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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

May 20, 2008

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 08-18

Vitapurity
Vitapurity Corporation
Vitapurity Nutraceuticals
5246 Dobrot Way
PO Box 5462
Central Point, Oregon 97502-0060

Dear Sir or Madam

WARNING LETTER

This is to advise you that the Food and Drug Administration (FDA) has reviewed your website at the Internet address www.vitapurity.com and has determined that the products "Citral," "Ellagic Ultra," "Lycopene 25TM," "Pacific Ocean Shark Cartilage," "Miracle Mushroom Blend," and "Buffered Vitamin C Crystals" are promoted for conditions that cause the products to be drugs under section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)(B)]. The therapeutic claims on your website establish that the products are drugs because they are intended for use in the cure, mitigation, treatment, or prevention of disease. The marketing of these products with these claims violates the Act.

Examples of some of the claims observed on your web site include:

Citral

- "Citral has been shown to cause apoptosis in cancer cells, in other words, it causes cancer cells to self-destruct!"
- "1,000mg of Lemon Grass contains enough Citral to prompt cancer cells to commit suicide!"
- "Citral in lemon grass kills cancer cells in vitro"
- "[L]emon grass containing citral may be consumed as a preventative measure against certain cancerous cells."

- “[A]ccording to Israeli scientists, cancer prevention can be added to the list of attributes associated with Citral.”

Ellagic Ultra

- “[T]he American Cancer Society states that Ellagic Acid has been found to promote cell death in cancer cells. They also write that Ellagic Acid, quote, ‘prevents the binding of carcinogens to DNA and strengthens connective tissue, which may keep cancer cells from spreading.’”
- “The American Cancer Society . . . also pointed out that studies demonstrated Ellagic Acid inhibited tumor growth and protected against chromosome damage from radiation therapy.”
- “According to Florida State University studies Ellagic Acid acts as a scavenger to ‘bind’ or chemically engage cancer-causing chemicals, making them inactive.”
- “Ellagic Acid prevents the binding of carcinogens to DNA and reduces the incidence of cancer in cultured human cells.”
- “Ellagic acid exhibits anticarcinogenic and antimutagenic activity in humans. Medical research has shown reductions in the size and number of cancerous tumors when mice are fed a diet of freeze dried strawberries or raspberries.”

Examples of some of the claims on your website in the form of testimonials include:

- “[I] was diagnosed with lesions and my doctor pronounced I had lung cancer. . . . I decided to start using VitaPurity Ellagic Ultra. I did not take any other treatments . . . the results are that today I don't have any cancer!”
- “My wife had ovarian cancer and our friend recommended Ellagic Ultra As far as the doctors tell us she has no evidence of ovarian cancer now.”

Lycopene 25™

- “[M]ay lower the risk of certain diseases including cancer and heart disease.”
- “Lycopene with tomato powder is far more effective . . . in the prevention of cancer.”
- “University of Illinois Professor John Erdman Jr. stated, ‘Tomato powder consumption clearly extended the life and reduced the cancer in this particular model.’ This University of Illinois study indicates that consuming Lycopene with Tomato Powder may offer the best anti-cancer effect.”

Vitapurity Corporation, Central Point, Oregon

Re: Warning Letter SEA 08-18

Page 3

- "Florida State University studies revealed that dietary consumption of Lycopene has been associated with a lowered risk of prostate cancer. Men with higher levels of Lycopene in their blood had statistically significant lower rates of cancer than did men with lower blood levels of Lycopene."
- "Lycopene can reduce the risk of . . . cancers of the lung, bladder, cervix and skin."
- "The Cancer Research Foundation of America writes that Lycopene is believed to 'turn off' free radicals in the body that can cause cell damage and lead to cancer."
- "[L]ycopene may ward off . . . prostate, cervical, bladder, breast, digestive-tract, skin and lung cancers."

Pacific Ocean Shark Cartilage

- "A study by the Massachusetts Institute of Technology concluded that shark cartilage contains an angiogenesis inhibiting substance that strongly inhibits the growth of new blood vessels that support solid tumors, thereby restricting tumor growth."

Miracle Mushroom Blend

- "An extract (Lentinan) from Shiitake has been licensed as an anti-cancer drug by the Japanese FDA."
- "The American Cancer Society notes that Shiitake Mushrooms are promoted to fight the development and progression of cancer"
- "The compounds contained in Maitake have the capacity to . . . inhibit tumor growth."
- "[P]reclinical studies suggest Maitake Mushrooms may have the ability to . . . induce apoptosis (cell death) in cancer cells."
- "A few randomized clinical trials suggest mushroom extracts may improve overall survival and quality of life for cancer patients."

