

WARNING LETTER

Lifevantage Corp

MARCS-CMS 510546 – APRIL 17, 2017

Recipient:

Lifevantage Corp
United States

Issuing Office:

Denver District Office
United States



Denver District Office
Denver Federal Center, Bldg 20
Denver, CO 80225

**VIA OVERNIGHT DELIVERY
RETURN RECEIPT REQUESTED**

**WARNING LETTER
Ref. # DEN-17-04-WL**

April 17, 2017

Darren Jensen
LifeVantage Corporation
9875 S. Monroe St
Suite 300
Sandy, UT 84070

Dear Mr. Jensen,

This is to advise you that the Food and Drug Administration (FDA) reviewed your websites at the Internet addresses www.nrf2science.com, www.lifevantage.com, and www.protandim.com in January 2017 and has determined that the claims on your websites establish that your Protandim NRF2 Synergizer product is a drug 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 it is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease. As explained further below, introducing or delivering this product for introduction into interstate commerce for such uses violates the Act. You can find the Act and FDA regulations through links on FDA's home page at www.fda.gov.

Examples of claims found on your websites that establish the intended use of your Protandim NRF2 Synergizer product as a drug include, but may not be limited to, the following:

On the www.nrf2science.com home page:

- “Anti-inflammatory”
- “Cardiovascular diseases prevention”
- “Diabetes prevention”
- “Alzheimers [sic] prevention”
- “Cancer prevention”
- “Cellular stress ... can lead to skin cancer. In the body, cellular stress is linked to cardiovascular disease, alzheimers [sic], cancer and other life threatening diseases ... When activated, Nrf2 turns on the production of specific antioxidants the body needs to fight cellular stress effectively”

Under the “Nrf2 & the Body,” “Nervous System” tab, www.nrf2science.com/nervous-system/:

- “Nrf2-activating phytonutrients such as EGCG from green tea, curcumin from turmeric, and quercetin from onions are known to reduce amyloid plaque accumulation (Alzheimer’s) and increase regeneration of dopamine fibers (Parkinson’s), suggesting a general neuro-protective benefit.”
- “Oxidative damage occurs early in virtually all nervous system disorders, including chronic conditions such as Alzheimer’s, Parkinson’s, Multiple Sclerosis, and ALS ... as well as acute brain injury such as stroke and traumatic brain injury (TBI, including concussions), suggesting that oxidative stress plays a prominent role in disease progression ... neurons with low Nrf2 activity are more susceptible to oxidative stress, but cellular damage can be reduced through Nrf2 activation”

Under the “Nrf2 & the Body,” “Cardiovascular System” tab, www.nrf2science.com/cardiovascular-system/:

- “Increases production of specific anti-atherogenic (heart-protecting) enzymes”
- “Protects blood vessels from inflammation”
- “Reduces high blood pressure”
- “Several cardiovascular diseases are associated with suboptimal cellular defenses, (and thus with elevated cellular stress), including atherosclerosis (blockage of blood vessels), hypertension (elevated blood pressure), and heart failure (loss of contraction ability)... Nrf2, a key protein that activates the body’s ultra-powerful antioxidant enzymes, has been shown by science to protect and benefit the cardiovascular system”
- “protects heart muscle cells in rats with hypertension (high blood pressure)”
- “keep blood vessels open by reducing overgrowth of the interior linings of specific blood vessels used in coronary bypass grafts”

Under the “Nrf2 & the Body,” “Skin Health” tab, www.nrf2science.com/skin-health/:

- “Minimizes inflammation”
- “Protects against UV radiation exposure”

- “Minimizes risk of skin cancers”
- “Nrf2 pathway can have a wide range of beneficial effects on skin, including reduced rates of skin cancers, protection from ultraviolet radiation, reduced inflammation ... and improved wound healing.”

Under the “Cancer” tab, www.nrf2science.com/cancer/:

- “Nrf2 Help Fight Against Cancer”
- “Restrict/modulate underlying mechanisms involved in carcinogenesis (formation of cancer cells)”
- “Positively influences genes involved in formation of cancer cells”
- “Shows ability to slow progression of and ‘kill’ cancer cells”
- ““Nrf2 as a promising molecular target for cancer prevention””
- ““protection against ... carcinogens””
- “Nrf2 is indeed a potentially powerful weapon against cancer.”
- “suppress both the development and spread of skin cancer ... 57% reduction in number of skin tumors”
- “significantly reduced the development of skin cancer”
- “chemopreventive agent due to their ability to modulate underlying mechanisms involved in carcinogenesis”
- “Nrf2 ... target the so-called ‘diseases of aging,’ including cancer, cardiovascular diseases, inflammatory and autoimmune diseases, and neurodegenerative diseases.”
- “suppress the growth and spread of breast cancer”
- “anti-cancer effects against ovarian cancer and myeloma (bone marrow cancer)”
- “anti-tumor and anti-proliferative effects (reduced tumor formation and growth) across 8 different ovarian cancer cell lines.

Under the “Nrf2 Studies” tab, www.nrf2science.com/studies/:

- “Prostate Cancer Prevention Trial”
- “associated with lower lung cancer risk”
- “mineral supplement use to prevent cancer”

On the blog posts, www.protandim.com/blog/:

Under the April 1, 2012 post, “Long-Used, Much-Studied Turmeric a key Protandim Ingredient”:

- “helpful for the following conditions: ... Stomach ulcers ... Osteoarthritis ... Heart Disease ... Bacterial and viral infections ... Cancer ... Alzheimer’s disease”

Under the April 6, 2012 post, “Ultra-Popular Green Tea has its Place in Protandim”:

- “lowering cholesterol... and fending off dementia”
- “reduce the risks of developing cancers such as breast, stomach, prostate, pancreatic and colorectal cancer.”

On the blog post, www.lifevantage.com/blog/study-confirms-protandim-nrf2-synergizer-extends-lifespan/:

Under the August 5, 2016 post, “Study Confirms Protandim Nrf2 Synergizer Extends Lifespan”:

- “Suppresses tumor-promoting oxidative stress... and inflammation”

- “Protects the heart from ... fibrosis”

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 product Protandim NRF2 Synergizer is intended for treatment of one or more diseases that are not amenable to self-diagnosis or treatment without the supervision of a licensed practitioner. Furthermore, your product is intended for prevention of one or more diseases that are not amenable to prevention by consumers without the supervision of a licensed practitioner. Therefore, it is impossible to write adequate directions for a layperson to use your product safely for its intended purposes. Accordingly, your product is 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 this misbranded drug violates 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 connection with your products. It is your responsibility to ensure that your products 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 enforcement action without further notice, such as seizure and/or injunction.

Please notify this office in writing within fifteen (15) working days from your 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 in the future. Your response should include any documentation necessary to show that correction has been achieved. If you cannot complete all corrections before you respond, please explain the reason for the delay and the date by which you will complete the corrections.

If you need additional information or have questions concerning any products distributed through your website, please contact the FDA. Your written response should be sent to Nancy G. Schmidt, Compliance Officer, U.S. Food and Drug Administration, 6th Avenue & Kipling Street – Building 20 DFC, P.O. Box 25087, Denver, Colorado 80225-0087. If you have any questions about this letter, please contact Ms. Schmidt at (303) 236-3046 or by email at nancy.schmidt@fda.hhs.gov.

Sincerely,

/S/

LaTonya M. Mitchell

District Director

Denver District

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