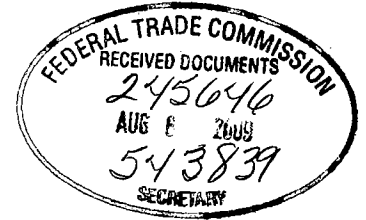


**ORIGINAL**



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

**COMMISSIONERS:** William E. Kovacic, Chairman  
Pamela Jones Harbour  
Jon Leibowitz  
J. Thomas Rosch

**PUBLIC**

**In the Matter of**

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

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

**DOCKET NO. 9330**

**RESPONDENTS' RESPONSE TO  
COMPLAINT COUNSEL'S PROPOSED FINDINGS OF FACT**

Pursuant to the Order On Post Trial Briefs, entered on July 1, 2009, by Chief Administrative Law Judge D. Michael Chappell, the Respondents respectfully submit their Response to 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).

**Response to Finding No. 1:**

Respondents have no specific response.

2. Respondent William H. Isely ("Isely") resides at 964 Walnut Creek, Franklin, North Carolina, 28734. (JX 8 (Answer) ¶ 2; Liggins, Tr. 126).

**Response to Finding No. 2:**

Respondents have no specific response.

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).

**Response to Finding No. 3:**

Respondents have no specific response.

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).

**Response to Finding No. 4:**

Respondents have no specific response.

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).

**Response to Finding No. 5:**

Respondents have no specific response.

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).

**Response to Finding No. 6:**

Respondents have no specific response.

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).

**Response to Finding No. 7:**

Respondents have no specific response.

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).

**Response to Finding No. 8:**

Respondents have no specific response.

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).

**Response to Finding No. 9:**

Isely continued his sole proprietor business under the name "Gemtronics" but never through Gemtronic's, Inc. and Gemtronics, Inc. was never active. (Isely Tr. 215-17, 223, 323-24; JX 9 at 4-5; JX 13)

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).

**Response to Finding No. 10:**

Isely formed Gemtronics, Inc. and has forever only been the registered agent of Gemtronics, Inc. (Isely Tr. 215-17, 223, 323-24; JX 9 at 4-5; JX 13)

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).

**Response to Finding No. 11:**

Respondents have no specific response.

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).

**Response to Finding No. 12:**

Respondents have no specific response.

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).

**Response to Finding No. 13:**

George Otto's e-mail address was the contact e-mail for agaricus.net. Isely was not the owner of agaricus.net and lacked control to alter its contents or who was the registrant. (Liggins Tr. 115-16; JX 16; JX 4, Velasco Dep. at 13; JX 5).

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](http://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).

**Response to Finding No. 14:**

False. Isely never advertised or sold RAAX11 to customers through agaricus.net. (Liggins, Tr. 115-16; JX 16; JX 4, Velasco Dep. at 13; JX 5).

**Deceptive Advertising Claims for RAAX11**

15. 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. (JX 7 (Complaint)).

**Response to Finding No. 15:**

All representatives and advertising claims found on [www.agaricus.net](http://www.agaricus.net) were made by an individual or business entity other than the Respondents. (Liggins, Tr. 70-71, 108, 110, 115-16, 122-23, 131, 133); (JX 4 (Velasco, Dep. at 10-13, 15, 18-19) (JX 5, JX 6, JX 16, JX 70, JX 71, JX 72)).

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).

**Response to Finding No. 16:**

All representatives and advertising claims found on [www.agaricus.net](http://www.agaricus.net) were made by an individual or business entity other than the Respondents. (Liggins, Tr. 70-71, 108, 110, 115-16, 122-23, 131, 133); (JX 4 (Velasco, Dep. at 10-13, 15, 18-19) (JX 5, JX 6, JX 16, JX 70, JX 71, JX 72)).

17. 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.”** (JX 7 (Complaint) at Ex. A (emphasis in original)).