Buffered Vitamin C Crystals

- "Researchers from Wichita State University Graduate School and Project RECNAC Bio-Communications Research Institute concluded that sufficient evidence exists to support the testing of intravenous Vitamin C . . . as a cytotoxic chemotherapy agent in doses high enough to maintain plasma levels sufficient to

destroy tumor cells in the laboratory. Vitamin C is relatively non-toxic and is destructive to tumor cells”

- “Final Thoughts on Fighting Cancer”
 - “Jonathan Chamberlain writes in his book, *Fighting Cancer – A Survival Guide*; ‘For cancer patients, sodium ascorbate is the preferred form.’”
 - “Dr. Pauling gave patients megadoses of Sodium Ascorbate and, as a result, he found that . . . ‘A significant percent of the ‘terminally ill’ cancer patients for whom death was considered inevitable within a matter of weeks or months went on to long term survival. In short, for some patients, Vitamin C cured their cancer.’”

Further, your website cites a number of publications about your products or their ingredients. Many of these publications concern the use of the products or their ingredients for treatment or prevention of cancer. When scientific publications are used commercially by the seller of 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 website:

- “Stoner, G.D. and H. Mukhtar. 1995. Polyphenols as cancer chemo-preventive agents. *J. of Cellular Biochemistry, Supplement* 22:169-180.”
- “Harris, G.K., G.D. Stoner and S.J. Schwartz. 2000. Effects of freeze dried black raspberries on ayoxymethane induced colon tumors in the F344 rat. OARDC poster session (unpublished).”
- “Maas, J.L., S.Y. Wang., G.J. Galletta. 1991a. Evaluation of strawberry genotypes for ellagic acid, an antimutagenic and anticarcinogenic plant phenol. In: *The Strawberry Into the 21st Century*, A. Dale and J.J. Luby, editors. Timber Press. p. 115-117.”
- “Maas, J.L., G.J. Galletta and G.D. Stoner. 1991b. Ellagic acid, an anticarcinogen in fruits, especially in strawberries. A review. *HortScience* 26(1)10-14.”
- “American Cancer Society’s *Guide to Complementary and Alternative Cancer Methods*. American Cancer Society 2002. p. 203.”
- “*Journal of the National Cancer Institute*, Vol. 95, No. 21, 1563-1565, November 5, 2003 DOI: 10.1093/jnci/djg112”
- “*Journal National Cancer Institute*, December 6, 1995, 87:23, 1767-76.”
- “Shark Cartilage Contains Inhibitors of Tumor Angiogenesis. *Science*. September 1983, Vol. 221: 1185-1187”
- “*Fighting Cancer – A Survival Guide*”

Vitapurity Corporation, Central Point, Oregon
Re: Warning Letter SEA 08-18
Page 5

Your products are not generally recognized as safe and effective for the above referenced uses and, therefore, the products are "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 "Citral," "Ellagic Ultra," "Lycopene 25TM," "Pacific Ocean Shark Cartilage," "Miracle Mushroom Blend," and "Buffered Vitamin C Crystals" are also misbranded within the meaning of section 502(f)(1) of the Act in that labeling for these drugs fails to bear adequate directions for use [21 U.S.C. § 352(f)(1)].

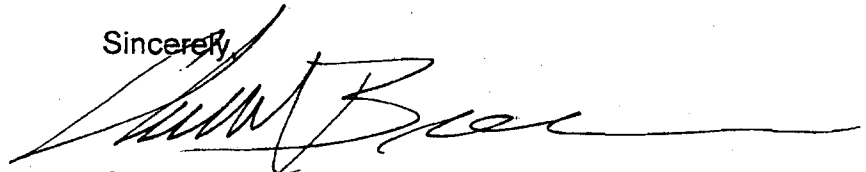
The above violations are not meant to be an all-inclusive list of deficiencies in your products and their labeling. While reviewing your web site, we noticed that you were promoting the products listed above for the treatment and/or prevention of diseases other than cancer and that you were also promoting other products for disease treatment and/or prevention. The unlawful disease treatment and prevention claims on your website were too numerous to list 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 website, 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 [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 the Food and Drug Administration, Attention: Lisa M. Elrand, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021.

Sincerely,



Charles M. Breen
District Director

Vitapurity Corporation, Central Point, Oregon
Re: Warning Letter SEA 08-18
Page 6

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