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Inspections, Compliance, Enforcement, and Criminal Investigations

BioAnue Laboratories, Inc. 2/9/12



Department of Health and Human Services

Public Health Service
Food and Drug Administration
Atlanta District Office
60 Eighth Street N.E.
Atlanta, GA 30309
Telephone: 404-253-1161

February 9, 2012

VIA UNITED PARCEL SERVICE

WARNING LETTER (12-ATL-08)

Gloria Raber
BioAnue Laboratories, Inc.
123 Wood Tech Drive
Rochelle, GA 31 079

Dear Ms. Raber:

This is to advise you that the U.S. Food and Drug Administration (FDA) reviewed your websites at www.tumorx.com, www.cancerx.org, www.hopewelltechnologieslimited.com, and www.vmhe.com in February 2012 and has determined that your "Bovine Cartilage," "TumorX BioEnerGenics Co-Enzyme -Q10," "TumorX Cardio Clean," "Diabetic Mender," "TumorX Formula CX," and "Stroke Mender" products are promoted for conditions that cause these 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 websites, www.tumorx.com, www.cancerx.org, and www.hopewelltechnologieslimited.com, establish that these products are drugs because they are intended for use in the cure, mitigation, treatment, or prevention of disease. The marketing of your products with these claims violates the Act. You may find the Act and FDA's regulations through links on FDA's home page at <http://www.fda.gov>¹.

Your websites, www.tumorx.com, www.cancerx.org, and www.hopewelltechnologies.com, link to your website, www.vmhe.com, where consumers can purchase your products.

On your websites, www.tumorx.com, www.cancerx.org, and www.hopewelltechnologieslimited.com, the tab called "Cancers" opens to a list of various cancers (e.g., Breast Cancer, Pancreatic Cancer, Throat Cancer, Vaginal Cancer, Acute Lymphocytic Leukemia, Hodgkin's Lymphoma, Lung Cancer, and Uterine Cancer, etc.) that hyperlink to Tumor X Protocols and products your firm recommends for the treatment of cancer.

Examples of some of the claims observed on your websites, www.tumorx.com, www.cancerx.org, and www.hopewelltechnologieslimited.com, including the following:

"Bovine Cartilage"

- "Bovine Cartilage Stops Tumor Growth"

- "Bovine cartilage has been demonstrated ... to stop/inhibit the spread, growth and proliferation of cancer cells."
- "Bovine cartilage is used to prevent and treat cancer and treat HIV/AIDS ... "
- "[B]ovine cartilage has antitumor and immunoregulatory effects."
- "TumorX Brand products aid in the structure and function of the body; this allows deficiency induced diseases such as cancer, heart disease, diabetes and Alzheimer's, just to name a few, to be reversed "

"TumorX BioEnerGenics Co-Enzyme -010" (product name is an implied claim)

- "Co-Enzyme Q10: Squamos cell carcinoma can be reversed and cured using this natural substance."
- "[T]umorX BioEnerGetics CoQ-10, an immune stimulant that has been proven to defeat cancers."
- "[C]o-Enzyme Q10 in the prevention and treatment of heart disease is due to its ability to ... inhibit blood clot formation "
- "[C]o-Enzyme Q10 supplements help reduce swelling in the legs, enhance breathing by reducing fluid in the lungs "
- "[C]o-Enzyme Q10 may lower blood pressure."
- "[C]o-Enzyme Q10 may help prevent heart damage caused by certain chemotherapy drugs "
- "[C]o-Enzyme Q10 prior to heart surgery, including bypass surgery and heart transplantation, can reduce damage caused by free radicals, strengthen heart function, and lower the incidence of irregular heart beat (arrhythmias) during the recovery phase."
- "[C]o-Enzyme Q10 supplements ... may shrink tumors, reduce pain associated with the condition, and cause partial remission in some individuals."
- [C]o-Enzyme Q10 may:
 - o "Improve immune function in individuals with immune deficiencies (such as acquired immunodeficiency syndrome or AIDS) and chronic infections (such as yeast, bacteria, and viral infections.)"
 - o "Be used as part of the treatment for Alzheimer's disease and Parkinson's disease"
 - o "Reduce damage from stroke"

"Tumor X Cardio Clean" (product name is an implied drug claim)

- "Cardio Clean can be used when a build up of fat in arteries has occurred, you have high cholesterol or high triglycerides [C]lean out your arteries and eliminate high cholesterol and triglycerides."
- "Cardio Clean ... transforms artery clogging cholesterol into disease fighting substances needed for proper function inside the body."

"Diabetic Mender" (product name is an implied drug claim)

- "[C]an start to control diabetes for most people within the first 2 capsules of the product."
- "[W]ill in most people control, repair and reverse their diabetes."