**Response to Finding No. 17:**

All representatives and advertising claims found on [www.agaricus.net](http://www.agaricus.net) were made by an individual or business entity other than the Respondents. (Liggins, Tr. 70-71, 108, 110, 115-16, 122-23, 131, 133); (JX 4 (Velasco, Dep. at 10-13, 15, 18-19) (JX 5, JX 6, JX 16, JX 70, JX 71, JX 72)).

18. 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: **“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)).

**Response to Finding No. 18:**

All representatives and advertising claims found on [www.agaricus.net](http://www.agaricus.net) were made by an individual or business entity other than the Respondents. (Liggins, Tr. 70-71, 108, 110, 115-16, 122-23, 131, 133); (JX 4 (Velasco, Dep. at 10-13, 15, 18-19) (JX 5, JX 6, JX 16, JX 70, JX 71, JX 72)).

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)).

**Response to Finding No. 19:**

All representatives and advertising claims found on [www.agaricus.net](http://www.agaricus.net) were made by an individual or business entity other than the Respondents. (Liggins, Tr. 70-71, 108, 110, 115-16, 122-23, 131, 133); (JX 4 (Velasco, Dep. at 10-13, 15, 18-19) (JX 5, JX 6, JX 16, JX 70, JX 71, JX 72)).

20. 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.” (JX 7 (Complaint) at Ex. D (emphasis in original)).

**Response to Finding No. 20:**

All representatives and advertising claims found on [www.agaricus.net](http://www.agaricus.net) were made by an individual or business entity other than the Respondents. (Liggins, Tr. 70-71, 108, 110, 115-16, 122-23, 131, 133); (JX 4 (Velasco, Dep. at 10-13, 15, 18-19) (JX 5, JX 6, JX 16, JX 70, JX 71, JX 72)).

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)).

**Response to Finding No. 21:**

All representatives and advertising claims found on [www.agaricus.net](http://www.agaricus.net) were made by an individual or business entity other than the Respondents. (Liggins, Tr. 70-71, 108, 110, 115-16, 122-23, 131, 133); (JX 4 (Velasco, Dep. at 10-13, 15, 18-19) (JX 5, JX 6, JX 16, JX 70, JX 71, JX 72).

**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).

**Response to Finding No. 22:**

All representatives and advertising claims found on [www.agaricus.net](http://www.agaricus.net) were made by an individual or business entity other than the Respondents. (Liggins, Tr. 70-71, 108, 110, 115-16, 122-23, 131, 133); (JX 4 (Velasco, Dep. at 10-13, 15, 18-19) (JX 5, JX 6, JX 16, JX 70, JX 71, JX 72).

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).

**Response to Finding No. 23:**

All representatives and advertising claims found on [www.agaricus.net](http://www.agaricus.net) were made by an individual or business entity other than the Respondents. (Liggins, Tr. 70-71, 108, 110, 115-16, 122-23, 131, 133); (JX 4 (Velasco, Dep. at 10-13, 15, 18-19) (JX 5, JX 6, JX 16, JX 70, JX 71, JX 72).

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).

**Response to Finding No. 24:**

All representatives and advertising claims found on [www.agaricus.net](http://www.agaricus.net) were made by an individual or business entity other than the Respondents. (Liggins, Tr. 70-71, 108, 110, 115-16, 122-23, 131, 133); (JX 4 (Velasco, Dep. at 10-13, 15, 18-19) (JX 5, JX 6, JX 16, JX 70, JX 71, JX 72).

25. Dr. Kucuk conducts clinical research treating cancers of the prostate, bladder, kidney and testis. (JX 1 ¶ 2).

**Response to Finding No. 25:**

All representatives and advertising claims found on [www.agaricus.net](http://www.agaricus.net) were made by an individual or business entity other than the Respondents. (Liggins, Tr. 70-71, 108, 110, 115-16, 122-23, 131, 133); (JX 4 (Velasco, Dep. at 10-13, 15, 18-19) (JX 5, JX 6, JX 16, JX 70, JX 71, JX 72).

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).

