CCPF ¶¶ 66, 67.

Second, Respondent Isely was prominently featured throughout the website and his name and telephone number were included on a number of webpages on www.agaricus.net as a contact for consumers to purchase RAAX11, to obtain product information, and to participate in an “ongoing study in the USA” of RAAX11. CCPF ¶ 68. Respondent Isely was also aware that his name, his telephone numbers, and his health history were being used on the website www.agaricus.net, but he testified that he did nothing about it and did not challenge these representations on the website. CCPF ¶ 69. Further, Respondent Isely acknowledged that he received telephone calls from consumers inquiring the website’s advertising regarding participating “in our ongoing study in the USA” of RAAX11, when he knew there was no such study and that this was an advertising ploy. CCPF ¶ 70. Respondent Isely also admitted that he

frequently visited the website www.agaricus.net – going to the site’s home page and navigating to the website’s sales pages check its prices for RAAX11. CCPF ¶ 71. In fact, Respondent Isely admitted that consumers could purchase RAAX11 on the website www.agaricus.net using a credit card, and that Isely would receive the payment. CCPF ¶ 72.

Finding Respondent Isely individually liable is necessary in order to ensure fully effective relief for the deceptive practices alleged in the Commission’s Complaint. The courts and the Commission have held that, when liability is based on personal participation in the unlawful acts, nothing more need be shown. *See, e.g., Removatron Int’l Corp.*, 111 F.T.C. 206, 290 (1988), *aff’d*, 884 F.2d 1489 (1st Cir. 1989); *FTC v. NCH*, 1995-2 Trade Cas. (CCH) ¶71,114, at 75,351 (D. Nev. Sept. 6,1995). Given Respondent Isely’s creation of and control over the practices of the corporate Respondent Gemtronics, and based upon his personal participation in the website and sales emanating from it, Respondent Isely should be held individually liable for violations of Sections 5 and 12 of the FTC Act.

C. Respondents Disseminated or Caused to be Disseminated the Challenged Representations

Respondents do not challenge either the content or interpretation of the www.agaricus.net website advertisements challenged in the Commission’s complaint. Rather, Respondents state that “a third party, not named in this action, disseminated or cause to be disseminated advertisements” through the website and that they believe that this third party is Takesun do Brasil. CCPF ¶ 73. Thus, Respondents contest any liability for the dissemination of the advertising claims for RAAX11 by denying their association with the website www.agaricus.net, even though Respondents were the sole beneficiaries of the website’s challenged claims and took in significant consumer sales of the product. CCPF ¶ ¶ 74, 75.

Section 12(a) of the FTC Act states in relevant part:

It shall be unlawful for any person, partnership, or corporation to disseminate, or cause to be disseminated, any false advertisement. 15 U.S.C. §52(a)

While there is case law examining the issue of liability for dissemination of advertising, there is a dearth of cases examining what constitutes disseminating or causing to be disseminated. In examining the term “disseminated,” the court in *Mueller v. United States*, rejected the defendant’s argument that he was not liable under the FTC Act because the Act is “applicable only if the false advertising is disseminated the defendant himself.” 262 F.2d 443, 466 (5th Cir. 1958). Here, the court noted that it was not “necessary that the false advertising be directly disseminated by the respondents. The statute makes it unlawful for the respondents to cause such false advertising to be disseminated. Under these plain, unambiguous provisions of the statute, petitioners’ contentions that they . . . did not personally disseminate any false advertisement do[es] not constitute a defense to the action.” *Mueller v. United States*, 262 F.2d at 466 (citing *In Shafe v. FTC*, 256 F.2d 661, 664 (6th Cir. 1956)) In examining the “cause to be disseminated” provision of the statute, the court further noted that the “term ‘cause’ is in the statute without qualification relating to the advertisers state of mind” and that “the statute holds him liable for the natural consequences of his act regardless of his intentions.” *Mueller v. United States*, 262 F.2d at 466.

The issue of liability for dissemination of advertisements has more recently arisen in Commission cases regarding advertising agency liability. An advertising agency may be held liable for a deceptive advertisement if the agency was 1) an active participant in the preparation of the advertisement and 2) if it knew or should have known that the advertisement was deceptive. *Standard Oil Co.*, 84 F.T.C. 1401, 1475 (1974), *aff’d and modified*, 577 F.2d 653 (9th

Cir. 1978). For instance, in *Colgate-Palmolive Co.*, the Commission ordered both Colgate-Palmolive and its advertising agency to cease and desist from misrepresenting claims for shaving cream. 59 F.T.C. 1452 (1961), *order set aside on other grounds*, 310 F.2d 89 (1st Cir. 1962), *order reinstated*, 380 U.S. 374 (1965). Although the agency argued that it should not be liable since it merely acted as Colgate-Palmolive's agent in preparing and placing commercials, the Commission found the agency's participation in the creation and dissemination of the commercials sufficient to establish liability.

In *Porter & Dietsch*, the Commission found a retailer who took no active role in the creation of the challenged advertisements for a diet pill and was unaware that the representations in the ads it had been provided for a product sold by the retailer were false or unsubstantiated liable for disseminating false advertisement. 90 F.T.C. 770 (1977), *aff'd and modified*, 605 F.2d 294 (7th Cir. 1979), *cert. denied*, 445 U.S. 950. The Commission noted that under Section 12 of the Act it is unlawful to "disseminate, or cause to be disseminated" false advertisements and the fact that the retailer was not a principle in the preparation of the ads did not preclude liability. *Porter & Dietsch*, 90 F.T.C at 875-76.

In this instant matter, assuming *arguendo* that Respondents did not push the proverbial button that launched the challenged advertising claims into cyberspace, Respondents, nonetheless, 1) directly participated in and were the beneficiaries of the deceptive claims and 2) had knowledge that the advertisements were deceptive. CCPF ¶ 91.

As note above, Respondents were the designated website outlet in the United States for sales of RAAX11 and the website's sole beneficiaries for US sales. CCPF ¶ 74. Consumers could purchase RAAX11 from Respondents either by calling Isely's telephone number listed on the website or through the website via credit card. CCPF ¶¶ 72, 80, 81.

