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# "Operation Cure.All" Wages New Battle in Ongoing War Against Internet Health Fraud

FTC, FDA and other law enforcement agencies move to stop Internet scams for supplements and other products that purport to cure cancer, HIV/AIDS and countless other life-threatening diseases. FTC also warns of risks associated with some supplements, including drug interactions.

As part of an ongoing and comprehensive law enforcement and consumer education campaign begun in 1997, the Federal Trade Commission today announced a new round of enforcement actions against the fraudulent marketing of supplements and other health products on the Internet. The FTC's action is part of a coordinated effort with the U.S. Food and Drug Administration (FDA), Health Canada, and various state Attorneys General to crack down on unscrupulous marketers who use the Internet to prey on the sickest and most vulnerable consumers. The six new FTC enforcement actions target companies marketing a variety of devices, herbal products, and other dietary supplements to treat or cure cancer, HIV/AIDS, arthritis, hepatitis, Alzheimer's, diabetes and many other diseases. Among the many products for which unfounded claims were being made were a DHEA hormonal supplement, St. John's Wort, various multi-herbal supplements, colloidal silver and a variety of electrical therapy devices. The FTC's cases were also prompted by representations by some marketers that their products are safe when, in fact, there may be potentially dangerous interactions with other medications.

Among the many false and unsubstantiated claims challenged in today's cases were promises that:

- People could cancel their surgery, radiation or chemotherapy in favor of herbal cures that cost hundreds of dollars:
- A device that delivered mild electric current would kill the parasites that cause such serious diseases as cancer and Alzheimer's; and
- Those with HIV or AIDS could use St. John's Wort as a safe treatment for the disease. In fact, the FTC alleged, there is inadequate evidence to support the use of the herb to treat AIDS. Indeed, St. John's Wort is known to interfere with proven HIV/AIDS medications.

"Many of the Web sites targeted today are jeopardizing the health and safety of consumers with outlandish promises and false hope," said FTC Chairman Timothy J. Muris. "Unfortunately, examples of questionable products being peddled on the Web abound, and the Federal Trade Commission, with its partners, will step up its efforts to protect consumers from these compelling, but deceptive health claims."

"The Internet provides many benefits. But, its unique qualities - including its broad reach, relative anonymity, and ease of creating new websites or removing old ones - pose new enforcement challenges," said Bernard A. Schwetz, DVM, Ph.D., Acting Commissioner of the FDA. "FDA and the FTC are working together to protect the public from those who try to take advantage of consumers through this new technology."

"Health Canada fully shares the concerns of the U.S. FDA and FTC about the potential public health risks involved in the marketing of untested, unlicensed, and in some cases, fraudulent and dangerous drugs and devices. In an era of globalization, it is a problem that knows no borders, and intergovernmental cooperation is essential. Health Canada accordingly welcomes opportunities to work with its U.S. and other international counterparts to ensure that devices and drugs are safe and effective, and that they are compliant with the regulations and laws put in place to protect the public," said Daniéle Dionne, Associate Director General, Health Products and Food Branch, Health Canada.

Today's announcement by the FTC marks the fourth group of targeted enforcement actions to address marketing of unproven health products on the Internet. The cases in this phase of "Operation Cure.All," like earlier cases, often involve dramatic treatment and cure claims, often for a multitude of serious diseases. Some of the cases also raise serious safety implications.

Moreover, two cases challenge the promotion of St. John's Wort as a safe treatment for HIV/AIDS, a claim that presented serious drug interaction risks. In February 2000, FDA issued a Public Health Advisory to alert health care providers and consumers to the results of an NIH study and other reports in the medical literature indicating that taking St. John's Wort

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may cause a loss of therapeutic effect for any drug metabolized along the same specified pathway, including HIV medications, drugs to prevent transplant rejection, and oral contraceptives. The Advisory is posted on FDA's web site at <a href="http://www.fda.gov/cder/drug/advisory/stjwort.htm">http://www.fda.gov/cder/drug/advisory/stjwort.htm</a>. "Many herbal products and other supplements are promoted as natural and having no side effects. We want consumers to understand that these products are pharmacologically active and can be very potent. Patients know to be careful not to mix medications without consulting their doctor, pharmacist, or health care professional. They need to be just as cautious about combining supplements with their medications," cautioned Chairman Muris.

