

# Newton Everett/WR Group Inc. 9/7/17



Office of Human and Animal Food Operations  
-  
Division IV West

## WARNING LETTER

September 7, 2017

### VIA UPS Overnight

Newton-Everett, L.L.C.  
Attn: Carey Williams, CEO  
7702 E. Doubletree Ranch Rd.  
Suite 300, PMB #7863  
Scottsdale, AZ 85258

W/R Group, Inc.  
9160 E. Bahia Dr  
Suite 200  
Scottsdale, AZ 85260

**Ref: HAF4W(DEN)-17-19-WL**

Dear Mr. Williams,

This is to advise you that the U.S. Food and Drug Administration (FDA) reviewed your websites at [www.biovea.com](http://www.biovea.com), [www.neulook.com](http://www.neulook.com), and [www.newton-everett.com](http://www.newton-everett.com) in July 2017, and has determined that you take orders on these websites for the following products: AHCC 500mg, Alpha Lipoic Acid 300mg, Borage Oil 1000mg, Cholest-Rite Advanced, FirstBiotic Advanced, Liverol Advanced, Lycopene 10mg, Odorless Garlic 1000mg, Omega-3 Fish Oil 1360mg, and Xanthadrene. The claims on your websites establish that the products are 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)] because they are intended for use in the cure, mitigation, treatment, or prevention of disease. As explained further below,

introducing or delivering these products for introduction into interstate commerce violates the Act. You can find the Act and FDA regulations through links on FDA's home page at [www.fda.gov](http://www.fda.gov) (<http://www.fda.gov>).

Examples of some of the website claims that provide evidence that these products are intended for use as drugs include:

### **AHCC 500mg**

Your website at [www.biovea.com](http://www.biovea.com) links directly to your blog at <http://blog.biovea.com>. On your November 3, 2014, blog post, titled "AHCC Can Help Fight HPV; A Study," found on your website, <http://blog.biovea.com/ahcc-can-help-fight-hpv-a-study.html>:

- "AHCC may help eradicate human papillomavirus (HPV) in women."
- "[I]nhibiting symptoms that are associated with type 2 diabetes, suggesting that the properties in AHCC have a positive effect on insulin receptors"
- "AHCC Supplement Can Help Fight HPV | Balance Blood Sugar"

### **Alpha Lipoic Acid 300mg**

- "Alpha-lipoic acid ... provide protection to the brain under conditions of damage or injury . . . . [M]ight also be helpful in certain liver diseases"
- "[A]lpha lipoic acid may help with the following conditions:
  - o Hypertension (High Blood Pressure)
  - o Coronary Heart Disease
  - o Metabolic Syndrome (high blood pressure and elevated cholesterol)
  - o Peripheral Neuropathy (caused by diabetes and other conditions, such as Lyme disease, alcoholism, shingles, thyroid disease and kidney failure)
  - o Diabetes (improving glucose metabolism and helping diabetics utilize insulin better)
  - o Liver Disease
  - o Metastatic Pancreatic Cancer ...
  - o Impaired Brain Function (as a treatment for stroke and other brain disorders involving free radical damage, including Alzheimer's disease) ...
  - o Degenerative Disease (ALA is a strong anti-inflammatory agent)
  - o Glaucoma and Cataracts"

On your November 2, 2012, blog post, titled "5 Benefits of Alpha Lipoic Acid" found on your website, <http://blog.biovea.com/5-benefits-of-alpha-lipoic-acid.html>:

- "Manages blood sugar – ALA can help remove glucose from the blood more quickly, benefitting diabetics by regulating blood sugar levels. This can also benefit people with heart disease or battling obesity."
- "Removes toxins – ALA aids the liver in ridding the body of toxins that cause liver scarring or failure. It can also protect brain and nerve tissue, preventing stroke."
- "ALA ... prevent cataracts from developing."

