

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

DOCKET NO. 9330

GEMTRONICS, INC., a corporation, and

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

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

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.

 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.

 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.

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.

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 <u>www.agaricus.net</u>. (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 <u>www.agaricus.net</u>, 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 <u>www.agaricus.net</u> 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 <u>www.agaricus.net</u> 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 <u>www.agaricus.net</u> 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 <u>www.agaricus.net</u> 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 <u>www.agaricus.net</u> 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 <u>www.agaricus.net</u> 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 <u>www.agaricus.net</u> 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 <u>www.agaricus.net</u> 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 <u>www.agaricus.net</u> 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 <u>www.agaricus.net</u> 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 <u>www.agaricus.net</u> 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 <u>www.agaricus.net</u> 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 <u>www.agaricus.net</u> 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 <u>www.agaricus.net</u> 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 $1 \parallel 3$).

Response to Finding No. 26:

All representatives and advertising claims found on <u>www.agaricus.net</u> 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 <u>www.agaricus.net</u> 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 <u>www.agaricus.net</u> 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 <u>www.agaricus.net</u> 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 <u>www.agaricus.net</u> 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 <u>www.agaricus.net</u> 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 <u>www.agaricus.net</u> 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 <u>www.agaricus.net</u> 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 RAAX11separately, 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 \P 18).

Response to Finding No. 34:

All representatives and advertising claims found on <u>www.agaricus.net</u> 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 \P 20).

Response to Finding No. 35:

All representatives and advertising claims found on <u>www.agaricus.net</u> 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).

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).

Response to Finding No. 36:

All representatives and advertising claims found on <u>www.agaricus.net</u> 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).

<u>Respondents Provided No Competent and Reliable Evidence to Support the Claims for</u> <u>RAAX11</u>

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).

Response to Finding No. 37:

Respondents have no specific response.

<u>The Website Identified Gemtronics and Isely as the Exclusive Source for RAAX11 in the</u> <u>United States</u>

38. In numerous instances, the Internet website <u>www.agaricus.net</u> advertised Respondents as the <u>only</u> 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).

Response to Finding No. 38:

Isely did not give G. Otto, the owner of <u>agaricus.net</u>, permission to use his name, contact information or likeness appearing to originate from Isely on the <u>agaricus.net</u> webpage. Isely only learned that his name was being used without his permission when he was contacted by Complaint Counsel. Isely only permitted G. Otto to use his name for the

purpose of a testimonial during a time period when RAAX11 was not available. Isely received no benefit from products sold through <u>agaricus.net</u>. Isely did not own or control the content of <u>agaricus.net</u>. G. Otto and a business entity owned by Otto owned <u>agaricus.net</u> and controlled the content of <u>agaricus.net</u>, not Isely. (Isely, Tr. 199, 260-62, 266-69, 271, 286-87, 292, 350-51, 353). (JX 4 (Velasco, Dep. at 12-16; JX5, JX 6). (Liggins, Tr. 70-71, 108, 115-16, 122-23, 131-33, JX 16).

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).

Response to Finding No. 39:

Respondents incorporate their response to proposed finding of fact number 38 herein.

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).

Response to Finding No. 40:

Respondents incorporate their response to proposed finding of fact number 38 herein.

41. A "Shopping Cart for USA only" webpage from <u>www.agaricus.net</u>, 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).

Response to Finding No. 41:

Respondents incorporate their response to proposed finding of fact number 38 herein.

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).

Response to Finding No. 42:

Respondents incorporate their response to proposed finding of fact number 38 herein.

43. Beginning in 2004 and continuing on into 2008, the website <u>www.agaricus.net</u> 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).

Response to Finding No. 43:

Respondents incorporate their response to proposed finding of fact number 38 herein.

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).

Response to Finding No. 44:

Respondents incorporate their response to proposed finding of fact number 38 herein.

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).

Response to Finding No. 45:

Respondents incorporate their response to proposed finding of fact number 38 herein.

46. Another webpage, dated February 10, 2005, advertises the sale of RAAX11 <u>exclusively</u> 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).

Response to Finding No. 46:

Respondents incorporate their response to proposed finding of fact number 38 herein.

47. A home webpage advertising RAAX11 from <u>www.agaricus.net</u> 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).

Response to Finding No. 47:

Respondents incorporate their response to proposed finding of fact number 38 herein.

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).

Response to Finding No. 48:

Respondents incorporate their response to proposed finding of fact number 38 herein.

49. Similarly, two webpages from <u>www.agaricus.net</u>, 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).

Response to Finding No. 49:

Respondents incorporate their response to proposed finding of fact number 38 herein.

50. A more recent <u>www.agaricus.net</u> 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).

Response to Finding No. 50:

Respondents incorporate their response to proposed finding of fact number 38 herein.

