

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

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

In the Matter of

GEMTRONICS, INC.,
a corporation, and

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

DOCKET NO. 9330

COMPLAINT

The Federal Trade Commission, having reason to believe that Gemtronics, Inc., a corporation, and William H. Isely, individually and as the owner of Gemtronics, Inc. (“respondents”), have violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

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.
2. Respondent William H. Isely (“Isely”), also known as Bill Isely, is the owner of Gemtronics. Individually, or in concert with others, he formulates, directs, controls, or participates in the policies, acts, or practices of Gemtronics, including the acts and practices alleged in this complaint. His principal office or place of business is the same as that of Gemtronics.
3. Respondents have advertised, promoted, offered for sale, sold, and distributed an herbal product, RAAX11. According to the product label, RAAX11 contains the ingredients *agaricus blazei murill* mushroom extract and *chysobalanus icaco* extract. RAAX11 is a “food” or “drug” within the meaning of Sections 12 and 15 of the Federal Trade Commission Act.

4. The acts and practices of respondents as alleged in this complaint have been in or affecting commerce, as “commerce” is defined in Section 4 of the Federal Trade Commission Act.

5. Respondents disseminated or caused to be disseminated advertisements for RAAX11 through an Internet website, www.agaricus.net, including, but not limited to, the attached Exhibits A through D. These advertisements contain the following statements, among others (*all emphasis, punctuation, grammar, and spelling in the original*):

A. **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. The substance is so promising it is being kept under wraps at present.

. . .

Anti cancer effect: ABM contains natural steroids, known for it’s anti cancer effect. . . . It is particularly effective in prevention of uteran cancer.

[Exhibit A.]

B. Scientists report that during laboratory tests the substance destroyed cancer cells that had been resistant to treatment up to now.

. . .

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.

[Exhibit B.]

C. 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%. If you would like to find out how you too can participate in our ongoing study in the USA, call 828-369-7590

[Exhibit C.]

D. B-Cell Chronic Lymphocytic Leukemia

Patient, m, 54, in remission taking the RAAX11 protocol.

[Exhibit D.]

6. Through the means described in Paragraph 5, including the statements and depictions contained in the advertisements attached as Exhibits A through D, among others, respondents have represented, expressly or by implication, that reliable scientific evidence demonstrates that RAAX11 is effective in the prevention, treatment, and cure of cancer.

7. In truth and in fact, reliable scientific evidence does not demonstrate that RAAX11 is effective in the prevention, treatment, and cure of cancer. Therefore, the representation set forth in Paragraph 6 is false and misleading.

8. Through the means described in Paragraph 5, including the statements and depictions contained in the advertisements attached as Exhibits A through D, among others, respondents have represented, expressly or by implication, that:

- A. RAAX11 is effective in the treatment and cure of various types of cancer, including, but not limited to leukemia and cancers of the breast, brain, lung, larynx, pancreas, and bowel; and
- B. RAAX11 is effective in the prevention of cancer, including, but not limited to uterine cancer.

9. Through the means described in Paragraph 5, including the statements and depictions contained in the advertisements attached as Exhibits A through D, among others, respondents have represented, expressly or by implication, that they possessed and relied upon a reasonable basis that substantiated the representations set forth in Paragraph 8, at the time the representations were made.

10. In truth and in fact, respondents did not possess and rely upon a reasonable basis that substantiated the representations set forth in Paragraph 8, at the time the representations were made. Therefore, the representation set forth in Paragraph 9 was, and is, false or misleading.

11. The acts and practices of respondents as alleged in this complaint constitute unfair or deceptive acts or practices, and the making of false advertisements, in or affecting commerce in violation of Sections 5(a) and 12 of the Federal Trade Commission Act.

NOTICE

Proceedings on the charges asserted against the respondents named in this complaint will be held before an Administrative Law Judge (ALJ) of the Federal Trade Commission, under Part 3 of the Commission's Rules of Practice, 16 C.F.R. Part 3. A copy of Part 3 of the Rules is enclosed with this complaint.

