

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 MOTION FOR SUMMARY DECISION

Pursuant to Section 3.24 of the Commission's Rules of Practice, Complaint Counsel moves for summary decision in this matter. Based on the pleadings and other evidence in this case, as described in Complaint Counsel's Statement of Material Facts as to Which There is No Genuine Dispute, Complaint Counsel is entitled to summary decision as to violations of Sections 5(a) and 12 of the Federal Trade Commission Act. The arguments supporting Complaint Counsel's motion are set forth in the accompanying Memorandum in Support of Complaint Counsel's Motion for Summary Decision.

Respectfully Submitted,

A handwritten signature in black ink, appearing to read "Barbara E. Bolton".

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Federal Trade Commission
225 Peachtree Street, Suite 1500
Atlanta, GA 30303

Dated: March 16, 2009

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**COMPLAINT COUNSEL'S MEMORANDUM IN SUPPORT OF
MOTION FOR SUMMARY DECISION**

I. INTRODUCTION

Complaint Counsel moves for Summary Decision, pursuant to Commission Rule of Practice 3.24, against Respondents Gemtronics, Inc. ("Gemtronics"), and William H. Isely ("Isely"), individually and as the owner of Gemtronics. The Federal Trade Commission ("FTC") issued its Complaint in this matter on September 18, 2008, alleging that Respondents violated Sections 5(a) and 12 of the Federal Trade Commission Act ("FTC Act") by making false and unsubstantiated claims that the product, RAAX11, a food or drug within the meaning of Sections 12 and 15 of the FTC Act, is effective in preventing, treating, or curing various types of cancer and that these claims are proven by reliable scientific evidence.

The uncontroverted evidence presented herein reveals that Respondents made false and unsubstantiated cancer claims in Internet advertisements that deceived consumers nationwide about the about the benefits of RAAX11. The evidence presented also clearly demonstrates that scientific evidence does not support any cancer-related claims for RAAX11 and that

Respondents did not possess adequate substantiation for their claims.

Summary decision is appropriate in this case because the evidence demonstrates that Respondents made the alleged claims, in violation of Section 5(a) and 12 of the FTC Act. There is no genuine issue of material fact as to whether Respondents made the representations challenged in the Commission's Complaint, or as to whether such representations are false and unsubstantiated.

Complaint Counsel seeks a proposed order that, among other things, 1) 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 2) requires Respondents to notify their customers who purchased RAAX11 that scientific studies do not demonstrate that RAAX11, or its ingredients, are effective in the treatment of cancer.

II. STATEMENT OF FACTS¹

A. Respondents' Business

Starting in at least 2004, Respondent Isely was operating a business from his residence that advertised and sold dietary supplements to consumers nationwide through mail order, telephone, and the Internet. (CCSF ¶¶ 3, 4.) He ran this business as a sole proprietor under the assumed name Gemtronics. (CCSF ¶ 3.) 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. (CCSF ¶¶ 1, 4.) Respondent Isely is the owner, registered agent, and general manager of Gemtronics (CCSF ¶ 5.) After incorporating Gemtronics, Isely

¹ Pursuant to Rule of Practice § 3.24(a), Complaint Counsel has submitted the accompanying Statement of Material Facts As To Which There Is No Genuine Issue ("CCSF") as a separate document.

continued his business advertising and selling dietary supplements through this corporate entity. (CCSF ¶18.)

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. (CCSF ¶19.) 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. (CCSF ¶ 20.) From 2004 through 2008, Respondents sold approximately 1150 bottles of RAAX11 at a cost of approximately \$120 per bottle. (CCSF ¶21.) Respondents charged shipping and handling fees of \$15.00. (CCSF ¶ 22)

B. Respondents' Deceptive Advertising Claims for RAAX11

Through the website advertising claims, listed below, 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.

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

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.

(CCSF ¶ 9.)

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.

(CCSF ¶ 7.)

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%.

(CCFS ¶ 9.)

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.
(CCSF ¶ 9.)

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

Beneath the webpage representations, noted above in Section II.B.1., 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.
(CCSF ¶ 9.)

