DEPARTMENT OF HEALTH & HUMAN SERVICES **Food and Drug Administration**

Atlanta District Office
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Atlanta, GA 30309

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October 13, 2005

Via Federal Express

Timothy Collins
Organic Pharmacy, Inc.
3 Tingle Alley, Suite E
Asheville, North Carolina 28801

Dear Mr. Collins:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web sites at the Internet addresses http://www.organic-pharmacy.com and http://www.organicpharmacy.org and has determined that the products "Nattokinase Extra-Strength," and "VitalZym", as well as other products, 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 web sites 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:

Nattokinase Extra-Strength

"[*N*]*attokinase represents the most exciting new development in the prevention and treatment of cardiovascular related diseases* …."
"Nattokinase is a potent fibrinolytic enzyme extracted and highly purified from a traditional Japanese food called Natto. Natto is a fermented cheese-like food that has been used in Japan for over 1000 years … as a folk remedy for heart and vascular diseases."
"The Discovery of Nattokinase
Doctor Hiroyuki Sumi had long researched thrombolytic enzymes searching for a natural agent that could successfully dissolve thrombus associated with cardiac and cerebral infarction (blood clots associated with heart attacks and stroke). Sumi discovered nattokinase in 1980 while working as a researcher …. After testing over 173 natural foods as potential thrombolytic agents, Sumi found what he was looking for when Natto was dropped onto artificial thrombus …. The thrombus around the natto dissolved gradually and had completely dissolved within 18 hours."
"'In some ways, Milner says, [sic] nattokinase is actually superior to conventional clot-dissolving drugs. T-PAs (tissue plasminogen activators) like urokinase (the drug), are only effective when taken intravenously and often fail simply because a stroke or heart attack victim's arteries have hardened beyond the point where they can be treated by any other clot-dissolving agent. Nattokinase, however, can help prevent that hardening with an oral dose of as little as 100 mg a day.'"
"Nattokinase produces a prolonged action (unlike antithrombin drugs that wear off shortly after IV treatment is discontinued) in two ways: it prevents coagulation of blood and it dissolves existing thrombus."
"The Mechanism Behind Thrombus…
Blood clots (or thrombi) form when strands of protein called fibrin accumulate in a blood vessel. In the heart, blood clots cause blockage of blood flow to muscle tissue. If blood flow is blocked, the oxygen supply to that tissue is cut off and it eventually dies. This can result in angina and heart attacks … In the brain, blood clots

also block blood and oxygen from reaching necessary areas, which can result in senility and/or stroke. This mechanism can lead to cardiac or cerebral infarction …. Nattokinase is capable of directly and potently decomposing fibrin…."

"It has recently been revealed that thrombotic clogging of the cerebral blood vessels may be a cause of dementia. It has been estimated that sixty percent of senile dementia patients in Japan is caused by thrombus. Thrombotic diseases typically include cerebral hemorrhage, cerebral infarction, cardiac infarction and angina pectoris, and also include diseases caused by blood vessels with lowered flexibility, including senile dementia and diabetes (caused by pancreatic dysfunction). … Cardiac infarction patients may have an inherent imbalance in that their thrombolytic enzymes are weaker than their coagulant enzymes. Nattokinase holds great promise to support patients with such inherent weaknesses in a convenient and consistent manner, without side effects."
""In all my years of research as a professor of cardiovascular and pulmonary medicine, natto and nattokinase represents the most exciting new development in the prevention and treatment of cardiovascular related diseases," Dr. Milner said. "We have finally found a potent natural agent that can thin and dissolve clots effectively, with relative safety and without side effects.""
"Natto has been consumed not only for cardiovascular support, but also to lower blood pressure. In recent years, this traditional belief has been confirmed by several clinical trials. In 1995, researchers from Miyazaki Medical College and Kurashiki University of Science and Arts in Japan studied the effects of nattokinase on blood pressure in both animal and human subjects (see below). In addition, the researchers confirmed the presence of inhibitors of angiotensin converting enzyme (ACE), which converts angiotensin I to its active form angiotensin II within the test extract, which consisted of 80% ethanol extract of lyophilized viscous materials of natto. ACE causes blood vessels to narrow and blood pressure to rise - by inhibiting ACE, nattokinase has a lowering effect on blood pressure."
"After a single intraperitoneal administration of 400-450 grams of the test extract (equivalent to 25 mg of natto food) into male Wister rats, systolic blood pressure (SBP) significantly decreased from 166 + mmHg to 145 + 24 mmHg in just two hours ($p<0.05$), and decreased further to 144 + 27 mmHg in 3 hours ($p<0.05$). On average, this data represents a 12.7 percent drop in SBP within two hours."
"The same natto extract was then tested on human volunteers with high blood pressure. Blood pressure levels were measured after 30 grams of lyophilized extract (equivalent to 200 grams of natto food) was administered orally for 4 consecutive days. In 4 out of 5 volunteers, the systolic blood pressure (SBP) decreased on average from 173.8 + 20.5 mmHg to 154.8 + 12.6 mmHg. Diastolic blood pressure (DBP) decreased on average from 101.0 + 11.4 mmHg to 91.2 + 6.6 mmHg. On average, this data represents a 10.9 percent drop in SBP and a 9.7 percent drop in DBP."