Since 2000, Respondents were closely associated and in near constant communication with Takesun, the manufacturer of RAAX11. CCPF ¶¶ 76, 77. Respondents did not import products from any company other than Takesun. CCPF ¶ 78. In fact, Respondent Isely had registered his home as an FDA warehouse to receive and store Takesun products. CCPF ¶ 78. Moreover, Respondent Isely admitted redesigned the labels of Takesun products he imported to facilitate their clearance into the United States by the FDA. CCPF ¶ 79.

Respondents had a profitable business relationship with Takesun; purchasing \$5,000 to \$8,000 per month of various dietary supplements for importation into the United States. CCPF ¶¶ 75, 76. Indeed, to highlight his association with Takesun, Respondent Isely also did business under the name Takesun USA. CCPF ¶¶ 6, 82, 83. He prominently displayed the name Takesun USA in a brochure that he created so that customers would recognize his affiliation with Takesun. CCPF ¶ 82. He also used the name Takesun USA to establish a wholesale business in which he sought to sign up distributors to sell Takesun products, such as RAAX11. CCPF ¶ 83. Respondents' customer invoice and Distributor Introductory Package identified Respondent Isely as the General Manager of Takesun USA. CCPF ¶ 84.

Respondent Isely knew that the advertisements disseminated on the website were deceptive and that the domain name "agaricus.net" was registered to him. CCPF ¶¶ 65, 70, 88. He also knew that his name and telephone number were on various webpages of the website www.agaricus.net, and were being used to sell RAAX11.² CCPF ¶ 69. Respondent Isely

² It is illustrative to note that, under the standard set forth for individual liability in seminal FTC cases, such as *FTC v. Amy Travel*, 875 F.2d 564 (7th Cir.), *cert. denied*, 493 U.S. 594 (1989), to satisfy the knowledge requirement, the Commission need not demonstrate that an individual defendant possessed the intent to defraud. *FTC v. Bay Area Business Council*, 423 F. 3d 627, 636 (7th Cir. 2005); *FTC v. Freecom Communications, Inc.*, 401 F. 3d 1192, 1207 (10th Cir. 2005); *FTC v. Think Achievement*, 144 F. Supp. 2d 993, 1012 (N.D. Ind. 2000); *FTC v. Jordan Ashley*, 1994-1 Trade Cas. (CCH) ¶ 70,570, 72,096 (S.D. Fla. 1994) (citing *FTC v. Amy Travel*, 875 F.2d at 573-74). Nor must the Commission demonstrate that the defendant had actual knowledge of the

VII. THE PROPOSED ORDER IS THE APPROPRIATE RELIEF AGAINST RESPONDENTS

The Commission has previously dealt with bogus cancer claims for products in cases that have resulted in consent orders with requirements similar to those in the proposed order Complaint Counsel seeks here. *See, e.g., In re Native Essence Herb Co.*, No. 9328 (F.T.C. Jan. 29, 2009) (order withdrawing matter from adjudication for the purpose of considering a proposed consent agreement); *FTC v. Westberry Enterprises, Inc.*, 2008 F.T.C. LEXIS 99 (F.T.C. Sept. 18, 2008); *In re Jenks*, 2008 F.T.C. LEXIS 94 (F.T.C. Sept. 18, 2008); *FTC v. Natural Solution, Inc.*, No. CV 06-06112-JFW OTLx) (C.D. Cal. Sept. 4, 2007) (judgment and permanent injunction). Accordingly, Complaint Counsel respectfully requests that the Court enter the proposed order accompanying the Complaint. The undisputed facts and the law warrant the relief sought here. *See Telebrands Corp. v. FTC*, 457 F.3d 354, 358 (4th Cir. 2006) (“Congress has given the FTC primary responsibility for devising orders to address... deceptive practices, and the FTC has broad discretion to do so”); *FTC v. Colgate-Palmolive*, 380 U.S. at 395 (“reasonable for the (FTC) to frame its order broadly enough to prevent respondents from engaging in similar illegal practices in future advertisements”).

The proposed order would prohibit Respondents from making the types of misrepresentations challenged in the Complaint and provides fencing-in relief, requiring Respondents to possess competent and reliable scientific evidence supporting future claims about the health benefits, performance, safety, or efficacy of any dietary supplement, food, drug, or other health-related product, service, or program. The proposed order also contains the standard provisions regarding record-keeping, dissemination of the order to officers and employees, prior notification of corporate changes, filing compliance reports, and sunseting of

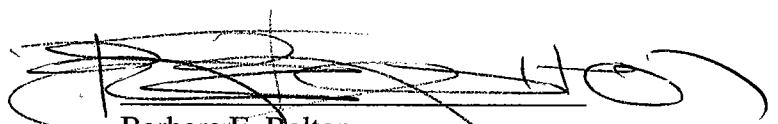
the order.

VIII. CONCLUSION

The evidence at trial demonstrated that Respondents violated Sections 5 and 12 of the FTC Act by making false and unsubstantiated claims on the website www.agaricus.net that RAAX11 is effective in preventing, treating, or curing various types of cancer and that these claims are proven by reliable scientific evidence.

Dated: July 21, 2009

Respectfully submitted,



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**UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION
OFFICE OF ADMINISTRATIVE LAW JUDGES**

In the Matter of
GEMTRONICS, INC.,
a corporation, and
WILLIAM H. "BILL" ISELY,
individually and as the owner
of Gemtronics, Inc.