You are notified that the opportunity is afforded you to file with the Commission an answer to this complaint on or before the twentieth (20th) day after service of it upon you. An answer in which the allegations of the complaint are contested shall contain a concise statement of the facts constituting each ground of defense; and specific admission, denial, or explanation of each fact alleged in the complaint or, if you are without knowledge thereof, a statement to that effect. Allegations of the complaint not thus answered shall be deemed to have been admitted.

If you elect not to contest the allegations of fact set forth in the complaint, the answer shall consist of a statement that you admit all of the material allegations to be true. Such an answer shall constitute a waiver of hearings as to the facts alleged in the complaint, and together with the complaint will provide a record basis on which the ALJ shall file an initial decision containing appropriate findings and conclusions and an appropriate order disposing of the proceeding. In such answer you may, however, reserve the right to submit proposed findings and conclusions and the right to appeal the initial decision to the Commission under Section 3.52 of the Commission's Rules of Practice for Adjudicative Proceedings.

Failure to answer within the time above provided shall be deemed to constitute a waiver of your right to appear and contest the allegations of the complaint and shall authorize the ALJ, without further notice to you, to find the facts to be as alleged in the complaint and to enter an initial decision containing such findings, appropriate conclusions and order.

The ALJ will schedule an initial prehearing scheduling conference to be held not later than 7 days after the last answer is filed by any party named as a respondent in the complaint. Unless otherwise directed by the ALJ, the scheduling conference and further proceedings will take place at the Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580. Rule 3.21(a) requires a meeting of the parties' counsel as early as practicable before the prehearing scheduling conference, and Rule 3.31(b) obligates counsel for each party, within 5 days of receiving a respondent's answer, to make certain initial disclosures without awaiting a formal discovery request.

Notice is hereby given to each of the respondents named in this complaint that a hearing before the ALJ on the charges set forth in this complaint will begin on December 16, 2008, at 10:00 a.m., or such other date and time as determined by the ALJ, in Room 532, Federal Trade Commission Building, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580. At the hearing, you will have the right under the Federal Trade Commission Act to appear and show cause why an order should not be entered requiring you to cease and desist from the violations of law charged in this complaint.

The following is the form of order which the Commission has reason to believe should issue if the facts are found to be as alleged in the complaint. If, however, the Commission should conclude from record facts developed in any adjudicative proceedings in this matter that the proposed order provisions might be inadequate to fully protect the consuming public, the Commission may order such other relief as it finds necessary or appropriate.

Moreover, the Commission has reason to believe that, if the facts are found as alleged in the complaint, it may be necessary and appropriate for the Commission to seek relief to redress injury to consumers, or other persons, partnerships or corporations, in the form of restitution for past, present, and future consumers and such other types of relief as are set forth in Section 19(b) of the Federal Trade Commission Act. The Commission will determine whether to apply to a court for such relief on the basis of the adjudicative proceedings in this matter and such other factors as are relevant to consider the necessity and appropriateness of such action.

ORDER

For purposes of this Order:

1. “Commerce” shall mean “commerce” as defined in Section 4 of the Federal Trade Commission Act (“FTC Act”), 15 U.S.C. § 44.
2. “Competent and reliable scientific evidence” shall mean 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.
3. “Covered Product or Service” shall mean any dietary supplement, food, drug, or other health-related product, including, but not limited to, RAAX11, or any health-related service or program.
4. “Endorsement” means as defined in 16 C.F.R. § 255.0(b).
5. “Food” and “drug” shall mean “food” and “drug” as defined in Section 15 of the FTC Act, 15 U.S.C. § 55.

6. Unless otherwise specified, “respondents” shall mean:
- A. Gemtronics, Inc., a corporation, and its successors and assigns and its officers; and
 - B. William H. Isely, individually and as the owner of Gemtronics, Inc;

and each of the above’s agents, representatives, and employees.