"It's bad enough when someone, with little or no evidence, touts unproven remedies to vulnerable populations such as people infected with HIV/AIDS; it's even more frightening when they do so despite -- and without so much as a mention of -- emerging risks that those remedies pose to the very people to whom they are pitching their sale. St. John's Wort and protease inhibitors: THEY DON'T MIX." said Walter H. Carr, Partnership Council Chairman of the National AIDS Health Fraud Task Force Network.

To alert consumers to the drug interaction risks, today's actions by the FTC will require the two companies that had been promoting St. John's Wort as a safe treatment for HIV and other diseases to include a disclosure warning of interaction risks in certain future marketing of St. John's Wort products.

In the six FTC cases announced today, the companies were charged with making false and unsubstantiated health and safety claims for a variety of products advertised on the Internet. Five of the companies agreed to settle the charges and the proposed settlement agreements were announced today for public comment. The Commission has filed a complaint in federal district court against the sixth company.

# Panda Herbal International, Inc., also doing business as Viable Herbal Solutions, and its owner, Everett L. Farr III

According to the agency, Panda Herbal International, based in Bensalem, Pennsylvania, and its owner, Everett L. Farr III, marketed and sold two products: "Herbal Outlook" - a dietary supplement that contains St. John's Wort; and "Herb Veil 8," -- a topical ointment. Panda claimed that consumers could safely use Herbal Outlook to treat such diseases as HIV/AIDS, herpes simplex, tuberculosis, influenza and hepatitis B infections. They also claimed that ingestion of Herbal Outlook has no known contraindications or drug interactions. In addition, the respondents claimed that Herb Veil 8 is effective in the treatment of carcinomas, adenocarcinomas and melanomas. The complaint alleges that the Herbal Outlook and Herb Veil 8 treatment claims are unsubstantiated and that the claim that Herbal Outlook has "no known contraindications or drug interactions" is false.

The proposed settlement would resolve the charges by prohibiting Panda from making any unsubstantiated claims that Herb Veil 8, Herbal Outlook, or any covered product or service, is effective in the mitigation, treatment, prevention, or cure of any disease or illness, or about the health benefits, performance, safety, or efficacy of any such product. The proposed consent order would require the respondents to place a disclosure warning in any advertisement, promotional material or product label for any Herbal Outlook or similar product that states:

WARNING: St. John's Wort can have potentially dangerous interactions with some prescription drugs. Consult your physician before taking St. John's Wort if you are currently taking anticoagulants, oral contraceptives, antidepressants, anti-seizure medications, drugs to treat HIV or prevent transplant rejection, or any other prescription drug. This product is not recommended for use if you are or could be pregnant unless a qualified health care provider tells you to use it. The product may not be safe for your developing baby.

The disclosure would be required in connection with any claim made about the efficacy, performance, or safety of such product. This disclosure was developed after discussions with the FDA. FDA has announced that it intends to initiate a rulemaking for dietary supplements for women who are or who may become pregnant. In the event that FDA issues a final rule requiring a warning for pregnant women on dietary supplements, respondents must substitute that warning for the relevant part of the FTC disclosure.

In addition, the settlement would require Panda to send a notice to all purchasers of Herbal Outlook and Herb Veil 8 informing them of the Commission's settlement, and to offer full refunds upon request to consumers who purchased HerbVeil 8 products during the relevant time period.

# ForMor, Inc., doing business as ForMor International, and its president, Stan Gross

ForMor, Inc., based in Conway, Arkansas, and its president, Stan Gross, made numerous health-related claims for the products: St. John's Kava Kava, colloidal silver, and Ultimate II Shark Cartilage Concentrate. ForMor made claims that ingestion of St. John's Kava Kava, a product containing St. John's Wort and other herbs, is effective in the treatment of HIV/AIDS, colds, syphilis, tuberculosis, dysentery, whooping cough, mania, hypochondria, fatigue and hysteria. The complaint also alleges that ForMor failed to disclose that ingestion of St. John's Kava Kava is not compatible with use of protease inhibitors used in the treatment of HIV/AIDS. ForMor also falsely represented that ingestion of St. John's Kava