DOCKET No. 9330

Public Document

**COMPLAINT COUNSEL'S POST TRIAL
PROPOSED FINDINGS
OF FACT AND CONCLUSIONS OF LAW**

I. COMPLAINT COUNSEL'S PROPOSED FINDINGS OF FACT

Respondents' Business Operations

1. Respondent Gemtronics, Inc. ("Gemtronics") is a North Carolina corporation with its principal office or place of business at 964 Walnut Creek Road, Franklin, North Carolina 28734. (Complaint Counsel and Respondents' Joint Trial Exhibit (hereinafter "JX __") 8 (Respondents' Answer to FTC's Complaint, dated October 10, 2008 (hereinafter "Answer") ¶ 1).
2. Respondent William H. Isely ("Isely") resides at 964 Walnut Creek, Franklin, North Carolina, 28734. (JX 8 (Answer) ¶ 2; Liggins, Tr. 126).
3. Starting in late least 2004, Respondent Isely was operating a business from his residence that advertised and sold dietary supplements to consumers nationwide through mail order, telephone, the Internet. (Isely, Tr. 180-82, 187; JX 9 (Respondent William Isely's Answers to Interrogatories, February 3, 2009 (hereinafter "Isely, Ints.)) # 1, 2, 8, Ex. A; JX 12 (Deposition of William H. Isely, February 4, 2009 (hereinafter "Isely, Dep.)) at 12-13).
4. Isely ran his dietary supplement business as a sole proprietor under the assumed name Gemtronics. (Isely, Tr. 182; JX 12 (Isely, Dep.) at 19).
5. In 2000, Respondent Isely began to purchase dietary supplements wholesale from a Brazilian manufacturer named Takesun do Brasil Ind. Com. e Exp. Ltda. ("Takesun") for resale to consumers. (Isely, Tr. 183-86, 337; JX 12 (Isely, Dep.) at 16; JX 55; JX 69).

6. In 2001, Respondent Isely established a business under the name Takesun USA (“Takesun USA”) to import Takesun products into the United States from Brazil for resale to consumers. (Liggins, Tr. 81-82; JX 9 (Isely, Ints.) # 1, 8; JX 12 (Isely, Dep.) at 17-18, 61-62, 67-68; JX 48).
7. In 2003, Respondent Isely also registered his residence as an FDA approved warehouse to import and store Takesun products for resale. (Isely, Tr. 202-06; JX 9 (Isely, Ints.) # 13); JX 12 (Isely, Dep.) at 19-20, 92-93).
8. Respondent Isely incorporated Gemtronics in North Carolina in September 2006, making his home in Franklin, North Carolina the corporation’s principal place of business and listing himself as the corporation’s registered agent. (Liggins, Tr. 58-60; 127-28; Isely, Tr. 215, 323-24; JX 8 (Answer) ¶¶ 1, 2; JX 9 (Isely, Ints.) # 2; JX 12 (Isely, Dep.) at 31, 99-100; JX 13).
9. After incorporating Gemtronics, Inc., he continued his business advertising and selling dietary supplements. (Isely, Tr. 182, 215-16; JX 9 (Isely, Ints.) # 1, 2).
10. Respondent Isely holds himself out as the owner, registered agent and general manager of Gemtronics. (Liggins, Tr. 81-82; Isely, Tr. 287-88; JX 9 (Isely, Ints.) # 1; JX 48).
11. In 2004, Respondent Isely began to offer for sale and sell the Takesun product, RAAX11, to consumers and importing RAAX11 from Takesun about every four months. (Isely, Tr. 182; JX 9 (Isely, Ints.) # 3; JX 12 (Isely, Dep.) at 19-20, 31-32).
12. In 2004, he sold 19 bottles of RAAX11 at the price of \$400 per bottle. Thereafter, from 2005 through 2008, Respondents sold approximately 1115 bottles of RAAX11 at the price of \$120 per bottle. Respondent Isely charged shipping and handling fees of \$15.00. (Liggins, Tr. 151, 172-173; Isely, Tr. 237-38; JX 9 (Isely, Ints.) # 5; JX 48; JX 56).
13. Since at least 2006, Respondent Isely was identified as the registrant for the domain name “agaricus.net” on internet searches of WHOIS domain name registries. Specifically, his name, address and telephone number have been listed on the “agaricus.net” domain name registration as the domain’s registrar and its administrative, technical, and zone contact. (Liggins, Tr. 63-66, 121, 125-26; Isely, Tr. 241-44; JX 9 (Isely, Inst.) # 1; JX 12 (Isely, Dep.) at 28; JX 16; JX 17).
14. Since 2004, Respondent Isely and, since 2006, Respondent Gemtronics have advertised and sold the dietary supplement RAAX11 to consumers nationwide through telephone and Internet websites, including, *inter alia*, the website www.agaricus.net. (Liggins, Tr. 75-91; Isely, Tr. 182; JX 2; JX 3; JX 9 (Isely, Ints.) # 3; JX 12 (Isely, Dep.) at 34-35, 38, 39-40, 70, 120-24; JX 43-JX 60).

Deceptive Advertising Claims for RAAX11

15. Through the advertising claims found on www.agaricus.net, as well as other claims found elsewhere in the website, Respondents have made both express and implied representations that RAAX11 is effective and/or is scientifically proven to be effective in preventing, treating or curing various types of cancer. (JX 7 (Complaint)).
16. The website contains claims that RAAX11 is scientifically proven effective as a treatment or cure of various types of cancer, including but not limited to leukemia, and cancers of the breast, brain, lung, bowel, larynx, and pancreas. (JX 7 (Complaint) at Exs. A-B).
17. Two webpages found on www.agaricus.net contain similar representations that RAAX11 has been proven effective as a treatment or cure of “human cancers,” including, but not limited to leukemia, and cancers of the breast, brain, lung, bowel, larynx, and pancreas: **“Has a cancer killer been discovered? RAAX11 Extract . . . Brazilian scientists have discovered a tropical plant substance that holds great promise in the fight against various types of cancer. . . . Scientists report that during laboratory tests the substance destroyed cancer cells that had been resistant to treatment up to now. This is a rare occurrence. This substance is so promising it is being kept under wraps at present.”** (JX 7 (Complaint) at Ex. A (emphasis in original)).
18. Two webpages found on www.agaricus.net contain similar representations that RAAX11 has been proven effective as a treatment or cure of “human cancers,” including, but not limited to leukemia, and cancers of the breast, brain, lung, bowel, larynx, and pancreas: **“Even very resistant Leukemia cells die off** The successful lab tests were carried out on cells from breast- brain- lung- bowel- larynx- and pancreas tumors. ‘What has been most surprising to us, is the fact that besides these cancer cells, leukemia cells that are normally resistant to a lot of medicines and methods of treatment, were also killed’ reported the scientists. It was initially questioned whether the substance, obtained from the Chrysobalanus Icaco plant was suited for the treatment of human cancers, but the results showed that it worked with 90% of the patients.” (JX 7 (Complaint) at Ex. B (emphasis in original)).
19. In addition to the representation regarding breast cancer, above, another webpage on the website contains the claim that RAAX11 has been scientifically proven effective in treating or curing breast cancer: “Breast Cancer Patients in remission (2006) 621 out of 749 People in remission taking the RAAX11 protocol * * * **RAAX11 Offers New Hope for an Alternative Breast Cancer Treatment** In a recent study, 91 women who were suffering from breast cancer at stage IIIb or IV took part in our RAAX11 protocol. By April 2004, 41 women had totally recovered, 23 women were in remission, 27 were stable, and only 9 had not survived, a survival rate of 91.27%.” (JX 7 (Complaint) at Ex. C (emphasis in original)).
20. A fourth webpage on www.agaricus.net contains a representation that RAAX11 is