I.

IT IS HEREBY ORDERED that respondents, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of RAAX11, or any substantially similar product or any other Covered Product or Service, in or affecting commerce, shall not represent, in any manner, directly or by implication, including through the use of a product name, endorsement, depiction, or illustration, that:

- A. Such product is effective in the treatment or cure of cancer; or
- B. Such product is effective in the prevention of cancer;

unless such representation is true, non-misleading, and, at the time the representation is made, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

II.

IT IS FURTHER ORDERED that respondents, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product or Service, in or affecting commerce, shall not make any representation, in any manner, directly or by implication, including through the use of a product name, endorsement, depiction, or illustration, about the efficacy, performance, or health-related benefits of any Covered Product or Service unless the representation is true, non-misleading, and, at the time it is made, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

III.

IT IS FURTHER ORDERED that respondents, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product or Service, in or affecting commerce, shall not misrepresent, in any manner,

expressly or by implication, including through the use of any product name or endorsement, the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.

IV.

IT IS FURTHER ORDERED that:

A. Nothing in this order shall prohibit respondents from making any representation for any drug that is permitted in labeling for such drug under any tentative or final standard promulgated by the Food and Drug Administration, or under any new drug application approved by the Food and Drug Administration; and

B. Nothing in this order shall prohibit respondents from making any representation for any product that is specifically permitted in labeling for such product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990.

V.

IT IS FURTHER ORDERED that:

A. Respondents shall, within seven (7) days after the date of service of this order, deliver to the Commission a list, in the form of a sworn affidavit, of all consumers who purchased RAAX11 on or after May 2004 through the date of service of this order. Such list shall include each consumer's name and address, the product(s) purchased, and, if available, the consumer's telephone number and email address;

B. Within forty-five (45) days after the date of service of this order, respondents shall send by first class mail, postage prepaid, an exact copy of the notice attached as Attachment A to all persons identified in Part V.A. The face of the envelope containing the notice shall be an exact copy of Attachment B. The mailing shall not include any other documents; and

C. Except as provided in this order, respondents, and their officers, agents, servants, employees, attorneys, and representatives shall not sell, rent, lease, transfer, or otherwise disclose the name, address, telephone number, credit card number, bank account number, e-mail address, or other identifying information of any person who paid any money to any respondent, at any time prior to issuance of this order, in connection with the purchase of RAAX11. *Provided, however,* that respondents may disclose such identifying information to the FTC pursuant to Part V.A., above, or any law enforcement agency, or as required by any law, regulation, or court order.

VI.

IT IS FURTHER ORDERED that for a period of five (5) years after the last date of dissemination of any representation covered by this order, respondents shall maintain and upon request make available to the Federal Trade Commission for inspection and copying:

- A. All advertisements and promotional materials containing the representation;
- B. All materials that were relied upon in disseminating the representation; and
- C. All tests, reports, studies, demonstrations, or other evidence in their possession or control that contradict, qualify, or call into question such representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.

VII.

IT IS FURTHER ORDERED that respondents shall deliver a copy of this order to all current and future principals, officers, directors, and managers, and to all current and future employees, agents, and representatives having responsibilities with respect to the subject matter of this order, and shall secure from each such person a signed and dated statement acknowledging receipt of the order. Respondents shall deliver this order to current personnel within thirty (30) days after the date of service of this order, and to future personnel within thirty (30) days after the person assumes such position or responsibilities.

VIII.

IT IS FURTHER ORDERED that respondent Gemtronics, Inc. and its successors and assigns shall notify the Commission at least thirty (30) days prior to any change in the corporation that may affect compliance obligations arising under this order, including but not limited to a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor corporation; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this order; the proposed filing of a bankruptcy petition; or a change in the corporate name or address. **Provided, however,** that, with respect to any proposed change in the corporation about which respondent learns less than thirty (30) days prior to the date such action is to take place, respondent shall notify the Commission as soon as is practicable after obtaining such knowledge. All notices required by this Part shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, Washington, D.C. 20580.