III. NO SCIENTIFIC EVIDENCE SUPPORTS THE RAAX11 CANCER CLAIMS

In support of its Motion for Summary Decision, Complaint Counsel submits the Expert Report of Dr. Omer Kucuk, an expert in the fields of cancer research and treatment, and in the use of botanical compounds on cancer patients. (CCSF ¶ 23.) Dr. Kucuk is Board Certified in Medical Oncology with the American Board of Internal Medicine. (CCSF ¶ 24.) Dr. Kucuk has been a practicing in the field of medical oncology for over 27 years. (CCSF ¶ 24.) His areas of expertise include cancer prevention, nutrition and cancer, chemoprevention, chemotherapy, medical oncology and clinical trials. (CCSF ¶ 24.) Dr. Kucuk conducts clinical research treating cancers of the prostate, bladder, kidney and testis. (CCSF ¶ 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. (CCSF ¶ 26.)

In his report, Dr. Kucuk 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. (CCSF¶ 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. (CCSF¶ 28.)

Dr. Kucuk's report details his 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. (CCSF¶ 29.) After completing his review, Dr. Kucuk's expert opinion is 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. (CCSF¶ 30.)

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

According to his expert report, Dr. Kucuk found no published scientific literature evaluating either RAAX11 or evaluating the combination of *icaco* and *agaricus* as a cancer treatment. (CCSF¶ 31.) Specifically, Dr. Kucuk reported finding no published scientific literature evaluating the efficacy of RAAX11 or any clinical trial data with RAAX11. (CCSF¶ 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. (CCSF¶ 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*. (CCSF¶ 34.) While Dr. Kucuk's report states 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. (CCSF ¶ 35.)

Further, specifically evaluating the scientific literature in light of the allegations contained in the Commission's Complaint, Dr. Kucuk concluded 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 (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 (Complaint ¶ 8.A.); and (3) RAAX11 is effective in the prevention of cancer, including, but not limited to uterine cancer (Complaint ¶ 8.B.). (CCSF ¶ 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 in his report. After reviewing the materials, it is Dr. Kucuk's 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. (CCSF ¶ 50.)

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

A. Respondents' Advertising Claims are Facially Clear and Material

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).

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.*, 118 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.

Applying this standard, claims made in Respondent's advertisements highlighted are clear on their face. Therefore, there is no requirement for extrinsic evidence to determine if these claims are conveyed to reasonable consumers. In fact, Respondents have not contested that the

claims were made. (Answer ¶ 5.) Respondents' advertising claims are also 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. *See, e.g., Deception Statement*, 103 F.T.C. at 182.

B. Respondents' Claims are False and Unsubstantiated

The Commission has consistently held that objective claims made without a reasonable basis constitute a deceptive practice in violation of Section 5. *FTC Policy Statement Regarding Advertising Substantiation*, 104 F.T.C. 839 (1984) (*Substantiation Statement*); *see, e.g., Automotive Breakthrough Sciences, Inc.*, 126 F.T.C. 229, 293 & 293 n.20 (1998); *Jay Norris, Inc.*, 91 F.T.C. 751, 854 (1978), *aff'd as modified*, 598 F.2d 1244 (2d Cir. 1979), *cert. denied*, 444 U.S. 980 (1979). What constitutes a reasonable basis is an objective standard: advertisers must possess at least the level of substantiation expressly or impliedly claimed in the advertisement. *See Honeywell, Inc.*, 126 F.T.C. 202 (1998); *FTC v. Natural Solution, Inc.*, No. CV 06-6112-JFW, 2007 U.S. Dist. LEXIS 60783, at *10 (C.D. Cal. Aug. 7, 2007) (citing *FTC v. U.S. Sales Corp.*, 785 F. Supp. 737, 748 (N.D. Ill. 1992)).

For health and safety claims, advertisers must possess competent and reliable scientific evidence substantiating their claims in order to have a reasonable basis for such claims. *See FTC v. National Urological Group, Inc.*, No. 1:04-CV-3294-CAP, 2008 U.S. Dist. LEXIS 44145, at *77 (N.D. Ga. June 4, 2008) (granting FTC's summary judgment motion, court finds safety and efficacy claims for dietary supplements must be substantiated by competent and reliable scientific evidence); *Natural Solution*, 2007 U.S. Dist. LEXIS 60783, at *11-13 (granting FTC's summary judgment motion, court requires competent and reliable scientific evidence for cancer prevention and treatment claims for product); *FTC v. QT, Inc.*, 448 F. Supp.

