



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

**In the Matter of**

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

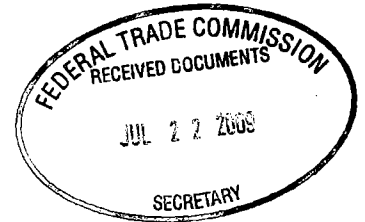
**WILLIAM H. ISELY,  
individually and as the owner  
of Gemtronics, Inc.**

**PUBLIC**

**DOCKET NO. 9330**

**COMPLAINT COUNSEL'S POST TRIAL BRIEF**

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**

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.

Barbara E. Bolton  
Attorney for Complaint Counsel  
Federal Trade Commission  
225 Peachtree Street, Suite 1500  
Atlanta, GA 30303  
404-656-1362 (direct line)  
404-656-1379 (facsimile)  
[bbolton@ftc.gov](mailto:bbolton@ftc.gov) (email)

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

**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**

**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](http://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](http://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 FACTS<sup>1</sup>

### 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.

---

<sup>1</sup> 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](http://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](http://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](http://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](http://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*

