

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 PROPOSED FINDINGS
OF FACT AND CONCLUSIONS OF LAW

I. COMPLAINT COUNSEL'S PROPOSED FINDINGS OF FACT

A. 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. Respondents' Answer to FTC's Complaint, dated October 10, 2008 (hereinafter "Answer") ¶ 1 (Complaint Counsel's Trial Exhibit (hereinafter "CX __") 2).
2. Respondent William H. Isely ("Isely") resides at 964 Walnut Creek, Franklin, North Carolina, 28734. Answer ¶ 2.
3. Beginning in 1993, and continuing thereafter, Respondent Isely owned and operated a sole proprietor business under the unregistered assumed name Gemtronics in which he sold dietary supplements from his home via mail order, telephone and the Internet. Respondent William Isely's Answers to Interrogatories, February 3, 2009, (hereinafter "Isely Ints. Resp. __") 1, 2, 8, Ex. A (CX 3); Isely Deposition Transcript (hereinafter "Isely Dep.") 12-13 (CX 5).
4. Respondent Isely incorporated Gemtronics, Inc. in North Carolina in 2006. Answer ¶ 1; Isely Ints. Resp. 2 (CX 3); Isely Dep. 31, 99-100 (CX 5); CX 60.
5. Respondent Isely is the owner, registered agent, and general manager of Gemtronics. Isely Ints. Resp. 1 (CX 3); Isely Dep. 101, 105 (CX 5); CX 15.
6. Respondent Isely also registered Gemtronics, Inc. at his home address as an FDA approved warehouse. Isely Ints. Resp. 13 (CX 3); Isely Dep. 20 (CX 5).

7. Respondent Isely has also used another assumed name, Takesun USA, to sell dietary supplements. Isely Ints. Resp. 1, 8 (CX 3); CX 15; Isely Dep. 17-18, 61-62, 67-68 (CX5).
8. Since 2004, Respondent Isely and, since 2006, Respondent Gemtronics have advertised and sold the dietary supplement RAAX11 to consumers nationwide through mail order, telephone, and Internet websites, including, *inter alia*, the website www.agaricus.net. Isely Ints. Resp. 3 (CX 3); Isely Dep. 34-35, 38, 39-40, 70, 120-24 (CX 5); CX 9-CX 27.
9. From 2004 through 2008, Respondents sold approximately 1134 bottles of RAAX11 at prices ranging from \$400 to \$120 per bottle. Isely Ints. Resp. 5 (CX 3); Isely Dep. 41-42 (CX 5).
10. Respondents have charged shipping and handling fees of \$15.00. CX 15, CX 23.

B. Respondents Sold RAAX11 Through the Website www.Agaricus.net

The Domain Name Agaricus.net was registered to Isely

11. 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, technical, and zone contact. Isely Ints. Resp. 1 (CX 3); CX 38, CX 53.
12. Respondent Isely received notice that the domain "agaricus.net" and other domain names were registered in his name through domain renewal notices and annual website search engine listings. Isely Dep. 28 (CX 5); CX 66, CX 72.

Respondents Were the Website's Exclusive Sales Outlet in the US

13. Beginning in 2004 and continuing into 2008, Respondents offered for sale and sold the herbal product, RAAX11, through the website www.agaricus.net. Isely Dep. 70-71, 120, 123-24 (CX 5); CX 9 - CX 27.
14. In numerous instances, this website touted Respondents as the only source for RAAX11 in the United States, advertising that consumers could purchase the product by calling telephone numbers belonging to Respondent Isely and/or through credit card payments made directly to Gemtronics. CCPF ¶¶ 15-27.
15. 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)." CX 3, CX 45, CX 49.
16. This webpage allows consumers to 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.” CX 3, CX 45, CX 49.

17. Another webpage from the website dated May 9, 2004, advertises that RAAX11 can be purchased from an “FDA registered Warehouse in USA to guarantee you best quality.” CX 59.
18. A February 10, 2005, www.agaricus.net webpage again advertises the sale of RAAX11 exclusively through Respondents by credit card payments: “Note: By pressing the ORDER confirmations button below, I agree to pay Takesun do Brasil (GEMTRONICS) For any question call 1 828-369-7590. CX 3 #21, CX 46.
19. On a 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.” CX 3 #21, CX 49, CX 52; Isely Dep. 56 (CX 5).
20. 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. CX 1 (Exhibit A to the FTC’s Complaint), CX 3 #21, CX 49, CX 51; Isely Dep. 54 (CX 5).
21. In fact, this webpage states “if you are living in the US, just call Mr. Isely and he will explain how it works.” CX 1 (Exhibit A to the FTC’s Complaint), CX 51.
22. 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. CX 1 (Exhibit C to the FTC’s Complaint).
23. Each of the three telephone numbers belongs to Respondent Isely. CX 3 #21, CX 49; Isely Dep. 56-57 (CX 5).
24. This webpage goes on to describe a clinical study using RAAX11 for treating breast cancer and states: “If you would like to find out how you too can participate in our ongoing study in the USA, call 828-369-7590.” CX 1(Exhibit C to the FTC’s Complaint), CX 3 #21, CX 49; Isely Dep. 56-57 (CX 5).