IX.

IT IS FURTHER ORDERED that respondent William H. Isely, for a period of ten (10) years after the date of issuance of this order, shall notify the Commission of the discontinuance of his individual current business or employment, or of his individual affiliation with any new business or employment. The notice shall include the respondent's new business address and telephone number and a description of the nature of the business or employment and his duties and responsibilities. All notices required by this Paragraph shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, Washington, D.C., 20580.

X.

IT IS FURTHER ORDERED that respondent Gemtronics, Inc., and its successors and assigns, and respondent William H. Isely shall, within sixty (60) days after the date of service of this order, and at such other times as the Federal Trade Commission may require, file with the Commission a report, in writing, setting forth in detail the manner and form in which they have complied with this order.

XI.

IT IS FURTHER ORDERED that this order will terminate twenty (20) years from the date of its issuance, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; ***provided, however***, that the filing of such a complaint will not affect the duration of:

- A. Any paragraph in this order that terminates in less than twenty (20) years;
- B. This order's application to any respondent that is not named as a defendant in such complaint; and
- C. This order if such complaint is filed after the order has terminated pursuant to this paragraph.

Provided further, that if such complaint is dismissed or a federal court rules that the respondents did not violate any provision of this order, and the dismissal is either not appealed or upheld on appeal, then the order will terminate according to this paragraph as through the complaint was

never filed, except that the order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

THEREFORE, the Federal Trade Commission this sixteenth day of September, 2008, has issued this complaint against respondents.

By the Commission.

Donald S. Clark
Secretary

SEAL

ATTACHMENT A
LETTER TO BE SENT BY FIRST CLASS MAIL

[To be printed on letterhead of Gemtronics, Inc./www.agaricus.net]

[Date]

To Whom It May Concern:

Our records show that you bought RAAX11 from our website www.agaricus.net. We are writing to tell you that the Federal Trade Commission (“FTC”) has found that our advertising claims for these products were false or unsubstantiated, and has issued an Order prohibiting us from making those claims in the future. The Order entered against us also requires that we send you the following information about the scientific evidence on these products.

No scientific research has been done concerning the product RAAX11 as a prevention, treatment, or cure for cancer in humans. Very little scientific research has been done concerning either of the ingredients in RAAX11, *Chrysobalanus Icaco* extract and *Agaricus blazei Murill* mushroom extract, as a prevention, treatment, or cure for cancer in humans. The scientific studies that have been done do not demonstrate that RAAX11, or the ingredients in RAAX11, are effective when used as treatments for cancer.

It is very important that you talk to your doctor or health care provider before using **any** alternative or herbal product, including RAAX11. Speaking with your doctor is important to make sure that all aspects of your medical treatment work together. Things that seem safe, such as certain foods, herbs, or pills, may interfere or affect your cancer or other medical treatment, or other medicines you might be taking. Some herbs or other complementary or alternative treatments may keep your medicines from doing what they are supposed to do, or could be harmful when taken with other medicines or in high doses. It also is very important that you talk to your doctor or health care provider before you decide to take any alternative or herbal product, including RAAX11, instead of taking conventional cancer treatments that have been scientifically proven to be safe and effective in humans.

If you would like further information about complementary and alternative treatments for cancer, the following Internet web sites may be helpful:

1. The National Cancer Institute: www.cancer.gov/cancertopics/pdq; or
2. The National Center for Complementary and Alternative Medicines: www.nccam.nih.gov

You also can contact the National Cancer Institute's Cancer Information Service at 1-800-4-CANCER or 1-800-422-6237.

Sincerely,

William H. "Bill" Isely
Gemtronics, Inc./www.agaricus.net

ATTACHMENT B

William H. Isely
Gemtronics, Inc./www.agaricus.net
964 Walnut Creek Road.
Franklin, North Carolina 28734

[name and address of purchaser]

GOVERNMENT ORDERED NOTICE