### **Borage Oil 1000mg**

- "[C]ystic fibrosis, asthma, diabetes and multiple sclerosis. It is possible that supplementing with borage oil may help to prevent or at least delay the onset of these conditions."
- "GLA may be effective in reversing neuropathy in diabetic patients"

### **Cholest-Rite Advanced**

- “Tocotrienol has proven efficacy to lower blood cholesterol levels ... cleanse the arteries of accumulated cholesterol ... can prevent plaque formation in the arteries”
- “Policosanol ... appears to normalize cholesterol as well or better than cholesterol lowering drugs ...”
- “garlic may help to decrease your LDL ...”
- “Guggal extract ... can dramatically lower blood cholesterol levels in people for ... cholesterol-lowering drugs have failed ... used in the management of arthritis, rheumatism ... cardiovascular problems, dermatitis, eczema, high cholesterol, obesity and psoriasis.”
- “Chromium ... Used for diabetes, hypoglycemia, obesity, heart disease.”

### **FirstBiotic Advanced**

- “[A]lleviation of eczema”
- “[P]revent colon cancer”

### **Liverol Advanced**

- “Dandelion ... used for ailments such as eczema and cancer ... and diseases of the liver such as hepatitis”
- “Turmeric is documented as effective in conditions ranging from cancer to Alzheimer’s disease. New research is now revealing its benefits as a preventative and treatment for lung, colon, and liver diseases.”

### **Lycopene 10mg**

- “[M]ay lower the risk of heart disease; macular degenerative disease ... lower LDL”
- “[P]revention and treatment of cancers of the lung, prostate, stomach, bladder, cervix, skin, and especially prostate...[S]tudies have found lower risk of cancer among people who eat lycopene-rich foods.”
- “[A]nti-cancer properties of lycopene against many cancer cells”
- “[A]ntibacterial and antifungal properties ... help to reduce inflammation of the gums and can help to fight infections of Candida albicans.”
- “[P]revent arteriosclerosis by reducing inflammatory agents”
- “[A]ntitoxic properties against many toxins such as aflatoxin, cyclosporine and cadmium.”

### **Odorless Garlic 1000mg**

- “[P]rotecting the body against disease, and fighting microbial and fungal infections”
- “[R]eductions in total and low-density lipoprotein, or ‘bad,’ cholesterol levels. Garlic can help to reduce blood pressure”
- “[P]revention and treatment of the common cold”
- “[M]ay help to reduce the severity of upper-respiratory infections, including coughs and colds”

### **Omega-3 Fish Oil 1360mg**

- “Omega-3 fatty acids are believed to have health benefits ranging from reducing the risk of heart attack ... to combating depression, bipolar disorder and schizophrenia”
- “[E]ffective for psoriasis ... prevent the blood from clotting easily”
- “May protect from stroke and heart attack”

- “May lessen depression”

### **Xanthadrene**

- “[A]nti-obesity implications”
- “[R]educe obesity”
- “[C]ombat obesity and associated disease, such as Type II Diabetes”
- “[D]ecrease insulin and blood glucose levels”
- “[A]nti-diabetes effect”
- “[I]ncrease insulin sensitivity ... and reduce LDL (‘bad’) cholesterol”
- “[A]nti-tumor effects”

Moreover, 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 dietary supplement is considered to be 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 publications that are used to market your product for disease treatment and prevention on your website and thus provide evidence of your product’s intended use as a drug:

On your November 3, 2014, blog post also referenced above, titled “AHCC Can Help Fight HPV; A Study” found on your website, <http://blog.biovea.com/ahcc-can-help-fight-hpv-a-study.html>:

- “UTHealth research shows mushroom [sic] extract, AHCC, helpful in treating HPV”
- “Anti-diabetic effect of an alpha-glucan from fruit body of Maitake”

We also noted claims on your Facebook account, accessible at [www.facebook.com/BIOVEA](http://www.facebook.com/BIOVEA), which links to your website, [www.biovea.com](http://www.biovea.com), from which your products can be purchased, provide further evidence that your products are intended for use as drugs:

Posts by your company on your Facebook timeline page include the following:

- On March 7, 2017: “Tea tree oil can destroy airborne pathogens ... also an antiseptic agent and has anti-inflammatory properties”

Photo posts by your company on your Facebook page include the following:

- On December 10, 2014, along with an image of your BIOVEA st.john’s wort, BIOVA maca, and BIOVEA 5-HTP products: “These three supplements can ... help with depression and anxiety symptoms”
- On November 18, 2014: “Recent studies show how AHCC can help eradicate HPV”
- On July 21, 2014, along with an image of your BIOVEA panax ginseng, ginkgo biloba, and pycnogenol products : “Learn how these three remedies can ... reduce ADHD symptoms”

On your firm’s Twitter account, accessible at [www.twitter.com/BIOVEA](http://www.twitter.com/BIOVEA), which links to your website, [www.biovea.com](http://www.biovea.com), in the BIOVEA (@BIOVEA) account description:

- On March 7, 2017: “Tea tree oil can destroy airborne pathogens ... also an antiseptic agent and has anti-inflammatory properties”
- On June 28, 2016: “#DMannose: For the elimination of bladder and Urinary Tract Infection”

- On November 19, 2015, along with an image of your BIOVEA st.john's wort, BIOVA maca, and BIOVEA 5-HTP products: "These three #supplements can ... help with #depression and #anxiety"

On your firm's Instagram account, which directs viewers to your firm's website, [www.biovea.com](http://www.biovea.com):

- On the photo post of your product, BIOVEA oregano oil (alcohol free): "Oregano Oil is a natural antibacterial"

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 introduced or delivered for introduction into interstate commerce without prior approval from the FDA, as described in sections 301(d) and 505(a) of the Act [21 U.S.C. 331(d), 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.

A drug is misbranded under section 502(f)(1) of the Act [21 U.S.C. 352(f)(1)] if the drug fails to bear adequate directions for its intended use(s). "Adequate directions for use" means directions under which a layperson can use a drug safely and for the purposes for which it is intended (21 CFR 201.5). Prescription drugs, as defined in section 503(b)(1)(A) of the Act [21 U.S.C. 353(b)(1)(A)], can only be used safely at the direction, and under the supervision, of a licensed practitioner.

Your products AHCC 500mg, Alpha Lipoic Acid 300mg, Borage Oil 1000mg, Cholest-Rite Advanced, FirstBiotic Advanced, Liverol Advanced, Lycopene 10mg, Odorless Garlic 1000mg, Omega-3 Fish Oil 1360mg, and Xanthadrene are intended for treatment of one or more diseases that are not amenable to self-diagnosis or treatment without the supervision of a licensed practitioner. Therefore, it is impossible to write adequate directions for a layperson to use your products safely for their intended purposes. Accordingly, your products fail to bear adequate directions for their intended use and, therefore, the products are misbranded under section 502(f)(1) of the Act [21 U.S.C. 352(f)(1)]. The introduction or delivery for introduction into interstate commerce of the misbranded drugs violates section 301(a) of the Act [21 U.S.C. 331(a)].

The violations cited in this letter are not intended to be an all-inclusive list of violations that exist in connection with your products. You are responsible for investigating and determining the causes of the violations identified above and for preventing their recurrence or the occurrence of other violations. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations.

You should take prompt action to correct the violations cited in this letter. Failure to promptly correct these violations may result in legal action without further notice, including, without limitation, seizure and/or injunction.

Within fifteen (15) business days of receipt of this letter, please notify this office in writing of the specific steps you have taken to correct the violations noted above. Your response should include any documentation that would assist in evaluating your corrections. If you cannot complete corrective action within fifteen working days, please explain the reason for the delay and the date by which you will make the correction.

Your response should be sent to U.S. Food and Drug Administration, Hanna L. Potter, Compliance Officer,

Food and Drug Administration, 6<sup>th</sup> Avenue & Kipling St, DFC Bldg. 20, PO Box 25087, Denver, CO 80225-0087. If you have any questions with regards to this letter, please contact Hanna L. Potter at (303) 236-3094 or [hanna.potter@fda.hhs.gov](mailto:hanna.potter@fda.hhs.gov).

Sincerely,

/S/

LaTonya M. Mitchell

Program Division Director