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Kava has no serious drug interactions. In addition, ForMor claimed that ingestion of colloidal silver is proven effective in treating over 650 infectious diseases, and that medical tests prove that ingestion of colloidal silver is safe and has no adverse side effects. The company also claimed that ingestion of colloidal silver is effective in the treatment of arthritis, blood poisoning, cancer, cholera, diphtheria, diabetes, dysentery, gonorrheal herpes, influenza, leprosy, lupus, malaria, meningitis, rheumatism, shingles, staph infections, strep infections, syphilis, tuberculosis, whooping cough, and yeast infections. Further, the company claimed that shark cartilage pills are effective in the treatment of arthritis and other degenerative and inflammatory conditions; scientific research establishes that ingestion of shark cartilage is effective in the treatment of arthritis and other degenerative and inflammatory conditions; and ingestion of shark cartilage is effective in the treatment of brain cancer. The complaint alleges that these claims are false or unsubstantiated.

The proposed settlement would resolve the charges by prohibiting the ForMor respondents from making the specific health claims for its St. John's Wort, colloidal silver and shark cartilage treatments, unless they have competent and reliable scientific evidence to support such claims, and from misrepresenting the results of any tests, study or research. The settlement would require the respondents, in connection with any claim about the performance, benefits, safety, or efficacy of any product containing St. John's Wort, to place a disclosure in any advertisement, promotional material or product label for the product. The disclosure language and the provision for substituting warning language promulgated by FDA parallel that in the Panda settlement described above.

In addition, the settlement would require ForMor to send a notice to all purchasers of St. John's Kava Kava, colloidal silver, and Ultimate II Shark Cartilage Concentrate informing them of the Commission's settlement and would require them to give refunds upon request to people who purchased colloidal silver and Ultimate II Shark Cartilage Concentrate during the relevant time period.

# MaxCell BioScience, Inc., also doing business as Oasis Wellness Network, and its president, Stephen Cherniske

MaxCell BioScience, based in Broomfield, Colorado, and its president, Stephen Cherniske, marketed and sold dietary supplements through a multi-level marketing scheme. The respondents made numerous allegedly false and unsubstantiated health claims in cassette and audio and video tapes, as well as on their website, for two products: "Longevity Signal Formula" ("LSF") - a dietary supplement containing the hormone DHEA; and their at-home urine test called the "Anabolic/Catabolic Index<sup>TM2</sup> Test" ("ACI Test"). MaxCell claimed that LSF reverses the aging process and prevents, treats or cures numerous age-related diseases and conditions, including atherosclerosis, arthritis, high blood pressure, elevated cholesterol levels, weight gain, and poor liver function. They also claimed that their ACI Test provided a clinical gauge of an individual's overall healthiness and youthfulness.

The proposed settlement would prohibit the respondents from making unsubstantiated health claims and from disseminating deceptive marketing material to distributors. It would prohibit the respondents from making any representations about the health benefits of their products or any other food, dietary supplement or drug, without adequate substantiation. In addition, it would require MaxCell to pay \$150,000 for consumer redress to the FTC, and to notify their distributors of the settlement and warn them of possible termination if they do not conform their representations to the requirements placed on MaxCell.

# Robert C. Spencer and Lisa M. Spencer, doing business as Aaron Company

Robert C. Spencer and Lisa M. Spencer, d/b/a Aaron Company, based in Palm Bay, Florida, sold three products: Colloidal Silver - a dietary supplement allegedly containing suspended particles of silver, intended to be taken orally for the cure and treatment of more than 650 diseases; Chitosan with vitamin C -- a tablet purportedly containing chitin for weight loss; and Ultimate Energizer -- a product containing ephedra (ma huang) marketed as a stimulant.

The complaint alleges that the respondents disseminated deceptive advertising for Colloidal Silver, Chitosan with vitamin C and Ultimate Energizer through the Internet. The ads allegedly contained false and unsubstantiated claims in the text of the site, as well as in the embedded source code or "metatags" for the Web site, that the colloidal silver product has been medically proven to kill over 650 disease-causing organisms in the body; that its colloidal silver product is effective in curing diseases ranging from cancer and multiple sclerosis to HIV/AIDS; and that its colloidal silver product was medically proven to work. The complaint also alleges that the respondents made unsubstantiated claims that the Chitosan product enables consumers to lose substantial weight without a restricted calorie diet and that the Ultimate Energizer product, which contains ephedra (ma huang), a natural source of ephedrine, is safe and has no side effects.