effective in treating leukemia: “**B-Cell Chronic Lymphocytic Leukemia** Patient, m, 54, in remission taking the RAAX11 protocol.” (JX 7 (Complaint) at Ex. D (emphasis in original)).

21. Beneath the webpage representations that “scientists have discovered a tropical plant substance” found to be effective in “during laboratory tests,” the claim is made in that “ABM” (*agaricus blazei murill* mushrooms), one of the two ingredients in RAAX11, has been proven effective in the prevention of cancer, particularly uterine cancer: “**Anti cancer effect:** ABM contains natural steroids, known for it’s anti cancer effect. . . . It is particularly effective in prevention of uteran (sic) cancer.” (JX 7 (Complaint) at Ex. A (emphasis in original)).

No Scientific Evidence Supports the RAAX1 Cancer Claims

22. Complaint Counsel has presented the expert report of Dr. Omer Kucuk, the FTC’s expert in this case. (JX 1).
23. Dr. Kucuk is an expert in the fields of cancer research and treatment, and in the use of botanical compounds on cancer patients. (JX 1 ¶¶ 1, 9).
24. Dr. Kucuk is Board Certified in Medical Oncology with the American Board of Internal Medicine. Dr. Kucuk has been practicing in the field of medical oncology for over 27 years. His areas of expertise include cancer prevention, nutrition and cancer, chemoprevention, chemotherapy, medical oncology and clinical trials. (JX 1 ¶ 1).
25. Dr. Kucuk conducts clinical research treating cancers of the prostate, bladder, kidney and testis. (JX 1 ¶ 2).
26. He has authored or co-authored approximately 125 articles published in peer-reviewed scientific journals and more than 20 published book chapters and reviews. (JX 1 ¶ 3).
27. Dr. Kucuk’s expert report states that cancer is not a single disease but many different diseases, and there is no known treatment that is generally accepted as effective for all forms of cancer. (JX 1 ¶¶ 15, 32).
28. According to Dr. Kucuk, to support cancer treatment claims for a product, qualified experts in the field of oncology would require such claims to be supported by well conducted, placebo-controlled, randomized, double-blind, clinical trials demonstrating the product’s efficacy for the specific type(s) of cancer for which the claims are made. (JX 1 ¶¶ 32, 34).
29. Dr. Kucuk’s expert report includes a review of the RAAX11 product label, the documents submitted by Respondents as substantiation for the RAXX11 product claims, and his own independent search of the existing scientific literature. (JX 1 ¶¶ 12-14, 16, 19-21, 50).

30. It is Dr. Kucuk's expert opinion that the existing body of scientific literature does not provide competent and reliable evidence that RAAX11, or either of its ingredients *Chrysobalanus icaco* ("icaco") and *Agaricus blazei murill* ("agaricus"), alone or in combination, has been scientifically proven to, or effectively can prevent, treat or cure any form of cancer. (JX 1 ¶¶ 12, 15, 50, 51).

No Scientific Evidence on RAAX11 or its Ingredients on Cancer Patients

31. Dr. Kucuk reported that he found no published scientific literature evaluating either RAAX11 or evaluating the combination of *icaco* and *agaricus* as a cancer treatment. (JX 1 ¶¶ 16, 17).
32. Specifically, Dr. Kucuk found no published scientific literature evaluating the efficacy of RAAX11 or any clinical trial data with RAAX11. (JX 1 ¶ 16).
33. Further, Dr. Kucuk's search of the published scientific literature revealed no articles about the efficacy of taking the combination of *icaco* and *agaricus* as a cancer treatment, or even looking at potential mechanisms of anticancer activity. (JX 1 ¶ 17).
34. In examining the ingredients in RAAX11 separately, Dr. Kucuk found no published studies that evaluate *icaco* extract as a cancer treatment nor did he find a single human or animal study of *icaco*. (JX 1 ¶ 18).
35. While Dr. Kucuk found eight publications reporting the results of clinical or human studies using *agaricus*, he found no reports of properly conducted clinical trials regarding the efficacy of *agaricus* extract in patients with cancer. (JX 1 ¶ 20).
36. Further, specifically evaluating the scientific literature in light of the allegations contained in the Commission's Complaint, Dr. Kucuk reported that there is no scientific support for the claims that: (1) reliable scientific evidence demonstrates that RAAX11 is effective in the prevention, treatment, and cure of cancer (JX 7 (Complaint) ¶ 6); (2) RAAX11 is effective in the treatment and cure of various types of cancer, including, but not limited to leukemia and cancers of the breast, brain, lung, larynx, pancreas, and bowel (JX 7 (Complaint) ¶ 8.A.); and (3) RAAX11 is effective in the prevention of cancer, including, but not limited to uterine cancer. (JX 1 ¶¶ 11, 16, 51; JX 7 (Complaint) ¶ 8.B).

Respondents Provided No Competent and Reliable Evidence to Support the Claims for RAAX11

37. Respondents submitted three articles downloaded from the Memorial Sloan Kettering database regarding *agaricus* which were analyzed by Dr. Kucuk. After reviewing these materials, Dr. Kucuk concluded that the materials do not provide any data from randomized, placebo-controlled clinical trials with cancer patients and therefore, they do

not provide any additional relevant clinical data to substantiate or otherwise support the cancer claims challenged in the Commission's Complaint for RAAX11. (JX 1 ¶ 50).