***Respondents Not Only Fulfilled Website Orders,
But Also Advertised the Website to Consumers***

25. Respondents acknowledged fulfilling orders for RAAX11 made on the website www.agaricus.net. Isely Dep. 58-66, 70 (CX 5); CX 9 - CX 27.
26. Respondent Isely admitted that consumers could purchase RAAX11 directly from him

through the website via credit card payment. Isely. Dep. 70, 120, 123-24 (CX 5); CX 17.

27. An Internet purchase confirmation webpage from the website states: "Your Credit Card is charged using a SSL secured server. On your statement will appear 'GEMTRONICS SECURE PAYMENTS.'" CX 17.
28. Respondents included their own invoices in the orders they fulfilled from the website which included their email address and telephone numbers, and, in some instances, requested that future orders be placed directly with them by email or telephone. CX 15, CX 23; Isely Dep. 41, 60-61, 64 (CX 5).
29. Respondents developed their own promotional materials that they included in the packages of RAAX11 and other products that they mailed to consumers. CX 14, CX 24, CX 25, CX 26; Isely Dep. 18, 34-35, 40, 66, 69, 70-71, 74-76 (CX 5); Isely Ints. Resp. 3, 5, 7 (CX 3).
30. These promotional materials specifically direct consumers to "[g]o to the website www.agaricus.net" and "[c]lick on USA sales." Isely Dep. 40 (CX 5); CX 24.
31. Respondents' Distributor Package likewise directs consumers to go to the website www.agaricus.net. CX 74.

C. Respondents' Relationship to The Manufacturer of RAAX11

32. In 2000, Respondents began to purchase dietary supplements wholesale from Takesun do Brasil Ind. Com. e Exp. Ltda. ("Takesun"), a Brazilian company, run by an individual named George Otto Kather. CX 3 # 7, Ex. A, CX 22; Isely Dep. 15-16 (CX 5).
33. From that time, until some point in 2008, Respondent Isely had a profitable business relationship with Otto; purchasing about \$5,000 per month of various herbal products from Takesun for resale. Isely Ints. Resp. 5, 7(CX 3); Isely Dep. 16, 41-42, 44, 62-63 (CX 5).
34. Respondents did not import products from any company other than Takesun. Isely Dep. 20 (CX 5).
35. In 2004, Respondents began to import RAAX11 from Takesun about every four months. CX 3 #3, Ex. A; Isely Dep. 31-32 (CX 5).
36. Although earlier in the business relationship, Respondent Isely had been a distributor for Takesun, he refused to enter into a distributor agreement with the company because he knew that FDA had contacted Otto regarding advertising claims on the website www.agaricus.net. Isely Dep. 21-22 (CX 5).
37. Respondent Isely admitted that he was aware that Otto was promoting RAAX11 as a medicine and as a cancer cure, but that he thought that he could avoid any liability for

being associated with such claims by having no formal legal ties with Takesun. Isely Dep. 21-22, 53-54, 69-71 (CX 5).