The proposed settlement would prohibit the respondents from making the types of claims alleged in the complaint, unless they have competent and reliable scientific evidence to substantiate those claims. The proposed settlement would require the respondents to possess competent and reliable scientific evidence to substantiate any future claim that any covered product or service is effective in mitigating, treating, preventing, or curing any disease, illness or health condition; or about the health benefits, performance, safety, or efficacy of any such product or service. In addition, they would be prohibited from misrepresenting the results of any tests, studies or research. The order would also require that all future advertising and labeling of products containing ephedra include affirmative disclosures concerning the serious risks associated with

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that botanical. The primary warning would state:

WARNING: This product contains ephedra or ephedrine alkaloids, which can have dangerous effects on the central nervous system and heart and can result in serious injury. Risk of injury can increase with dose, and may even include heart attack, stroke, seizure or death. Consult a healthcare provider prior to use if you have high blood pressure, heart or thyroid disease, diabetes, difficulty urinating, prostate enlargement, or glaucoma, or are using any prescription drug. Do not use if you are taking a MAO inhibitor or any allergy, asthma, or cold medication containing ephedrine, pseudoephedrine or phenylpropanolamine. Discontinue use if you experience rapid heart beat, chest pain, severe headache, shortness of breath, dizziness, sleeplessness or nausea. This product is not recommended for use if you are or could be pregnant unless a qualified health care provider tells you to use it. The product may not be safe for you or your developing baby.

A shorter warning is permitted for television and radio advertisements. The warning was developed after discussions with FDA and contains a provision parallel to that in Panda and ForMor.

### Michael Forrest, doing business as Jaguar Enterprises of Santa Ana, also known as Jaguar Enterprises

Michael Forrest, d/b/a Jaguar Enterprises, based in Mesquite, Texas, and using business addresses in Black Mountain, North Carolina and Miami, Flordia, sold, distributed, promoted, and advertised various products, including various electronic therapy devices known as the Black Box; Magnetic Pulser; Magnetic Multi-Pulser; Beck-Rife unit; Portable Rife Frequency Generator; PC-Rife #1; PC-Rife #2; PC-Rife #3; as well as a combination of herbal ingredients known as "Miracle Herbs," a purported cure for cancer and other serious diseases.

The complaint alleges that Jaguar made unsubstantiated claims that their electronic devices will cure or prevent serious diseases, such as cancer, AIDS, arthritis, Gulf War Syndrome, and Chronic Fatigue Syndrome, by passing an electric current or magnetic pulse through the body, and that Miracle Herbs is effective in treating cancer of all types, AIDS, bacterial and viral infections. It also alleges that the respondent falsely represented that Miracle Herbs has been scientifically proven to be safe and effective and that the electronic devices have been scientifically proven to kill bacteria and viruses and other parasites in the body.

The proposed settlement would prohibit the respondent from making the challenged claims or any other claim about the health benefits, performance, safety or efficacy of its products or services without adequate substantiation. The settlement also would prohibit the respondent from misrepresenting the results of any test, study or research. Finally, the settlement requires the respondent to offer refunds to purchasers of the challenged products.

# Western Dietary Products Co., doing business as Western Herb & Dietary Products, Inc. and its owners Marvin and Miguelina Beckwith

The complaint against Western Dietary Products, based in Blaine, Washington, and Marvin and Miguelina Beckwith, the company's owners, charges that the defendants marketed various herbal formulas and herbal cure packages including Black Walnut Tincture, Wormwood Tincture, and Cloves Tincture to treat and cure cancer, Alzheimer's, diabetes, arthritis, and HIV/AIDS; that they marketed the "Zapper Electrical Unit" to treat and cure Alzheimer's and HIV/AIDS; and that the defendants claimed their herbal products would make surgery and chemotherapy unnecessary for persons with cancer. According to the complaint, all of these claims were unsubstantiated. The complaint against Western Dietary Products Co. was filed in the U.S. District Court for the Western District of Washington, in Seattle, on June 4, 2001. At a June 13th hearing, the defendants agreed to entry of a preliminary injunction.

### **FDA**

As part of the coordinated Cure.All effort, FDA is also highlighting a variety of initiatives it has taken in the past year to combat Internet Health Fraud.

