

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration  
Atlanta District Office60 8th Street, N.E.  
Atlanta, Georgia 30309

June 2, 2008

**VIA FEDERAL EXPRESS**

John Stigaard  
Fem Health  
Superb Herbs  
2379 Red Barn Road  
Marietta, GA 30064

**WARNING LETTER**  
(08-ATL-10)

Dear Mr. Stigaard:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your websites at the Internet addresses [www.femhealth.com](http://www.femhealth.com) and [www.superbherbs.com](http://www.superbherbs.com) and has determined that the products "New Sun NKC-C Agaricus Blazei capsules," "New Sun NKC-C Agaricus Blazei Super Concentrate Vial," "New Sun Green Tea," "New Sun Grape Seed Extract," "New Sun LIV Combination," "New Sun Flax Seed Oil," "New Sun Super Sam (Super Sam Generic Samento, Cat's Claw)," "New Sun Vital PR. & BR." and "New Sun Yew/Olive Combination," among numerous other products marketed on your websites, are promoted for conditions that cause the products to be drugs under section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)]. The therapeutic claims on your websites establish that the products are drugs because they are intended for use in the cure, mitigation, treatment, or prevention of disease. The marketing of the products with these claims violates the Act.

Examples of some of the claims observed on your websites include:

**New Sun NKC-C (or Agaricus Blazei NKC-C) capsules and New Sun Agaricus Blazei NKC-C Super Concentrate Vial**

- [www.femhealth.com](http://www.femhealth.com)
  - "Agaricus Blazei Natural Killer cells have (Anti-tumor effect)"
  - "Active ingredients: . . . Known collectively as Beta Glucan, these substances are the most potent immunopotentiating (immune enhancing) substances yet found. They also have very powerful anti-tumor properties."

- “Research studies over the last 25 years have shown Agaricus Blazei stimulate the immune system and promote natural mechanisms to battle infectious disease.”
- “Agaricus Blazei turned out to be a very powerful antiviral agent preventing viruses from entering tissues.”
- “[T]he following people may obtain beneficial results . . . People with an impaired or suppressed immune system . . . People with a high occurrence of infectious diseases . . . People with chronic diseases such as diabetes, chronic inflammation . . . People with arteriosclerosis.”
- “Agaricus Blazei helps draw extra cholesterol from the blood, thus preventing plaque formation on the arterial walls.”

○ [www.superbherbs.com](http://www.superbherbs.com)

- In an "Alternative Cancer Guide," your website promotes this product as follows: “For serious cancer problems, try Agaricus Blazei medicinal mushroom capsules.”
- “Agaricus blazei extract is a potent immune system stimulant which promotes the body’s natural defense mechanisms to fight a variety of infectious agents, including cancer . . .”
- “The polysaccharide contained in Agaricus blazei . . . indirectly functions to destroy or prevent proliferation of cancer cells.”
- “Research studies over the last 25 years have shown Agaricus Blazei...to battle infectious diseases and cancers. . . . Agaricus Blazei turned out to be a very powerful antiviral agent preventing viruses from entering tissues.”
- “[T]he polysaccharide in Agaricus Blazei is effective against Ehrlich’s ascites carcinoma, sigmoid colonic cancer, ovarian cancer, breast cancer, lung cancer, liver cancer as well as solid cancers.”
- “Agaricus Blazei was found to eliminate all cancerous tumors in 90% of experimental mice.”
- “The studies in Japan showed Agaricus Blazei to be 80% more effective than the world’s number one cancer drug, PSK.”
- “Agaricus Blazei with Beta-1,3 / 1,6-glucan can benefit: . . . Anyone with suppressed immune system . . . Anyone with high occurrence of infectious diseases . . . People with allergies or skin conditions, including skin cancer . . . Anyone with chronic diseases such as diabetes, gout, hepatitis, chronic inflammation and chronic fatigue”
- “If you have cancer, are recovering from cancer, have a family history of cancer or just want to reduce your chances of getting cancer or viral infections, give Agaricus Blazei a try.”

### **New Sun Green Tea (Green Tea Extract)**

- [www.femhealth.com](http://www.femhealth.com) and [www.superbherbs.com](http://www.superbherbs.com)
  - “Green Tea’s ability to fight cancer is even more potent and varied than scientists suspected . . .”
- [www.femhealth.com](http://www.femhealth.com)
  - “Green tea concentrate may help some people boost their metabolic defense against toxins capable of causing cancer . . .”