38. As an inducement to buy product and as part of its business relationship with its customers, Takesun supplied Isely with a variety of free web services, such as links to Takesun websites from which consumers could purchase product from Respondents. CX 3 #7, Ex A; Isely Dep. 22-23, 52 (CX 5).
39. In 2004, Respondent Isely asked Otto set up websites for Respondents to sell products over the Internet and to register the domain names under Isely's name. Isely Dep. 26-27, 44-46 (CX 5).
40. Otto paid for the domain registrations and the websites, and managed the websites, but Respondent Isely received the annual notices to renew the registrations. Isely Dep. 27-28, 52 (CX 5).
41. Respondent Isely received a number of notices from registrant companies, some for other domain names that Isely had not asked Otto to registered for him. Isely Dep. 28 (CX 5).
42. During his business relationship with Takesun, Respondent Isely knew or intentionally avoided any knowledge of his and his business's close association with the website www.agaricus.net and the advertising claims it contained. Isely Dep. 21-22, 54, 57, 69-71 (CX 5).
43. Respondent Isely admitted going to the website to check its prices. Isely Dep. 54 (CX 5).
44. Respondent Isely gave Otto permission to use his name, telephone numbers, and health history for a testimonial on the website and he knew that consumers were able to order product directly from Respondents via this website. CX 3 #11, #13, CX 17; Isely Dep. 70, 120, 123-4 (CX 5).
45. Respondent Isely acknowledged receiving telephone calls from consumers inquiring about participating in a study of RAAX11 in the United States, when he knew there was no such study. CX 3 #15; Isely Dep. 57 (CX 5).
46. Respondent Isely admitted that did not follow up on notices he received regarding domain registrations that he was not aware were registered to him. Isely Dep. 28 (CX 5); CX 66, CX 72.
47. As the sole beneficiary of these claims for sales in the United States, Respondents profited from their association with Takesun. CCPF ¶¶ 14, 33.

D. Deceptive Advertising Claims for RAAX11

48. Through the website 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. CX 1.

49. 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. CX 1 (Commission Complaint Ex. A and Ex. B).
50. 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. CX 1 (Commission Complaint Ex. A).
51. 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. CX 1 (Commission Complaint, Ex. B).
52. 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%. CX 1 (Commission Complaint, Ex. C).
53. 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. CX 1 (Commission Complaint, Ex. D).

54. Claim that RAAX11 is scientifically proven effective in preventing cancer, including but not limited, to uterine cancer. 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 cancer. CX 1 (Commission Complaint, Ex. A).

III. NO SCIENTIFIC EVIDENCE SUPPORTS THE RAAX11 CANCER CLAIMS

55. At trial, Complaint Counsel will present the testimony of Dr. Omer Kucuk, the FTC’s expert, supporting his expert report. CX 6.
56. Dr. Kucuk is an expert in the fields of cancer research and treatment, and in the use of botanical compounds on cancer patients. CX 6 ¶¶ 1, 9.
57. 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. CX 6 ¶ 1.
58. Dr. Kucuk conducts clinical research treating cancers of the prostate, bladder, kidney and testis. CX 6 ¶ 2.
59. He has authored or co-authored approximately 125 articles published in peer-reviewed scientific journals and more than 20 published book chapters and reviews. CX 6 ¶ 3.
60. Dr. Kucuk will testify 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. CX 6 ¶¶ 15, 32.
61. 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. CX 6 ¶¶ 32, 34.
62. Dr. Kucuk’s testimony will include 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. CX 6 ¶¶ 12-14, 16, 19-21, 50.
63. Dr. Kucuk will testify that it is his 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. CX 6 ¶¶ 12, 15, 50, 51.

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

64. Dr. Kucuk will testify that he found no published scientific literature evaluating either RAAX11 or evaluating the combination of *icaco* and *agaricus* as a cancer treatment. CX 6 ¶¶ 16, 17.
65. Specifically, Dr. Kucuk found no published scientific literature evaluating the efficacy of RAAX11 or any clinical trial data with RAAX11. CX 6 ¶ 16.
66. 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. CX 6 ¶ 17.
67. 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*. CX 6 ¶ 18.
68. While Dr. Kucuk will testify that he 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. CX 6 ¶ 20.
69. Further, specifically evaluating the scientific literature in light of the allegations contained in the Commission’s Complaint, Dr. Kucuk will testify 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. CX 6 ¶¶ 11, 16, 51.

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

70. Respondents submitted three articles downloaded from the Memorial Sloan Kettering database regarding *agaricus* which were analyzed by Dr. Kucuk. Dr. Kucuk will testify that after reviewing the materials, it is his conclusion 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. CX 6 ¶¶ 50.

IV. ADDITIONAL FACTS

71. After Respondents received notice of potential law violations from the FTC and FDA in 2008, Respondent Isely contacted the webhost service for www.agaricus.net which notified him what actions he needed to take to shut-down the website. CX 63.
72. Respondents also contacted Mr. Otto and 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. CX 3 #13.

II. COMPLAINT COUNSEL'S PROPOSED CONCLUSIONS OF LAW

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

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. *Deception Statement*, 103 F.T.C. at 176; *see, e.g., Telebrands Corp.*, 140 F.T.C. at 290; *Novartis*, 127 F.T.C. at 680; *Stouffer*, 118 F.T.C. at 798; *Kraft*, 114 F.T.C. at 121. 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 Foods Corp.*, 188 F.T.C. 746, 798, *citing Kraft, supra*, at 121 and *Thompson Medical Co.*, 104 F.T.C. 648, at 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.