# **Colloidal Silver**

The FDA and FTC have identified firms that marketed Colloidal Silver as a cure, treatment, or prevention of serious diseases. As part of Cure.All, the FDA identified forty-eight (48) Web sites that made serious drug claims for Colloidal Silver, as well as a number of other products. The FDA sent these Web sites *Cyber Letters*, untitled letters sent via electronic mail, informing them that their products were being promoted for conditions that may cause the products to be considered drugs and therefore may be in violation of the Federal Food, Drug, and Cosmetics Act. As a direct result of these Cyber Letters, 27 percent of the sites complied by removing or changing the violative claims.

## **Rife Frequency Generators and Zappers**

Rife Frequency Generators and Zappers are devices that purportedly send different amounts of electrical energy into the

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body to destroy parasites and/or shatter cells to cure serious diseases, such as cancer and AIDS. As part of "Operation Cure.All," the FDA has taken several actions with respect to these devices:

- FDA issued warning letters to several firms selling these devices informing them that they were in violation of the Federal Food, Drug, and Cosmetic Act. FDA also issued several untitled letters to firms questioning the legality of the marketing of these devices. Most of these firms have either removed or modified their Web sites; and
- FDA placed the Zapper promoted by one foreign firm on automatic detention without physical examination, which will prevent this device from legally entering the United States.

# **Aristolochic Acid**

The FDA has determined that aristolochic acid -- a substance found in some traditional herbal medicines -- poses significant health risks to consumers because it is carcinogenic and extremely toxic to the kidney. FDA has taken several actions in response to the marketing of dietary supplements containing aristolochic acid:

- FDA has issued two public warnings to consumers, health care providers, and dietary supplement manufacturers;
- FDA has prohibited the importation of botanicals that are suspected to contain or be contaminated with aristolochic acid, unless firms can prove that their products are free of the toxic substance;
- FDA has warned manufacturers that they must take steps to ensure that their products are free of these toxic substances:
- FDA has issued warning letters to several firms informing them that their products are adulterated within the
  meaning of the Food, Drug, and Cosmetic Act, present a significant risk to consumer health, and should be
  immediately recalled from the marketplace; and
- FDA has worked with a number of firms to initiate recalls of the affected products and ensure that customers were immediately notified.

#### **Consumer Education**

In addition to announcing today's enforcement actions, the FTC will continue its education campaign to alert consumers to health fraud online. Because promoters of fraudulent healthcare products often use similar claims and practices to lure consumers into buying their products, the FTC advises consumers to be suspicious of:

- Claims that the product is "natural" or "non-toxic," suggesting it does not have side effects. "Natural" or "non-toxic" does not necessarily mean safe. Some "natural" supplements contain potent stimulants; others, like St. John's Wort, can result in negative interactions with medicines.
- Testimonials from people who claim amazing results. Testimonials often are undocumented and are not a substitute for scientific proof.
- Claims that a product is a "scientific breakthrough," "miraculous cure," "secret ingredient" or "ancient remedy."
- Claims that the product is an effective cure for a wide range of ailments.
- Claims that use impressive-sounding medical terms.
- Claims that the product is available from only one source, and payment is required in advance.
- Claims of a "money-back" guarantee.
- Websites that fail to list the company's name, physical address, phone number or other contact information.

To ensure the safe use of supplements and other health-related products, consumers should let their health care provider know if they are using these products.

Additional tips on buying healthcare products on the Internet and using supplements and other healthcare products are on the FTC's Virtual Health Treatments website, <a href="https://www.ftc.gov/healthclaims">www.ftc.gov/healthclaims</a>, and FDA's Buying Medicines and Medical Products Online website, <a href="https://www.ftda.gov/oc/buyonline">www.ftda.gov/oc/buyonline</a>.

The FTC expresses its appreciation for the assistance of FDA, Health Canada, and the state Attorneys General who participated in this and earlier phases of "Operation Cure.All."

The Commission vote to accept the five consent agreements for public comment and the Commission vote to authorize the filing of the federal court complaint was 5-0.

**NOTE:** The Commission files a complaint when it has "reason to believe" that the law has been violated, and it appears to the Commission that a proceeding is in the public interest. The complaint is <u>not</u> a finding or ruling that the defendants have actually violated the law. The case will be decided by the court.

NOTE: The consent agreements are for settlement purposes only and do not constitute an admission of a law violation.

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When the Commission issues a consent order on a final basis, it carries the force of law with respect to future actions. Each violation of such an order may result in a civil penalty of \$11,000.