### **New Sun Grape Seed Extract**

- [www.femhealth.com](http://www.femhealth.com)
  - “Grape Seed Extract . . . Anti-Cancer”
  - “Chemicals found in grape seeds significantly inhibit growth of colorectal tumors in both cell cultures and in mice, according to researchers (October 2006) who have already demonstrated the extract’s anti-cancer effects in other tumor types.”
  - “[G]rape seed extract helps prevent heart disease, deter various types of cancer, fight skin disease, slow the progression of macular degeneration and cataracts and lower cholesterol levels.”
- [www.superbherbs.com](http://www.superbherbs.com)
  - “Grape Seed Extract supports capillary resistance against fragility and rupture, therefore, it is most useful to help prevent diseased blood vessels associated with varicose veins, peripheral hemorrhage, diabetic retinopathy, high blood pressure and skin damage.”

### **New Sun Flax Seed Oil**

- [www.superbherbs.com](http://www.superbherbs.com)
  - “Flax Seed Oil’s Omega 3 Essential Fatty Acids benefit . . . High Blood Pressure, High Cholesterol, Cardiovascular Disease, . . . Arthritis, . . .”
- [www.superbherbs.com](http://www.superbherbs.com) and [www.femhealth.com](http://www.femhealth.com)
  - “Flax Seed Oil Benefits . . . Omega-3 has been shown to selectively kill human cancer cells in tissue culture studies, without harming normal cells. Clinical studies are confirming the potential of high doses of Omega-3 to reduce tumor growth.”

- “Flaxseed Oil is the highest beneficial source of lignans. . . . Lignans . . . may give some protection against cancers occurring in hormone sensitive tissues such as the breasts and uterus.”

○ [www.femhealth.com](http://www.femhealth.com)

- “A diet rich in flaxseed seems to reduce the size, aggressiveness and severity of tumors in mice that have been genetically engineered to develop prostate cancer, according to new research from Duke University Medical Center. And in 3 percent of the mice the flaxseed diet kept them from getting the disease at all.”
- “Tumors in the untreated control group were twice the size of tumors in the flaxseed group . . .”

**New Sun LIV Combination Milk Thistle Extract (Liver Detox Cleanse Formula, Liver Cleanse with Curcumin & Silymarin):**

○ [www.superbherbs.com](http://www.superbherbs.com)

- “Benefits of Silymarin (milk thistle) and Tumeric Herbal Liver Detox Cleanse Formula for hepatitis cirrhosis and cancer.”
- “Milk thistle may be better known as a cancer fighter. Scientists have uncovered a compound they believe can pack a powerful punch against prostate cancer, one of the most dangerous cancers in men. . . . Milk thistle silymarin compounds . . . have also been shown to reduce damage to liver cells caused by . . . prescription drugs, and may protect liver from alcohol (ethanolic damage), cirrhosis, hepatitis . . .”
- “Tumeric, also known as Curcumin, . . . exerts its anti-carcinogenic activity by lowering activation of carcinogens while increasing the detoxification of those that are activated. Curcumin inhibits the growth of cancer cells...”
- “[T]umeric may play a role in slowing down the progression of neurodegenerative disease. . . . Alzheimer’s is linked to the build up for knots in the brain called amyloid plaques. Tumeric reduced the number of these plaques by a half . . . Curcumin also appeared to reduce Alzheimer’s-related inflammation in the brain tissue.”

○ [www.femhealth.com](http://www.femhealth.com)

- “Liver Cleanse and Detox helps prevent Arthritis, Cancer, Alzheimer’s, Heart Attacks . . .”
- “[H]elp against alcohol (ethanol), cancer, cirrhosis, hepatitis...”
- “[T]umeric could help prevent and possibly even cure cancer.”

- “[Tumeric] has been shown to have antioxidant and anti-inflammatory properties that can heal wounds and possibly fight Alzheimer’s disease and multiple sclerosis.”
- “The study, published in the journal Cancer, demonstrated how curcumin stops laboratory strains of melanoma from proliferating and pushes the cancer cells to commit suicide.”
- “[Tumeric] could be Mother Nature’s miracle cure for cancer . . .”