2d 908, 961 (N.D. Ill. 2006) *aff'd*, 512 F.3d 858 (competent and reliable scientific standard applied for evidence that bracelet relieves pain). Competent and reliable scientific evidence is typically defined as tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results. *See, e.g., Brake Guard Products, Inc.*, 125 F.T.C. 138 (1998); *ABS Tech Sciences, Inc.*, 126 F.T.C. 229 (1998).

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

The product at issue in this case, RAAX11, is dietary supplement that is advertised and sold as a cancer treatment, prevention and cure. Respondents' advertising representations relate to health and safety and, thus, require substantiation consisting of competent and reliable scientific evidence. As noted above, Complaint Counsel's expert, Dr. Kucuk concludes that to support cancer treatment claims for a product, 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. Therefore, Respondents lacked a reasonable basis for their advertising claims for RAAX11, and accordingly, have violated Sections 5 and 12 of the FTC Act.

V. RESPONDENTS ARE LIABLE FOR FTC ACT VIOLATIONS

A. Liability of Respondent Gemtronics

The corporate Respondent Gemtronics, by and through its owner, William Isely, violated Sections 5 and 12 of the FTC Act. Gemtronics fulfilled orders for RAAX11 made on the website www.agaricus.net. (CCSF ¶¶ 12-17.) On January 3, 2008, and again on January 28, 2008, an FTC Investigator purchased RAAX11 from the website www.agaricus.net. (CCSF ¶¶ 12-17.) 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.” (CCSF ¶ 15.) 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. (CCSF ¶¶ 14-17.) The promotional literature in one package included a Gemtronics brochure stating “for more information . . . go to the website www.agaricus.net and click on USA sales” and providing telephone and email contact information for Gemtronics. (CCSF ¶ 17.)

B. Individual Liability of Respondent Isely

The Commission and the courts examine, separately or in combination, a number of factors when determining individual liability: the unlawful practices involved; the respondent’s involvement with the practices; the type of corporate entity; the respondent’s ownership interest; the corporate office (if any) held; and the influence he exercised over corporate affairs.

Telebrands Corp., 140 F.T.C. at 450; *National Housewares*, 90 F. T. C. 512, 598 (1977).

Gemtronics is a closely-held corporation and Respondent Isely is its owner and manager. (CCSF ¶ 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.

Respondent Isely clearly is liable in this case because he was actively involved in and controlled every facet of Gemtronics' business. Respondent Isely ran Gemtronics business from his home and controlled the company's bank account. (CCSF ¶¶ 3, 6, 38.) Further, Respondent Isely individually participated in the acts and practices at issue in this matter. Isely acknowledged personally fulfilling the two orders for RAAX11 that were placed on the www.agaricus.net website by the FTC. (CCSF ¶ 39.) In addition, Isely was personally identified on the Gemtronics packages, invoices, and in the promotional literature received by the FTC and Isely admitted that these were his materials. (CCSF ¶ 40.)

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. (CCSF ¶ 20.) 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. (CCSF ¶ 41.) 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. (CCFS ¶¶ 7-11.) 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. (CCSF ¶ 42.)

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).

As shown above, Respondent Isely should be held individually liable because of the type of corporate entity Gemtronics is and because of Respondent Isely’s ownership interest in the company. In addition, Respondent Isely had authority to and did control the acts and practices of Respondent Gemtronics. Moreover, he directly participated in the acts and practices at issue in this case. Finally, finding Respondent Isely individually liable is necessary in order to ensure fully effective relief for the deceptive practices alleged in the Commission’s Complaint.

Accordingly, 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.