The Website Identified Gemtronics and Isely as the Exclusive Source for RAAX11 in the United States

38. In numerous instances, the Internet website www.agaricus.net advertised Respondents as the only source for products in the United States. The website directed consumers to call Respondent Isely personally and/or telephone numbers belonging to Respondents for product ordering or information. (JX 35; JX 38; JX 39; CCPF ¶¶ 40-46).
39. The website also indicated that credit card payments for orders on the website would be made directly to Gemtronics or to Takesun USA. (JX 27; JX 35; JX 39).
40. Three telephone numbers are or were registered to William H. Isely during the relevant time periods, including: 828-369-7590, 866-944-7359, and 828-369-5861. (Liggins, Tr. 55-58; JX 9 (Isely, Ints.) # 21; JX 15; JX 12 (Isely, Dep.) at 56-57).
41. A "Shopping Cart for USA only" webpage from www.agaricus.net, dated April 2, 2004, advertises that consumers can purchase products from an "FDA registered Warehouse in NC/USA" by telephoning Respondents directly: "Retail prices valid only for USA. Phone 1 828 369 7590 (other countries contact the national agent)." (Liggins, Tr. 94-98, 158-89; JX 35).
42. This webpage further indicates that consumers can purchase from Respondents by credit card by authorizing "Takesun USA to charge my credit card . . ." and notes "[b]y pressing the ORDER confirmations button below, I agree to pay Takesun do Brasil (GEMTRONICS) For any question call 1 828-369-7590." (Liggins, Tr. 95-98, 158-159; JX 35; JX 50; CCPF ¶ 40).
43. Beginning in 2004 and continuing on into 2008, the website www.agaricus.net advertised and offered for sale RAAX11 in the United States by making cancer-related claims for the product. (Liggins, Tr. 41-41; 98-103; Isely, Tr. 280-82; JX 12 (Isely, Dep.) at 70-71, 120, 123-24; JX 32-34; JX 36-43).
44. The website, www.agaricus.net, advertised Respondents as the sole source for RAAX11 in the United States. (Liggins, Tr. 100-102; 280-82; JX 39; JX 40; CCPF ¶¶ 38-43).
45. One of these webpages, dated May 9, 2004, advertised that RAAX11 can be ordered from an "FDA registered Warehouse in USA." (Liggins, Tr. 98-99; JX 36).
46. Another webpage, dated February 10, 2005, advertises the sale of RAAX11 exclusively through Respondents either by credit card authorizing "Takesun USA to charge my credit card" and agreeing to pay "GEMTRONICS" or by calling Respondent Isely's telephone

- number “[f]or any question call 1 828-369-7590.” (Liggins, Tr. 101-02; Isely, Tr. 280-82; JX 39).
47. A home webpage advertising RAAX11 from www.agaricus.net dated January 7, 2006, contains a box with the title: “Prostate Cancer Patient - now cancer free” and directs consumers to call “Bill at 828-369-7590.” (Liggins, Tr. 101-02; JX 40).
 48. On a home webpage advertising RAAX11, dated August 15, 2007, another telephone number belonging to Respondent Isely is provided as the only number to call to order: “Chemo and Radiation not working. This could be the alternative treatment. Call now 1 866 944 7359 for US information” and “USA only Order Information call 866 944 7359.” (Liggins, Tr. 92-93; Isely, Tr. 278-79; JX 12 (Isely, Dep.) at 56; JX34; CCPF ¶¶ 40).
 49. Similarly, two webpages from www.agaricus.net, dated August 15, 2007, and January 3, 2008, show only Isely’s telephone number, 828-369-7590, for consumers to call in the United States for information about RAAX11. This webpage specifically directs American consumers to call Respondents Isely: “if you are living in the US, just call Mr. Isely and he will explain how it works.” (Isely, Tr. 266-67; JX 7 (Complaint) at 13, Ex. A; JX 33).
 50. A more recent www.agaricus.net webpage advertising RAAX11 from January 3, 2008, specifically instructs consumers: Contact: Intl. Tel.xx1 828-369-7590, US Tel. (Free) 866-944-7359, FAX. 828-369-5861. Each of the three telephone numbers belongs to Respondent Isely. (Isely, Tr. 271-72; JX 7 (Complaint) at 17 Ex. C; JX 15; CCPF ¶ 40).
 51. This January 3, 2008 www.agaricus.net webpage describes a clinical study using RAAX11 for treating breast cancer and directs American consumers to call Respondent Isely: “If you would like to find out how you too can participate in our ongoing study in the USA, call 828-369-7590.” (Isely, Tr. 271-72; JX 7 (Complaint) at 17 Ex. C)

Liability of Respondent Gemtronics

52. Gemtronics fulfilled orders for RAAX11 made on the website www.agaricus.net (CCPF ¶¶ 53-56)
53. On January 3, 2008, and again on January 28, 2008, an FTC Investigator purchased RAAX11 from the website www.agaricus.net. (Liggins, Tr. 71-90, 147-48, 170-72; JX 2; JX 3; JX 43-JX 60).
54. A confirmation webpage from one purchase stated: “Your Credit Card is charged using a SSL secured server. On your statement will appear “GEMTRONICS SECURE PAYMENTS.” (Liggins, Tr. 83-84, 136-37; Isely, Tr. 290-92; JX 12 (Isely, Dep.) at 124; JX 50).