**New Sun Super Sam (Super Sam Generic Samento, Cat’s Claw)**

○ [www.femhealth.com](http://www.femhealth.com)

- “Super Sam Generic Samento . . . is helpful for a wide range of conditions, including Lyme Disease, arthritis, bursitis, cancer, rheumatism, allergies, ulcers, candida, herpes, diabetes, lupus and chronic fatigue syndrome.”
- “Samento was one of the plants researched by the National Institute for Health as an anti-cancer agent.”
- “Worldwide research on this powerful herb has led scientists to patent many of the single chemicals found in it for use in healing cancer, arthritis, AIDS and other diseases.”
- “Samento can be used for Crohn’s disease, hemorrhoids, parasites, leaky bowel syndrome, ulcers, gastritis, allergic disorders, diverticulitis . . .”
- “Hungarian authorities state, that ‘Samento is approved for use as a sole or adjunct therapy for cancer.’”
- “An 8-month pilot study was recently conducted with 28 patients suffering from ADVANCE CHRONIC LYME BORRELIOSIS. . . . The experimental group was treated with SAMENTO. At the end of the study 85% of the patients in this group tested negative for Lyme Disease and all the patients experienced a dramatic improvement in their clinical condition.”
- “Cat’s Claw outrivaled everything known in therapy on at least several criteria: safety, power and speed of action or efficacy. It has healing range unseen so far. These claims . . . rely on . . . my own practice as a healer. My files include thousands of patients: lung cancer cases exceed 100, Helicobacter (sic) pylori infections - 400, lupus erythematosus, bronchial asthma, polycystic kidney disease, etc. My files encompass more than 100 different diseases . . .”

**New Sun Vital PR. & BR. (Chinese Breast Health Formula)**

○ [www.femhealth.com](http://www.femhealth.com)

In describing your Chinese Herbal Breast Health Formula plus Homeopathic Breast Formula you imply that the ingredients in this product, Chinese medicinal herbs, can treat breast cancer and other diseases. For example, your website makes the following claims: “Chinese medicinal

herbs are used to prevent and treat breast challenges with direct antiproliferative effects, anti-mutagenic activity. . . . Chinese medicinal herbs are traditionally used to prevent and treat a variety of diseases, including cancer. . . . Chinese medicine is useful in all stages of the disease to augment the benefits of conventional treatments, to prevent recurrence and metastasis in early stage breast cancer . . .”

### **New Sun Yew/Olive Combination**

○ [www.superbherbs.com](http://www.superbherbs.com) and [www.femhealth.com](http://www.femhealth.com):

- “Researchers have found that olive leaf extract destroys virus, bacteria and fungus. This means that it is beneficial for bacterial infections and conditions where antibiotics are ineffective, such as viral infections like colds and flu, and fungal problems like candida.”
- “[R]ecent research reveals [olive leaf extract] can kill the herpes virus.”
- “Dr. Morton Walker documents cases of people with HIV and AIDS who used olive leaf extract therapeutically. The subjects changed their HIV status from positive to negative as tested on both the ELISA and Western Blot standard AIDS tests.”
- “Dr. Walker reports a case in which a HIV patient reduced his viral load from 160,000 organisms per millilitre [sic] of blood . . . to 692 in eleven weeks. Dr. Walker comments that a fall in viral load this dramatic has never been achieved from the use of AZT.”
- “Research suggests that supplemental olive leaf extract may be beneficial in the treatment for . . . such conditions [as] influenza, the common cold, Epstein-Barr virus, encephalitis, herpes, pneumonia, dengue fever, severe diarrhea and some sexually transmitted diseases.”
- “Other researchers have found olive leaf extract relieves arrhythmias (heart beat irregularities) . . .”
- “Both Olive Leaf Extract and Yew Extract are excellent for periodontal disease.”

○ [www.femhealth.com](http://www.femhealth.com):

- “A famous study at Johns Hopkins University showed that yew was able to help women with ‘incurable’ ovarian cancer.”
- “Yew Olive Leaf Combination is effective against herpes, flu and colds, bacterial infections, diabetes, rheumatoid arthritis, chronic fatigue syndrome, allergies, vaginal yeast infections . . . malaria, hepatitis B and hepatitis C.”