VI. SUMMARY DECISION STANDARD

Commission Rule of Practice 3.24(a)(2) provides that summary decision “shall be

rendered . . . if the pleadings and any depositions, answers to interrogatories, admissions on file, and affidavits show that there is no genuine issue as to any material fact and that the moving party is entitled to such decision as a matter of law.” Rule 3.24(a)(3) provides that once a motion for summary decision is made and adequately supported, “a party opposing the motion may not rest upon the mere allegations or denials of his pleading; his response, by affidavits or as otherwise provided in this rule, must set forth specific facts showing that there is a genuine issue of fact for trial.” *See also Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986); *Adikes v. S.H. Kress & Co.*, 398 U.S. 144, 157 (1970). The provisions of FTC Rule 3.24 are virtually identical to the provisions of Fed. R. Civ. P. 56, governing summary judgment in the federal courts. *In re Kroger Co.*, 98 F.T.C. 639, 726 (1981); *Hearst Corp.*, 80 F.T.C. 1011, 1014 (1972).

The Supreme Court has held that where the record, taken as a whole, could not lead a rational trier of fact to find for the non-moving party, there is no genuine issue for trial. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986). The party moving for summary judgment must satisfy the evidentiary burden that it would bear at trial. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 254 (1986). If the moving party meets its burden, the opposing party must come forward with specific facts showing there is a genuine issue for trial. *See Matsushita*, 475 U.S. at 585-88. The “mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment.” *Liberty Lobby*, 477 U.S. at 247-48.

A determination of whether an advertising practice complies with the laws or regulations enforced by the FTC is a question of law that can be resolved on summary decision. *See FTC v.*

Bronson Partners, 564 F. Supp. 2d 119 (D. Conn. 2008) (granting summary judgment for FTC, court found defendants made deceptive advertising claims for purported weight-loss product); *FTC v. National Urological Group, Inc.*, No.1:04-CV-3294, 2008 U.S. Dist. LEXIS 44145 (N.D.Ga. June 4, 2008) (granting FTC's summary judgment motion, court found defendants deceptively advertised dietary supplements); *FTC v. Natural Solution, Inc.*, No. 06-6112, 2007 U.S. Dist. LEXIS 60783 (C.D.Cal. Aug. 7, 2007) (summary judgment ruling that defendants' advertisements for a purported cancer treatment were deceptive).

As set forth above, there is no genuine issue as to any material fact relating to whether Respondents made the representations challenged in the Commission's Complaint. In addition, there is no genuine issue as the fact that Respondents' advertising representations were false and unsubstantiated. Accordingly, Complaint Counsel is entitled to summary decision as a matter of law.

VII. THE PROPOSED ORDER

Complaint Counsel respectfully requests that the Court enter the accompanying proposed Order. The proposed Order is substantially similar in form and content to those recently approved by the Commission in cases challenging deceptive advertising of bogus cancer cures. *See, e.g., FTC v. Westberry Enterprises, Inc.*, 2008 F.T.C. LEXIS 99 (F.T.C. Sept. 18, 2008).

The proposed Order prohibits Respondents from making the types of misrepresentations that gave rise to the violations in this matter. Specifically, Part I of the proposed order would require that Respondents possess and rely upon competent and reliable scientific evidence that

substantiates any representations they make about the ability of the RAAX11, any substantially similar products, and any other covered products (as defined in the order), to prevent, treat or cure cancer. Part II of the proposed order would prohibit Respondents from making representations about the comparative benefits, performance, efficacy, safety or side effects of any covered product or service, unless they have the required substantiation. Part III prohibits any misrepresentations regarding the existence, contents, validity, results, conclusions, or interpretations of any test or study.

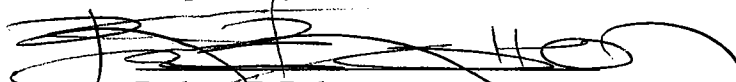
Part IV of the proposed order is the FDA Safe Harbor provision allowing representations permitted in labeling by the FDA. Part V requires Respondents to provide notice via first class mail to consumer purchasers that the product claims for RAAX11 are false or unsubstantiated. The remaining provisions, Parts VI through X of the proposed Order, contain the standard administrative record-keeping and reporting requirements.