55. The two packages of RAAX11 received by the FTC were sent by Gemtronics and included Gemtronics invoices indicating that payment had been made to the company, one of which stated that Gemtronics was responsible for retail sales. (Liggins, 81-82, 170-72; Isely, Tr. 287-88; JX 12 (Isely, Dep.) at 59-60, 64-66; JX 48; JX 56).
56. Respondents fulfilled orders for RAAX11 made on the website www.agaricus.net. (Liggins, Tr. 74-90, 170-72; Isely, Tr. 286-87, 292-93; JX 2; JX 3; JX 12 (Isely, Dep.) at 58-66, 70; JX 43-JX 60).
57. The promotional literature in one package of RAAX received by the FTC included a Gemtronics brochure, which Isely termed “his brochure,” featuring Takesun USA and stating “for more information ... go to www.agaricus.net” and “click on USA sales or www.our-agaricus.com.” This brochure provided telephone and email contact information for Gemtronics and Isely. (Liggins, Tr. 89-90; Isely, Tr. 294-96; 356-58; JX 12 (Isely, Dep.) at 40; JX 57).
58. Although Respondent Isely admitted at trial that Gemtronics no longer conducts business, the Gemtronics corporation has not been dissolved. (Isely, Tr. 323-24; JX 9 (Isely, Ints.) # 18).

Individual Liability of Respondent Isely

59. Gemtronics is a closely held corporation and Respondent Isely is its owner and manager. (CCPF ¶¶ 1, 3, 10).
60. Respondent Isely ran Gemtronics business from his home and controlled the company’s bank account. (Isely, Tr. 217; JX 9 (Isely, Ints.) # 18; CCPF ¶¶ 1, 3, 4, 10).
61. Isely individually participated in the acts and practices at issue in this matter. (CCPF ¶¶ 62-72)
62. Isely was personally identified on the Gemtronics packages, invoices, and in the promotional literature received by the FTC. (JX 46; JX 48; JX 54; JX 56; JX 57; JX 59; CCPF ¶¶ 53, 57, 63).
63. Respondent Isely received notice that the domain name “agaricus.net” as well as other domain names were registered in his name and at his home address through domain renewal notices and annual website search engine listings mailed to his home. (Isely, Tr. 83, 306-09; JX 12 (Isely, Dep.) at 28; JX 61; JX 62).
64. Respondent Isely received the registration renewal notices for domain names including www.our-agaricus.com and www.our-agaricus.us. (JX 12 (Isely, Dep.) at 27-28).
65. Respondent Isely admitted that he ignored or did not follow up on notices he received

regarding domain registrations that he was not aware were registered to him. (Isely, Tr. 306-309; JX 12 (Isely, Dep.) at 28; JX 61).

66. In fact, on April 17, 2008, the FDA sent a “Warning Letter” to Respondents regarding their advertising claims for RAAX11 and other products found on their website www.agaricus.net and another website. (Liggins, Tr. 103-04, 176-77; Isely, Tr. 312-13; JX 65).
67. Respondents had 1) Respondent Isely removed from the domain registration; 2) Isely’s name taken off of the website; and 3) the website cease sales in the United States. (Isely, Tr. 327; JX 9 (Isely, Ints.) # 14; JX 66; JX 67).
68. Isely was prominently featured throughout the website and his name and telephone number were included on a number of webpages on www.agaricus.net as a contact for consumers to purchase RAAX11, to obtain product information, and to participate in an “ongoing study in the USA” of RAAX 11. (JX 7 (Complaint) Exs. A, C; CCPF 30-51).
69. Respondent Isely was also aware that his name, his telephone numbers, and his health history were being used on the website www.agaricus.net, but he admitted that he did nothing about it and did not challenge these representations on the website. (Isely, Tr. 260-62, 268-70, 272-73, 342-344; JX 12 (Isely, Dep.) at 37-39, 51).
70. Respondent Isely acknowledged that he received telephone calls from consumers inquiring about participating “in our ongoing study in the USA” of RAAX11, when he knew there was no such study and that this was an advertising ploy. (Isely, Tr. 271-72; JX 12 (Isely, Dep.) at 57).
71. He admitted that he frequently went to the home page of www.agaricus.net and navigated to the website’s sales pages to check its prices for RAAX11. (Isely, Tr. 233-37; JX 12 (Isely, Dep.) at 54, 66).
72. Respondent Isely admitted that consumers could purchase RAAX11 on the website www.agaricus.net using a credit card, that Isely would receive the payment. (Isely, Tr. 364; JX 12 (Isely, Dep.) at 70, 120, 123-24).

Respondent Disseminated or Caused to be Disseminated the Challenged Representations

73. Respondents state that “a third party, not named in this action, disseminated or cause to be disseminated advertisements” through the website and that they believe that this third party is Takesun do Brasil. (JX 8 (Answer) ¶ 5).
74. Respondent Isely’s business was the sole beneficiary of these claims for sales of RAAX11 in the United States. (CCPF ¶¶ 38).

75. Respondent Isely had a profitable business selling dietary supplements including RAAX11. (JX 9 (Isely, Ints.) # 5; Isely, Tr. 287; JX 12 (Isely, Dep.) at 16, 20, 41-42, 44, 62-63).
76. Until some point in 2008, Respondent Isely had a profitable business relationship with Takesun; purchasing \$5,000 to \$8,000 per month of various dietary supplements for import into the United States and resale to consumers. (Isely, Tr. 207, 211, 287; JX 9 (Isely, Ints.) # 5, 7; JX 12 (Isely, Dep.) at 16, 20, 41-42, 44, 62-63).
77. Each order that Respondent Isely placed would require multiple emails to Mr. Otto to coordinate the shipments. (Isely, Tr. 201).
78. Respondent Isely did not import products from any company other than Takesun and he had registered his home as an FDA warehouse to receive and store Takesun products. (Isely, Tr. 202-06; 238-39; JX 9 (Isely, Ints.) # 13); JX 12 (Isely, Dep.) at 18-20, 92-93).
79. Respondent Isely redesigned the labels of Takesun products he imported to facilitate their clearance into the United States by the FDA. (JX 12 (Isely, Dep.) at 94-98).
80. In instances where consumers saw Internet advertising for RAAX11, Respondent Isely testified that they would order the product from him by telephone. (Isely, Tr. 199; JX 12 (Isely, Dep.) at 36).
81. Isely testified that the only way he could take credit card payments was through telephone orders and that he did not accept Paypal. (Isely, Tr. 217-18, 222; JX 12 (Isely, Dep.) at 40).
82. To highlight his association with Takesun, Respondent Isely even did business under the name Takesun USA. He prominently displayed the name Takesun USA in his brochure that he created which he mailed to consumers to advertise RAAX11 and included in product shipments to customers so that they would recognize his affiliation with Takesun. (Isely, Tr. 288-89; 295-96; Liggins, Tr. 89-90; JX 12 (Isely, Dep.) at 17-18, 34-35, 40-41, 60-61, 66, 67-68, 75-76, Ex. 9, Ex. 10; JX 57).
83. Isely used the name Takesun USA to establish a wholesale business in which he sought to sign up distributors to sell Takesun products, such as RAAX11. (Isely, Tr. 214-15; JX 12 (Isely, Dep.) at 88-89; JX 73 (*see, e.g.*, JX 73, p. 4)).
84. Both the invoice included in customer orders and the Distributor Introductory Package sent to potential distributors identified Respondent Isely as the General Manager of Takesun USA. (Liggins, Tr. 88-89; Isely, Tr. 215, 287-288; JX 12 (Isely, Dep.) at 60-61, 88-89, Ex. 6; JX 48; JX 73).
85. Respondent Isely admitted that, although, at one point, he had been a distributor for