51. This January 3, 2008 <u>www.agaricus.net</u> 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)

Response to Finding No. 51:

Respondents incorporate their response to proposed finding of fact number 38 herein.

Liability of Respondent Gemtronics

52. Gemtronics fulfilled orders for RAAX11 made on the website <u>www.agaricus.net</u> (CCPF ¶¶ 53-56)

Response to Finding No. 52:

Isely drop-shipped two single bottle orders made by the FTC at the request of Takesun do Brasil for no money. (Liggins, Tr. 162) (Isely, Tr. 286-87, 292).

53. On January 3, 2008, and again on January 28, 2008, an FTC Investigator purchased RAAX11 from the website <u>www.agaricus.net</u>. (Liggins, Tr. 71-90, 147-48,170-72; JX 2; JX 3; JX 43-JX 60).

Response to Finding No. 53:

Respondents have no specific response.

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).

Response to Finding No. 54:

Liggins testified that he could not tell who was receiving payment for the undercover purchases. For the same purchase described herein, separate webpage confirmations showed that payment was being made to "Takesun Portugal Lda. Verkauf" and "TAKESUNPORT." (Liggins, Tr. 162) (JX 51, JX 52, JX 60).

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).

Response to Finding No. 55:

The invoices do not state that any payment had been made to Gemtronics. (JX 48) See Response to No. 54.

 Respondents fulfilled orders for RAAX11 made on the website <u>www.agaricus.net</u>. (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).

Response to Finding No. 56:

Isely drop-shipped two single bottle orders made by the FTC at the request of Takesun do Brasil for no money. (Liggins, Tr. 162) (Isely, Tr. 286-87, 292).

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 <u>www.agaricus.net</u>" 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).

Response to Finding No. 57:

No specific response.

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).

Response to Finding No. 58:

No specific response.

Individual Liability of Respondent Isely

59. Gemtronics is a closely held corporation and Respondent Isely is its owner and manager. (CCPF ¶¶ 1, 3, 10).

Response to Finding No. 59:

Respondent formed Gemtronics, Inc. and is only the registered agent for the same. Gemtronics, Inc. has no owner. (Isely, Tr. 215-217, 223, 323-24; JX 9 at 4-5, JX 16).

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).

Response to Finding No. 60:

Respondent Isely is the sole proprietorship of "Gemtronics."

61. Isely individually participated in the acts and practices at issue in this matter. (CCPF ¶¶ 62-72

Response to Finding No. 61:

No culpable acts.

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).

Response to Finding No. 62:

Respondents have no specific response.

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).

Response to Finding No. 63:

Respondents incorporate their response to proposed finding of fact number 38 herein.

64. Respondent Isely received the registration renewal notices for domain names including <u>www.our-agaricus.com</u> and <u>www.our-agaricus.us</u>. (JX 12 (Isely, Dep.) at 27-28).

Response to Finding No. 64:

Respondents incorporate their response to proposed finding of fact number 38 herein.

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).

Response to Finding No. 65:

Respondents have no specific response.

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 <u>www.agaricus.net</u> and another website. (Liggins, Tr. 103-04, 176-77; Isely, Tr. 312-13; JX 65).

Response to Finding No. 66:

Respondents have no specific response.

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).

Response to Finding No. 67:

Respondents have no specific response.

68. Isely was prominently featured throughout the website and his name and telephone number were included on a number of webpages on <u>www.agaricus.net</u> 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).

Response to Finding No. 68:

Respondents incorporate their response to proposed finding of fact number 38 herein.

69. Respondent Isley was also aware that his name, his telephone numbers, and his health history were being used on the website <u>www.agaricus.net</u>, 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).

Response to Finding No. 69:

Respondents incorporate their response to proposed finding of fact number 38 herein.

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).

Response to Finding No. 70:

Respondents incorporate their response to proposed finding of fact number 38 herein.

71. He admitted that he frequently went to the home page of <u>www.agaricus.net</u> 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).

Response to Finding No. 71:

Respondents incorporate their response to proposed finding of fact number 38 herein.

72. Respondent Isely admitted that consumers could purchase RAAX11 on the website <u>www.agaricus.net</u> using a credit card, that Isely would receive the payment. (Isely, Tr. 364; JX 12 (Isely, Dep.) at 70, 120, 123-24).

Response to Finding No. 72:

Respondent Isely did not admit what Complaint Counsel has stated herein. Complaint Counsel has misquoted Isely's testimony and drawn unsupported conclusions.

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).

Response to Finding No. 73:

Respondents have no specific response.

74. Respondent Isely's business was the sole beneficiary of these claims for sales of RAAX11 in the United States. (CCPF ¶¶ 38).

Response to Finding No. 74:

Respondents incorporate their response to proposed finding of fact number 38 herein.

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).

Response to Finding No. 75:

Respondents have no specific response.

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).