VitalZym

"VitalZym… Reducing Inflammatory and Pain States"
"I just started taking Vitalzym yesterday. I have Fibromyalgia, have had lower back surgery, am going to have surgery on my neck for a bulging disk and pain in my right arm, have had numerous surgeries on my feet and have had 3 female surgeries. I have headaches on a regular basis and basically I am always in pain. I took two of the pills late yesterday afternoon and two more this morning. It is now 1:00 p.m. and I am virtually pain free. I have not been pain free in at least 10 years."
"I have suffered with TMJ disease (Temporo-Mandibular Joint or Jaw Joint) for several years. I have had laser surgery, physical therapy, and acupuncture with no relief. I have been unable to sleep and eat at times because of the pain. Two months ago I started taking Vitalzym and this week I have no pain and feel better than I have in years."
"I have had many reports of improvements for various complaints from pains, to swelling of joints, to Raynaud's... being relieved by Vitalzym. Two of the most remarkable were in cardiac patients with claudication of their legs besides the angina they had."
"I am writing you to thank you for your miracle product, VITALZYM….I fell into a pocket of radiation …. I survived, but had the worst Asthma …. I have suffered for many years with severe allergies and continual back pain …. I now [after taking Vitalzym] have … virtually no pain…!"

"I gave a bottle of Vitalzym to a good friend after her knee surgery and she not only quit taking pain medicine she had a prescription for, she quit taking Tylenol."
"I got my bottle of Vitalzym …and decided to take one before going to bed. When I woke up the next morning…[m]y knees didn't hurt. Now I don't normally have a lot of knee pain, just what I call old age creeping up. But what made me stop and notice was that I had NO knee pain … I kept taking my enzymes that day, and several times went up and down the stairs just to make sure I wasn't hurting. Now, a few days later, still no knee pain and my chronic low back pain is about half of normal. Can it really be that one pill knocked out my knee pain???"
"I have heard that [Vitalzym] is good for inflammation … [M]y nose, cheeks and eyes were starting to swell. So, I quickly took 20 Vitalzym Capsules … By the time I retired for the evening, the external swelling had already disappeared and there wasn't any internal swelling at all … I took 10 more Vitalzym Capsules and all of the swelling again disappeared. Plus, the pain and discomfort was also almost totally gone …. I attribute the total lack of internal and external swelling … to the Vitalzym."

In addition, under the "Condition" section of your web site, you list several disease categories that link to products, which cause the products to be drugs under section 201(g)(1) of the Act because they imply that the products are useful in the cure, mitigation, treatment, or prevention of the diseases they are linked to. Examples of some of the disease categories listed on your web site for which you offer products include: "AIDS," "Allergy," "Arthritis," "Asthma," "Cancer," "Cold," "Diabetes," "Lupus," and "Osteoporosis."

Furthermore, 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.

FDA is aware that Internet distributors may not know that the products they offer are regulated as drugs or that these drugs are not in compliance with the law. Many of these products may be legally marketed as dietary supplements if claims about diagnosis, cure, mitigation, treatment, or prevention are removed from the promotional materials and the products otherwise comply with all applicable provisions of the Act and FDA regulations.

Under the Act, as amended by the Dietary Supplement Health and Education Act, dietary supplements may be legally marketed with truthful and non-misleading claims to affect the structure or function of the body (structure/function claims), if certain requirements are met. However, claims that dietary supplements are intended to prevent, diagnose, mitigate, treat, or cure disease (disease claims), excepting health claims authorized for use by FDA, cause the products to be drugs. The intended use of a product may be established through product labels and labeling, catalogs, brochures, audio and videotapes, Internet sites, or other circumstances surrounding the distribution of the product. FDA has published a final rule intended to clarify the distinction between structure/function claims and disease claims. This document is available on the Internet at <http://vm.cfsan.fda.gov/~lrd/fr000106.html> (codified at 21 C.F.R. § 101.93(g)).

In addition, only products that are intended for ingestion may be lawfully marketed as dietary supplements. Topical products and products intended to enter the body directly through the skin or mucosal tissues, such as transdermal or sublingual products, are not dietary supplements. For these products, both disease and structure/function claims may cause them to be new drugs.

Certain over-the-counter drugs are not new drugs and may be legally marketed without prior approval from FDA. Additional information is available in Title 21 of the Code of Federal Regulations (21 C.F.R.) Parts 310 and 330-358, which contain FDA's regulations on over-the-counter drugs.

This letter is not intended to be an all-inclusive review of your web site and products your firm markets. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations.

If you need additional information or have questions concerning any products distributed though your web site, please contact the FDA. You may respond in writing to Compliance Officer James MacLaughlin at the address noted in the letterhead.

If you have any questions concerning this letter, please contact Mr. MacLaughlin at 404-253-1220.

Sincerely,

/s/

Mary H. Woleske
Director, Atlanta District