VIII. CONCLUSION

For the reasons stated above, Complaint Counsel respectfully request that this motion for summary decision be granted.

Dated: March 16, 2009

Respectfully submitted,



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**COMPLAINT COUNSEL'S STATEMENT OF MATERIAL FACTS
AS TO WHICH THERE IS NO GENUINE ISSUE**

Pursuant to Commission Rule of Practice 3.24, 16 C.F.R. § 3.24, and in support of its motion for summary decision, Complaint Counsel submits this separate statement of material facts as to which there is no genuine issue.

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.
2. Respondent William H. Isely ("Isely") resides at is 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 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.") No. 1, 2, 8; Exhibit A to Isely Ints. Resp. (hereinafter "Isely Ints. Resp. Ex. ____"); Isely Deposition Transcript (hereinafter "Isely Dep.") 12-13.
4. Respondent Isely incorporated Gemtronics, Inc. in North Carolina in 2006. Answer ¶ 1; Isely Ints. Resp. No. 2; Isely Dep. 31, 99-100, Respondents' Exhibit to Isely Dep. (hereinafter "Resp. Ex.") 1.
5. Respondent Isely is the owner, registered agent, and general manager of Gemtronics. Isely Ints. Resp. 1; Isely Dep. 101, 105, Resp. Ex. 1; Isely Dep. Complaint Counsel's

Exhibit to Isely Dep. (hereinafter (“CC Ex.”) 6.

6. Respondent Isely registered Gemtronics, Inc., located at his home, as an FDA approved warehouse to import dietary supplements for resale. Isely Ints. Resp. No. 13; Isely Dep. 19-21.
7. On December 12, 2007, FTC Investigator Michael S. Liggins (“Liggins”) found advertisements for RAAX11 that also included Respondent Isely’s name and telephone numbers on the website www.agaricus.net. On that same date, December 12, 2007, Liggins reviewed and preserved to a CD an exact copy of this website. Exhibit B to the Commission’s Complaint in this matter is taken from this CD. Complaint Counsel’s Summary Decision Exhibit (hereinafter “S.D. Ex. ___”) 2, Declaration of Michael S. Liggins, FTC Investigator, dated March 12, 2009 (hereinafter “Liggins Dec.”) ¶ 6.A., Att. C.
8. On December 13, 2007, Liggins printed out copies of webpages directly from captured CD of the website www.agaricus.net that included RAAX11 and either references to Respondent Isely and/or his telephone numbers. S.D. 2 (Liggins Dec. ¶ 6.B., Att. D.)
9. On January 3, 2008, Liggins found advertisements for RAAX11 that also included the name and telephone numbers for Respondent Isely on the website www.agaricus.net. On that same date, January 3, 2008, Liggins reviewed and preserved to a CD an exact copy of this website. Exhibits A, C, and D to the Commission’s Complaint in this matter are taken from this CD. S.D. 2 (Liggins Dec. ¶ 6.C., Att. E.)
10. On January 30, 2008, Liggins printed out copies of webpages directly from the website www.agaricus.net that included RAAX11 and either references to Respondent Isely and/or his telephone number. S.D. 2 (Liggins Dec. ¶ 6.D., Att. F.)
11. At each time that Liggins reviewed the website www.agaricus.net, the only telephone numbers that Liggins found listed on the website for information on, or product ordering for RAAX11 in the United States were those belonging to Respondent Isely. S.D. 2 (Liggins Dec. ¶ 6.E.) (*see also* Liggins Dec. ¶ 4, Att. A. (Verizon CID Response identifying Respondent Isely as the owner of the telephone numbers.))
12. On January 3, 2008, Liggins made an undercover purchase of one bottle of RAAX11 from the Internet website www.agaricus.net. S.D. 2 (Liggins Dec. ¶ 7, Att. I.)
13. On January 17, 2008, Liggins received the package containing the bottle of RAAX11. The package was mailed by U.S. mail from Franklin, NC and listed William Isely, 964 Walnut Creek Road, Franklin, NC 28734 as the sender. S.D. 2 (Liggins Dec. ¶¶ 8, 9, Att. I.)
14. Included in the shipment of RAAX11 ordered by Liggins was an invoice for the purchase from Gemtronics at 964 Walnut Creek Road, Franklin, NC 28734, and included