Response to Finding No. 76:

Respondents have no specific response.

77. Each order that Respondent Isely placed would require multiple emails to Mr. Otto to coordinate the shipments. (Isely, Tr. 201).

Response to Finding No. 77:

Respondents have no specific response.

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).

Response to Finding No. 78:

Respondents have no specific response.

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).

Response to Finding No. 79:

Respondents have no specific response.

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).

Response to Finding No. 80:

Respondent Isely did not admit what Complaint Counsel has stated herein. Complaint Counsel has misquoted Isely's testimony and drawn unsupported conclusions.

81. Isely testified that they 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).

Response to Finding No. 81:

No specific response.

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) at17-18, 34-35, 40-41, 60-61, 66, 67-68, 75-76, Ex. 9, Ex. 10; JX 57).

Response to Finding No. 82:

This Takesun USA partnership was formed in 2001, before the relevant time period defined under the Complaint, and dissolved only eight months after formation. There is no evidence that the distribution agreement has ever been disseminated to any third party. (Isely, Tr. 214-16; JX 73).

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)).

Response to Finding No. 83:

This Takesun USA partnership was formed in 2001, before the relevant time period defined under the Complaint, and dissolved only eight months after formation. There is no evidence that the distribution agreement has ever been disseminated to any third party. (Isely, Tr. 214-16; JX 73).

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).

Response to Finding No. 84:

This Takesun USA partnership was formed in 2001, before the relevant time period defined under the Complaint, and dissolved only eight months after formation. There is no evidence that the distribution agreement has ever been disseminated to any third party. (Isely, Tr. 214-16; 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 <u>www.agaricus.net</u>. (Isely, Tr. 211-212; 229, 312-18; JX 9 (Isely, Ints.) #1; JX 12 (Isely, Dep.) at 21-22).

Response to Finding No. 85:

Isely was never a distributor for Takesun. He had been a distributor for another company but not Takesun. (Isely, Tr. 211).

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).

Response to Finding No. 86:

Respondents have no specific response.

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).

Response to Finding No. 87:

Materials were included only in two (2) single bottle drop shipments to FTC investigator Liggins. They make no challenged claims. (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 <u>www.agaricus.net</u> 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)

Response to Finding No. 88:

Isely was not aware that his identity was on agaricus.net except with respect to his testimonial as to his own use of herbal products prior to the inception of RAAX11. When Isely learned that his name was being used without his permission he demanded Otto cease using his name. (Isely, Tr. 199, 241-43, 260-62, 266, 269, 271, 327-29, 353; JX 16, JX 70, JX 71, JX 72).

89. Respondent Isely also developed a Distributor Package that likewise directed consumers to go to the website <u>www.agaricus.net</u>. (Isely, Tr. 215; JX 73).

Response to Finding No. 89:

There is no evidence that the distributor package has been disseminated to any third party. The JX 73 exhibit makes no challenged claims. (Isely, Tr. 214-16; 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 <u>www.agaricus.net</u>. (Liggins, Tr. 90-91; Isely, Tr. 298-304; 356-58; JX 12 (Isely, Dep.) at 69-74; JX 59).

Response to Finding No. 90:

Counsel was ordered by the presiding ALJ to not refer to JX 59 in a post-trial brief (Isely, Tr. 305-306; JX 59).

The brochure referred to by Complaint Counsel refers to a different product/protocol than RAAX11, the challenged product. (Isely, Tr. 299-305) (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).

Response to Finding No. 91.

Respectfully Submitted, MATTHEW I. VAN HORN

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Attorney for Respondents Gemtronics, Inc. and William H. Isley

This day August 4, 2009

CERTIFICATE OF SERVICE

This is to certify that the undersigned has this date served this **RESPONDENTS'**

RESPONSE TO COMPLAINT COUNSEL'S PROPOSED FINDINGS OF FACTS in the

above entitled action upon all other parties to this cause by depositing a copy hereof in a postpaid wrapper in a post office or official depository under the exclusive care and custody of the United States Postal Service, properly addressed to the attorney or attorneys for the parties as listed below.

One (1) e-mail copy and four (4) paper copies served by United States mail delivery to:

Honorable D. Michael Chappell Chief Administrative Law Judge (Acting) Federal Trade Commission H106 600 Pennsylvania Ave., NW Washington, D.C. 20580

The original and one (1) paper copy via United States mail delivery and one (1) electronic copy via e-mail:

Honorable Donald S. Clark Secretary Federal Trade Commission H135 600 Pennsylvania Ave., NW Washington, D.C. 20580

One (1) electronic copy via e-mail and one (1) paper copy via United States mail delivery to:

Ms. Barbara E. Bolton Federal Trade Commission 225 Peachtree Street, N.E. Suite 1500 Atlanta, GA 30303

This day August 4, 2009.

MATTHEW I. VAN HORN