Takesun, he declined to enter into a distributor agreement with the company because, among other things, he knew that FDA had contacted Takesun in 2002 concerning advertising on the website www.agaricus.net. (Isely, Tr. 211-212; 229, 312-18; JX 9 (Isely, Ints.) #1; JX 12 (Isely, Dep.) at 21-22).

86. Respondent Isely was aware that Takesun was promoting RAAX11 as a medicine and as a cancer cure. Respondent Isely admitted that he thought that he could avoid any liability for being associated with such claims by having no formal, legal ties with Takesun (JX 12 (Isely, Dep.) at 21-22, 53-54, 69-71, 92).
87. Respondents developed their own brochure and other promotional materials that they included in the packages of RAAX11 and other products that they mailed to consumers. (Liggins, Tr. 80, 89-91, 146-147; Isely, Tr. 294-96, 298-304, 356-58; JX 12 (Isely, Dep.) at 18, 34-35, 40, 66, 69-71, 74-76; JX 47; JX 57; JX 58; JX 59).
88. Respondent Isely knew or intentionally avoided any knowledge of his business's continued identification on the website www.agaricus.net and the cancer-related advertising claims for RAAX11 contained in this website. (Isely, Tr. 262, 273, 306-309; JX 12 (Isely, Dep.) at 21-22, 28, 53- 54, 57, 69-71; JX 29; JX 61)
89. Respondent Isely also developed a Distributor Package that likewise directed consumers to go to the website www.agaricus.net. (Isely, Tr. 215; JX 73).
90. Respondent Isely also sent out another promotional piece that he received from Takesun that made cancer claims for RAAX-11 that were made in the website www.agaricus.net. (Liggins, Tr. 90-91; Isely, Tr. 298-304; 356-58; JX 12 (Isely, Dep.) at 69-74; JX 59).
91. Respondents directly participated in and were the beneficiaries of the deceptive claims and had knowledge that the advertisements were deceptive. (JX 12 (Isely, Dep.) at 53-54; CCPF ¶¶ 61, 66, 75, 85, 88).

II. COMPLAINT COUNSEL'S PROPOSED CONCLUSIONS OF LAW

1. The acts and practices charged in the Complaint in this matter took place in or affecting commerce within the meaning of the Federal Trade Commission Act, as amended. Nationwide advertising, marketing, or sales activity of the sort that Respondents engaged in constitutes "commerce" under the FTC Act. *See, e.g., P.F. Collier & Son Corp. v. FTC*, 427 F.2d 261,272 (6th Cir. 1970); *see, e.g., Ford Motor Co. v. FTC*, 120 F.2d 175, 183 (6th Cir. 1941) (noting that commerce also includes the actions, communications, and other acts or practices that are incident to those activities).
2. The Complaint charges Respondents with violating Sections 5 and 12 of the FTC Act. The Commission has jurisdiction over the subject matter of this proceeding pursuant to those sections of the FTC Act. Section 5(a) provides that "unfair or deceptive acts or practices in or affecting commerce are hereby declared unlawful." 15 U.S.C. § 45(a)(1). The FTC is "empowered and directed" to prevent unfair or deceptive practices in commerce by "persons, partnerships, or corporations." 15 U.S.C. § 45(a)(2).
3. The Commission has jurisdiction over persons, partnerships, and corporations. 15 U.S.C. § 45(a)(2). "Corporations" are defined in Section 4 of the FTC Act as "any company . . . which is organized to carry on business for its own profit or that of its members." 15 U.S.C. § 44. Therefore, the Commission has jurisdiction over Respondent Gemtronics and Respondent Isely.
4. Section 12 prohibits the dissemination of "any false advertisement" in order to induce the purchase of "food, drugs, devices, or cosmetics." 15 U.S.C. § 52(a)(2). RAAX11 is a "food" or "drug" within the meaning of Sections 12 and 15 of the Federal Trade Commission Act. Section 12 defines "false advertisement" as "an advertisement, other than labeling, which is misleading in a material respect." 15 U.S.C. § 55.
5. Respondents' advertising claims for RAAX11 clearly misrepresent that the product is effective in preventing, treating and curing cancer. The *prima facie* evidence of what representations an advertisement conveys to reasonable consumers is the advertisement itself. *FTC Policy Statement on Deception*, 103 F.T.C. 174, 176 (1984) (*Deception Statement*); *see, e.g., Telebrands Corp.*, 140 F.T.C. 279, 290 (2005); *Novartis Corp.*, 127 F.T.C. 580, 680 (1999), *aff'd*, 223 F.3d 783 (D.C. Cir. 2000); *Stouffer Foods Corp.*, 118 F.T.C. 746, 798 (1994); *Kraft, Inc.*, 114 F.T.C. 40, 121 (1991), *aff'd*, 970 F.2d 311 (7th Cir. 1992), *cert. denied*, 507 U.S. 909 (1993).
6. When the language of an advertisement is clear enough to permit the Commission to conclude with confidence that the ad can reasonably be read to contain a particular claim, a facial analysis, alone, will permit the Commission to conclude that the ad contains the claim. *Stouffer*, 188 F.T.C. at 798, *citing Kraft, Inc.*, 114 F.T.C. at 121 and *In re Thompson Medical Co.*, 104 F.T.C. 648, 789 (1984), *aff'd*, 791 F.2d 189 (D.C. Cir. 1986), *cert. denied*, 479 U.S. 1086 (1987).