- Respondent Isely's telephone number and email address. The invoice also identified William Isely as the general manager of Gemtronics for retail sales. S.D. 2 (Liggins Dec. ¶ 9, Att. I.)
15. On January 23, 2008, Liggins made a second undercover purchase of one bottle of RAAX11 from the Internet website www.agaricus.net. The Internet confirmation webpage from the website stated: "Your Credit Card is charged using a SSL secured server. On your statement will appear "GEMTRONICS SECURE PAYMENTS." S.D. 2 (Liggins Dec. ¶ 10, Att. J.)
 16. On February 11, 2008, Liggins received the package containing the bottle of RAAX11. The package was mailed by U.S. Express Mail from Franklin, NC and listed William Isely and Gemtronics at the Walnut Creek Road as the sender. S.D. 2 (Liggins Dec. ¶¶ 11, 12, Att. J.)
 17. Included in the shipment of RAAX11 ordered by Liggins was an invoice for the purchase from Gemtronics and promotional literature for RAAX11. The package invoice was from Gemtronics at 964 Walnut Creek Road, Franklin, NC 28734, and listed Respondent Isely's telephone number and email address as well as a note from him asking that future orders be placed with him directly by phone or email. The promotional literature included in the package from Gemtronics consisted of three printed color pages. One promotional page included the heading "Takesun U.S.A." and directed consumers to go to the website www.agaricus.net and "click on USA sales," and listed Gemtronics and a telephone number and an email address for Respondent Isely to obtain more product information. S.D. 2 (Liggins Dec. ¶ 12, Att. J.)
 18. After incorporating Gemtronics, Isely continued his business advertising and selling dietary supplements through this corporate entity. Isely Ints. Resp. No. 13; Isely Dep. 19-21; S.D. 2 (Liggins Dec. ¶¶6 - 12, Atts. C-J.)
 19. 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. Ints. Resp. No. 3; Isely Dep. 34-35, 38, 39-40; S.D. 2 (Liggins Dec. ¶¶6 - 12, Atts. C-J.)
 20. 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. Isely Ints. Resp. No. 1; S.D. 2 (Liggins Dec. ¶ 5.A.)
 21. From 2004 through 2008, Respondents sold approximately 1150 bottles of RAAX11 at a cost of approximately \$120 per bottle. Isely Ints. Resp. No. 3; Isely Dep. 41-42.
 22. Respondents charged shipping and handling fees of \$15.00. S.D. 2 (Liggins Dec. Atts. I, J.)

23. Dr. Omer Kucuk is an expert in the fields of cancer research and treatment, and in the use of botanical compounds on cancer patients. Complaint Counsel's Summary Decision Exhibit 4 is the Expert Report of Dr. Omer Kucuk, ¶¶ 1, 9 (hereinafter cited as Kucuk ¶ ____.)
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. (Kucuk ¶ 1.)
25. Dr. Kucuk conducts clinical research treating cancers of the prostate, bladder, kidney and testis. (Kucuk ¶ 2.)
26. He has authored or co-authored approximately 125 articles published in peer-reviewed scientific journals and more than 20 published book chapters and reviews. (Kucuk ¶ 3.)
27. Dr. Kucuk's 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. (Kucuk ¶¶ 15, 32.)
28. Dr. Kucuk concludes that 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. (Kucuk ¶¶ 32, 34.)
29. Dr. Kucuk's report details his 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. (Kucuk ¶¶ 12, 13, 14, 16, 19, 20, 21, 50.)
30. After completing his review, Dr. Kucuk's expert opinion is 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. (Kucuk ¶¶ 12, 15, 50, 51.)
31. According to his expert report, Dr. Kucuk found no published scientific literature evaluating either RAAX11 or evaluating the combination of *icaco* and *agaricus* as a cancer treatment. (Kucuk ¶¶ 16, 17.)
32. Dr. Kucuk reported finding no published scientific literature evaluating the efficacy of RAAX11 or any clinical trial data with RAAX11. (Kucuk ¶ 16.)