"Formula CX"

- "Formula CX will reverse wasting disease."
- "TumorX Formula CX contains the key nutrients allowing the body to reverse wasting disease."
- "[A]ll cancer patients should supplement with TumorX Formula CX to prevent the poisoning of the body that leads to a wasting syndrome known as cachexia."
- TumorX Formula CX supplementation is even more important for those patients who have

stage two cancer and higher."

"Stroke Mender" (product name is an implied drug claim)

- "[O]ne can repair the brain using Stroke Mender."
- "Peer reviewed studies have proven that when Stroke Mender was given to patients, significant positive improvements were shown within the first 90 days of taking Stroke Mender."
- "Stoke Mender will repair the neurons in the brain, reversing the effects of stroke in the human body."
- "Studies have shown that Stroke Mender (Citicoline) is effective in helping stroke victims recover."

Your websites also contains disease claims in the form of personal testimonials. The following are excerpts from your www.tumorx.com, www.cancerx.org, and www.hopewelltechnologieslimited.com homepages under the title "Testimonials":

- "Diagnosed with liver cancer that had metastasized to the colon After only one year of using the protocol, her test results demonstrated that she is now cancer free."
- "I had been diagnosed with breast cancer. I had 4 lumps in my left breast and 2 in my right breast with the largest being 5cm. I found TumorX and began taking the full protocol. After only one month of the products, the AMAS Test came back! I am now cancer free! ! "
- "I had been diagnosed with prostate cancer that had spread to my lungs. I was looking for an alternative cure that would really treat the cancer when I found the TumorX Products. I. . . began taking the Tumor X enzyme and Tumor X Apoptosis Protocols. Three months later I went for a CAT scan and the doctors couldn't find any cancer in my body! The spots on my lungs were gone and my PSA was back to normal."
- "I began taking the TumorX Enzyme and TumorX Apoptosis when I was diagnosed with breast cancer. . . . When the doctors performed the surgery they informed me that there was no cancer and that all the margins were clear. I continued to take the TumorX Protocols for thirty days to make sure any lingering cells were destroyed. Thank you Tumor X for ridding me of my cancer!"
- "I had cancer on my lip, eyebrow, and nose; the cancer on my nose was open and bleeding. I purchased the Tumor X package 1 after taking the products for 10 days the cancer on my nose disappeared. I will continue to take the products and continue to heal and repair my body."

The claims quoted above are supplemented by the metatags used to bring consumers to your web pages through Internet searches. Examples of some of the metatags include:

- www.tumorx.com, www.cancerx.org, and www.hopewelltechnologieslimited.com homepages: cancer, Alzheimer's, HIV/AIDS, diabetes, heart disease, memory mender, alternative cancer treatment, stroke.
 - Acute Lymphocytic Leukemia (type of cancer listed on your websites): Acute lymphocytic leukemia treatment, cancer all, cancer breakthrough, stage 4 cancer, stage 3 cancer, stage 3 cancer, stage 1 cancer.
 - Co-Enzyme-Q10: Anti-cancer vitamin, virus cancer, Squamous cell carcinoma, heart disease, heart failure, diabetes, high cholesterol, breast cancer, chemo drugs.

The claims listed above establish that your products are a drug, because they are intended for use in the cure, mitigation, treatment, or prevention of disease. See section 201(g)(1)(B) of the Act [21 U.S.C. § 321(g)(1)(B)]. Your product is 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.

Furthermore, because your "Bovine Cartilage," "TumorX BioEnerGenics Co-Enzyme -Q10," "TumorX Cardio Clean," "Diabetic Mender," "TumorX Formula CX," and "Stroke Mender" products are offered

for conditions that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners, adequate directions for use cannot be written so that a layman can use the products safely for their intended uses. Thus, these products are misbranded within the meaning of section 502(f)(1) of the Act [21 U.S.C. § 352(f)(1)], in that their labeling fails to bear adequate directions for use. The introduction of a misbranded drug into interstate commerce is a violation of section 301(a) of the Act [21 U.S.C. § 331(a)].

The above violations are not meant to be an all-inclusive list of violations in your products and their labeling. While reviewing your website, we noticed that you were promoting other products for disease treatment and/or prevention. The unlawful disease treatment and prevention claims on your website and in metatags were too numerous to list in this letter. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations. We advise you to review your websites, metatags, 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 ensure that similar violations do not occur. Your response should 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 date by which the corrections will be completed.

Please send your written response to the attention of Marie Mathews, Compliance Officer, Food and Drug Administration, 60 Eighth Street NE, Atlanta, GA 30309. If you have any questions regarding any issues in this letter, please contact Ms. Mathews at 404-253-1279.

Sincerely,

/s/

John R. Gridley
Atlanta District Office
District Director

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