○ [www.superbherbs.com](http://www.superbherbs.com):

- “Yew (*Taxus brevifolia*) & Olive Leaf Extract (*olea europaea*) oleuropein Combination are both natural antibiotic antiviral herbs”

Further, the "References" listed for a number of products on your websites cite a number of articles about human and animal studies of the products or their ingredients. The titles of many of these articles concern the use of the products or their ingredients for treatment or prevention of cancer and other diseases. When scientific publications are used commercially by the seller or a product to promote the product to consumers, such publications may become evidence of the product's intended use. For example, under 21 CFR 101.93(g)(2)(iv)(C), a citation of a publication or reference in the labeling of a product is considered a claim about disease treatment or prevention if the citation refers to a disease use, and if, in the context of the labeling as a whole, the citation implies treatment or prevention of a disease.

The following are examples of reference citations used to market your products for disease treatment and prevention on your websites:

- [www.superbherbs.com](http://www.superbherbs.com) and [www.femhealth.com](http://www.femhealth.com)
  - New Sun Agaricus Blazei: "Antitumor Effects of New Polysaccharide-protein Complex (ATOM) Prepared from Agaricus blazei (Iwade strain 101) 'Himematsutake' and Its Mechanisms in Tumor-Bearing Mice. Ito H, Shimura K, Itoh H, Kawade M, Department of Pharmacology, Mie University School of Medicine, Japan"
  - New Sun Flaxseed Oil: "Thompson LU, Rickard SE, Orcheson LJ, Seidi MM. Flaxseed and its lignan and oil components reduce mammary tumor growth at a late stage of carcinogenesis."
- [www.femhealth.com](http://www.femhealth.com)
  - New Sun Green Tea: "Prostate cancer chemoprevention by green tea."

The reference citations and other claims quoted above are supplemented by the metatags used to bring consumers to your websites through Internet searches. Examples of the metatags include the following:

[www.superbherbs.com](http://www.superbherbs.com): arthritis, high blood pressure

[www.femhealth.com](http://www.femhealth.com): heart disease, cancer, diabetes, arthritis pain

Your products are not generally recognized as safe and effective for the above referenced conditions and therefore, the products are also "new drugs" under section 201(p) of the Act [21 U.S.C. § 321(p)]. New drugs may not be legally marketed in the U.S. without prior approval from FDA as described in section 505(a) of the Act [21 U.S.C. § 355(a)]. FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective. Your products "New Sun NKC-C Agaricus Blazei capsules," "New Sun NKC-C Agaricus Blazei Super Concentrate Vial," "New Sun Green Tea," "New Sun Grape Seed Extract," "New Sun LIV Combination," "New Sun Flax Seed Oil," "New Sun Super Sam (Super Sam Generic Samento, Cat's Claw)," "New Sun Vital PR. & BR." and "New Sun Yew/Olive Combination" are also misbranded within the meaning of section 502(f)(1) of the Act, in that

labeling for these drugs fail to bear adequate directions for use [21 U.S.C. § 352(f)(1)].

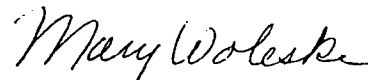
The above violations are not meant to be an all-inclusive list of deficiencies in your products and their labeling. The disease claims for other products marketed on your websites are too numerous to mention in this letter. It is your responsibility to ensure that products marketed by your firm comply with the Act and its implementing regulations. We advise you to review your websites, product labels, and other labeling and promotional materials for your products to ensure that the claims you make for your products do not cause them to violate the Act.

You should take prompt action to correct the violations described above and prevent their future recurrence. Failure to do so may result in enforcement action without further notice. The Act authorizes the seizure of illegal products and injunctions against manufacturers and distributors of those products for causing violations of the Act [21 U.S.C. §§ 332 and 334].

Please notify this office, in writing, within fifteen (15) working days of the receipt of this letter, as to the specific steps you have taken to correct the violations noted above and to assure that similar violations do not occur. Include any documentation necessary to show that correction has been achieved. If corrective actions cannot be completed within fifteen working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be directed to Philip S. Campbell, Compliance Officer, at the address noted in the letterhead. If you wish to discuss this letter, you should contact Mr. Campbell at (404) 253-1280.

Sincerely,



Mary Woleske, Director  
Atlanta District

cc: Cecilia Salvadori, President  
New Sun, Inc.  
215 Linda Vista Dr.  
Hendersonville, NC 29792

cc: Associate Director  
Division of Advertising Practices  
Federal Trade Commission  
600 Pennsylvania Avenue, N.W.  
Washington, D.C. 20580