7. Where the language in the challenged advertisement is clear, the Commission may rely on the ad itself and need not resort to extrinsic evidence to determine if the claim is conveyed to reasonable consumers. *Novartis*, 127 F.T.C. at 680; *see Stouffer*, 118 F.T.C. at 798; *Deception Statement*, 103 F.T.C. at 176.
8. Respondents' advertising claims are material, not only because they are express, but also because they relate to the purpose, safety, and/or efficacy of RAAX11, a product advertised specifically as a cancer prevention, treatment and cure. An advertisement is deceptive if it contains a representation or omission of fact that is likely to mislead consumers acting reasonably under the circumstances, and that representation or omission is material to consumers' purchasing decisions. *Deception Statement*, 103 F.T.C. at 175; *see, e.g., Telebrands*, 140 F.T.C. at 290; *Novartis*, 127 F.T.C. at 679; *Stouffer*, 118 F.T.C. at 798; *Kraft*, 114 F.T.C. at 120.
9. Advertising claims are also presumed to be material if they are express or if they pertain to the purpose, safety, or efficacy of the product. *Deception Statement*, 103 F.T.C. at 182, *see, e.g., Telebrands Corp.*, 140 F.T.C. 379, 450 (Initial Decision 2004).
10. The Commission has consistently held that objective claims made without a reasonable basis constitute a deceptive practice in violation of Section 5. *FTC Policy Statement Regarding Advertising Substantiation*, 104 F.T.C. 839 (1984) (*Substantiation Statement*); *see, e.g., Automotive Breakthrough Sciences, Inc.*, 126 F.T.C. 229, 293 & 293 n.20 (1998); *Jay Norris, Inc.*, 91 F.T.C. 751, 854 (1978), *aff'd as modified*, 598 F.2d 1244 (2d Cir. 1979), *cert. denied*, 444 U.S. 980 (1979).
11. What constitutes a reasonable basis is an objective standard: advertisers must possess at least the level of substantiation expressly or impliedly claimed in the advertisement. *See Honeywell, Inc.*, 126 F.T.C. 202, 204-05 (1998); *FTC v. Natural Solution, Inc.*, No. CV 06-6112-JFW, 2007 U.S. Dist. LEXIS 60783, at *10 (C.D. Cal. Aug. 7, 2007) (citing *FTC v. U.S. Sales Corp.*, 785 F. Supp. 737, 748 (N.D. Ill. 1992)).
12. For health and safety claims, advertisers must possess competent and reliable scientific evidence substantiating their claims in order to have a reasonable basis for such claims. *See FTC v. National Urological Group, Inc.*, No. 1:04-CV-3294-CAP, 2008 U.S. Dist. LEXIS 44145, at *77 (N.D. Ga. June 4, 2008) (granting FTC's summary judgment motion, court finds safety and efficacy claims for dietary supplements must be substantiated by competent and reliable scientific evidence); *Natural Solution*, 2007 U.S. Dist. LEXIS 60783, at *11-13 (granting FTC's summary judgment motion, court requires competent and reliable scientific evidence for cancer prevention and treatment claims for product); *FTC v. QT, Inc.*, 448 F. Supp. 2d 908, 961 (N.D. Ill. 2006) *aff'd*, 512 F.3d 858 (competent and reliable scientific standard applied for evidence that bracelet relieves pain).
13. Competent and reliable scientific evidence is typically defined as tests, analyses,

research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results. *See, e.g., Brake Guard Products, Inc.*, 125 F.T.C. 138 (1998); *ABS Tech Sciences, Inc.*, 126 F.T.C. 229 (1998).

14. To provide adequate substantiation to support the truthfulness of health-related efficacy claims, courts have consistently required double-blind, placebo-controlled studies. *See, e.g., FTC v. SlimAmerica, Inc.*, 77 F. Supp. 2d 1263, 1274 (S.D. Fla. 1999) (double-blind study of the combination of product's ingredients required to support product claims); *FTC v. Sabal*, 32 F. Supp. 2d 1004, 1008-09 (N.D. Ill. 1998) (study found not valid as substantiation, in part, because neither blinded nor placebo controlled); *FTC v. QT, Inc.*, 448 F. Supp. 2d at 962 (medical claims for bracelet required a well-conducted, placebo-controlled, randomized, double-blind study).
15. The product, RAAX11, is dietary supplement that is advertised and sold as a clinically proven treatment, prevention and cure for cancer. These representations relate to health and safety and, thus, require substantiation consisting of competent and reliable scientific evidence.
16. There is no competent and reliable scientific evidence that RAAX11 is scientifically proven to be effective in the prevention, treatment, and cure of cancer, and such representations are false and misleading in violation of Sections 5 and 12 of the FTC Act.
17. Respondents did not possess a reasonable basis for their advertising claims for RAAX11, that RAAX11 is effective in the treatment and cure of various types of cancer, including, but not limited to leukemia and cancers of the breast, brain, lung, larynx, pancreas, and bowel; and RAAX11 is effective in the prevention of cancer, including, but not limited to uterine cancer, at the time these representations were made. Therefore such representation are false or misleading and accordingly, have violated Sections 5 and 12 of the FTC Act.
18. The corporate Respondent Gemtronics, by and through its owner, William Isely, violated Sections 5 and 12 of the FTC Act.
19. Respondent Isely clearly is individually liable in this case because he was actively involved in and controlled every facet of Gemtronics' business, whether running the business as a sole proprietorship or as a corporation. The Commission and the courts examine, separately or in combination, a number of factors when determining individual liability: the unlawful practices involved; the respondent's involvement with the practices; the type of corporate entity; the respondent's ownership interest; the corporate office (if any) held; and the influence he exercised over corporate affairs. *Telebrands Corp.*, 140 F.T.C. at 450; *National Housewares*, 90 F.T.C. 512, 598 (1977).