6. 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. *FTC Policy Statement on Deception*, 103 F.T.C. 174, 175 (1984) (Deception Statement); *see, e.g., Telebrands Corp.*, 140 F.T.C. 279, 290 (2005); *Novartis Corp.*, 127 F.T.C. 580, 679 (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, 120 (1991), *aff'd*, 970 F.2d 311 (7th Cir. 1992), *cert. denied*, 507 U.S. 909 (1993). 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).
7. 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 (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)).
8. 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).
9. 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).

10. 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).
11. 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. 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. 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. Respondents, therefore, lacked a reasonable basis for their advertising claims for RAAX11, and accordingly, have violated Sections 5 and 12 of the FTC Act.

B. RESPONDENTS ARE LIABLE FOR FTC ACT VIOLATIONS

Liability of Respondent Gemtronics

12. The corporate Respondent Gemtronics, by and through its owner, William Isely, violated Sections 5 and 12 of the FTC Act. Since 2006 to 2008, Gemtronics offered for sale and sold orders for RAAX11 made on the website www.agaricus.net. CCPF ¶¶ 8, 13-31. 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 ¶ 27. The promotional literature disseminated by Gemtronics directs consumers to "go to the website www.agaricus.net and click on USA sales" and provides telephone and email contact information for Gemtronics. CCPF ¶¶ 30-31.

Individual Liability of Respondent Isely

13. 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).

14. Gemtronics is a closely-held corporation and Respondent Isely is its owner and manager. CCPF ¶ 5. 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.
15. Respondent Isely clearly is liable for violations of Section 5 and 12 of the FTC Act in this case because he was actively involved in and controlled every facet of Gemtronics' business. CCPF ¶ 5. Respondent Isely ran Gemtronics business from his home and used the corporation's name to register his house as an FDA approved warehouse. CCPF ¶¶ 5, 6. Further, Respondent Isely individually participated in the acts and practices at issue in this matter. Isely was personally identified in the Gemtronics packages, invoices, and in the promotional literature disseminated to consumers for RAAX11. CCPF ¶¶ 13, 14.
16. Respondent Isely also played an integral part in the website www.agaricus.net. As discussed, *supra*, the "agaricus.net" domain was registered in Isely's name. CCPF ¶ 11. Respondent Isely admitted that he received notices in the mail for the renewal of the domains that were registered in his name and he produced a renewal notice for "agaricus.net" that had been mailed to him. CCPF ¶ 12. In addition, 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 consumer to purchase RAAX11, to obtain product information, and to participate in an "ongoing study in the USA" of RAAX11. CCPF ¶¶ 14-24. In fact, Respondent Isely admitted that when consumers purchase products on the website www.agaricus.net using a credit card, that Isely receives the payment. CCPF ¶¶ 8, 14.
17. 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.

Respondents Disseminated or Caused to be Disseminated the Challenged Representations

18. Respondents assert: First, Respondents do not challenge either the content or interpretation of these advertisements. CX 2 ¶ 5 Second, Respondents' claim that "they have forever lacked the authority or ability to disseminate any information or alter the content of the alleged offending website www.agaricus.net." CX 2 ¶ 5 Third, Respondents "state that a third party, not named in this action, disseminated or cause to be disseminated advertisements" through the website and further state that they believe that this third party is Takesun do Brasil. CX 2 ¶ 5. Thus, Respondents contest any liability for the dissemination of the contested advertising claims for RAAX11 by denying their association with the website www.agaricus.net, although Respondents were the sole beneficiaries of the website's challenged claims and took in significant consumer sales of the product. CCPF ¶¶ 9, 14, 33.
19. 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)
20. 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." *Id.* (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." *Id.*
21. 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.