A summary of each of the proposed consent agreements will be published in the Federal Register shortly. They will be subject to public comment for 30 days, until July 16, 2001, after which the Commission will decide whether to make them final. Comments should be addressed to the FTC, Office of the Secretary, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580.

Copies of the complaints, proposed consent agreements, and analyses to aid public comment, as well as the consumer education information, are available from the FTC's web site at <a href="http://www.ftc.gov">http://www.ftc.gov</a> and also from the FTC's Consumer Response Center, Room 130, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580. The FTC works for the consumer to prevent fraudulent, deceptive and unfair business practices in the marketplace and to provide information to help consumers spot, stop and avoid them. To file a complaint, or to get free information on any of 150 consumer topics, call toll-free, 1-877-FTC-HELP ( 1-877-382-4357 ), or use the complaint form at <a href="http://www.ftc.gov">http://www.ftc.gov</a>. The FTC enters Internet, telemarketing, identity theft and other fraud-related complaints into Consumer Sentinel, a secure, online database available to hundreds of civil and criminal law enforcement agencies in the U.S. and abroad.

## **Media Contact:**

Brenda Mack, Office of Public Affairs 202-326-2182

#### **Staff Contact:**

Richard Cleland or Michelle Rusk

Bureau of Consumer Protection

202-326-3088 or 202-326-3148

Rae Jones (Print Media) Food and Drug Administration 301-827-6242

Broadcast Media Food and Drug Administration 301-827-3434

Panda Herbal International
Michael Bloom or Donald D'Amato - Northeast Region
212-607-2801or 212-607-2802

ForMor

Michael Bloom or Donald D'Amato - Northeast Region 212-607-2801or 212-607-2802

MaxCell BioScience Matthew Daynard, *Bureau of Consumer Protection* 202-326-3291

Jaguar Enterprises
Michael Milgrom - East Central Region
216-263-3419

Aaron Company James Rohrer - Southeast Region 404-656-1361

Western Dietary Products
Michael Milgrom - East Central Region
216-263-3419

(FTC File No. 002 3229 -- Panda Herbal International, Inc.) (FTC File No. 002 3226 - ForMor, Inc.,) (FTC File No. 002 3098 -- MaxCell BioScience) (FTC File No. 012 3091 - Michael Forrest d/b/a Jaguar Enterprises,) (FTC File No. 002 3312 - Aaron Company) Operation Cure.All Page 7 of 7

(FTC File No. 012 3090 - Western Dietary; Civil Action No. C01-0818 R)

#### E-mail this News Release

If you send this link to someone else, the FTC will not collect any personal information about you or the recipient.

#### **Related Documents:**

Virtual Health "Treatments"

File No. 002 3229

In the Matter of Panda Herbal International, Inc., and Everett L. Farr III.

Agreement [PDF 37K] Complaint [PDF 12K] Exhibits A-C [PDF 1.78M] Analysis

File No. 002 3226

In the Matter of ForMor, Inc., and Stan Goss.

Agreement A [PDF 41K] Complaint [PDF 18K] Exhibits A-F [PDF 2.32M] Analysis

File No. 002 3098

In the Matter of MaxCell BioScience, Inc., and Stephen Cherniske.

Agreement [PDF 25K] Complaint [PDF 17K] Exhibits A-B [PDF 2.54M] Analysis

File No. 012 3091

In the Matter of Michael Forrest, individually and doing business as Jaguar Enterprises of Santa Ana.

Agreement [PDF 23K] Attachments A and B [PDF 9K] Complaint [PDF 18K] Exhibits A-H [PDF 2.8M] Analysis

File No. 002 3312

*In the Matter of* Robert C. Spencer, individually and doing business as Aaron Company, and Lisa M. Spencer, individually and doing business as Aaron Company.

Agreement [PDF 26K] Complaint [PDF 33K] Exhibits 1-8 [PDF 1.97M] Analysis

FTC v. Western Dietary Products Co. (Skookum), a corporation, doing business as Western Herb & Dietary Products, Inc., and Marvin Beckwith, and Miguelina Beckwith (Western District of Washington at Seattle), Civil Action No. C01-0818R.

Plaintiff's Complaint for Permanent Injunction and Other Equitable Relief [PDF 1.01M

Permanent Injunction [PDF 628KB