**Response to Finding No. 26:**

All representatives and advertising claims found on [www.agaricus.net](http://www.agaricus.net) were made by an individual or business entity other than the Respondents. (Liggins, Tr. 70-71, 108, 110, 115-16, 122-23, 131, 133); (JX 4 (Velasco, Dep. at 10-13, 15, 18-19) (JX 5, JX 6, JX 16, JX 70, JX 71, JX 72).

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).

**Response to Finding No. 27:**

All representatives and advertising claims found on [www.agaricus.net](http://www.agaricus.net) were made by an individual or business entity other than the Respondents. (Liggins, Tr. 70-71, 108, 110, 115-16, 122-23, 131, 133); (JX 4 (Velasco, Dep. at 10-13, 15, 18-19) (JX 5, JX 6, JX 16, JX 70, JX 71, JX 72).

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).

**Response to Finding No. 28:**

All representatives and advertising claims found on [www.agaricus.net](http://www.agaricus.net) were made by an individual or business entity other than the Respondents. (Liggins, Tr. 70-71, 108, 110, 115-16, 122-23, 131, 133); (JX 4 (Velasco, Dep. at 10-13, 15, 18-19) (JX 5, JX 6, JX 16, JX 70, JX 71, JX 72).

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).

**Response to Finding No. 29:**

All representatives and advertising claims found on [www.agaricus.net](http://www.agaricus.net) were made by an individual or business entity other than the Respondents. (Liggins, Tr. 70-71, 108, 110, 115-16, 122-23, 131, 133); (JX 4 (Velasco, Dep. at 10-13, 15, 18-19) (JX 5, JX 6, JX 16, JX 70, JX 71, JX 72).

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).

**Response to Finding No. 30:**

All representatives and advertising claims found on [www.agaricus.net](http://www.agaricus.net) were made by an individual or business entity other than the Respondents. (Liggins, Tr. 70-71, 108, 110, 115-16, 122-23, 131, 133); (JX 4 (Velasco, Dep. at 10-13, 15, 18-19) (JX 5, JX 6, JX 16, JX 70, JX 71, JX 72).

**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).

**Response to Finding No. 31:**

All representatives and advertising claims found on [www.agaricus.net](http://www.agaricus.net) were made by an individual or business entity other than the Respondents. (Liggins, Tr. 70-71, 108, 110, 115-16, 122-23, 131, 133); (JX 4 (Velasco, Dep. at 10-13, 15, 18-19) (JX 5, JX 6, JX 16, JX 70, JX 71, JX 72).

32. Specifically, Dr. Kucuk found no published scientific literature evaluating the efficacy of RAAX11 or any clinical trial data with RAAX11. (JX 1 ¶ 16).

**Response to Finding No. 32:**

All representatives and advertising claims found on [www.agaricus.net](http://www.agaricus.net) were made by an individual or business entity other than the Respondents. (Liggins, Tr. 70-71, 108, 110, 115-16, 122-23, 131, 133); (JX 4 (Velasco, Dep. at 10-13, 15, 18-19) (JX 5, JX 6, JX 16, JX 70, JX 71, JX 72).

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).

**Response to Finding No. 33:**

All representatives and advertising claims found on [www.agaricus.net](http://www.agaricus.net) were made by an individual or business entity other than the Respondents. (Liggins, Tr. 70-71, 108, 110, 115-16, 122-23, 131, 133); (JX 4 (Velasco, Dep. at 10-13, 15, 18-19) (JX 5, JX 6, JX 16, JX 70, JX 71, JX 72).

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).

**Response to Finding No. 34:**

All representatives and advertising claims found on [www.agaricus.net](http://www.agaricus.net) were made by an individual or business entity other than the Respondents. (Liggins, Tr. 70-71, 108, 110, 115-16, 122-23, 131, 133); (JX 4 (Velasco, Dep. at 10-13, 15, 18-19) (JX 5, JX 6, JX 16, JX 70, JX 71, JX 72).

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).