22. 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. *Id.* at 875-76.
23. Parties may be held liable if they provide others with the means and instrumentalities for engaging in deceptive conduct. See *Castrol North America Inc.*, 128 F.T.C. 682 (1999) (consent order), and *Shell Chemical Co.*, 128 F.T.C. 729 (1999) (challenging both Castrol’s role in disseminating deceptive claims for its fuel additives and Shell’s role in providing customers, including Castrol, with promotional materials containing deceptive claims for active ingredient in Syntec, which Shell developed and tested).
24. Given the various standards set forth, above, a strong argument can be made that Respondents directly participated in the deceptive website advertising to the extent that: 1) they were the designated website outlet in the United States for sales of RAAX11 and the website’s sole beneficiaries for US sales; 2) they disseminated their own created promotion literature directing consumers and potential distributors to the www.agaricus.net website; 3) 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 the contact for consumers to purchase RAAX11, to obtain product information, and to participate in an “ongoing study in the USA” of RAAX11. CCPF ¶¶ 14-31. More important, Respondent Isely knew or intentionally avoided any knowledge of his and his business’s close association with the website www.agaricus.net and the advertising claims it contained. CCPF ¶¶ 42-47.
25. Alternatively, an analysis of Respondents’ claim that they lacked the authority or ability to disseminate any information or alter the content cannot be supported. As the court in *FTC v. Atlantex Associates*, held, “direct participation in fraudulent practices is not a requirement for liability. Awareness of fraudulent practices and failure to act within one’s authority to control such practices if sufficient to establish liability.” 1987-2 Trade Cas. (CCH) ¶ 67,788 (S.D. Fla. 1987) *FTC v. Int’l Diamond*, 183-2 Trade Cases (CCH) ¶ 65,725 at 69,707-09 (N.D. Cal. 1983) (internal citations omitted). As noted above, Respondents were aware of the fraudulent nature of the website claims. CCPF ¶¶ 36-37, 42, 45. Respondent Isely was also aware that he held the domain registration “agaricus.net” having received notification of this fact through a renewal for the domain that had been mailed to him, which he disregarded. CCPF ¶ 42.
26. In choosing to disregard the fraudulent claims and domain notification, Respondents made a conscious decision not to act and to enjoy the continued financial benefits of the

challenged website representations, while believing that they could not be found responsible for the website. CCPF ¶¶ 36, 37. Courts have found that “one may not enjoy the benefits of fraudulent activity and then insulate oneself from liability by contending that one did not participate directly in the challenged practices.” *FTC v. Atlantex* 1987-2 Trade Cas. (CCH) at 59,255.

27. After Respondents received notice of potential law violations from the FTC and FDA in 2008, Respondent Isely contacted the webhost service for www.agaricus.net which notified him what actions he needed to take to shut-down the website. CCPF ¶ 71. Respondents also contacted Mr. Otto and had: 1) Respondent Isely removed from the domain registration; 2) Isely’s name taken off of the website; and 3) had the website cease sales in the United States. CCPF ¶ 72; CX 3 #13. All of these actions could have been taken by Respondents prior to this time, but Respondents would have had no motivation and certainly no incentive to take such actions.

CERTIFICATE OF SERVICE

I hereby certify that on this date, I filed and served the attached:

- 1) COMPLAINT COUNSEL'S PRE-TRIAL BRIEF; and
- 2) COMPLAINT COUNSEL'S PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW

The original and one (1) paper copy via overnight delivery and one (1) electronic copy via email to:

Donald S. Clark, Secretary
Federal Trade Commission
600 Pennsylvania Ave., N.W., Room H-159
Washington, D.C. 20580
email: secretary@ftc.gov

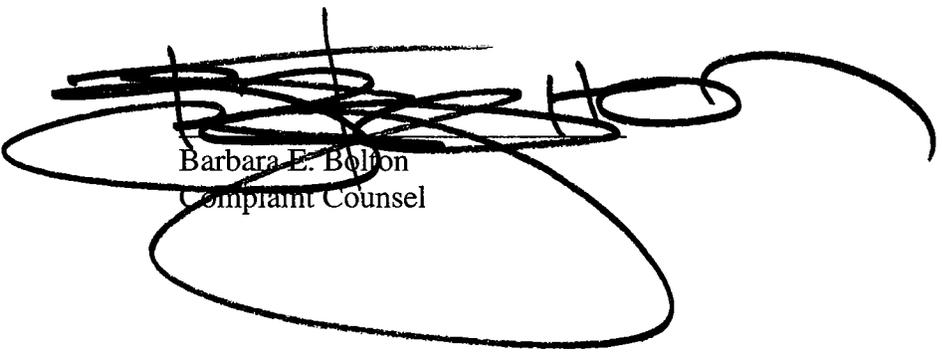
One (1) email copy and two (2) paper copies served by overnight mail delivery to:

The Honorable D. Michael Chappell
Chief Administrative Law Judge
600 Pennsylvania Ave., N.W. Room H-112
Washington, D.C. 20580
email: oalj@ftc.gov

One (1) electronic copy via email and one (1) paper copy via overnight delivery to:

Matthew I. Van Horn
16 W. Martin Street, Suite 700
Raleigh, NC 27601
email: matthew@vanhornlawfirm.com

Dated: June 3, 2009



Barbara E. Bolton
Complaint Counsel